Obstetric Cervical Ripening Device

A Major Qualifying Project Report:
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Authorship

Each team member contributed equally to the development of the report. The writing and revisions were a collaborative effort that involved all members of the team.
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Abstract:

Nearly one quarter of the four million annual births in the United States are performed through chemical or mechanical labor induction. Currently, the most widely used methods of mechanical induction are variations of balloon catheters, which require a procedure involving extensive handling of the cervix. Through design, testing, and consultation with the client, a device was devised that allowed the physician to attach the device directly to their fingers, reducing the time and cervical handling needed to successfully insert the device. The proposed device would incorporate two straps to affix it to the finger of the physician, and a balloon at the proximal tip to reduce the time between insertion and inflation of the balloon.
Chapter 1: Introduction

In the United States alone, there are approximately 4 million births per year [1]. Of these 4 million births, 23.2% are induced via pharmaceutical or mechanical stimulation [1]. Induction of labor becomes necessary for women under a variety of circumstances. These include health conditions that pose a risk to mother or child, such as preeclampsia or high blood pressure, if the amniotic sac ruptures but labor does not start, and if labor has not naturally started one to two weeks past the patient’s due date [2]. Logistical reasons for labor induction includes if the patient lives far away from medical care or if a potential health risk to the mother or baby is identified [2].

When inducing labor, obstetricians utilize one of multiple methodologies: pharmaceutical stimulation methods such as Pitocin, the synthetic version of the naturally occurring hormone oxytocin, and prostaglandins or mechanical stimulation such as inserting a balloon catheter into the cervix [3]. While each method of labor induction has its own distinct set of advantages and disadvantages, the Foley balloon catheter serves as the gold standard. The Foley catheter is both safe and effective for the mother and child as it has not been shown to cause prolonged, high frequency contractions and maintains the same success rate as that of pharmaceutical methods [3].

While the Foley catheter is the gold standard, there are drawbacks to its use in this application as it was originally designed for bladder drainage [4]. The initial placement of the device is time consuming and painful for the patient, and the doctor must contort his or her hand to attempt to guide the catheter into the cervix. The handling of the cervix is painful for the patient and many will opt not to use the catheter due to this initial pain [7].

The overall goal of this project was to develop a simple, cost effective, mechanical device to induce labor that will increase ease of use for the physician and reduce discomfort for the patient. This device will be used by doctors in a hospital setting. It will not change the current procedure, and will maintain the low cost of using a Foley catheter. Currently Foley catheters cost less than $3 each, so the newly designed device must be similarly priced or be designed to outperform the Foley catheter enough to justify a higher price.

The design of this device focuses on the current problems associated with the gold standard, the Foley catheter. Problems include handling time of the cervix which causes pain for the patient and it’s not optimal for the doctor as they have to contort their hand. Design drawbacks include the Foley catheters off label use, the device is hard to grip, lacks rigidity and the balloon is difficult to inflate.

Because the current gold standard for mechanical labor induction is a urinary catheter that has been approved for off label use, the new device was designed and tested for the specific application of inducing labor via cervical ripening. The overall strength and flexibility has been altered in the new device to make placement easier for the doctor. Stiffness through a wire provides
a solid base for inserting the balloon tip into the cervix and the balloon itself was repositioned to reduce materials used overall in the design. Influences from heart and lung catheters will also be applied to this design, potentially in the form of guide wires or placement devices.

The process of developing this project began with defining the project. The need statement was derived from the initial statement posed by the client. This statement outlined the problem that is being faced, the population affected by it, and the desired outcome of the project, and was constructed in order to eliminate any implied solutions. For this project, the need is to develop a simple and cost effective cervical balloon designed specifically for obstetrical practice that will increase ease of use for the physician and reduce discomfort for the patient.

Once the direction of the project had been determined and understood, the design process commenced. In this process, the team outlined the objectives and functions for the device, as well as any constraints that existed in the design space. Objectives for the design were listed and ranked in order of importance. Research was conducted in order to learn of current state of the art solutions to the problem defined in the needs statement. The team then considered the functions that the device might or must perform, then considered various means by which the device could perform each function. From there, the team began to brainstorm ideas for what the device might look like and what materials might be used based on the information gleaned through the initial design process. These designs were considered by all team members, modified, and a final three to four designs were selected for prototyping and testing.

With these finalized designs, the process of prototyping began. Use was made of several on-campus rapid prototyping options, used in conjunction with Solidworks. Once prototypes were in hand, testing could begin. These tests were intended to assess the shape, ease-of-use, material properties, and biocompatibility of the device. Ease-of-use and shape were assessed by determining how easily the device could be manipulated using just one hand, and whether the device would be able to fit into a limited amount of space while maintaining directional control. The material properties of the design were assessed using force measurements on an Instron, known biocompatibility properties, the overall rigidity, and ultimately the cost-effectiveness and manufacturing feasibility of the material. When all of the designated qualities and specifications set for the designs had been tested, a final design was selected based on overall performance in these areas. This design was modified as needed, prototyped again according to those modifications, and validated for performance.

The final design consists of two separate designs. The first part of the design solves the problems associated with increasing ease of use. The final device is a 18Fr catheter size with two finger straps, found 1 and 3 cm from the proximal tip of the catheter. This was determined to help with ease of placement through placement time trials. The second design aspect solves the problem of a device made for the obstetric space. The balloon was moved to the proximal tip of the catheter to reduce the time the doctor has to spend placing the catheter and handling the cervix. All of the
design considerations will also reduce discomfort for the patient due to reducing time spent during the procedure.
Chapter 2: Literature Review

Every year worldwide there are approximately 134.5 million births [1], four million of those births occur in the United States. Within the 4 million births 32.3% are done via Cesarean Section and 23.2% are through labor induction [1]. Labor induction is “a procedure used to stimulate uterine contractions during pregnancy before labor begins on its own” [6]. The aim of labor induction is to safely lead to a natural birth instead of a C-section to avoid high costs associated with surgery and an extended recovery time [7].

2.1 Anatomy and Physiology

The natural process of pregnancy and childbirth, known as parturition, involves significant changes to the reproductive anatomy [8]. The development of the fetus takes place within the uterus, which must expand over the course of a nine month parturition to many times its original size, while maintaining a state of quiescence, meaning no contractions take place before the labor begins [8]. The cervix gradually softens as the fetus grows, while maintaining its structural integrity to ensure that the fetus remains inside the uterus through gestation. However, at the end of the gestation period, the cervix must undergo a structural change before muscle contractions in the uterus begin. This allows the previously rigid connective tissue that comprise the majority of the cervix to efface and dilate enough for the fetus to pass through [8].

The cervix is comprised of connective tissue and smooth muscle. Collagen is the main component, with collagen types I, III, and IV being the most common [9]. The cervix also includes small amounts of elastin, glycosaminoglycans, and proteoglycans, and smooth muscle [8]. The collagen crosslinks into stiff structures that give the cervix the ability to retain its shape while remaining pliant. However, during the phase of cervical ripening, the increased production of glycosaminoglycans, prostaglandins, and collagen cause the cervix to take on a more disorganized molecular structure [8]. The increase in prostaglandins lead to a greater rate of collagen degradation, allowing the synthesis of new collagen. Glycosaminoglycans are hydrophilic, and as a result of their increased production, newly formed collagen is unable to crosslink due to the higher water content [10]. The cervical ripening phase allows for further effacement and dilation of the cervix as labor begins.

2.2 Bishop Score and Measuring Dilation

The ripeness of the cervix must be measured when determining whether labor needs to be induced [11]. Currently the system for measuring the structure of the cervix in vivo is not standardized. During pregnancy, a physician will give a digital examination and declare the cervix to be firm, medium, or soft [11]. For a normal pregnancy, this is sufficient in determining that the pregnancy is progressing as expected, however it lacks the ability to give an idea of whether the
cervix will be insufficient to hold the pregnancy to term and result in a premature birth, spontaneous abortion, if the cervix will not be ripened enough to give birth when the pregnancy is at term [11]. Currently, elastography is used to determine the deformation of the cervix when a force is applied, but this method does not give standardized values [11]. There are several methods that researchers are currently investigating that would give standardized values for the consistency of the cervix based on its deformation [12]. These include aspiration, in which softness is quantified by the amount of tissue that can be sucked into a standard, 10mm diameter tube, and use of a cervical consistency index, which would use multiple images of a cervix, before and after maximum compression. Quantitative ultrasound, a technique which measures the amount of ultrasound waves that are lost when encountering a material such as collagen that will scatter the waves, can provide valuable information about the amount and structure of collagen in the cervix in a non-invasive manner [12].

In order for a physician to determine whether the cervix has undergone ripening or not, an examination is carried out in which the physician observes multiple properties of the cervix and assigns it a score. This score, called the Bishop’s score, incorporates several different indicators of the readiness of the cervix for labor [13]. It assesses the effacement of the cervix, or how thin it is, the percentage it has already effaced, the dilation of the cervix in centimeters, the position of the presenting end of the fetus (most often the head) in relation to the ischial spines of the pelvis, the position of the cervix in the vagina, and whether the cervix is firm, medium, or soft [14].

If the Bishop Score is 5 or less, the cervix is considered “unfavorable” and must either be allowed more time to ripen, or be mechanically or chemically ripened [15]. A summary of the Bishop Scoring System is shown in the table seen below.

*Table 1: Bishop Scoring System [27]*

<table>
<thead>
<tr>
<th>Score</th>
<th>Dilation (cm)</th>
<th>Position of Cervix</th>
<th>Effacement (%)</th>
<th>Station</th>
<th>Cervical Consistency</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Closed</td>
<td>Posterior</td>
<td>0-30</td>
<td>-3</td>
<td>Firm</td>
</tr>
<tr>
<td>1</td>
<td>1-2</td>
<td>Midposition</td>
<td>40-50</td>
<td>-2</td>
<td>Medium</td>
</tr>
<tr>
<td>2</td>
<td>3-4</td>
<td>Anterior</td>
<td>60-70</td>
<td>-1, 0</td>
<td>Soft</td>
</tr>
<tr>
<td>3</td>
<td>5-6</td>
<td>---</td>
<td>80</td>
<td>+1, +2</td>
<td>---</td>
</tr>
</tbody>
</table>

The Bishop score is partially based on centimeters of dilation of the cervix during labor. This is represented in Figure 1 through comparisons between everyday objects and the size associated
with the dilation. Usually a cervix that is roughly the size of a banana slice or smaller will be the perfect candidate for cervical ripening techniques (highlighted box).

**Figure 1:** Representation of cervical dilation. Labor induction is deemed necessary when the cervix does not dilate past 3 cm. At 5 cm labor is progressing naturally and labor induction is no longer necessary.

