Pelvic Organ Prolapse Teaching Model

Client:

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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, and uterus, and vagina fall onto the vagina or the vagina collapses onto itself. 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 different types of prolapse by pressing on a silicone tube with clay pelvic organs in different areas. Future work includes calibrating and testing the model, as well as incorporating a lateral prolapse mechanism.

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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 complex 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 Organ Prolapse Background

Pelvic organ prolapse occurs when there is a weakening in the pelvic support system causing the pelvic organs to fall onto the vaginal tube (Herschorn, 2004). There are several types of pelvic organ prolapse. They include cystocele, which is prolapse of the bladder onto the anterior wall of the vagina, rectocele, which is prolapse of the rectum onto the posterior wall of the vagina, uterine, which is the prolapse of the uterus through the top of the vagina, and finally vault prolapse, which occurs post-hysterectomy causing the vagina to invert (Figure 1, Beus 2003). It is possible to have multiple types of prolapse occurring simultaneously.

Pelvic Organ Prolapse Quantification Exam Background

In order to quantify the type and severity of prolapse, doctors use the Pelvic Organ Prolapse Quantification Exam (POP-Q). The exam, which has been used since 1996 (Geiss *et al.*, 2007), utilizes different anatomical landmarks as measurement sites. The different severities are categorized by a staging system based upon the distance that prolapse occurs from an anatomical reference point. Each type of prolapse has three stages except for vault, which has four.

Motivation

Pelvic organ prolapse occurs in approximately half of those who bear children (Beus 2003). Other causes include aging and obesity (Beus 2003). Due to the large number of women who experience pelvic organ prolapse, the POP-Q is needed to describe and stage their pelvic support (Flesh 2008). The POP-Q, however, is complicated and fairly difficult to learn and perform due to the number of measurements that must be made, and the locations of these measurements (Figure 1).

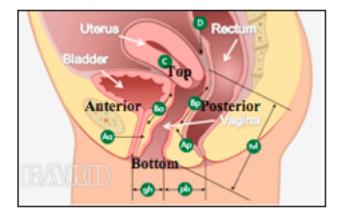


Figure 1. This figure shows the different organs of the pelvic region in white, labeled orientations of a vertical model in black, and the measurement sites of the POP-Q exam in green. This is a female pelvis without any prolapse (Bard Urological 2007).

Client Requirements

In order to be an effective teaching device, the pelvic organ prolapse model must

be designed according to certain specifications set by the client. The main requirement is

that the model must be accurate from the viewpoint of the physician so that residents operating the model will learn how to perform the POP-Q exam accurately. The model must contain structures to represent the four organs most involved with prolapse: the vagina, cervix, bladder, and rectum. In addition to showing the four different types of prolapse, the model must also accurately simulate the three stages (four for vault) of cystocele, rectocele, uterine, and vault prolapse.

The model must be easy to manipulate and reset to its original position since it will be used in repeated trials over short periods of time. It must be scaled up, allowing for greater visuals and more effective teaching. Residents should thus be able to take measurements on the model and apply them to realistic prolapse conditions. Since the design will be used as a teaching model on which residents will be tested, the model should not have anatomical labels. The materials used should be durable and easy to replace if any repairs are necessary. Lastly, the design should be completely safe, posing no danger to its users.

Competition

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

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hat, which represents the vagina. The buttons are sewed onto the hat to represent 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.

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

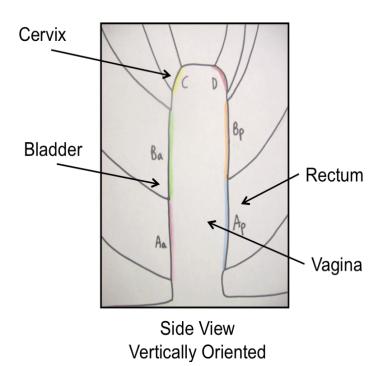


Figure 2. This figure shows the weighted system design, vertically oriented.

vertically to allow the objects to fall (Figure 2). Heavier objects will be used to simulate a more severe stage of prolapse.

One advantage of the weighted system design is that it is easy to operate initially. In order to reset the model, the user 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.

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 one rod, which will push against the back of the silicone tube to simulate uterine prolapse.

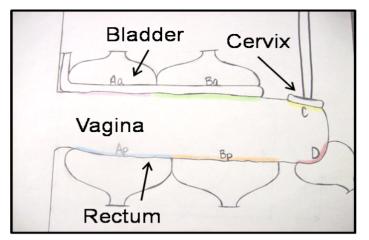
Prolapse will be simulated on the anterior and posterior vaginal walls with airfilled balloons. Since the pelvic model needs to show different types of prolapse, balloons will be placed at specified sites along the silicone tube. The model also must demonstrate the three (or four for vault) stages of 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

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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 uterine and vault prolapse. 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.



