Radially Expanding Uterine Cervical Dilator

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Abstract

Dr. Dan Lebovic would like a uterine cervical dilator that, once inserted through the cervical canal, can be radially expanded by the use of a dial, which will be controlled by a doctor. Current methods for dilating the cervix include inserting a dilator into the cervix and then taking it out, followed by reinsertion of a larger dilator and taking it out, and so on, until the desired diameter is reached. This current method for dilating the cervix is tiresome for the doctor doing the procedure and puts patients at a higher risk for uterine perforations. Our goal is to create a device that can radially expand after it is inserted into the cervical canal. We will do this by using a cone-like design that has a "screwing" mechanism, which a doctor can control with the use of a dial. A prototype of our design was built and testing was performed to determine the accuracy and functionality of the device.

Problem Statement

The current procedure for dilating a cervix requires the doctor to use progressively thicker dilators until the desired diameter is reached. This method is very tedious for the surgeon and may put patients at a higher risk for a uterine perforation. To decrease the risk of a uterine perforation, we are going to make a device that, once inserted through the cervical canal, can be controlled by a surgeon to radially dilate the cervix to a desired diameter as indicated on a dial.

Anatomy of Uterus

The uterus is a female reproductive organ that is located in the pelvis between the bladder and rectum. The main function of the uterus is to nourish the developing fetus prior to birth [1]. On average, the uterus is 7.5 cm in length, 5 cm in breadth, and 2.5 cm in thickness. As seen in Figure 1, the uterus has three tissue layers, the endometrium, myometrium, and perimetrium and can be separated anatomically into four segments, the fundus, corpus, cervix, and internal orifice [2]. The cervix, which is the main focus for our device, is approximately 3.5 cm in length, and the lowest area of the uterus. It acts as a passage between the vaginal cavity and uterine cavity. The cavity running the length of

the cervix is known as the endocervical canal. The opening of the endocervical canal into the uterine cavity is referred to as the internal orifice, or internal os, and the cervical opening into the vagina is called the external orifice, or external os. Due to the cervix being densely fibrous, it is much more rigid than the other uterine tissue, which can make the cervix difficult to dilate [3].

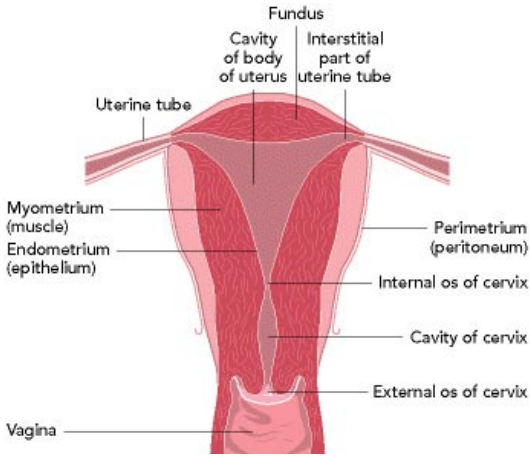

Figure 1: Parts of the uterus

Existing Products

There are currently two devices, Hegar dilators and Pratt dilators, on the market that are most commonly used for cervical dilation. Hegar and Pratt dilators are usually made out of stainless steel and can be imagined as small metal rods. As shown in Figures 2 and 3, Hegar dilators have a slight curve and rounded tips, while Pratt dilators are straight with long, tapered tips. Most of these dilators are double ended with two different diameter measurements. This minimizes the amount of devices that are required to dilate the cervix to the desired diameter. The size of a Hegar dilator is measured by the diameter, with units of millimeters (mm) and can be between 1 mm and 26 mm in diameter. Pratt dilators are usually measured using the French Scale system. French (Fr) measurements can be converted to the dilator's diameter in millimeters by dividing the French value by pi (π). For example, a 35 Fr Pratt dilator would be 11.67 mm in diameter. Pratt dilators can be found in sizes ranging from 9 Fr to 79 Fr [4].

