Pelvic Organ Prolapse Model

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Abstract

Pelvic organ prolapse occurs when the muscles in the pelvic region become weakened or damaged. Due to this weakening, the bladder, rectum, uterus, and vagina fall onto or into the vagina. Currently, there is no easy way to teach the pelvic organ prolapse quantification exam (POP-Q), which uses different measurement sites and distances to quantify the stage of prolapse. The goal of this project is to design and fabricate a dynamic, scaled-up model to simulate the different types and stages of pelvic organ prolapse. The model should be easy to manipulate and reset. The final design incorporates the use of rods to simulate the prolapse. Future work includes finalizing the dimensions of the vaginal tube, fabricating the model, and testing the accuracy of the simulations.

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Problem Statement

Currently, residents have to use computer animations and static, anatomical models to learn how to perform the pelvic organ prolapse quantification exam (POP-Q). This exam is a complicated method of quantification that is difficult to learn. Therefore, it has been proposed to design and fabricate a dynamic, scaled-up model showing the multiple types and different stages of pelvic organ prolapse.

Introduction

Pelvic Prolapse Background

Pelvic organ prolapse can be explained as the falling of the female pelvic organs including the bladder, uterus, and rectum onto the vagina (Milton S. Hershey Medical Center, 2006). There are multiple causes of pelvic organ prolapse. Pregnancy accounts for one of these causes. Approximately half of all women who have children will experience some type of prolapse in their lifetime. Other causes include aging and obesity (Beus, 2008).

Pelvic prolapse occurs when muscles supporting the pelvic organs weaken (Herschorn, 2004). Depending on which muscles weaken, a different type of prolapse will occur. Cystocele is prolapse of the bladder, which falls onto the anterior vaginal wall. Rectocele is the collapse of the rectum onto the posterior wall of the vagina. Uterine prolapse is when the uterus falls from the top of the vagina to the bottom (Figure 1). Lastly, vault prolapse occurs post hysterectomy, when the vagina collapses onto itself. Most cases involve the prolapse of multiple organs simultaneously and can occur centrally or laterally. Central prolapse is when the collapsed organs fall directly on the anterior or posterior vaginal walls, while lateral prolapse occurs due to a break in a side support structure, causing the organs to fall against the vaginal wall at an oblique angle (Ablove, 2008).

Pelvic Organ Prolapse Quantification Exam (POP-Q) Background

The pelvic organ prolapse quantification exam (POP-Q) is a method used since 1996 that gynecologists use to measure the extent of pelvic organ prolapse (Geiss *et al.*, 2007). Different anatomical landmarks are used as measurement sites for the POP-Q staging system (Flesh, 2008). The exam can be extremely complex due to the number of measurements that must be made, and the locations of these measurements (Figure 1).

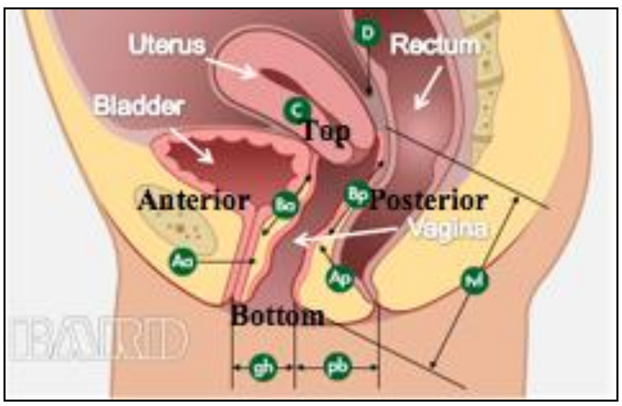


Figure 1. This figure shows the different organs of the pelvic region in white, labeled orientations of a vertical model in black, and the measurement sites of the POP-Q exam in green. This is a female pelvis without any prolapse.

Design Specifications

The model must contain the organs that are the most involved in pelvic organ prolapse, specifically the bladder, uterus, rectum, and vagina. The model should also include a support system comparable to that of the female pelvis, thus allowing the model to show central and lateral prolapse. It should be able to accurately simulate the three different stages (four for vault) of cystocele, rectocele, uterine, and vault prolapse.

The model must be easy to use, manipulate, and reset. The client will be using the model to test residents' knowledge of prolapse and therefore must be able to show different types of prolapse within short periods of time. It must be a scaled-up version of the female pelvis, so that residents can take measurements that apply to realistic prolapse conditions. The model will be used as a teaching model, and therefore should not have anatomical labels.

