

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 coil-like dilator that has an “unwinding” mechanism, which a doctor can control with the use of a dial. We plan to build a prototype of our device and perform testing with the possible use of a human or cow uterus.

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].

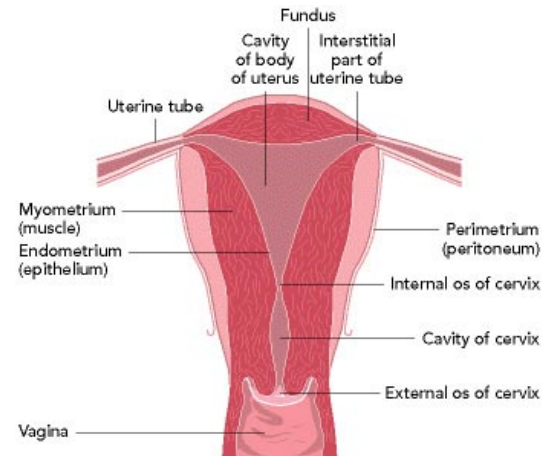


Figure 1: Parts of the uterus [2]

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

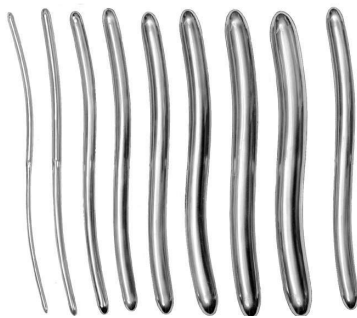


Figure 2: Hegar dilators in a variety of sizes [5]

made out of stainless steel and can be imagined as small metal rods. As shown in Figure 2 and Figure 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 3: Pratt dilators in a variety of sizes [5]

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 accidentally 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 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

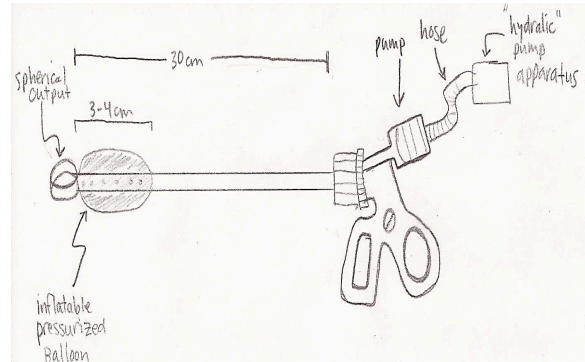


Figure 4: Design 1 features a balloon and hydraulic pump to dilate the cervix.

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.

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.

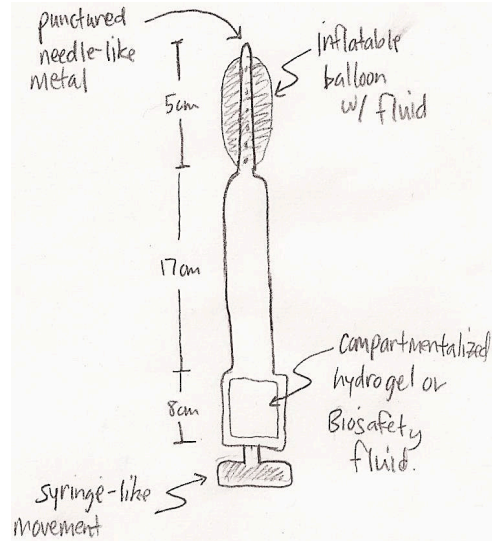


Figure 5: Design 2 consists of a balloon and a syringe-like structure with a plunger to dilate the cervix.

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 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

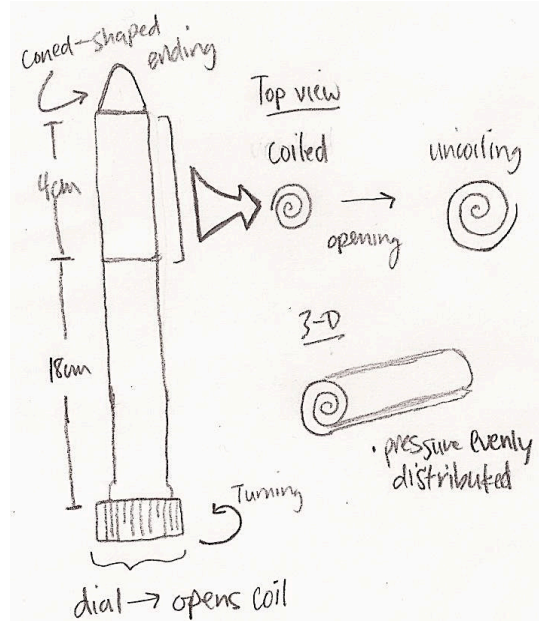


Figure 6: Design 3 features a thin sheet of material that wraps around a rod and uses a dial to control a coil-like method that unwinds the material and dilates the cervix