### 2.3 Labor Induction

In recent years, the number of labor inductions has significantly increased from 9.6% in 1990 [16] to 23.2% in 2014 [1]. Some of the contributing factors leading to this increase include the wider availability of cervical ripening agents, as well as demand from healthcare and pharmaceutical providers that stand to gain financially. Some patients desire to schedule and prepare for the birth [17]. Labor induction is also more convenient for physicians, as they are able to plan out their schedules and hospital staffing, and are less restricted by the unpredictability of natural labor. There have also been significant improvements in medical technology that allow for detection of conditions such as preeclampsia, low amniotic fluids, and high blood pressure, that indicate the need for induction for the safety of mother and child. Other instances in which induction is necessary include when a pregnancy lasts for an extended period past the expected due date (typically 1-2 weeks) and if the amniotic sac ruptures but labor does not start [2].
2.3.1 Mechanical vs. Chemical Stimulation

There are two types of induction; chemical and mechanical. Chemical induction relies on the introduction of outside hormones to the body while mechanical induction can be performed a variety of different ways depending on the need.

During chemical induction, prostaglandins are applied to the vagina in the form of a tablet, gel, suppository, or pessary [18]. Prostaglandins are hormones that are naturally produced by the body and serve to ripen the cervix during pregnancy. When applied, the hormones cause softening, shortening, and dilation of the cervix, while the uterus begins to contract [18]. This method of labor induction increases a patient’s chance of vaginal delivery within 24 hours. However, there is a higher risk of uterine hyperstimulation and deceleration of the fetal heart rate [18]. In a patient that has uterine scarring, hyperstimulation can lead to uterine rupture, a potentially fatal condition for both mother and child [18].

Similar to prostaglandins, oxytocin is a hormone that is produced by the body during pregnancy. When used in labor induction, the hormone is given continuously in an intravenous infusion to the patient. This method serves to ripen the cervix and stimulate uterine contractions, and patients will typically go into labor within 8 to 12 hours [19]. The use of this hormone introduces the risks of fetal distress, uterine hyperstimulation, and failed induction especially in patients with an unfavorable cervix. Due to the fact that it typically does not work on patients with an unfavorable cervix, it is often used in conjunction with prostaglandins, as they are more effective for cervical ripening [20].

Studies comparing mechanical induction and chemical induction rates favor mechanical induction rates [21]. This is not due to their success rates as they are comparable in that sense, meaning there is no statically significant difference in success rates of mechanical and chemical induction. However mechanical induction can be used on a wider range of people. Chemical induction cannot be used on patients who have previously had a C-section or uterine surgery [19]. Mechanical induction is also cheaper and one of the oldest forms of induction, and it can be stored in a wide range of environments making it highly accessible [22]. In order to avoid the risks associated with pharmaceutical induction, mechanical induction methods are available. These methods include sweeping or stripping of membranes, rupturing the amniotic sac to induce contractions, and use of a balloon catheter to encourage cervical ripening [21].

The sweeping of membranes was one of the first methods of mechanical induction, suggested in 1810 by Dr. James Hamilton [23]. Membrane sweeping is performed by inserting the finger through the cervix and sweeping it around in two full circles. This serves to detach membranes from the lower portion of the uterus, thus initiating the natural release of prostaglandins, which work to ripen an unfavorable cervix. However, labor typically does not start for two or more days with the membrane sweeping method [23]. This procedure also carries the risk
of introducing infection, causing bleeding in the uterus, or prematurely rupturing the amniotic sac. Because of this, sweeping of the membranes is no longer used in common practice.

Intentional rupturing of the amniotic sac, or an amniotomy, is performed by inserting a transcervical hook into the uterus and scratching or puncturing the amniotic sac [23]. This procedure is not recommended for patients with an unfavorable cervix; risks include umbilical cord prolapse, infection, bleeding, and fetal distress [23]. Evidence from two trials that studied the use of this procedure in labor induction did not support this as an effective method [23].

The final and most used method is the transcervical balloon. There are a number of different devices that can be used during this procedure but the procedure is still relatively the same. Doctors first insert their fore and middle fingers into the vagina to feel for the cervix. Once the cervix can be felt the doctor attempts to insert one or both fingers into the cervix. Then, using the other hand, the balloon is threaded along the hand still inside the cervix until the balloon is sitting above the cervix, in between the amniotic sac and the top of the cervix [5]. A nurse then inflates the balloon using saline to approximately 60ml, creating a balloon diameter of 5cm. Once the balloon is successfully inflated the doctor is able to remove his or her hand. There are two main devices used as transcervical balloons; the Foley catheter and the Cook® cervical ripening device [5].

Similar success rates are observed in chemical and mechanical methods of labor induction. However, with the use of oxytocin and the balloon catheter a patient is immobilized, while with the use of prostaglandins the patient is free to move around [5]. Additionally, while oxytocin and prostaglandins both cause uterine hyperstimulation, mechanical methods do not. Thus making mechanical induction one of the only options for women who have uterine scarring. Mechanical methods however can take a bit longer for a physician to place as it is more difficult to insert something through the cervix than it is to insert an IV. This can dissuade physicians from using this method on patients who can be given oxytocin or prostaglandins instead, since they are less time consuming methods.

2.4 The Foley Catheter

The Foley catheter, which can be seen in Figure 2, was developed in 1937 by Dr. Fredrick Foley with the intended use of draining urine from the bladder [4]. It is currently the gold standard for mechanical labor induction, despite its off-label application.

![Figure 2: Foley Catheter](image-url)
Foley catheters are made from latex and coated in silicone [24]. The latex provides flexibility and a high stretch ratio and the silicone coating ensures the biocompatibility of the device without limiting its flexibility [24]. Some Foley catheters have coatings that have antiseptic and antimicrobial properties to reduce the risk of infection when using the catheter for an extended period of time.

There are three types of catheters. Straight catheters have one lumen, or tube, with no balloon. A two way catheter has two lumens. One lumen is used for filling the balloon (a) and the other is used for draining urine (b), as shown in Figure 3. A three way catheter has three lumens. The first lumen is used for draining urine, the second for inflating the balloon and the third for adding liquid to the bladder, such as medicine or saline [25].

![Figure 3: Cross-sectional area of Foley Catheter](image)

Catheters of all types come in a variety of different sizes starting from 3 French and going all the way up to 48 French [25]. A French is a unit specifically used in catheter sizing, and represents three times the diameter in millimeters. For example, a 3 French catheter is one millimeter in diameter, a 6 French is two millimeters, and so on [25]. Figure 4 represents the French sizing scale. For labor induction the typical French size used is between 18-22 French.
The basic procedure for implanting the Foley catheter into the amniotic space can be seen in Figure 5. The area and the catheter are sterilized. A 16-22Fr catheter is typically used with an average usually between the 18-22Fr size. The balloon end of the catheter is inserted digitally into and above the cervix, through the inner os, the cervical opening into the uterus. The catheter is then pulled to a varying degree of tension depending on the doctor. The end outside of the patient is then folded and taped to the leg. This greatly restricts the patient’s mobility [5].

Success of the mechanical induction of labor through use of the Foley catheter is judged based off of three main categories: labor length, cesarean section rate and adverse effects on the fetus, which are monitored through the fetal heart rate [22,24].
Problems associated with the Foley Catheter stem from its off label use in obstetrics. The Foley catheter was meant for use in the urinary tract, therefore the catheter is flimsy and lacks the rigidity needed to place the catheter. Also due to the procedure necessary for cervical ripening doctors may be forced to handle the cervix multiple times when attempting to place the balloon. This can cause pain for the patient and in turn the patient may request to have to catheter taken out due to this discomfort [5]. While the Foley catheter is used off label for cervical ripening, there is a device currently on the market that is made specifically for this purpose.

2.5 Cook Cervical Ripening Device

The Cook Cervical Ripening device (Figure 6) is specifically marketed for the purpose of labor induction [26]. The Cook Cervical Ripening device features two balloons, one that sits above the cervix and one that sits below the cervix. It can have two or three lumens; two are used for the inflation of the balloon while the third in some models is used as a track for a rigid stylet [26].

![Figure 6: Cook Catheter with three lumens. The green and red ports are inflation lumens for the double balloons located at the right side of the frame. The blue port is a lumen for a rigid stylet.](image)

While the Cook Catheter was specifically designed for its purpose there are a number of problems associated with it, therefore it is not the preferred method by doctors [5]. Most importantly the cook catheter does not address the issue of ease of placement [5]. The two balloons cause the placement to be more difficult as the doctor can no longer slide the catheter along his hand. The rigid stylet provides guidance but since the space changes according to every patient and the stylet does not allow for flexibility. Also with a double balloon structure this can cause more pain and discomfort for the patient. The cervix is not just being pressed down upon, like with the foley, but rather squeezed between two balloons. Often the cook catheter will have to be removed before labor can be induced due to the patient being too uncomfortable [22]. The final major concern of the cook catheter is the price, which is roughly 16 times more expensive than the foley catheter [26]. The Foley Catheter is roughly $3 whereas the Cook Catheter can be priced as high as $41. Most hospitals do not stock the cook catheter because it has no significant advantage over the foley for the increase in price [5].

2.6 Natural Birth vs. Cesarean Section

Birth happens one of two ways, naturally or through Cesarean Section or C-section. Cervical ripening in most cases leads to a natural birth. Should labor not start naturally or with the help of
labor induction methods than a C-section may be necessary [27].

While there are definitive advantages and disadvantages to both methods vaginal birth, rather than a C-section, is the safest and best option for both the mother and child [27].

After a natural, or vaginal, birth, the mother and child are able to bond more quickly as the mother is capable of holding and breastfeeding the baby sooner [28]. Additionally, the recovery period and hospital stay is shorter after a vaginal birth than after a C-section. While the baby is being pushed through the birth canal, fluid in the lungs is expelled, resulting in fewer respiratory issues and allergy development throughout the lifespan of the child [29]. Vaginal birth also exposes the child to bacteria that will create the first colony in the gut [29].

Many disadvantages of vaginal delivery stem from the unpredictability of labor [28]. Labor may start within a wide range of time before or after the expected due date, and as a result it can be difficult for expectant parents to prepare for the birth. There are also physical risks, such as an abnormally long labor, and tearing and stretching of the vaginal tissue which could lead to urinary or bowel incontinence [28]. During natural vaginal birth, the physician will take the necessary precautions to ensure the safety of the baby, however if labor lasts too long it could result in severe injury or even fatality for both the mother and child. These injuries include fistulas, bone dislocation, suffocation which can lead to brain damage or death [28].

With delivery via C-section there are an additional set of advantages and disadvantages for the mother and child. Advantages include the elimination of hours of labor, and the uncertainty of delivery dates [28]. Unlike natural births, C-sections can be scheduled in advance and can also serve as an emergency option if vaginal delivery fails. This procedure also prevents damage to the pelvic floor and decreases a child's risk of infection in mothers that are HIV positive [28]. In cases where the fetus is positioned incorrectly (breech), overly large, or there are multiple babies to be delivered, C-sections may have a higher probability of success than a natural vaginal birth [28].