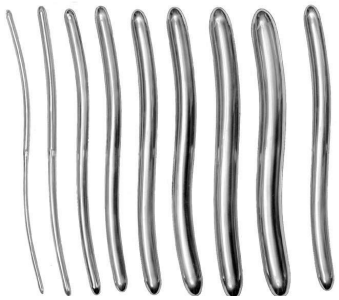

Figure 2: Hegar dilators in a variety of sizes [5]

Figure 3: Pratt dilators in a variety of sizes [5]

When dilating the cervix, the doctor first uses a tenaculum to grab the cervix at the entrance, and the tenaculum is then clamped onto the cervix. The tenaculum acts as an opposing force to the dilator and pulls the cervix down so that a dilator can be inserted. Using a tenaculum is necessary when dilating the cervix, because the cervix will

naturally try moving away from the dilator. When Hegar or Pratt dilators are used to dilate the cervix, the doctor begins by using a smaller sized dilator, usually between 1 mm and 3 mm in diameter. The doctor inserts the dilator into the cervical canal, using arm strength to push the dilator completely through the canal. After the first dilator is inserted, it is almost immediately removed. If the dilators being used are double ended, the opposite and larger end of the same dilator is then inserted into the cervix. If the dilators are single ended, a different dilator with a larger diameter is inserted into the cervix. The doctor usually increases the size of the Hegar or Pratt dilator by 1 mm each time a new dilator is inserted into the cervix. After the second dilator is inserted, it is then taken out, and the process is repeated with a variety of dilators until the desired diameter of dilation is reached. Since Hegar and Pratt dilators are required to be continually inserted until the desired diameter is reached, the risk of a uterine perforation is more likely. It can often be difficult to dilate a cervix, due to scarring from uterine surgery, never giving birth, and being post-menopausal, among other things. These can cause the cervix to be tighter and noncompliant. When a cervix is difficult to dilate, the doctor needs to use more force than they normally would use with a compliant cervix, which can cause the dilator to be accidently pushed through the uterus. By having to reinsert the Hegar and Pratt dilators several times, there are more opportunities for the uterus to be perforated.

Design Specifications

There are several requirements that our radially expanding dilator must meet. First, the device should be a minimum of 3 mm in diameter and expand to a diameter of 1 cm in diameter. The device should be able to expand by increments of 1 mm in diameter, thus allowing a doctor to dilate a patient's cervix from 3 mm to 1 cm in increments of 1 mm. The dilator will need to be used for several patients, which means that the device will need to be sterilized between uses and must be durable so that it does not break during use. The measured force required to dilate the cervix of a woman who has never given birth to 1 cm using a Hegar dilator is 52.4 N [6]. Therefore, the device will need to withstand over 52.4 N of force. The force required to dilate the cervix of a woman who has given birth can be neglected since it takes less force to dilate the cervix of a woman

who has given birth than one who has never given birth. The amount of time that the device is used during each procedure may vary from person to person and differs depending on how compliant the cervix is. However, on average, dilation will take approximately 10 minutes. For the patient's safety, the device should not be pointed or have sharp edges and should not be manufactured using latex or nickel, due to allergies. The device also needs to expand radially so that it does not tear the cervical canal. FDA approval is required to use this device.

Design Alternatives

Design 1

As seen in Figure 4, Design 1 requires the use of a balloon and hydraulic pump to dilate the cervix. Once the device is inserted through the cervical canal, the hydraulic pump will pump fluid, either a water or saline solution or gas, into the balloon, which will in turn dilate the cervical canal. The balloon would be made out of a Latex-free material and be removable so that the balloon could be switched after the device is used on a patient. The device would also have an indicator on one end. Once the doctor believes that the device is completely through the cervical canal, the doctor will be able to open a plastic-like sphere at the end of the device. Once the spherical indicator is opened, the doctor can then attempt to lightly pull the device back towards the opening of the cervix. If the device had been pushed successfully through the entire length of the cervical canal, the spherical indicator will stop the device, when pulled, from actually moving back down the cervix.

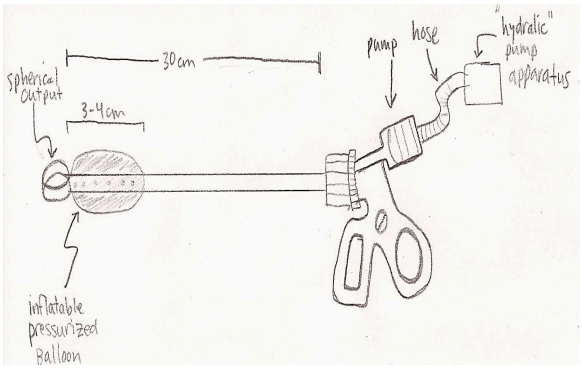

Figure 4: Design 1 features a balloon and hydraulic pump to dilate the cervix.