easy to control and use. To aid 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. 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. Like in Design 3, the dial would allow the doctor to control the rate and size of expansion of the device.

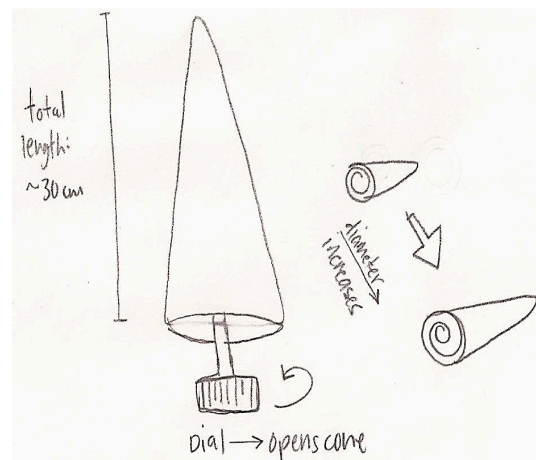


Figure 7: Design 4 uses a twisting motion to insert the cone-shaped device through the cervix.

Design Matrix

Criteria	Weight	Design 1	Design 2	Design 3	Design 4
Cost	10/100	4	2	9	9
Ease of Use	20/100	11	8	18	17
Feasibility	20/100	12	7	17	17
Safety	25/100	16	13	24	22
Durability	25/100	14	15	23	23
Total	100	57	45	91	88

Table 1: Design matrix: used to evaluate designs based on criteria in 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 3 scored the highest total score of 91 points and was the most favored by the client, due to the incorporation of a dial. It was thought to be the safest and easiest to use of the four designs. Design 3 has a simple and straightforward concept and should be very easy to use. Design 3 was tied with Design 4 for the highest rank in feasibility, durability, and cost. Both of these designs were believed to be very feasible since the designs are straightforward. They were also thought to be durable and not very costly since the designs are simple. Design 4 was ranked the second highest with a score of 88 points. This is only slightly lower than Design 3 and is due to ranking slightly lower in safety and ease of use. The cone shape and "twisting" method required to use this design

could make it more difficult to use than Design 3. The safety of Design 4 was questioned since Design 4 could possibly perforate the uterus if “twisted” too far into the uterus.

Design 1 and Design 2 were not much of a competition for Designs 3 and 4. 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 Designs 3 and 4. 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 Designs 3 and 4, 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 they try to insert the device that cleans out the uterus, it 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.

Final Design

For our final design, we chose Design 3. It scored the highest on the design matrix when evaluating our four designs according to five different criteria. Design 3 was also the most favored by our client, due to the use of a dial. We feel that this design is very feasible and plan on moving forward with modeling and fabricating this design.

Future Work

To further our design, we first plan on choosing very specific measurements for the length of the dilator and perfecting our dial design. We will then model the design in SolidWorks, selecting various materials that we think will work best with our device. We will add a radially applied load to the device to test the amount of force that the device

will be able to withstand when manufactured with each material. Once SolidWorks testing and analysis is complete, we plan on producing a prototype. After the prototype is finished, we will perform testing to make sure that the device is safe and works like we had expected. If possible, we hope to test our device on either a human or cow uterus.

Acknowledgements

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Appendix

Product Design Specifications

Radially Expanding Uterine Cervical Dilator

Contents of PDS – October 1, 2012

Alex Schmidt, Megan Courtney, Ryan Lane, and Michael Martinez

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 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

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 Nicolaidis 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.

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*: Our client does not have an exact cost that he has set for our device yet. Other cervical dilators on the market cost about \$40, so we would want our manufacturing cost to be less than \$40.

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.