Disadvantages of this procedure include longer recovery periods associated with a major surgery, scarring, and delayed bonding between mother and child [28]. This procedure may prevent mothers from vaginal delivery in future pregnancies, as pharmaceutical induction will pose a greater risk of uterine rupture in the event of hyperstimulation. Additionally, the risk of placental abnormalities increases for future pregnancies with each C-section [28]. It is important to avoid surgery for the mother and unborn child at all costs. Therefore it is necessary to attempt methods of inducing labor before resorting to a C-section.
Chapter 3: Project Strategy

3.1 Client Statement

The initial client statement for this project was to develop a mechanical labor induction device designed for obstetrical practice. This design was to focus on ease of placement for the physician and be cost-effective for hospitals [5].

3.2 Technical Design Requirements

The following technical design requirements will need to be met in order for the device to be successful. The objectives of the project detail what the project hopes to accomplish, the constraints are a list of scenarios that must be overcome, and functions and specifications detail what the project must accomplish and how to accomplish it.

3.2.1 Objectives

The objectives for this project, in order of importance, have been listed below.

1. Increase ease of use for physician
2. Reduce patient discomfort
3. Ensure safety
4. Simple device
5. Successful induction of labor within 24 hours of insertion

The primary focus when designing the cervical ripening device was ease of use for the physician. This was the fundamental request of the client, and thus became the primary objective of the project. Ease of use encompasses the number of attempts needed to place the device, as well as the amount of time required to complete the procedure. The goal of the project was that the device could be placed on the first attempt, and the time needed to complete the procedure would be less than three minutes.

Increasing the ease of use helped to achieve the second objective of reducing patient discomfort. The amount of time the procedure takes directly impacts patient comfort, as handling of the cervix is uncomfortable for patients [5]. By limiting the number of attempts needed to insert the device, handling time of the cervix was minimized. Although this objective was secondary to increasing ease of use, it was important to ensure that the comfort of the patient was not compromised to improve the speed of the procedure.

It was also important to ensure that the device is safe for patients. This involved using hypoallergenic materials, as the device could be left in the body for up to twelve hours [23].
Additionally the device should not cause any adverse effects or carry any risk of introducing infection. Structurally, the device must not have any features that could prematurely rupture the amniotic sac or cause damage to the cervix and vaginal canal.

The simplicity of the device was another objective identified during the design process. It was important that the device did not complicate the current insertion procedure or require physicians to re-learn it [30]. Thus, it was decided that the resulting device should be mechanical, as this kept the design simple and reduced the possibility of harmful side effects.

Finally, the device must be able to successfully induce labor within 24 hours of insertion at a rate equal to or greater than the current gold standard [22]. Since the method of induction of the current gold standard was not changed in the final device, the time to labor is unlikely to change. Additionally, it was not possible to test the success of this objective within the scope of the project and as a result it was not highly prioritized in the design process.

3.2.2 Constraints

There were four main constraints that affected this project including the potential space, the testability, budget, and completion deadline. Considering potential space, the cervix is normally ~3 cm, or the size of a banana slice, dilated when labor is induced [19]. In the current insertion process for the Foley and Cook® catheters the physician will sometimes put one or two fingers through the cervix to guide the catheter in [30]. Thus, the resulting device must be able to pass through the narrow cervical opening under a variety of cervical configurations.

The next constraint involved the testability of the device. Physicians generally observe the procedure to learn how to perform it themselves, and then later teach it to others [30]. This means that there is no standard or affordable model to practice catheter insertion on, thereby limiting the testability of the most important objective, increasing ease of use for the physician.

The last two constraints associated with this project include the budget and completion deadline. The budget allocated to this project was $250 per student. As a team of three this brought the total to only $750 to cover all expenses. Finally the project must be completed and validated by April of 2017.

3.2.3 Functions

There are a variety of functions that the resulting cervical ripening device was required to perform to be considered successful. The first function is that the device had to be transcervical. Since the main mechanical effect of labor induction occurs on the internal face of the cervix, it was crucial that the device be able to fit through the narrow aperture of a minimally dilated cervix. Another important function of the catheter was manipulability. For instance, the catheter had to
have the correct degree of stiffness that made it easy to use and handle, while maintaining structural integrity and preventing excessive rigidity.

The most important function identified for the device was that it must induce labor mechanically. To do this the device had to naturally stimulate the release of prostaglandins to begin the cervical ripening process [22]. Additionally, since chemical induction is not a viable option for patients with previous uterine scarring, the device could only operate utilizing mechanical methods.

3.2.4 Specifications

- The device must be at least 8 inches long to emerge from vagina after being placed in the uterus
- The device when placed in the cervix must not rupture the weakened wall of the amniotic sac
- Inflatable balloon must hold up to 100 mL of saline without rupturing (to ensure that the balloon can be rated to the desired 80 ccs) and be at most 5 centimeters in diameter
- Be able to be placed in the cervix, and force created in 5 minutes or less to reduce discomfort for the patient
- The device must meet all industry standards outlined in following section: 3.3

3.3 Design Requirements (Standards)

According to the ASTM F748-16 (Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices) an intravaginal and intrauterine labor induction device is classified as an intraoperative or short term external device communicating with an intact natural channel. It does not breach the membranes of the body and is in place for less than 24 hours. The device must, therefore, meet standards for cell culture cytotoxicity, sensitization, skin or intracutaneous irritation, mucous membrane irritation, and, in the case that the device is left in for more than 24 hours, acute or subchronic systemic toxicity [31].

When assessing the material properties of the device, ASTM F623 - Standard Performance Specifications for the Foley Catheter will be taken into account. These standards include tests to ensure that the catheter can withstand tensile stress, that the balloon can hold fluid without leaking or deflating, that the balloon will not rupture when tensile force is applied to the catheter, and that the balloon will deflate to its original shape, allowing for swift removal without injuring the patient [32].

Validation for this device comes from both ASTM F623 and from the 510(k) summary for the Cook® Cervical Ripening Balloon. In order for the device to gain FDA approval, it must prove to work as effectively or more effectively than preceding devices that are on the market. The 510(k)
summary for the Cook® Cervical Ripening Balloon contains summaries of tests run to validate the effectiveness and safety of the preceding device. These tests were used to validate the device that was developed through this project [26, 33].

3.4 Revised Client Statement

After delving into the objectives of this project, the initial client statement was revised to broaden the design space and eliminate any implied solutions. The revised client statement is as follows:

*Develop a simple and cost effective transcervical cervical ripening device, designed specifically for obstetrical practice that will increase ease of use for the physician and reduce discomfort for the patient.*

3.5 Management Approach

The major milestones for this project were determined on a term by term basis, and the Gantt Charts and Work Breakdown Structures that represent these goals can be found in the Appendix.

For the first major goal of the project, ideation of initial design concepts, the first step to completion was to identify the project objectives, functions, specifications, and constraints. Then the team members each brought several individual design ideas, that would address these objectives, functions, etc. for review. These ideas were compared and modified based on further consideration and aspects of the separate designs were combined to create initial design concepts that would best achieve the project’s main objectives. Ultimately the final designs that were selected to move forward with at this point included the channel guide, wire and coil.

Once the initial designs were selected, they were sketched and dimensioned. Then based on materials that were found in the lab, proof of concept models were created for each design. The purpose of this was to identify any issues or advantages associated with the designs, that may not have been immediately apparent upon ideation. Additionally the channel guide was prototyped using a 3D printer and can be seen in Figure 7.
At the same time that the proof of concept models were being created, the team members also focused on creating a model that could be used to simulate use conditions for the design prototypes. This consisted of creating a birth canal and cervix model, that went through a number of iterations. The final material selections for this model were made based on feedback from the client, and thus the final model was constructed.

The next major goal for the project was to test the prototypes that had been constructed. While this testing was mainly performed on Foley catheters and Cook® Cervical Ripening Balloons, as the team did not have official prototypes, the testing informed design decisions. These tests were constructed to verify that the outlined objectives of this project would be successfully met by the device. These tests included two phases of placement time trials, tensile strength testing, and latex puncture testing.

After this testing was conducted on the initial design concepts, the designs were reassessed based on both the testing results and client feedback. As the concepts were modified, more tests were conducted to verify the design’s ability to achieve the outlined objectives. Once these design options had been narrowed down, the validation process began. Similarly to the testing phase of the project, the validation was used to verify design aspects and continue modifying the final device. Once the validation process was complete the final device for the project had been selected.

In the final phase of the project the final design was prototyped and more testing was conducted. Once this was completed the team filed for a provisional patent on the design. Additionally a presentation was created and continuously modified that represented the progression and result of this project. This presentation was practiced and presented to Biomedical Engineering peers and judges on April 20, 2017. Finally the team revised and continued writing the report.
Chapter 4: Design Process

4.1 Needs Analysis

The needs statement that was developed for this project is as follows: Develop an obstetric specific labor induction device which is easy to use for doctors and poses minimal risk to the mother and baby that results in safely inducing labor. A device that is considered “easy to use” will allow the physician to insert it correctly on the first try each time they perform the procedure. Risks to the patient that must be minimized or eliminated by the design include hyperstimulation, which can disrupt the fetal heart rate and cause uterine rupture in the mother, laceration of the cervix or vagina, premature rupture of the amniotic sac, or allergic reaction. This statement outlines all of the major functional or characteristic needs that were described by the client.

The objectives for this project were derived from the different parts of the client statement. Prior to ranking objectives, the client statement was dissected into its component parts, and each part was classified as a “need”, something that was integral to the success of the project, or a “want”, something that is desired, but not necessary for the functionality of the device.

4.1.1 Design For Obstetrics

The first need that was defined from the client statement was that the device be designed specifically for application in the physical obstetric space. The Foley catheter, the current gold standard for mechanical cervical ripening, was designed for use in the urinary tract for bladder drainage [4]. Its use as a cervical ripening device is off-label, as it was designed for use in an area that is spatially different from the cervix and vagina. Most Foley catheters have at least two lumens, one for inflating the balloon at the end and then one for draining urine. The lumen for draining urine is the larger of the two, and serves no purpose in the process of cervical ripening [4]. When the Foley catheter is inserted into the bladder doctors use ultrasound to visually guide the catheter into the bladder [4]. During insertion of the Foley catheter into the cervix doctors rely on tactile methods [5]. The Foley catheter is very flexible and has a smooth exterior that is difficult for doctors to hold on to while inserting into the cervix [5].
While the Foley catheter (Figure 8) is not designed specifically for obstetric use, the Cook® cervical ripening balloon is [26]. However, the Cook® balloon is not considered significantly better than the gold standard [22]. This is due to numerous factors that include its higher price, its large size, and its rate of effectiveness. In a study that compared the Foley catheter to the Cook® balloon, the Foley Catheter took significantly less time from insertion to expulsion of the balloon than the Cook® balloon [22]. This was likely due to the smaller size of the Foley balloon, which was filled with just 30 ccs of saline in comparison to the 80 ccs in each balloon of the Cook® balloon [22]. The time to delivery from insertion of the Foley catheter was also significantly shorter than that of the Cook® balloon [22]. This was attributed to the ability of the physicians to provide an extra-amniotic saline infusion through the Foley catheter. Despite the difference in the average durations, there was no significant difference in the success rates or the patient satisfaction of the different methods [22]. When designing our device it was crucial to keep in mind that even a device specifically designed for an application may not produce the best results for the application, as demonstrated by the Cook® balloon. The new device must be well validated through testing and comparison to the current standards to ensure that it has a significant impact on the ease of the insertion procedure or the ripening of the cervix.