Design 2

As seen in Figure 5, Design 2 also uses a balloon to dilate the cervix. This design also consists of a mechanism that is comparable to a syringe. Design 2 has a syringe

shaped structure, with a plunger that when pressed down, inputs fluid, either a water or saline solution or gas, into the balloon at the end of the device. When the balloon fills up with fluid, it will radially expand and dilate the cervix. The syringe structure would have markings to show the amount of fluid contained in the syringe and corresponding markings for each dilation increment in millimeters for the diameter. Using some mathematical equations, we would need to figure how much the cervix dilates per amount of fluid. Like in Design 1, the balloon for the device would be Latex-free and be disposable so that each patient will have a new, clean balloon. We decided that the balloon section of the device should be approximately 5 cm long and the rest of the device would be a total of about 25 cm long to ensure that the plunger will be outside of the body cavity, which will enable doctors to have an easier time using the device.

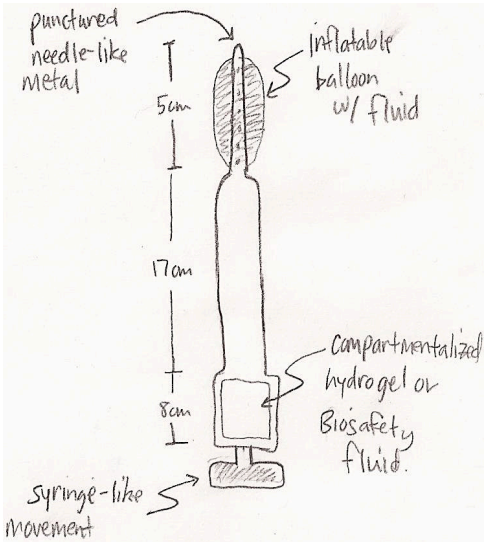

Figure 5: Design 2 consists of a balloon and a syringe-like structure with a plunger to dilate the cervix.

Design 3

Design 3 entails a coil-like method to dilate the cervix. The design consists of a thin sheet of plastic or metal material that will be wrapped around part of a metal rod. One end of the sheet material will be first be welded to the rod. The sheet will then be tightly wrapped around the rod. The free end of the material will then need to be welded to a second rod. The sheet will cover approximately 4 cm of each rod's length. Since the cervix is about 3.5 cm in length, we decided to make the dilation

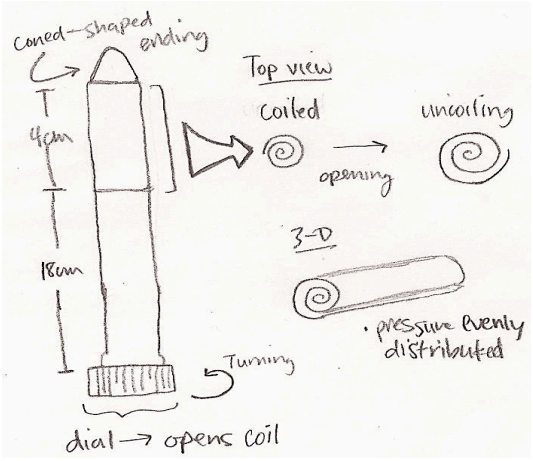

Figure 6: Design 3 features a thin sheet of material that wraps around a rod and uses a dial to control a coil-like method that unwinds the material and dilates the cervix.

mechanism for the device a little longer to ensure the entire cervix will be dilated. When the inner rod of the device is twisted, while holding the outer rod steady, the sheet material will begin to uncoil and expand radially around the inner rod. The inner rod will also have a dial on the end so that the doctor can control the rate and size of expansion during dilation. The dial will have a series of notches that correspond to certain diameters, which will make the device easy to control and use. To aide in the prevention of uterine perforations, the tip of the device will be rounded, and a stopper will be placed on a part of the device that remains outside the cervix so that the device can only be inserted up to the point of the stopper. The exact materials and dial design are still being decided upon.