Side View

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

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. Also, this design is difficult to scale up for the same reason. The larger the model, the more air will be required to deform the silicone, and it will be difficult to find materials durable enough to perform the required task.

Final Design-Rod System

In the rod system, rods will be connected to organ-like objects and the top of the vagina. Each rod connected to an organ-like object will correspond to the different measurement sites to replicate prolapse of the bladder or rectum. Uterine and vault prolapse will be shown using the same mechanism as described in the calibrated pressure and rod system.

The rod system has a high level of accuracy because the user controls the actuation. Because of this, the resident will have a more realistic view of prolapse. The rods can move independently and can be reset more quickly than the other two designs. Another advantage of this system is its durability. The organs will be securely attached to the rods, which will not wear out like the balloons in the previous design.

Design Matrix

To compare 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. Safety was given a yes or no option.

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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 of 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 the three designs. It scored well in the ease of use category because it 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 advantages of 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 pursued. Its best attribute was its durability. The rods would be stronger than the flexible balloons used in the calibrated pressure and rod system making it more reliable. Unlike the weighted system, the rods would be controlled manually and therefore pressure on the silicone tube would be more freely regulated adding to its accuracy. The user can depict

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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.

compared to one another. The rod system ended up with the highest score.

Table 1. The design matrix shows how all of the alternative designs

| 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 |

Final Design: Fabrication

The pelvic organ prolapse model was fabricated as a box structure with a durable wooden exterior (Figure 4). Holes were drilled at 5 positions near the back of the box so that wooden dowels push through these holes to simulate prolapse. The dowels enter the box at 35° angles from the top and bottom, 65° angles from the top and bottom of the back of the box, and perpendicular to the back of the box, all pointing towards the front face (See Appendix Part B). The box has two sides that are longer to elevate the box in

order to access the bottom dowel more easily. The ovular hole at the front represents the vaginal opening (Figure 5). A hinged door on the side of the box allows for the quick replacement of interior components.



Figure 4. Point-ofview of residents.

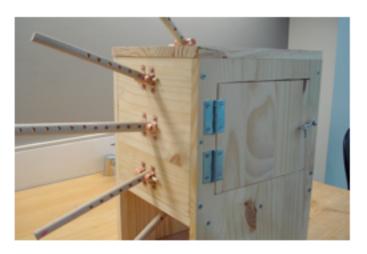


Figure 5. Raised wooden box structure showing the 5 wooden dowels and the hinged-door system.

The interior of the model contains the vaginal tube and the organ-like objects, which are attached to the actuation rods (Figure 6). The vaginal tube is made out of EcoFlexTM 0030 durability silicone. Silicone was chosen because it stretched far enough to simulate the severity of prolapse required for the model and afterwards returned to its original tube-shape with no deformation. In order to create the tube, a flat sheet of silicone was used and its sides were glued together with silicone adhesive. VelcroTM strips were glued to the silicone tube and the interior surface of the box. This allowed the tube to be easily removable in case any repairs are needed. The dowel that pushes through the center of the back of the box has a cylindrical silicone attachment. This attachment contains a small magnet that holds the small magnetized cervix in place. Attached to the ends of the other rods are clay structures that represent the different organs. The clay organs have a greater surface area than the ends of the wooden dowels,

allowing for a more realistic simulation of prolapse.



Figure 6. Silicone tube attached with VelcroTM to the front and back of the model. Wooden dowels with SculpeyTM clay attached to them move through the 5 holes positioned at the top, bottom, and back of the model.



Figure 7. Rod and Pin System.

Final Design: Actuation

To actuate the prolapse model, a system of movable rods is used. Each wooden dowel rod has a series of holes along its length at equally spaced intervals of 2 cm. The degree of prolapse is measured in 1 cm intervals in relation to the front opening of the vaginal tube. Because the model is scaled up to two times the size of normal, measurement intervals of 2 cm on the rods is appropriate and consistent with the chosen dimensions. Each rod is held in a given position using a pin and hole system (Figure 7). In order to actuate each rod, the operator removes the pin and pushes the rod further into the box. Then the pin is inserted into the desired hole to hold the rod in a new location. To return the rod to its original position, the same process is used. No rods are connected to each other and can therefore be actuated independently, allowing the model to display multiple types of prolapse at once (Figure 8). Since many women experience more than one type of prolapse at a time, this design can train residents for a more realistic diagnosis.



Figure 8. Left image shows vaginal opening without prolapse. Right image shows vaginal opening with both cystocele and rectocele.