4.1.2 Placement

The next important aspect of the need statement is that the device allows doctors to achieve placement on the first try. Currently the physician placing the device must hold the cervix in a forward position with their fingers, as the cervix can present in different positions, even pointing backwards, away from the opening of the birth canal as indicated in Figure 9 [30]. The physician must then feed the catheter along their hand and through the cervix [30]. The flexibility of the
catheter might cause it to bend in the wrong direction or get caught on the hand, and often the cervix slips off of the fingers before the catheter can be fully inserted [30]. This results in multiple instances of handling of the cervix thus increasing the duration of the patient’s discomfort, so it is important that the doctor is able to place the catheter swiftly, to decrease the handling of the cervix.

![Figure 9: Possible Cervical Positions](image)

4.1.3 Safety

The device must be safe for both the mother and the fetus. There should be no risk that the device can introduce infections, cause an allergic reaction, rupture the amniotic sac, or cause lacerations. Materials research was conducted to understand the materials currently in use for this purpose, and standards were consulted for testing protocols to ensure that the chosen material was not cytotoxic, would not have sharp edges, and would not leach toxins into the surrounding tissue [26]. This is essential in receiving FDA approval for the device, and ensures that the device will be approved in a premarket application.
4.1.4 Success

The last major objective for the device is that it fall out within 12 hours of insertion and induce labor within 24 hours of insertion. In order to fall out without requiring removal, the balloon diameter should not exceed five centimeters [23]. In order to be approved for sale by the Food and Drug Administration (FDA), this device must have a success rate that is better than or equal to that of the devices currently on the market. If the device does not induce labor within 24 hours of insertion at a rate greater than or equal to that of the Foley catheter, then it will be an ineffective device and will not replace the current gold standard.

4.1.5 Desires Outside the Need Statement

The “wants” of the client are additional to the needs that are outlined above. Wants can be defined as aspects of the device that are not necessary for functionality, however are desired by the client. One of the wants would be to increase the success rate of induction from 70 percent, the current standard of the Foley catheter, by 10% or more [21]. Improving the success rate is not a necessity of the design, as the client is interested in decreasing the duration of the placement procedure. However if there is any decrease in success rate then the device will not be approved for sale by the FDA.

Another desire of the client is to maintain the ability to find the cervical opening by tactile feel. In current procedures, the physician locates the cervical opening with their fingers and must hold the cervix with their fingers as the catheter is pushed along their hand until it transversed the cervix. This procedure could be done using a speculum and forceps, giving the physician the benefit of sight but adding multiple steps and devices to the procedure and increasing the time needed to complete the procedure.

A third desire is for the device to be flexible enough to allow the patient to stand and walk comfortably while the device is inserted. From insertion to dropout, the cervical ripening procedure can take up to twelve hours. Rendering the patient immobile for such an amount of time would take up space in the hospital or clinic and be unpleasant for the patient.

4.1.6 Limitations

There are many physical limitations that have contributed to the development of the objectives and specifications for this device. The device must rely solely on mechanical means to induce labor, as the pharmaceutical methods of labor induction carry an increased risk of uterine hyperstimulation, which can harm the uterus of the mother and open any pre-existing abdominal scars, as well as cause fetal distress which will harm the baby [18]. The device must also be able to fit through the opening of the cervix. This opening may be as small as 1.5 centimeters in diameter.
Therefore, the device, prior to inflation of a balloon, must be less than a centimeter in diameter, so as to fit through the opening of the cervix.

Testing of the effectiveness of the device was limited, as tests could not be carried out in human subjects. The design is also limited by the cost of development. The process of prototyping the developed solutions must fall within the allotted budget of $750.

### 4.2 Design Concepts and Feasibility

The initial design concepts were based around solving two major problems associated with labor induction, the current rate of success and the difficulty of placement. Designs were conceptualized to solve these problems.

The first problem is the current effectiveness of labor induction. Mechanical and chemical labor induction both have success rates of 70%, with a 30% rate of delivery by C-section [21]. Currently, the mechanical method of induction involves stimulating the cervix to encourage the release of prostaglandins, which are important for the remodeling of the cervix for the onset of labor [23].

Several concepts were considered that could increase the pressure put on the cervix and are depicted in Figure 10. Using a larger, wider balloon that would hold more liquid than the Foley catheter would increase the weight of the balloon. Currently, balloon dilators such as the Foley catheter and the Cook® Cervical Ripening Balloon are inflated with 60-80 cubic centimeters of saline. The increased weight due to the increased volume would increase the gravitational force on the balloon, creating greater pressure on the cervix. Filling a balloon with a liquid denser than saline would also increase the weight of the balloon without changing the dimensions.

![Figure 10: Three Conceptual Designs for Increasing Procedure Success](image-url)
Additionally, methods could be employed to put pressure on the inside of the cervix to dilate it. As cervical ripening involves an increase of water in the tissue of the cervix, facilitated by the increase of hydrophilic glycosaminoglycans, osmosis did not seem to be an option for a cervical dilator [30]. The ideas put forward for dilation involved smaller secondary balloons placed within the cervix, and a tapered balloon with a maximum diameter of 5 centimeters that would gradually push the internal os of the cervix open as gravity or the tension on the catheter pulled it downward.

The second problem identified was the difficulty of placement of cervical ripening catheters by the physician, due to the variable angle of the cervix, and the discomfort that the procedure causes to the patient [5]. This problem could be addressed by several means of guiding the catheter. The methods include a guide wire, which could be placed before the catheter, a guide channel which could be worn on the hand of the physician, or a reinforcement of the catheter to increase the stiffness all of which can be seen in Figure 11. An increased stiffness would allow the physician to slide the catheter past their fingers without it bending in the wrong direction, but would make the catheter more difficult to bend into the cervix if the cervix was in a mid or posterior facing position.

![Guide Wire Diagram](https://via.placeholder.com/150)

![Guide Channel Diagram](https://via.placeholder.com/150)

![Catheter Reinforcement Diagram](https://via.placeholder.com/150)

*Figure 11: Three Conceptual Designs for Decreasing Placement Time*

When initially assessing the conceptual designs generated in this phase, the decision was made to pursue design concepts that addressed the need to decrease placement time. This need was the prominent objective outlined in the client statement. The desire to increase the rate of success of
the device was not testable within the scope of the project, as studies in humans would not be carried out. Due to this decision, the method of induction was not changed through the design process. The device remained a transcervical balloon catheter throughout the design process. The design concepts that were pursued would aid the physician in placing the catheter in under a minute on the first try, without adjusting the method that affects cervical ripening.

4.3 Modeling the Biological System

In order to test the proposed devices a model system was needed. The model that was built consists of two parts. The first part is a close approximation of the vaginal cavity with an opening for the cervix, and the second part is an approximation of the cervix itself. These two parts were separate so that the cervix could be placed in various positions, as cervical position varies from patient to patient, and users had the ability to physically move the cervix with their fingers, an ability expressed by Dr. Callery. For the first part of the model, the vaginal approximation, the process of modeling occurred in three iterations; a Styrofoam model, a sponge model and a memory foam model. After each iteration feedback from the sponsor was obtained in order to make sure the correct test system was being modeled.

The final version of the model was made from memory foam (Figure 12). The dimensions allow for the potential of stretching the material and return to its original shape. The representation of the vaginal opening was 3 cm in diameter and the slot for the cervical opening was 2 cm x 6 cm. According to the client, these dimensions were accurate to the biological system, and allowed for the natural variation seen therein.
The second component of our model system was the cervix (Figure 13). This was made from Crayola Model Magic to represent the stiffness associated with an unripened cervix. The top of the model has a diameter of 5 cm, the bottom has a diameter of 3 cm. The hole that represents the cervical canal has a diameter of 2 cm and the piece is 2.5 cm tall.

![Figure 13: Cervix Model](image)

Several interchangeable cervix models were created that fit into the slot at the top of the birth canal model. These models were each 2 cm tall, and had inner diameters of 2.1 cm, 1.6 cm, and 1.2 cm. This created a system that mimicked the consistency and dimensions of the birth canal and possible cervical sizes in a patient at 40 weeks of pregnancy. This system, seen all together in Figure 14, allowed testing of the time needed to place prototypes, and allowed the client to gauge the ease of use of the prototype.

![Figure 14: Entire model system](image)
4.4 Alternative Designs

In this phase of the project, three alternate designs were isolated to perform the desired functions. All of the designs are similar to the Foley catheter that is currently used off-label for mechanical labor induction, but each has been changed to specialize it for placement in the cervix, rather than the urethra for which it had been designed. These three designs consisted of a coil-reinforced method of stiffening the catheter, creating a new catheter with a lumen for a wire that will be flexible at the end in order to better place in a cervix in the mid or posterior position, and a method of attaching the catheter to the finger of the physician so that they would be able to place the device at the same time as they find the cervix (Figure 15).

![Diagram of alternative designs](image)

Each alternate design includes a balloon that will fill to 80 ccs, a single lumen for filling the balloon, and a distance between the top of the uninflated balloon and the top of the catheter of 5 mm. The single lumen was chosen after discussion with Dr. Ryan Callery, who conveyed that a lumen for drainage was not necessary for the purpose of cervical ripening. The lack of a drainage lumen also allowed for the catheter to be a smaller French size while still performing the cervical ripening function.

The three design variations all focus on the method of placement of the catheter in the cervix. The methods of decreasing time and increasing consistency of catheter placement are
increasing the stiffness of the end of the catheter that is manipulated during insertion, or providing an aspect of the catheter design that allows the physician to grip the catheter at the end to guide it into the cervix. An increase in the stiffness of the catheter could be achieved by using a flexible, removable stylet, or reinforcing the catheter with a coil.

The design of the removable, flexible stylet carries the least amount of change from the original Foley catheter (see Figure 2). It will increase the stiffness of the catheter without increasing the size, by using a metal wire that is flexible in the last 10 centimeters. This will make the catheter more manipulable by the physician, as to insert the catheter into the cervix, the catheter must be curved to various degrees depending on whether the cervix is in an anterior, middle, or posterior position. Current stylets are straight and rigid, which helps in pushing the catheter into place, but does not provide any aid in curving the catheter. This stylette will also be removeable, so that the catheter becomes flexible, and will not impede the ability of the patient to move or cause additional discomfort by putting additional pressure on the cervix. The wire stylet design was chosen because it requires the physician to make few or no changes to their procedure.