Design 4

Design 4 features a cone design. This design is very similar to Design 3, but instead of being straight, it uses a cone shape. This design consists of a dial that is connected to a rod, which is surrounded by a sheet of plastic or metal. As seen in Figure 7, the sheet of plastic or metal is wound into a cone shape around the rod. Instead of pushing the device straight through the cervical canal, a twisting motion would be used. We felt that a twisting motion could possibly reduce the amount of force needed to insert the dilator and as a result, make dilating the cervix much less tedious for the doctor performing the dilation and decrease the risk of perforating the uterus. The cone-like structure would have four panels that once inserted through the cervical canal, would open and then allow the doctor to perform a procedure without needing to remove the dilator. This action would be similar to opening an umbrella. Similar to Design 3, the dial would allow the doctor to control the rate and size of expansion of the device.

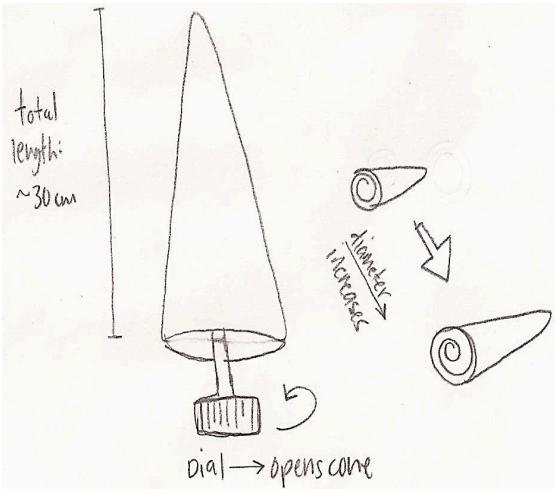

Figure 7: Design 4 uses a twisting motion to insert the cone-shaped device through the cervix.

Design 5

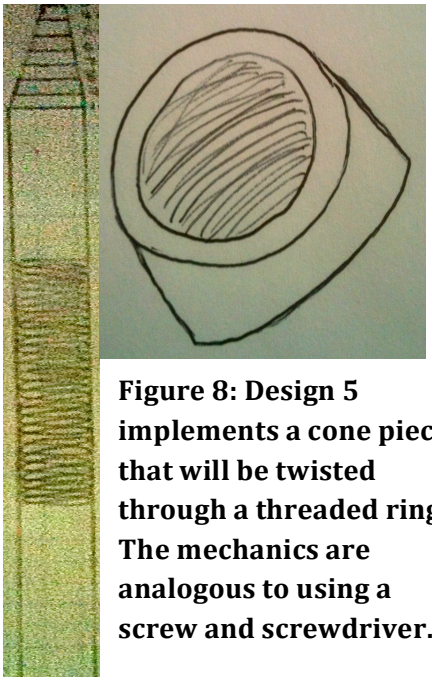

Figure 8: Design 5 implements a cone piece that will be twisted through a threaded ring. The mechanics are analogous to using a screw and screwdriver.

Design 5 features a ring that is attached to a tenaculum and a separate cone piece. The cone piece involves a cone shaped tip, which starts at 3 mm in diameter and increases to 10 mm in diameter. The cone then turns into a straight shaft, which has a constant 10 mm diameter. Part of the straight shaft has threading on the outside so that it can be "screwed" through the threaded ring. The tip of the cone will be dull and rounded to insure safety. A dial will also be placed at the end of the straight shaft of the cone. To use the device, the tenaculum will grasp the cervix at the opening. The cone piece will start at a position in which the tip of the cone is directly at the entrance to the cervix. The cone piece will then be screwed through the ring and into the cervical canal. The cone will travel axially through the cervix each time the cone completes one revolution. When the first thread of the cone reaches the entrance to the cervix, the entire cervix will be completely dilated to 10 mm. The length of the device and the location of the threading will be strategically placed so that the cone will not be able to perforate the uterus. The cone and shaft will be hollow and made out of a clear plastic, which will allow a doctor to insert a laparoscopic camera through the cone, enabling the doctor to see the location of the uterus relative to the dilator. We believe that this will further decrease the risk of uterine perforations. Both the tenaculum and threaded ring will be made out of stainless steel.

Design Matrix

Criteria	Weight	Design 1	Design 2	Design 3	Design 4	Design 5
Cost	10/100	4	2	9	9	9
Ease of Use	20/100	11	8	16	15	19
Feasibility	20/100	12	7	16	16	18
Safety	25/100	16	13	23	22	24
Durability	25/100	14	15	23	23	24
Total	100	57	45	87	85	94

Table 1: Design matrix that was used to evaluate designs based on criteria in the left-most column.