Furthermore, the model must be durable, because it will be used consistently for long periods of time. The components of the model should be easy to replace so that the client can make repairs if necessary. Lastly, the model should be completely safe, presenting no danger to its users.

Current Designs

Many static, anatomical models of the female pelvis exist. These models show the different organs involved in pelvic organ prolapse, and some even show the supporting structures of the pelvis. These models, however, do not allow organs to move, which means that they cannot show pelvic organ prolapse.

There are very few dynamic pelvic organ prolapse models. In fact, only one was found. This model consists of an inverted Santa Claus hat, a wooden embroidery frame, and buttons. The wooden frame acts as the pelvic structure supporting the Santa Claus hat, which represents the vagina. The buttons are sewed onto the hat to simulate anatomical landmarks and POP-Q measurement sites. This model replicates prolapse by collapsing the Santa Claus hat in different positions (Geiss *et al.*, 2007). This model is not very accurate, and does not give the user a realistic representation of pelvic organ prolapse.

Static Components of Alternative Designs

There are several static components that are present in all of the design alternatives. A box of wood or metal will serve as the outer structure. Inside the box are the organs, vaginal tube, posterior spine, pubic bone, and supporting structures. Because this design is a teaching model, it needs several external physical landmarks to aid in teaching and training for the POP-Q exam. These landmarks include false holes for the rectal opening and urethra. The purpose of these external structures is to aid residents in finding the relative position of the vagina and pelvic organs.

Since residents will view the model as if they are performing the actual POP-Q exam, the vaginal tube is an important element of the design. The vagina will be made of a flexible silicone tube with 1-5 Shore A on the durometer scale. With these durometer values, the silicone will have the desired elastic properties. It will be able to stretch to the designated POP-Q measurements yet also have resiliency to return to its original form. The inner surface of the silicone will have distinct regions identified by different colors. Each region will correspond to sites along the vaginal wall (Aa, Ba, C, D, Ap, Bp) as specified in the POP-Q exam. The silicone tube will be anchored to the inner walls of the box at three sites: bottom, lateral walls, and top. The design will use a system of magnets to hold the silicone tube in a static position.

Alternative Designs

Weighted System

In the weighted system design, objects of varying weights will be dropped down chutes corresponding to each measurement site. The model needs to be oriented vertically to allow the objects to fall (Figure 2). Heavier objects will be used to simulate a more severe stage of prolapse. Chutes placed on the sides of the vaginal tube will show lateral prolapse.

One advantage of the weighted system design is that it is easy to operate initially. In order to reset the model, someone will have to reach into the chutes and take out the objects adding to the stress applied to the model. Furthermore, the residents will have to look up into it due to its vertical orientation, which does not mimic the POP-Q procedure. Also, the design will be difficult to calibrate because as the model is used the vaginal wall will begin to stretch and deform due to the stress from the weight of the object. Effectively, the vaginal tube will not be durable enough for this type of actuation. The design will also contain loose parts, adding to its inconvenience. Lastly, the chute model will not be able to show vault prolapse. All in all, the disadvantages outweigh the advantages in this design.

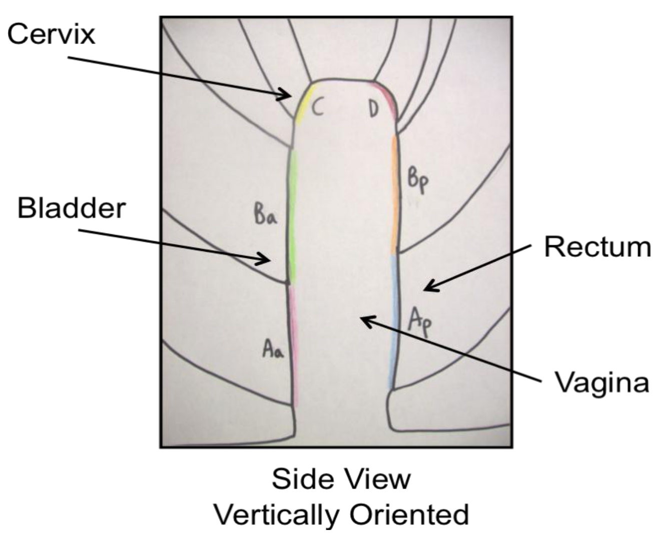


Figure 2. This figure shows the weighted system design, vertically oriented.