The coil reinforced catheter, seen in Figure 16, will also increase the stiffness of the catheter but will not increase the diameter. It will make the device easier to manipulate, but will still have enough flexibility to avoid putting excessive pressure on the cervix. It does not need to be removed from the catheter once the device has been inserted. The coil will not be stiff enough to cause discomfort, and it will not affect the tension on the catheter should the physician choose to pull the catheter and tape it to the leg of the patient to increase the force on the cervix. The fact that the coil does not need to be removed means that the physician does not have to add an additional step to
the procedure. The coil method was chosen as a method for increasing stiffness, as the manufacturing processes for catheters already exist using latex and silicone. The mechanical and biocompatibility properties of these materials are already known, and they are already used in this application without adverse effect, such as leaching of cytotoxic chemicals. Thus, reinforcing the catheter ensures that the body will be exposed only to materials that are already commonly used for these applications, and therefore the physician and patient can be confident that the material will not cause an adverse response.

Figure 17. The tip of a catheter with a lumen for inflation and a 20 gauge coil

A method for the physician to grip or attach the end of the catheter to their fingers will enable them to locate the cervix and place the catheter at the same time, a feature that does not exist for the reinforced catheters described above. This feature will cause the most dramatic change to the method of manufacture of the catheter, but it aligns the most with the desires and ideas of the client. This feature stands to drastically reduce the time to placement for the device. The finger attachment was chosen as an alternative to the guide channel and can be seen in Figure 18. It was indicated by Dr. Ryan Callery that the physician that was placing the device would not want to have a long channel as it would take up space and might impede placement through the cervix. The finger attachment was chosen as it would be attached to the catheter, meaning there would be no extra parts for the physician to keep track of during the procedure.
After the initial testing phase, the design of the base catheter was modified for use in the birth canal and cervix, this can be seen in Figure 19. This design was also a response to the issues that were associated with the use of the Foley catheters and Cook® Cervical Ripening Balloon in practice. The lumen size was chosen to be 2.7 mm in diameter due to calculation of the maximum tensile strength of the material. A 2.7 mm lumen allowed enough cross sectional area in the 18 French catheter that the catheter would be able to withstand 150 Newtons of force with a maximum tensile strength of 7 Newtons/mm², as is indicated in the CES Edupack database as the maximum tensile strength of medical silicone. The maximum diameter of the balloon, as specified by the client, was 5 centimeters. Because the volume of a sphere with a diameter of 5 cm is 65.45 cm³, the balloon would be rated for 80 cubic centimeters of saline. This excess volume accounts both for the fluid that would remain in the lumen of the device, and for any possible overfilling of the balloon. The balloon will not rupture upon immediate overfill.

The other modification to the catheter was to have the balloon inflate over the proximal tip of the catheter. This would completely eliminate the extra space at the tip of the catheter that could potentially rupture the amniotic sac. A representation of this obstetric specific catheter can be seen in Figure 19 below.
Figure 19: Alternative design for catheter made specifically for the obstetric practice that will increase ease of use by placing balloon at the tip of the catheter. By increasing ease of use the doctor will handle the cervix less therefore causing less discomfort for the patient.

A side by side comparison of this catheter in use in comparison to the Foley catheter can be seen in Figure 20.

Figure 20: A comparison of the Foley catheter in use (left) to the obstetric specific catheter design (right)

This figure demonstrates how relocating the balloon to the proximal tip of the catheter will eliminate the excess length at the top of the Foley catheter.

4.5 Alternative Design Prototypes

Once the alternative designs had been developed, they were all prototyped using 18 French latex tubing and balloons. These prototypes can be seen in the figure below.
Once the prototypes had been created, the client, Dr. Callery, was able to interact with them and practice the insertion procedure on the birth canal model system. Based on feedback from this interaction, the team decided to further pursue the stylet and finger strap designs, while the coil design was eliminated as an alternative option. Additionally, another design that incorporated two finger straps was added, in order to counteract the issues that became apparent with the one finger strap prototype after it was used in the model.

Figure 22 represents the changes that would be made to the catheter alone, based on issues that directly resulted from the use of the Foley catheter and Cook® Cervical Ripening Balloon in practice.
Chapter 5: Design Verification

In the design verification stage, tests were carried out to compare and improve aspects of each design to better fit the need statement, as well as to establish baseline values. A series of mechanical tests were conducted to measure the force of the Foley catheter on the cervix and amniotic sac, as well as the force required of 20 gauge copper wire to puncture latex, proving that a stylet of the same material would not puncture a catheter while placement was being performed. From these tests, an understanding was gained of the parameters the new device would have to meet. Besides force testing, placement time trials were conducted using Foley Catheters, design prototypes, and the birth canal model system to compare the proof of concept to the gold standard. These trials established the design space and showcased immediate changes.

Experiment 1: Force of balloon on cervix

Goal: This test was conducted in order to ensure that the act of pulling on the balloon once it was placed and inflated would not cause excessive discomfort to the patient. This test was performed using Foley catheters inflated to 60 cubic centimeters to establish a baseline for the amount of force experienced by the cervix during current insertion procedures.

Materials:

- Water
- Saline
- Model cervix - early Styrofoam iteration, as these tests were carried out in tandem with the development of the model.
- Two 16 French Foley balloon catheters
- Syringe for balloon inflation
- FSS005WNSB resistive force sensor 0 ~ 5N
- ELVIS II prototyping board
- Electrical tape

Methods:

To setup this experiment the resistive force sensor was connected to the ELVIS II prototyping board according the pin configuration depicted in Figure 23. Pin 1 of the wheatstone bridge was connected to the positive terminal of a 5 V supply, Pin 2 was connected to the positive lead of the board's voltmeter, Pin 3 to ground, and Pin 4 to the negative lead of the voltmeter.
According to this setup, the output voltage was measured as a differential voltage across Pin 2 and Pin 4 as shown by Equation 1, where $V_o$ represents the output voltage:

$$V_o = V_o(+) - V_o(-)$$

Eq. 1. The differential voltage across the force sensor

Once the force sensor was connected to the prototyping board the NI Instrument Launcher software was opened on the computer and the digital multimeter selected, to measure the output voltage of the force sensor. Next the force sensor was mounted so that it was completely flat on the surface of the cervix model, and placed close enough to the edge of the inner cervical opening that the catheter balloon would rest directly atop of it when fully inflated. The force sensor was fixed in this position using electrical tape. The first of the 16 French catheters was then fed through the cervical opening and the balloon inflated with 60 cc of water. Once the balloon had been inflated the cervix model was moved so that the entire cervical opening overhung the edge of the tabletop surface. This allowed the catheter to hang freely from the cervix, so that there would be no interference with the force being applied to the cervix by the inflated balloon. Once everything had been placed the balloon was balanced onto the force sensor using a finger. This was necessary as the balloon itself would not remain in an upright position without support, so the finger was used as that support while ensuring that it did not apply any additional forces on the sensor.

When the balloon was balanced the prototyping board was turned on to apply the 5V voltage supply and the digital voltmeter was run. Once the voltage value measured by the voltmeter stabilized, then the voltmeter was stopped and the resulting voltage recorded. The balloon catheter
was then drained of the 60 cc water. This entire process was repeated twice more, for a total of three trials with 60 cc of water, and three more times using 60 cc of saline. Once completed, the same six trials were performed on a new 16 French catheter. Figure 24 shows the setup of the experiment.

Figure 24: The experimental setup to measure the force of the 60cc balloon on the cervix

**Results:**

The results that were obtained for this experiment were recorded and can be seen in Table 2. The results were originally recorded as voltage (mV) but then converted to force applied (N) using the specified sensitivity of the force sensor, as shown below.

\[
\text{Sensitivity} = 7.2 \text{ mV/V/N} \\
\text{Sensitivity} \times \text{supply voltage} = 7.2 \times 5 = 36 \text{ mV/N} \\
\text{Thus, force applied (N)} = \frac{1 \text{ N}}{36 \text{ mV}} \times \text{measured voltage (mV)}
\]
Table 2: Recorded forces applied to the cervix

<table>
<thead>
<tr>
<th></th>
<th>60 cc Water</th>
<th></th>
<th>60 cc Saline</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Output Voltage (mV)</td>
<td>Force Applied (N)</td>
<td>Output Voltage (mV)</td>
<td>Force Applied (N)</td>
</tr>
<tr>
<td>Catheter 1:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial 1</td>
<td>9.218</td>
<td>0.256</td>
<td>10.397</td>
<td>0.289</td>
</tr>
<tr>
<td>Trial 2</td>
<td>8.399</td>
<td>0.233</td>
<td>10.640</td>
<td>0.296</td>
</tr>
<tr>
<td>Trial 3</td>
<td>9.030</td>
<td>0.251</td>
<td>11.401</td>
<td>0.317</td>
</tr>
<tr>
<td>Catheter 2:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial 1</td>
<td>8.456</td>
<td>0.235</td>
<td>11.241</td>
<td>0.312</td>
</tr>
<tr>
<td>Trial 2</td>
<td>9.339</td>
<td>0.259</td>
<td>10.999</td>
<td>0.306</td>
</tr>
<tr>
<td>Trial 3</td>
<td>9.142</td>
<td>0.254</td>
<td>11.295</td>
<td>0.314</td>
</tr>
<tr>
<td>Average Values:</td>
<td>8.931</td>
<td>0.248</td>
<td>10.996</td>
<td>0.305</td>
</tr>
<tr>
<td>Standard Deviation:</td>
<td>0.368</td>
<td>0.0102</td>
<td>0.365</td>
<td>0.0101</td>
</tr>
</tbody>
</table>

Experiment 2: Force of catheter on amniotic sac

**Goal:** Because there is a slight risk of the amniotic sac rupturing during placement of the Foley catheter, but no available data describing the forces exerted on the amniotic sac by any cervical ripening device, the test was conducted to establish a baseline for the amount of force experienced by the amniotic sac during a Foley catheter and Cook® balloon insertion.

**Materials:**
- Water
- Latex balloon
- Cervix model - Styrofoam iteration
• Memory foam birth canal model
• 16 French Foley balloon catheter
• 18 French Foley balloon catheter
• 18 French Cook® cervical ripening balloon
• 20 gauge copper wire
• Syringe for balloon inflation
• FSS005WNSB resistive force sensor 0 ~ 5N
• ELVIS II prototyping board
• Tape
• Plastic weigh dish

Methods:

First, the balloon was filled with water in the sink, then the force sensor was taped to the side of the inflated balloon, so that it was as level possible on the surface. The balloon was then rested on the tabletop (force sensor side facing upward) and taped in place to prevent rolling and sliding when force was applied.