As seen in Table 1, the four designs were evaluated according to cost, ease of use, feasibility, safety, and durability. Each criterion was weighted, with safety and durability having the most weight. Safety is extremely important in medical procedures, which is why safety was weighted heavier than some of the other criteria. If the device isn't safe, a patient could be seriously injured, and doctors will not want to use the device. Durability goes along with safety since if the device breaks while being used, the patient's safety could be at a higher risk. It is a necessity that the device be durable so that doctors feel comfortable using the device on patients and so the device can be used several times with a variety of patients.

Feasibility and ease of use were both weighted equally and slightly lower than safety and durability. It is essential that the device be feasible so that it can be manufactured and easily fixed if any problems occur with the device. Ease of use is also important, because doctors like things that are simple and easy to use. Doctors don't want to spend an ample amount of their time trying to figure out how a dilator works; they want to be able to figure out how the device works very quickly. Devices that look simpler and less intricate can also make patients feel less intimidated. Overall, a device that is simple and easy to use will make the doctor and patient happy.

The criterion with the lowest weight was cost. Cost was chosen to have the least weight, because it was not thought to have as large of an impact on the device. It is more important to base the design on the safety, durability, ease of use, and feasibility of the device than the cost of the device. The cost is expected to be relatively low, and thus, not very influential to our device.

Design 5 scored the highest total score of 94 points and was the most favored by the client, due to the incorporation of a dial. It was thought to be the safest, most durable, most feasible, and easiest to use of the five designs. Design 5 has a very simple and straightforward concept. Design 5 was tied with both Designs 3 and 4 for the highest rank in cost. These three deigns were thought to be more inexpensive than Designs 1 and 2 since the designs are simple and require less costly materials. Design 3 was ranked the second highest with a score of 87 points. This is only a few points lower than Design 5 and is due to ranking slightly lower in safety, ease of use, durability, and feasibility. Design 4 would most likely be more difficult to manufacture than Design 5, because it

requires the coil to be wound about three times around itself, which would be difficult when working with such small dimensions. Unwinding the coil could also be very difficult, which is why it was ranked lower in the ease of use category. Design 4 was ranked only two points below Design 3. Design 4 was thought to be equally feasible and durable to Design 3 but not as safe or easy to use. One problem with Design 4 is that it would not equally dilate the entire cervix due to its cone shape. This would make it difficult for the doctor to then insert another medical instrument after dilation is complete.

Design 1 and Design 2 were not much of a competition for Design 5. Design 1 had a score of 57 points, and Design 2 had a total score of 45 points. Both of these designs were not seen as very durable since a balloon was involved. There were concerns about the balloon popping under too much cervical resistance. These designs were also not as easy to use as Design 5. They required the use of a solution or gas to inflate the balloon, which requires these fluids to be available when needed. This just causes the doctor to need excess materials, whereas with Design 5, the doctor would only need the device and no extra materials or fluids. Another problem with the balloon method is that the pressure throughout the balloon does not stay constant. Some parts of the cervical canal can be harder to dilate, such as the internal os, so when the balloon begins to dilate the cervix, it will expand more in the areas that are easier to dilate and won't expand in the tighter areas as much. The fluid in the balloon will be pushed to the areas with less resistance. This creates problems for the doctor, because when he/she attempts to insert the device that cleans out the uterus, the device will not be able to go completely go through the cervical canal since parts of the cervix may not have dilated enough, like the internal os. Besides Designs 1 and 2 not being ranked as highly in the different criteria categories, they were also not as favored by the client since they did not involve the use of a dial.

Final Design

For our final design, we chose Design 5. It scored the highest on the design matrix when evaluating our five designs according to five different criteria. We feel that this design is very feasible and would be much easier to use and less costly than current

devices on the market. We believe that Design 5 would make the dilation process less tiresome for the doctor performing the procedure and decrease the risk of uterine perforations during dilation. Ideally, we would like the cone piece of Design 5 to be made using clear Lexan, since it is extremely durable and would allow for a laparoscopic camera to see through the device. We would like the ring piece to be made from medical grade stainless steel. To further the development of our final design, we modeled it and performed tests on the design models.