Calibrated Pressure and Rod System

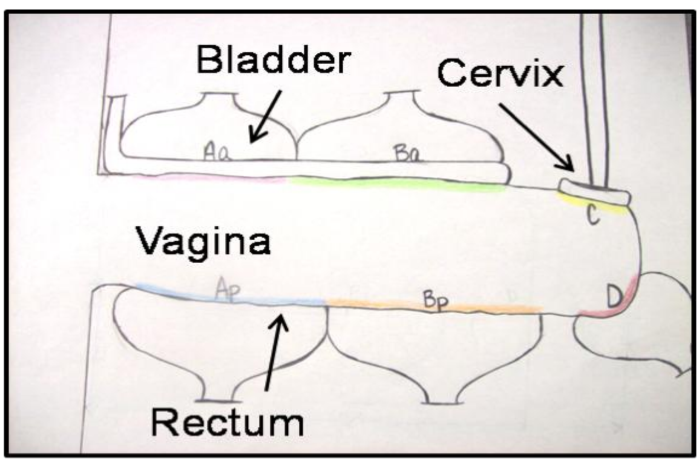
The calibrated pressure and rod model will incorporate balloons filled by calibrated syringes. The inflated balloons will push against the flexible silicone tube to simulate the presence of pelvic organs (bladder and rectum) pushing against the vaginal wall. The design will also include three rods to simulate uterine and lateral prolapse.

Prolapse will be simulated on the anterior and posterior vaginal walls with air-filled balloons. Since the pelvic model needs to show different types of prolapse, balloons will be placed at specified sites along the silicone tube. The model also must demonstrate the three (or four for vault) stages of prolapse. Thus, calibrated syringes will inflate the balloons with varying pressures, depending on the severity of the prolapse at that site. There will be three balloons attached to the anterior wall, one balloon at the Aa site, one balloon at the Ba site, and one long slender balloon, which extends over both the Aa and Ba sites. This long slender balloon will simulate prolapse occurring in both the Aa and Ba sites. On the posterior wall, there will be balloons at the Ap and Bp locations. Each balloon will be inflated and deflated independently to show prolapse in one location or multiple locations at once.

Not only must the model show prolapse on the anterior and posterior walls, but it must also replicate lateral, uterine, and vault prolapse. Instead of utilizing pressurized balloons, the model will use rods attached to the silicone tube. These rods, when moved up and down, move the vaginal wall causing the prolapse to come in at an angle. The top of the vagina will have a cervix attached by a magnet to the inside. When a rod attached to the top of the vagina is moved up and down, it will show uterine prolapse. In this model, vault prolapse will demonstrate the same mechanism as uterine prolapse except the magnetically attached cervix will be removed.

One of the major advantages of the calibrated pressure and rod model is that the calibrated pressure allows the operator to have a large amount of control over the results. Thus, the silicone tube will appear more visually accurate from the viewpoint of a resident performing the POP-Q exam.

Even though the calibrated pressure and rod design has a high degree of accuracy, there are several disadvantages to this model. The durability of the balloons is an issue because there is no solid guarantee of how quickly the balloons will wear out after being inflated and deflated multiple times. Due to this, the design would require strong durable balloons, which may need to be fabricated specially. Also, this design is difficult to scale up for the same reason. The larger the model, the more pressure will be required to deform the silicone, and it will be difficult to find materials durable enough to perform the required task.



Side View

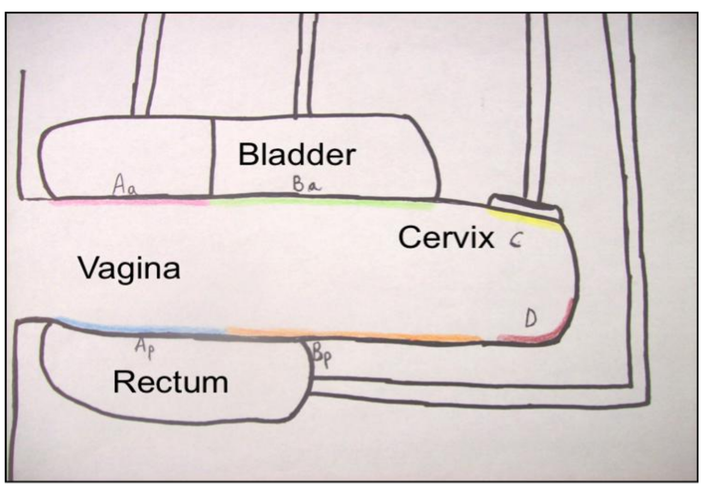
Figure 3. This figure shows the calibrated pressure and rod system from a side view.