The ELVIS II prototyping board and force sensor were then set up in the same configuration as Experiment 1 with Pin 1 of the wheatstone bridge connected to the positive terminal of a 5 V supply, Pin 2 connected to the positive lead of the board’s voltmeter, Pin 3 to ground, and Pin 4 to the negative lead of the voltmeter (see Figure 23). Once this step was completed, a circular plastic tab (cut from the plastic weigh dish) approximately the size of a quarter (~25 mm in diameter) was gently taped over the actuator ball of the force sensor. This was intended to evenly distribute the force applied over the actuator ball, as it was difficult to obtain an accurate reading when force was applied from the rounded tip of the catheter onto the rounded surface of the actuator ball. Figure 25 below depicts the setup of this experiment.
The NI Instrument Launcher software was opened on the computer and the digital multimeter selected, to measure the output voltage of the force sensor. Next the 16 French catheter was held at a distance of 15 cm from the tip in the non-dominant hand, while the catheter was fed down the dominant hand, using only the index and middle fingers for guidance, as is done in the medical procedure. The catheter was fed so that the tip of the catheter came into direct contact with the plastic tab, and the maximum resulting voltage was recorded to represent the maximum force that the catheter was capable of applying to the amniotic sac. These voltages were then converted to Newtons using the sensitivity factor that can be seen in Equation 1. This was repeated three times for each of the 16 and 18 French Foley catheters, as well as the Cook® catheter. Next the length of copper wire was inserted into the drainage lumen of the 16 French catheter, and experiment was repeated for three trials. The wire was inserted into the 18 French catheter next and the process repeated, for an overall total of six trials with the wire insertion. This procedure could not be performed on the Cook® catheter, as the catheter only has two lumens for inflating the balloons, and therefore the valves prevent the wire from being inserted.

**Results:**

The following Table 3 shows the average force values obtained from the three trials performed for each catheter with and without the copper wire. The results were originally obtained as output voltage values and then converted to measurements of force using Equation 1 from Experiment 1. Additionally these values are the difference of the maximum voltage when the
catheter tip applied force to the plastic tab and the starting voltage reading (resulting from the force of the plastic tab itself). For the raw data, see Appendix C.

Table 3: Force applied to amniotic sac in catheters with and without wire insert

<table>
<thead>
<tr>
<th></th>
<th>16Fr</th>
<th>18Fr</th>
<th>Cook®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without Wire</td>
<td>0.279 ± 0.009 N</td>
<td>0.361 ± 0.042 N</td>
<td>0.343 ± 0.025 N</td>
</tr>
<tr>
<td>With Wire</td>
<td>0.562 ± 0.045 N</td>
<td>0.683 ± 0.076 N</td>
<td>-------</td>
</tr>
</tbody>
</table>

Experiment 3: Force required to puncture latex

**Goal:** If a wire is to be incorporated in the design, whether as a stylet or as a coil incorporated into the device, it must be ensured that a wire would not be able to puncture the catheter and risk lacerations in the cervix and vagina or the puncturing of the amniotic sac. This test showed how much force was needed for a 20 gauge copper wire to puncture 3 and 6 mm sheets of latex. This helped to ensure that the coil and stylet would be separated from the body with enough latex or silicone that there would be no risk of puncture during use.

**Materials:**

- Instron 5544
- Bluehill Software
- 10cm lengths of 20 gauge copper wire (6)
- Sheets of 0.3mm thick latex (3)
- Sheets of 0.6mm thick latex (6)
- Rubber Bands

**Methods:**

A test method for the Instron 5544 was created in the Bluehill software interface. This method caused the upper clamp of the Instron to lower towards the pommels used for three point bending at a rate of 20mm/minute. The software recorded the time points at which it took measurements, the force being exerted by the upper clamp at each time point, and the distance that the upper clamp had traveled from its original position.
Once the method had been created, a 10 cm length of 20 gauge copper wire was inserted into the clamp with the end of the wire flush with the top of the clamp. The sheet of latex was placed taut over the clamps, which had been separated to two centimeters apart, and was secured in place with a rubber band.

![Figure 26: Experimental setup for the puncture test](image)

Once the setup was complete, as seen in Figure 26, the upper clamp was lowered until a pressure reading of less than 0.001 Newtons was displayed on the Bluehill interface and the extension was set to zero. A plexiglass safety shield was placed between the machine and the operators. The Bluehill method described above was run, causing the clamp to lower at 20 mm/min until a sudden drop in the force indicated that the latex had been punctured. The clamp stopped, and raw data was output to a spreadsheet. A new wire and latex sheet were used for each trial.
Results:

The maximum force recorded for the wire on the 0.3mm thick sheet of latex was $2.718 \pm 0.493$ Newtons, and the maximum for the 0.6mm sheet of latex was $5.005 \pm 0.858$ Newtons. In the three trials of the 0.3mm latex, all latex sheets were punctured by the wire. In two of the three trials of the 0.6mm latex, the wire bent between two and three centimeters above the interface between the latex and the wire, and the latex was not punctured. In the third trial of the 0.6mm latex, the wire did not bend and the latex was punctured.

Figure 27: a) A graph of the load vs. extension for a 20 gauge copper wire puncturing of a 0.3mm latex sheet. b) A load vs. extension graph for a 0.6mm latex sheet trial that experienced bending of the wire. c) A load vs. extension graph for the 0.6mm latex sheet trial that did not experience bending of the wire.
Table 4: The maximum forces on 0.3mm and 0.6mm thick latex by a 20 gauge copper wire

<table>
<thead>
<tr>
<th></th>
<th>0.3 mm thick latex</th>
<th>0.6 mm thick latex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial 1 - max force</td>
<td>3.25222 N</td>
<td>4.02051 N</td>
</tr>
<tr>
<td>Trial 2 - max force</td>
<td>2.28072 N</td>
<td>5.59268 N</td>
</tr>
<tr>
<td>Trial 3 - max force</td>
<td>2.62198 N</td>
<td>5.40203 N</td>
</tr>
<tr>
<td>Average ± Standard Deviation</td>
<td>2.718 ± 0.493 N</td>
<td>5.005 ± 0.858 N</td>
</tr>
</tbody>
</table>

Experiment 4: Placement Time

Goal: The purpose of this experiment was to assess which of the three French sizes of Foley catheter, that are commonly used in this application, was most effective during the placement procedure. This meant that the insertion procedure was timed, and the French size with the fastest average placement time would be used in the final design. This helped achieve the primary objective of increasing ease of use as a result of faster placement time.

Materials:
- Memory foam model
- Styrofoam cervix
- 16, 18, 22 French Foley catheters
- Cook® Cervical
- 24 in 20 gauge copper wire

Methods:
This test was performed in two phases. The first phase used Foley catheters of multiple French sizes, as well as the cook catheter, and a flexible wire stylet. One person held the model in place to prevent movement. Then the timer was started after indicated by the person conducting the trial. The tester then attempted to place the balloon above the cervix (using the index and middle fingers) and once proper placement was achieved the timer was stopped. This methodology was repeated three times for each catheter French size, three times with the 20 gauge copper wire inside and then one time each with the Cook® catheter.
For the second phase of the test, prototypes were created of each alternative design that was being pursued. The model was attached to a wooden board and clamped to the table and a blind was installed so that the user could not see the cervix. A timer was started when the fingers of the tester passed through the opening of the model, and was stopped when the balloon was entirely above the cervix.

**Results:**

The following Table 5 represents the average time (in seconds) that it took each of the three team members to insert the catheters into the model, both with and without the copper wire insert.

*Table 5: Average insertion time of different catheters with and without wire insert*

<table>
<thead>
<tr>
<th></th>
<th>Operator 1 Trials Average (sec)</th>
<th>Operator 2 Trials Average (sec)</th>
<th>Operator 3 Trials Average (sec)</th>
</tr>
</thead>
<tbody>
<tr>
<td>16 French</td>
<td>35.00 ± 15.27</td>
<td>9.37 ± 0.87</td>
<td>10.35 ± 2.08</td>
</tr>
<tr>
<td>16 French w/wire</td>
<td>15.03 ± 5.92</td>
<td>10.36 ± 3.03</td>
<td>9.78 ± 1.31</td>
</tr>
<tr>
<td>18 French</td>
<td>10.15 ± 1.99</td>
<td>7.76 ± 0.85</td>
<td>10.01 ± 1.56</td>
</tr>
<tr>
<td>18 French w/wire</td>
<td>6.15 ± 1.30</td>
<td>9.76 ± 4.26</td>
<td>10.75 ± 1.54</td>
</tr>
<tr>
<td>22 French</td>
<td>12.58 ± 1.97</td>
<td>15.57 ± 7.42</td>
<td>9.49 ± 2.95</td>
</tr>
<tr>
<td>22 French w/wire</td>
<td>6.89 ± 1.81</td>
<td>10.65 ± 2.63</td>
<td>7.71 ± 0.53</td>
</tr>
</tbody>
</table>

The same experimental procedure was also used in order to test the three major designs against the Foley catheter. The following table shows those results.
Table 6: Placement time trials of alternative designs

<table>
<thead>
<tr>
<th>Catheter Style</th>
<th>Operator 1 Trials (sec)</th>
<th>Operator 2 Trials (sec)</th>
<th>Operator 3 Trials (sec)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 Fr</td>
<td>12.33 ± 1.44</td>
<td>10.05 ± 3.60</td>
<td>15.74 ±1.99</td>
</tr>
<tr>
<td>18 Fr w/ wire</td>
<td>9.05 ± 0.77</td>
<td>5.78 ± 2.43</td>
<td>12.47 ± 2.12</td>
</tr>
<tr>
<td>18 Fr w/strap (3 cm from tip)</td>
<td>5.66 ± 0.46</td>
<td>4.27 ± 1.17</td>
<td>4.15 ± 0.99</td>
</tr>
<tr>
<td>18 Fr w/two straps (1 and 3 cm from tip)</td>
<td>2.82 ± 0.18</td>
<td>1.93 ± 0.48</td>
<td>2.48 ± 0.57</td>
</tr>
</tbody>
</table>

Experiment 5: Tensile Strength

**Goal:** this test was carried out in order to ascertain the maximum tensile forces that could be withstood by the mechanical labor induction devices currently in use. As the procedure for cervical ripening often involves pulling the catheter once it has been placed, it is important to know the maximum tensile strength of devices commonly used and approved for this procedure.

**Materials:**
- 9 cm sections of shaft of 18 Fr Foley catheter and Cook® Cervical Ripening Balloon
- Instron 5544 and accompanying Bluehill Software
- Gauze to prevent the catheter shaft from slipping from the Instron crosshead grips

**Methods:**
1. A procedure was set up in the Bluehill software that accompanied the Instron 5544. This procedure moved the top crosshead upwards at a rate of 500 mm/min and .
2. A Foley catheter was cut into a strip of 9 cm in length. This piece was taken from the shaft of the device and did not include any part of the balloon or joint near the bottom of the catheter.
3. Next the top end of the catheter was wrapped in gauze and placed into the upper grip of the Instron. This was tightly fixed in with approximately 2 cm of the catheter held in the grip.
4. The upper grip was then lowered so that it was positioned 5 cm above the bottom grip, and the bottom 2 cm of the catheter strip was fixed tightly into the grip.
5. The Bluehill procedure outlined in the first point of these methods was run, applying tensile force to the sample until the sample ruptured.
6. Once broken, the force data was recorded for the catheter.