Modeling

SolidWorks

To begin modeling our design, we chose to use SolidWorks. We modeled both the cone piece and ring component separately using various tools in SolidWorks. We were then able to choose materials to apply to our design components and use the necessary forces to test the amount of stress that the device is able to withstand and ensure that the device will not break under the required forces that may be applied. We chose to model the straight shaft component of the cone piece with Delrin 2700 NC010, a low viscosity acetal copolymer, the cone part of the cone piece with acrylic, and the ring with AISI Type 316L stainless steel. For testing, we chose to split the cone component into two pieces, the straight shaft and the cone tip, and test each piece separately. We then applied a force of 60 N to both parts of the cone component since the device must be able to withstand a maximum force of 52.4 N for a 1 cm dilation, which is the maximum dilation required. The results, as seen in Figures 9 and 10, show that both the straight shaft and the cone tip were able to withstand the applied 60 N force without failing. Testing also showed that the straight shaft had a factor of safety

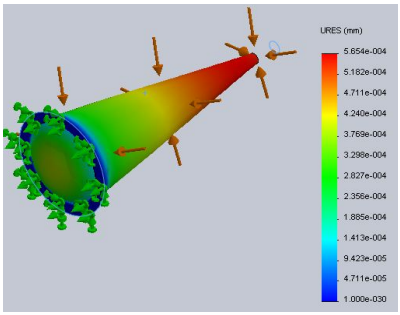

Figure 9: Results from modeling the cone tip of the design in SolidWorks and applying a 60 N force.

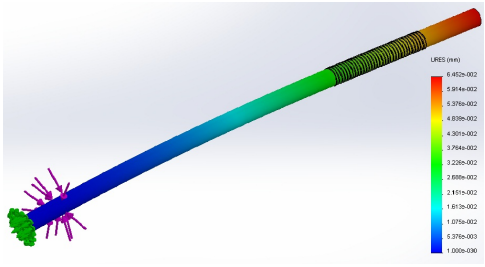

Figure 10: Results from applying a 60 N force to the straight shaft part of the cone component, which was modeled using SolidWorks.

(FOS) of 1,135, and the cone tip had an FOS of 352. Since these FOS values were so high, the safety aspect of the design was reinforced.

Prototype

After modeling our design in SolidWorks, we decided to contact Tosa Tool, a prototyping and manufacturing company, to manufacture our design. We felt that having Tosa Tool manufacture our device was the best option since working with such small dimensions can be very difficult. We also didn't feel confident enough in our own machining abilities to fabricate our device since our skill levels aren't very remarkable with respect to machining. We chose to have our device made out Delrin acetal, acrylic, and 316L stainless steel, as seen in Figure 11. The top of the cone was made out of acrylic so that we could demonstrate the clear aspect of our ideal device. The straight shaft part of the cone was made out of Delrin acetal, and the ring was made using 316L stainless steel. The ring is connected to the tenaculum with the use of a screw, which allows for the ring to be removed from the tenaculum. Having the ring piece be detachable will deplete the need for doctors to purchase the device with the tenaculum by enabling the doctors to attach the device to a tenaculum that they already own. The cone piece was also made to be hollow so that a camera can be inserted through the cone.

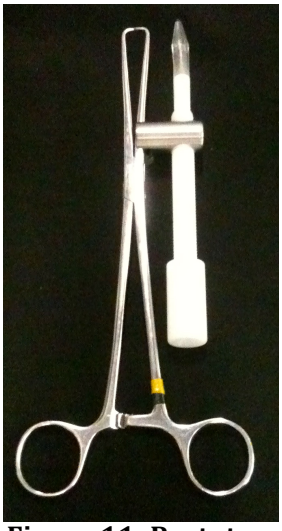

Figure 11: Prototype of device

Testing

To begin testing our device, we each took several measurements of our device and performed statistical analysis on the collected data. The measurements involved completing several revolutions of the cone through the ring, in which during the revolutions, the diameter of the cone was measured. Each group member repeated this process. Digital calipers were used to measure the various diameters. We then compiled our data and were able to calculate the mean diameter at various positions. The results,

which can be seen below in Table 2, show the mean diameter for every two revolutions. For the most part, the results are approximately equal to the expected values and shows that a doctor will need to complete two revolutions to increase dilation from one diameter to the next. The average measured diameters for 3 mm through 7 mm meet the accuracy requirement, which states that the device should not be off by more than 0.1 mm from the expected values. The standard deviation and percent error for each diameter were calculated as well. The results show that the standard deviations and percent errors between the measured diameter values were very small, which reinforces the accuracy of the device. During testing, we realized that the device was not manufactured exactly as desired and did not reach the full 10 mm dilation that we were expecting. This is a problem that could be easily fixed in the future by making a new cone piece.