Rod System

In the rod system, rods will be connected to organ-like objects, the top of the vagina, and on each side of the vaginal tube (Figure 4). Each rod connected to an organ-like object will correspond to the different measurement sites to replicate prolapse of the bladder or rectum. Lateral, uterine, and vault prolapse will be shown using the same mechanism as described in the calibrated pressure and rod system.

This design uses rods to provide the pressure needed to show prolapse, and therefore is easily manipulated and reset manually. This greater degree of control gives the rod system a high level of accuracy. Another advantage of this system is its durability. The rods will be securely attached to the organs and will not be able to slide once put in place.

The rod system could potentially be difficult to fabricate and use. The rods must be attached to the box in a way that would allow discrete, precise movements, and therefore anchoring the rods could be problematic. Also, this model might be confusing to use, due to the number of rods that could move.



Side View

Figure 4. This figure shows the rod system from a side view.

Design Matrix

To evaluate each of our designs, we developed a design matrix, which incorporates the main requirements for the pelvic prolapse model (Table 1). Because some categories were considered to be more important than others, each was weighted differently. The criteria chosen were feasibility, accuracy, ease of use, durability, cost, and safety. Feasibility was assigned the highest total value followed by accuracy and ease of use. Durability was deemed less crucial than feasibility, accuracy, and ease of use. The lowest value was given to cost because it was least important. Safety was given a yes or no option because we would not create a model that would not be safe for its users.

The weighted system scored the lowest of the three designs. It fell short in feasibility, accuracy, and ease of use, which were the central criteria for the model. It was decided that the weighted system was not a highly regulated working model, and this would have made it difficult to construct and calibrate. Also, the various weights and parts to the model contributed to its complexity and would have made it difficult to reset. It received the lowest score for accuracy because of its unrealistic vertical orientation. Although it was considered more durable than the calibrated pressure and rod system, this was not enough to overcome its other deficiencies, and it received a low score of 33.

The calibrated pressure and rod system scored the second highest of out of the three designs. It scored well in the ease of use category because only requires the user to press and refill the syringes to inflate and deflate the balloons. The pressure placed on the vaginal walls by the balloons would have appeared realistic from the viewpoint of the resident, which corresponds to the accuracy category. Despite these successes in the design, it was an extremely intricate system that would be very difficult to make. One difficulty included how the balloons, after pushing on the vaginal walls, would return to their original shape. The size of the model would make it difficult to find durable materials, especially balloons that could withstand constant inflation and deflation for long periods of time. These problems resulted in a design score of 62.

The rod system scored the highest out of the three designs and is the design we will pursue. Its best attribute was its durability. The rods will be more robust than the flexible balloons used in the calibrated pressure and rod system making it more reliable. Unlike the weighted system, the rods will be controlled manually and therefore pressure on the silicone tube will be more freely regulated adding to its accuracy. The user can depict any type and stage of prolapse using the rod system. In the most crucial category, feasibility, it scored the highest of the three designs. Due to the mechanisms of the moving rods and its highly regulated nature, the rod system will be the easiest to make. The rod system achieved the highest score of 80 and will be the design that we will go forward with.

Table 1. The design matrix shows how all of the alternative designs compared to one another. The rod system ended up with the highest score and will be the pursued design.

Criteria	Weight	Rod System	Weighted System	Calibrated Pressure/Rod System
Feasibility	40	**30**	10	20
Accuracy	20	**15**	5	15
Ease of Use	20	**15**	5	20
Durability	15	**15**	10	5
Cost	5	**5**	3	2
Safety	Y/N	**Y**	Y	Y
Totals	100	**80**	33	62

Future Work

Now that a design has been chosen, the next step is to obtain the materials necessary for the model. Before a full-scale prototype is fabricated, a smaller prototype made with paper, pipe cleaners, cardboard, and Play-Doh^{TM} will be created to ensure accurate rod placement. The paper will be the vaginal tube, the pipe cleaners will be the rods, the cardboard will simulate the outer box, and the Play-Doh^{TM} will be the organs. Afterwards, we will obtain silicone with Shore-A durability between 1 and 5. From this silicone, we will create a mold of the vaginal tube, which will have dimensions yet to be determined. In order to determine these dimensions, we are going to relate the hardness of the silicone with the amount that the material will stretch without breaking. This relationship will be applied to the known stretch of a human-sized prolapsed vagina. Usually the cervix lies 8 cm above the hymen (Bard Urological, 2007) so the back of the vagina should be able to go from the 8 cm above the hymen to 8 cm below the hymen. After we do these calculations, we will make a model of this size and do tests to make sure that all the desired deformations can occur. Once the model is completely assembled, we will move the rods into a certain prolapse formation and test the client to see if she can accurately determine what stage and type of prolapse should be occurring.