7. The procedure was then repeated for the Cook® Cervical Ripening Balloon.

Results:

The maximum force withstood by the Foley catheter was greater than the maximum force withstood by the Cook® Cervical Ripening Balloon, as shown in the table below. The cross sectional area of the Cook® Cervical Ripening Balloon was smaller than that of the Foley catheter, thus the calculation of the maximum tensile strength (in Newtons/mm$^2$) showed that the Cook® Cervical Ripening Balloon had a higher tensile strength. A visual comparison of the cross sectional area of the Cook® Cervical Ripening Balloon and the Foley Catheter can be seen in Figure 28.

![Image of cross sections]

Figure 28. Cross sections of a) the Cook® Cervical Ripening Balloon and b) the two-lumen Foley catheter.

<table>
<thead>
<tr>
<th></th>
<th>Expected: Tensile strength (N/mm$^2$)</th>
<th>Actual: Tensile Strength (N)</th>
<th>Actual: Tensile strength (N/mm$^2$)</th>
<th>Human Pulling Strength (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cook® Catheter</td>
<td>N/A</td>
<td>110</td>
<td>7.01</td>
<td>60-80 [33]</td>
</tr>
<tr>
<td>Foley Catheter</td>
<td>6.6 - 8 [35]</td>
<td>150</td>
<td>5.3</td>
<td>60-80 [33]</td>
</tr>
</tbody>
</table>

Table 7: Expected vs. Actual Tensile Strength

Figure 29 below shows the load versus extension data for the Foley catheter. The catheter withstood almost 150 Newtons of force, and broke at the grip.
Figure 29: Foley Catheter Load vs. Extension Graph

Figure 30 shows the load versus extension data for the Cook® Cervical Ripening Balloon. The shaft withstood about 110 Newtons of force, and also broke at the grip.

Figure 30: Cook® Catheter Load vs. Extension Graph
Chapter 6: Final Design & Validation

6.1 Final Design

The final design resulting from this project is a cervical ripening balloon catheter. It will consist of an 18 French catheter constructed entirely of silicone. There will be two lumens in the catheter, with one for balloon inflation with a diameter of 2.7 mm and one for a 20 gauge stainless steel stylet with a diameter of 0.81 mm. The catheter will end with a spherically shaped balloon that covers the top of catheter and is rated for 80 ccs of saline. Approximately 1 and 3 cm below the tip of the catheter, adjustable finger straps of 2 mm thickness and minimum diameter of 1 cm will be placed. This overall design can be seen in Figure 31 below.

![Figure 31: Final Design](image)

In this design, the project’s objective for ease of use was addressed by various design features. These features include:

- 2.7 mm balloon inflation lumen
- Stylet, in the case of the physician not being able to reach the cervix with their fingers
- Balloon repositioning (balloon over proximal tip of catheter)
- Two finger straps at 1 and 3 cm from the proximal tip of the catheter
The second objective of reducing patient discomfort was addressed by the following features, in addition to improving the ease of use which would in turn reduce handling of the cervix.

- 18 French catheter sizing
- Balloon position

The third objective of ensuring safety was addressed based on the materials that were selected for the device. Currently the Foley catheter is coated in silicone, and the Cook® Cervical Ripening Balloon is constructed entirely of silicone. As both of these devices are FDA approved and proven to be safe, silicone was the material selected for this application. Additionally, stainless steel was selected as the material for the stylet, because although ideally the stylet would never come in direct contact with the patient, it is a safe and hypoallergenic material [36].

The final two objectives were also addressed with the resulting device. It is a simple device and is a mechanical method of labor induction. The device also does not complicate the current procedure or incorporate any extra components that would require physicians to relearn the procedure. While the last objective of inducing labor at a rate equal to or greater than the current standard cannot be directly tested within the scope of this project, it was assumed that since the amount of saline held by the balloon would only change by the addition of 5 ccs, the induction time should not decrease.

6.2 Validation

The test that was performed during the validation process for this design was the placement time trials carried out on prototypes of alternate designs using the birth canal and cervix model. This test proved that the double finger strap design was the fastest to correctly place, in comparison with the current procedure and all other alternate designs. The step by step procedure for this test can be seen below and Figure 32 shows the beginning steps.

1. The birth canal and cervix model was set up so that the blind prevented the subject from viewing the cervix. Additionally, the cervix was held in place by the rubber band system.
2. The subject then put gloves on and placed the finger strap onto the forefinger of the preferred hand. The strap was placed so that the fingertip was approximately level with the tip of the catheter.
3. When the subject had properly placed the catheter on the finger, and was prepared to begin the procedure, the timer was started.
4. Next the subject inserted the catheter, middle and forefinger into the model and guided the catheter out through the cervix at the back of the model.
5. The timer was stopped when the catheter emerged from the cervix at the back of the model, and this time was recorded.
6. The procedure was repeated three times by each member of the team, for a total of 9 placement trials.

The purpose of this validation experiment was to test the success of the first three objectives for this project. The ease of use was tested both by assessing the number of attempts that it took to insert the catheter during each trial, and the total time required to complete the procedure. The second objective of reducing patient discomfort also relied on these two variables since an increased number of attempts at inserting the catheter results in increased handling time of the cervix. Additionally, the longer the procedure takes, the more discomfort a patient will experience. The third objective of ensuring safety was addressed by observing any resulting damage to the birth canal and cervix model. For instance, when performing a similar trial on the Cook® cervical ripening balloon, the double balloons caused lacerations on the cervix model. While the cervix model is not a perfect simulation of a natural cervix, the damage done to the model was significantly greater than that resulting from Foley catheter trials.

The following table represents the results that were obtained from timing the placement trials. Refer to Chapter 4, Figures 21 and 22, for pictures of the prototypes.

*Table 8: Placement Time Trials Data*

<table>
<thead>
<tr>
<th>Catheter Style</th>
<th>Operator 1 Trials (sec)</th>
<th>Operator 2 Trials (sec)</th>
<th>Operator 3 Trials (sec)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 Fr</td>
<td>12.33 ± 1.44</td>
<td>10.05 ± 3.60</td>
<td>15.74 ± 1.99</td>
</tr>
<tr>
<td></td>
<td>Average Placement Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>------------------------</td>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>18 Fr w/ wire</strong></td>
<td>9.05 ± 0.77</td>
<td>5.78 ± 2.43</td>
<td>12.47 ± 2.12</td>
</tr>
<tr>
<td><strong>18 Fr w/strap</strong></td>
<td>5.66 ± 0.46</td>
<td>4.27 ± 1.17</td>
<td>4.15 ± 0.99</td>
</tr>
<tr>
<td><strong>18 Fr w/wire &amp; strap</strong></td>
<td>2.82 ± 0.18</td>
<td>1.93 ± 0.48</td>
<td>2.48 ± 0.57</td>
</tr>
</tbody>
</table>

It was clear through the data obtained by this experiment that attaching the balloon to the hand of the person placing it through the cervix had the potential to reduce the time of the placement procedure by up to sixfold. The addition of the straps gave more consistency to those placing the device, causing the standard deviation to be smaller between trials with each addition of a strap.

The following graph is another representation of the data found in Table 8 above and represents the average of all nine trials for each of the catheter designs.

![Figure 33: Average placement times for alternative designs](image)

The average time to placement (Figure 33) decreased substantially with each addition of a design element. The 18 Fr catheter with the balloon at the proximal tip took the longest time to place and had a high overall variation between trials. The stylet reduced the time to placement, while still maintaining a high amount of variation. The strap in place of a stylet reduced the both the time of insertion and the variation between trials, and the addition of a second strap further reduced both. As a result of this trial, the two finger straps were added to the final design.
6.3 Wider Impact

6.3.1 Economics

The result of this project will not seriously impact the cost of everyday living for its intended patient population. However, during the process of delivery it may result in a highly reduced hospital bill. In the United States, a C-section procedure alone (not including hospital stay and postoperative care) costs on average more than $15,000 [37]. In this case, the alternative method of mechanical induction involves either a Foley catheter or Cook® cervical ripening device, both of which cost less than $50. The resulting cervical ripening device from this project would be similarly priced at approximately this value, allowing patients to save thousands of dollars.

6.3.2 Environmental Impact

The proposed design is meant to be very close to current devices on the market. This means the device will come sterilized and packaged to maintain sterility. Current devices are packaged in a paper and plastic mixed wrapping. The proposed device will come in a similar packaging therefore creating no significant additional impact on the environment both positive or negative. Also the device is for a small niche market so it will not be produced in quantities that would be detrimental to the environment.

6.3.3 Societal Influence

There are currently two major reasons why labor induction is performed. Either there are complications with the pregnancy and it is safer to have the baby than to let the pregnancy continue, or the induction is elective because the mother would prefer to have the baby to end the pregnancy. The former, indicated induction, occurs most often after the 40 week gestational period, while the latter, elective induction, occurs between 39 and 40 weeks.

In the case of indicated induction, the mother wishes to avoid a C-section if possible. It has been found through studies that include interviews and questionnaires that a majority of women prefer a natural birth to a C-section. The study also found that women are more likely to accept the risks that come with natural delivery than their doctors [38]. A C-section is a major surgery that the mother must recover from, delaying breastfeeding and bonding with the baby.

In the case of elective induction, many factors drive the mother to wish to end the pregnancy at the due date, or to schedule the delivery. In the study conducted, almost 50 percent of the women involved chose to incite labor using induction [39]. However,
inducing labor at term rather than waiting for it to start naturally increases the risk of a C-section [40].

6.3.4 Political Ramifications

With hope our proposed device will be cheaper and significantly easier to use than current labor induction devices. The intended use is for doctors in hospitals to use to ripen the cervix. However if the device can be marketed for low enough cost it could be sold to developing countries.

6.3.5 Ethical Concerns

The proposed design will ripen the cervix to induce later equal to or better than the current gold standard. The final design will also be easier for the doctor to use and place. This will make the procedure easier on the patient and more comfortable. With more comfort, patients will be less likely to want the device removed and therefore the device will have the time to induce labor. With more births resulting from labor inductions than fewer Cesarean Sections will have to be performed. It is crucial to avoid major surgery whenever possible.

6.3.6 Health & Safety Issues

Labor is induced in order to lower the incidence of C-sections in post-term pregnancies. The C-section is a major surgery and therefore carries many of the same risks of complications as most major surgeries. It also comes with a lengthy recovery period, and has possible repercussions for both mothers and babies.

According to a study, a high percentage of women do not conceive again after a C-section birth. Some report being scared to become pregnant again, as they do not want another C-section. Some women find they are unable to conceive again after a C-section [41].