	Measured Diameter Per Two Revolutions (mm)						
Diameter	**Alex**	**Megan**	**Michael**	**Ryan**	**Average**	**Std. Dev.**	**Percent Error**
3 mm	Device started at 3 mm						
4 mm	3.91	3.94	3.90	3.87	3.91	0.0289	2.30%
5 mm	4.90	4.85	4.90	4.93	4.90	0.0332	2.04%
6 mm	6.03	5.99	6.00	5.96	6.00	0.0289	0%
7 mm	7.08	7.03	6.97	6.99	7.02	0.0486	0.28%
8 mm	7.72	7.65	7.67	7.70	7.69	0.0311	4.03%
9 mm	NA	NA	NA	NA	NA	NA	NA
10 mm	NA	NA	NA	NA	NA	NA	NA

Table 2: The results from testing our device's accuracy, which involved measuring the diameter of the cone piece every time 2 revolutions of the cone through the ring were completed.

After testing the accuracy of our device, we decided to test the device's performance with the use of a pig's uterus. We chose to use a pig's uterus, because pigs are constantly being harvested or slaughtered, which we felt would ensure us to be able to find a pig's uterus. We considered using a cow's uterus but decided that it was much too large compared to a human's uterus

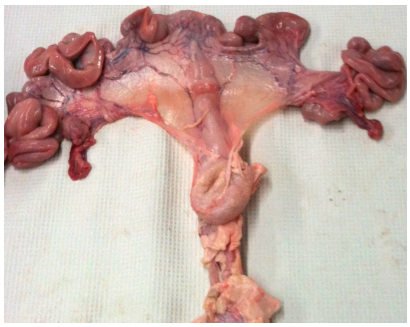

Figure 12: A pig's uterus used for testing

and that a pig's uterus was more comparable in size to a human's uterus. Ideally, we would have liked to use a human's uterus; however, obtaining a human's uterus and receiving clearance to perform testing on the uterus would have taken several months. Ultimately, we were able to easily obtain three pig's uterus from the University of Wisconsin's Meat Lab, one of which can be seen in Figure 12. We began testing by clamping the tip of the cervix with the tenaculum. As seen in Figure 13, we then began "screwing" the cone through the ring and through the cervical canal. After the dilation was complete, we measured the diameter of the cervical canal to check the performance of the device. We found that the cervix did dilate when using the device and were able to conclude that our device has the ability to simplify the dilation process for doctors.

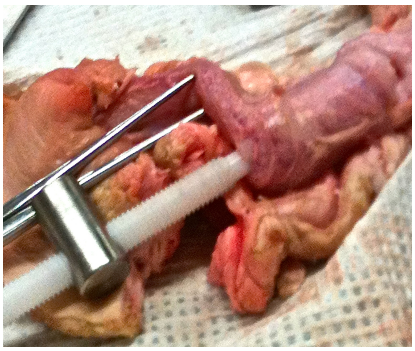

Figure 13: Testing the device using a pig's uterus

Costs

Item	Quantity	Estimated Cost
Manufacturing cone piece	1	$214.00
Manufacturing ring piece	1	$468.00
Tenaculum	1	$0 (donated)
Total	3	$682.00

Table 3: The estimated costs for manufacturing the various parts of the device and the overall cost.

As seen in Table 3, our main costs were due to the manufacturing completed by Tosa Tool. We were able to obtain the tenaculum, which was implemented in our design, from our client. We were able to acquire our testing equipment from the University of Wisconsin's Meat Lab. Therefore, there were no costs incurred for the tenaculum or testing equipment. The manufacturing costs for each piece included the cost of the materials used, however, most of the manufacturing cost is due to the amount of labor required to make the device. If the device was to be mass manufactured, production costs

would be expected to be much lower and the total cost of the device would be insignificant.