References

Ablove, MD, Tova. 2008.

Beus, Tamara. "Pelvic Organ Prolapse." *Women's Health*. 2003. 10 Sep 2008. http:/www.womenshealthlondon.org.uk/leaflets/prolapse/prolapse.html.

Flesh, MD, George. "Pelvic Organ Prolapse Quantification System." UpToDate. May 2008. 10 Sep 2008. http://www.uptodate.com/patients/content/topic.do?topicKey=~ikikJ23oMudzUc

Geiss, *et al*. "A simple teaching tool for training the pelvic organ prolapse quantification system." *International Urogynecology Journal*. 2007, 18: 1003-1005.

Herschorn, MD, FRCSC, Sender. "Female Pelvic Floor Anatomy: The Pelvic Floor, Supporting Structures, and Pelvic Organs." MedReviews. 2004.18 Sep 2008.

Pelvic Organ Prolapse: An Interactive Guide Test. *Bard Urological*. 2007. 17 Sep 2008. http://www.bardurological.com/pop-q/index.aspx

Vaginal/Pelvic Organ Prolapse. *Penn State Milton S. Hershey Medical Center.* 2006. 21 Oct 2008. http://www.hmc.psu.edu/healthinfo/uz/vaginalorganprolapse.htm.

Product Design Specification for BME 200/300 Group 1: Pelvic Prolapse Model

(September 15, 2008)

Group Members: Hallie Kreitlow, Andrew Bertram, Sarah Switalski, Graham Bousley

Problem Statement:

Currently, residents have to use computer animations and static, anatomical models to learn how to administer the Pelvic Organ Prolapse Quantification Exam (POP-Q). This exam is a complicated method of quantification that is difficult to learn. Therefore, it has been proposed to design and fabricate a dynamic, scale model showing the multiple types and different stages of pelvic organ prolapse.

Client Requirements:

The model must meet all of the requirements set forth by the client:

- Model dimensions must be to scale.
- Model must contain the bladder, uterus, rectum, vagina, and endopelvic fascia.
- Model must show central and lateral prolapse as well as the different stages.
- Model must not include labels.
- Model must be easy to manipulate and reset.

1. Design Requirements

a. *Performance requirements:* Model must accomplish the teaching goals set by the client.
b. *Safety:* Model must not be harmful to humans in any way.
c. *Accuracy and Reliability*: Model needs to have the proportional dimensions of a human pelvis. It must display structural support as well as the bladder, uterus, rectum, and inner walls of the vagina. It must be able to move accurately to demonstrate different types (cystocele, rectocele, uterine, and vaginal vault) and stages (0, I, II, III, IV) of prolapse.
d. *Life in Service*: Model must be durable and able to be reused for as long as the POP-Q exam is relevant.
e. *Operating Environment*: Must be able to operate in room temperature (30-40ºC) and normal humidity (40-60%).
f. *Ergonomics*: Model will be fabricated with no rough edges or points and it must be easy to manipulate.
g. *Size*: Model must be at least three times the size of an average female pelvis.
h. *Weight*: Must be light enough to be transported easily.
i. *Materials*: Model must be made of both flexible and rigid materials.
j. *Aesthetics, Appearance, and Finish*: Model must be able to function as a teaching model for the different stages of prolapse. It does not need to look exactly like a human female pelvis as long as it serves its purpose effectively.

2. Product Characteristics

a. *Quantity*: One working prototype.
b. *Target Product Cost*: $1000.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval is not required.
b. *Customer*: Physicians who need a model to teach the POP-Q exam to residents.
c. *Patient Related Concerns*: Model will not be used on humans; it is solely for teaching purposes.
d. *Competition*: There are static anatomical models, but few dynamic. One dynamic involves an inverted Santa Claus hat with a wooden embroidery frame and buttons.