There are also health concerns for the baby that was born through C-section. Natural birth gives the baby the first bacteria in its gut. Without this, it will have to cultivate gut bacteria on its own, which might take some time. This also might cause immune deficiencies for the child. Conditions such as obesity and coeliac disease have been found to have higher rates of occurrence in those born via C-section [42].

This device aims to ease the process of labor induction in postterm pregnancies, which will decrease the incidence of C-sections in these cases, avoiding lengthy recovery periods for the mother, and long-term negative effects on the child.
6.3.7 Manufacturability

Due to the design of the device being altered in order to fit the birth canal and cervix size and shape, some manufacturing processes will be altered as well. Currently, catheters are extruded, holes are cut into the lumens for drainage or balloon inflation, a sheet of latex is placed over the balloon inflation outlet to form the balloon, and the catheter as a whole, dipped into silicone [43]. For this new device, several changes will need to be made.

Manufacturing practices exist that account for various catheter diameters, lumen diameters, and balloon sizes. However, the balloon will sit at the tip of the catheter, so instead of a sheet, a cap will need to be added. A new process entirely will need to be added in order to affix the strap to the catheter. This would add a single step to the manufacturing process.

6.3.8 Sustainability

After use in the body, the device would be considered medical waste and disposed of appropriately in the hospital. Since the material is silicone, it would most likely be incinerated by a medical waste disposal vendor and thus is not recyclable.
Chapter 7: Discussion

In the course of designing, multiple questions have arisen regarding aspects of the design that could not be answered through the objectives or specifications. These questions required tests to be carried out in order to obtain the information needed to make decisions about the design. In the course of the design process, the following questions were asked. What should be the outer diameter of the device? Which method of placement will work best for the device? What is the best lumen diameter for inflation of the balloon? Tests were conducted in order to address each of these questions.

Much of the testing was carried out on the birth canal and cervix model designed and constructed for this purpose, as the testing of the device in live subjects was outside of the scope of the project.

7.1 Material Selection

Performing the tensile strength test contributed to design decisions regarding the material selection of the final device. To successfully achieve the project’s third objective of ensuring safety, the material needed to be able to withstand more tensile force than an operator would be able to exert on the device during the procedure. Although the Cook® device was able to withstand a lower tensile load than the Foley catheter, its smaller cross sectional area indicated that its tensile strength was significantly higher than that of the Foley catheter. Thus, silicone was ultimately the selected material for the final design. This decision was also due to the allergenic effect of latex. Although ideally this portion of the catheter never comes into contact with the patient, it is an unnecessary risk in this application.

7.2 Outer Diameter

In order to determine what the best outer diameter for the device would be, the time that it took to place catheters in the model was assessed for catheters of different French sizes. The catheters that were used for this experiment were between 16 and 22 French, as those are the sizes that have been indicated to be most often used for mechanical induction [22].

The 18 French catheters both with and without the 20 gauge copper wire, took consistently less time than the other French sizes, with both wired and unwired catheters reaching correct placement in under ten seconds, as shown in the figure below.
Figure 34. Average placement time for multiple French sizes of Foley catheter

The large errors shown in Figure 34 are due to the possibility of the model cervix slipping from the fingers during placement and time being taken to find it again. This was not a regular occurrence during the test, but it is an occurrence in real procedures. In this test, such an outlier only occurred during the testing of the 16 French catheter and was included in the data analysis to show occurrences of real problems.

In choosing the best outer diameter to work with, this data was considered alongside the outer diameter of mechanical devices for cervical ripening. The Cook® Cervical Ripening Balloon is a modification of a balloon catheter designed for the purpose of cervical ripening [44]. This has a French size of 18, thus an outer diameter of 6 mm.

Due to the experimental data and the precedent set by previous devices, it was decided that 18 French, or a 6 mm outer diameter, would be the outer diameter of the new device.

7.3 Placement Method

The primary objective of the project is to reduce the time needed for a physician to place a mechanical cervical ripening device correctly and securely. When deciding which method of placement to use, the time needed to place the device was the biggest factor.

To test the time needed to place the device using different methods, the birth canal and cervix model was used for a secondary phase of placement time trials. The fastest method involved attaching the device to the hand of the physician with two finger straps that sit at 1 and 3 cm from the proximal tip of the catheter. These straps give the physician more control of the device through the placement procedure. Figure 33 in Chapter 6 shows the relationship between the time it took to place the two strap design versus the control design.
Each addition of a new placement method reduced both the time to placement and the variation between the times of each trial. The 18 French device with no stylet or finger strap took the longest to place, and had a high variation between trials. The addition of a stylet reduced the time from insertion to correct placement, but did not greatly reduce the standard deviation. These methods both required the user to find the cervix with their fingers prior to threading the device along their hand and through the cervix.

The addition of a finger strap in place of a stylet reduced both the time needed for correct placement and the standard deviation by eliminating a step in the procedure. Instead of needing to find the cervix first and then thread the device along the hand, the device was attached to the hand, and could be placed as soon as the cervix was found. This both reduced the time to placement and increased the consistency with which the user was able to place the device.

Consultation with the client affirmed the desirability of the multiple finger strap design, with the client expressing his satisfaction with the device and observing that he felt more in control and was able to place it more quickly in the model than he was normally capable of. This consultation also yielded the importance of maintaining the option of using a stylet, in the event that the physician is unable to reach the cervix with their hand. Using a stylet as an alternate method in this case is common among physicians who place this device, and maintaining a lumen that will hold an optional 20 gauge wire stylet would increase the usability of the device.

7.4 Lumen Size

When determining the ideal lumen size, it was important to balance ease of balloon inflation with maintaining a high enough tensile strength that the device would stand no chance of breaking during use. The larger the lumen size, the higher the possible volumetric flow rate, which would decrease the amount of time needed for the procedure. However, because the catheter is often pulled during the placement procedure, the lumen size could not be too big, as that could risk breakage of the catheter.

To determine the best lumen size for the device, the first necessary piece of information needed was the minimum possible cross sectional area needed to ensure that the forces that were put on the catheter would not exceed the maximum tensile strength of the material. To determine the maximum forces that the device should be able to handle, an 18 French Foley Catheter and Cook® Cervical Ripening Balloon tested for their maximum tensile strength using an Instron 5544.

Due to the orientation of the grips on the Instron 5544 that was used to apply tensile force to the catheter samples, the samples were likely to slip from the grips or break at the grips. However, all samples withstood forces greater than the average human pulling strength, 60-80 Newtons [33]. A study comparing mechanical properties of different unnamed brands of Foley catheters was
consulted to ensure that the values found experimentally were valid. This study found that the maximum tensile strength of the catheters averaged between 6.6 and 8 megapascals (MPa).

The Cook® Cervical Ripening Balloon was found to withstand 110 Newtons of tensile force, while the 18 French Foley catheter was able to withstand 150 Newtons before it ruptured. The cross sectional areas of each type of catheter was measured, and the maximum tensile force that each catheter experienced was divided by its cross sectional area. Through this calculation, it was found that the Foley catheter experienced 5.3 MPa before rupture, and the Cook® Cervical Ripening Balloon experienced 7.01 MPa.

An additional piece of information that was used to determine lumen size was whether or not space should be allocated for a stylet. This information was gained through the second phase of placement trials, which assessed the different methods for placing the device in the cervix. The conclusion of these trials was that a stylet should be present, and that the stilet would be 20 gauge, or 0.81 mm in diameter.

Given this information, the inflation lumen was calculated to be 2.7 mm in diameter in order to maximize flow rate for balloon inflation and ensure that there was a large enough cross sectional area to withstand the potential tensile forces on the catheter.
Chapter 8: Conclusion and Recommendations

The aim of the final design was to fulfill our client statement as follows:

*Develop a simple and cost effective transcervical cervical ripening device, designed specifically for obstetrical practice that will increase ease of use for the physician and reduce discomfort for the patient.*

In conclusion the proposed design, seen in Figure 35, is an 18 Fr, double lumen, single top-oriented transcervical balloon catheter with a flexible wire stylet and finger strap. All aspects of the proposed final design have been backed by significant research into labor, labor induction, and problems associated with current methods. This device is easier to use for the physician as seen through the placement time trials and thus results in less pain and discomfort for the patient. Safety is ensured through tensile strength testing so that no harm comes to the patient or the baby. With ease of use for the physician and increased comfort for the patient the hope is that labor induction will lead to more natural births and the avoidance of c-sections.

In future iterations of this project, manufactured prototypes would be acquired for further testing. Biocompatibility tests would be carried out on the material according to the tests outlined in ASTM F748, for an intraoperative device coming into contact with intact natural channels.
Cytotoxicity, sensitization, skin irritation, and mucous membrane irritation assays would be carried out to ensure the safety of the material. Silicone is considered biocompatible and has been used in FDA approved products that come into contact with the same channels.

Mechanical tests would be carried out according to ASTM F623, the standard testing regimen for the Foley catheter, and the tests outlined in the 510(k) Premarket Approval application for the Cook device. These tests would ensure balloon integrity in simulated use conditions and catheter integrity under tensile stress.

The team also recommends reaching out to OB-GYNs in order to get a more robust opinion of labor induction and problems associated with the procedure. Much of the current design is based on the professional opinion of one doctor, and consultation with multiple physicians will help with understanding the market for this device.
Works Cited


Appendix

Appendix A: Gantt Charts & Work Breakdown Structures

Major Term Project Goals

<table>
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<th>Goals</th>
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<th>C Term</th>
<th>D Term</th>
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B-Term Work Breakdown Structure
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C- Term Work Breakdown Structure

- Incorporate Dr. Callery feedback
  - Incorporate Dr. Callery feedback for design
- Modify dimensions of foam model
  - Prototype new designs
- Select new material for foam model
  - Select appropriate material
- Build platform base for foam model
  - Model in the lab with available materials
- Add binder to prevent air from venting isotherm placement in oven
- Fix cork absorb cork to limit upward movement
- Urine model in testing
  - Select final design based on performance in testing & Dr. Callery feedback
  - Identify safety concerns
  - Identify manufacturing
  - Identify sustainability of the design
- Final Design Selection
  - Identify industry standards & verify final design's compliance
- Conduct testing
  - Review results & perform data analysis
- OR manufacture design samples in the lab
  - Evaluate results & make any necessary design changes
- Final Design Validation
  - Outline validation testing plan based on evaluating objectives
  - Conduct testing
  - Reach out to company to collaborate on manufacturing
  - Incorporate advisor feedback in report
- Final Design Production
  - Construction of final design
  - Write Chapters 6 & Final Design Validation
  - Write Chapters 7: Discussion
- Administrative Activities
  - Weekly meetings with advisor
  - Chapter 1-1 sessions
  - Weekly meetings with the testing center for feedback
  - Write Chapter 8: Construction & Recommendations
  - Pass objectives & grants for C-Team
  - Create C-Term Grant Chart & WEIS
### C-Term Gantt Chart

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