Future Work

In the future, we would alter some of the materials that would be used to build the device from the materials that were used to build the prototype. We would have the entire cone piece be made out of Lexan so that it would be completely clear, allowing a camera to see the uterus when inserted through the hollow cone. It would also be necessary to have the ring piece be made of medical grade stainless steel since the primary use of this device is for medical procedures. We would like to perfect the dial aspect of the device as well. To further the accuracy and effectiveness of our device, we would continue to perform testing to ensure that the device is safe and works well. Ultimately, we would like to be able to test our device on a human's uterus since the device is meant for use on humans. After further testing and perfecting any necessary design components, we would look into patenting our device and obtaining FDA approval.

Acknowledgements

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Appendix

Product Design Specifications

Radially Expanding Uterine Cervical Dilator

Contents of PDS – November 15, 2012

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Function: The current procedure for dilating a cervix requires the doctor to use progressively thicker dilators until the desired diameter is reached. This method is very tedious for the surgeon and may put patients at a higher risk for a uterine perforation. To decrease the risk of a uterine perforation, we are going to make a device that, once inserted through the cervical canal, can be controlled by a surgeon to radially dilate the cervix to a desired diameter as indicated on a dial.

Client requirements:

- Device should increase in diameter once inserted into cervix
- Device should increase in increments of 1 mm in diameter
- Device should have dial or another way to increase diameter of dilator
- Dial should have markings to let doctors know the size of dilation
- Would prefer device to be curved at the end
- Would like indicator to let doctor know if dilator passed through the entire cervical canal
- Must be able to withstand 52.4 N of force

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The device is expected to be used to dilate a patient's cervix so that a surgeon can then insert other medical devices into the uterus, which is then cleaned out. The device would be used repeatedly, but the actual number depends on the amount of women needing a procedure that requires the cervix to be dilated. The device must be strong enough to withstand the pressure from the cervix.

b. *Safety*: The device must not have any sharp points or edges. The device should only be manufactured using materials that are safe for the human body and that don't pose a large allergy risk.

c. *Accuracy and Reliability*: The device needs to be extremely accurate since the surgeon increases dilation by 1 mm increments. The device should be off by no more than 0.1 mm. The device will also need to be very precise. It should read the same diameter or a value within 0.1 mm of the desired diameter every time it is used.

d. *Life in Service*: The amount of time that the device will be used during each procedure will vary from patient to patient. The length of time it takes a surgeon to dilate the cervix depends upon the skill of the surgeon, how much strength the surgeon chooses to use when inserting the dilator, and the compliance of the cervix. An estimated time that the device will be used during each procedure is 10 minutes.

e. *Operating Environment*: During operation, the device will be used in either a hospital setting or a doctor's office. The device will be exposed to the cervical canal. A doctor will be operating the device.

f. *Ergonomics*: The force that the device puts on the cervix needs to be applied radially so that it does not tear the cervix. According to *Lamicel: a new technique for cervical dilation before first trimester abortion*, by Nicolaides et. al, it takes approximately 52.4 N of force to dilate the cervix 1 cm in women who have never given birth. Therefore, our device will need to be able to withstand over 52.4 N of force after taking into account a safety factor.

g. *Size*: Our device needs to start at a size of 3 mm in diameter and increase to a size of 1 cm in diameter. The length of our device should be between 9 in and 12 in.

h. *Weight*: The device should be able to be held in a single hand. Weight is not a huge concern since our device will be so small in size. However, the device should only weigh around 1 oz.

i. *Materials*: Due to allergies, latex and nickel should not be used when manufacturing the device. To use in a medical setting, medical-grade materials will be necessary.

j. *Aesthetics, Appearance, and Finish*: The device does not need to be a specific color. The texture should be smooth so that it does not irritate the cervical canal.

2. Production Characteristics

a. *Quantity*: 1

b. *Target Product Cost*: The budget to build the prototype is $1,000. Other cervical dilators on the market cost about $40, so we would want our manufacturing cost to be less than $40 if we were to mass manufacture the device.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval is required to use this device.

c. *Patient-related concerns*: The device will need to be sterilized between uses.

d. *Competition*: We have yet to find any devices that use a coil-like method to dilate the cervix. There are several patents for different dilators that use a balloon to dilate the cervix, which is partly why we decided not to follow through with our balloon designs.