Testing Procedure



In order to quantify how accurate our model is at reproducing pelvic organ prolapse, we will first calibrate and then test our model using residents and doctors that have experience with the POP-Q exam.

Calibration of our model will be done with the help of our client, Dr. Tova Ablove. Along with Dr. Ablove, we will create different types of prolapse by moving the organs in our model. Dr. Ablove will be able to let us know how far we have to push each rod and organ so that our model most accurately shows specific prolapse types. During calibration we will label rods so that the user of our model can easily and quickly display different types of prolapse.

Figure 9.After calibration, several doctors and residents who have experience withMeasuring
devicethe POP-Q exam will test our model. We will show them four different types of

prolapse, and ask them if they can identify which type of prolapse is shown. Measurements on our model can be made with the measuring device pictured in Figure 9. The number of doctors and residents that can successfully identify the four different types of prolapse will determine the accuracy of our model.

Cost Analysis

The total cost of our prototype was \$117.09, which means that we were able to stay well under our budget of \$1000. Ideally we would like our model to be larger, however, the size was limited by the cost of silicone, which is very expensive in large quantities. We decided to make the silicone tube smaller, and therefore more cost efficient if replacement is needed. Individual and total costs for our prototype can be found in Table 2.

| Item | Cost |
|--------------------|-------|
| Hinges | 2.78 |
| 2 oz. Gorilla Glue | 4.98 |
| Hook & Eye | 1.69 |
| Screws | 5.57 |
| Shelving (Pine) | 21.94 |

Table 2. Cost ofpelvic prolapse model.

| 3/4" Magnetic Disks | 2.49 |
|---------------------------------------|-----------|
| Wooden Dowels (Various Sizes) | 10.68 |
| Tube Straps | 1.98 |
| Ecoflex 00-30 Trial Kit | 28.67 |
| Sil-Poxy Silicone Adhesive-3 oz. Tube | 27.34 |
| Sculpey Clay | 5.97 |
| Total Cost | ~\$117.09 |

Future Work and Conclusion

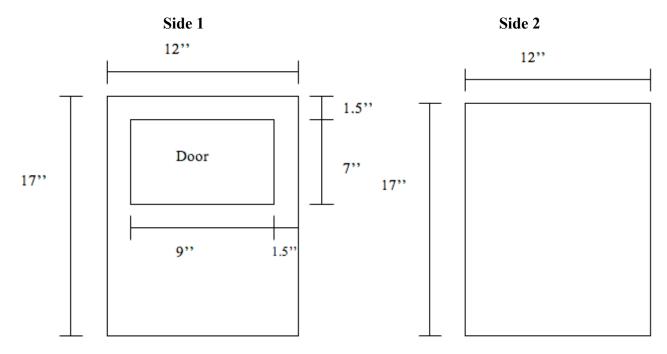
As a team, we feel that we have accomplished the goals set forth by our client this semester. We were able to design and fabricate a working pelvic organ prolapse model while managing to stay well under our budget of \$1000. Our model fits our client's requirements, although a few modifications to these requirements had to be made. For example, at the beginning of the semester our client wanted a scale model of a pelvis to be included in our prototype. After researching the fabrication of a pelvis, we decided that it would be best to focus on creating a model that showed prolapse from the physician's point of view rather than concentrate on creating an anatomically accurate model. Although we have created a working prototype, our pelvic prolapse model can be improved upon by the completion of calibration, testing, and by making a few modifications to our design.

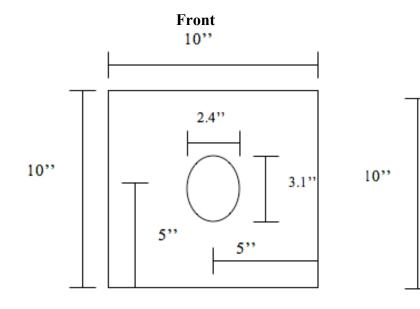
Future work to be completed includes the calibration and testing of our model in addition to modifying the vaginal tube and adding a mechanism to show lateral prolapse. Calibration and testing of our model could be performed as outlined in the testing procedure. The vaginal tube that we created is 4 separate pieces of silicone held together with Sil-Poxy[™] Silicone Adhesive. We think that if we created a mold to make the vaginal tube one piece, it would not only make the tube more durable, but it would also create a more realistic looking tube during prolapse. The issue with our model is that while it displays severe cases of cystocele, the opening of the tube becomes distorted. We believe that this could be prevented by either making the vaginal tube out of one piece of silicone or by modifying the shape of the opening on the outer box. Another issue with our model is that it does not have a mechanism to show lateral prolapse. 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). The vaginal tube in our model is supported in the front and back and therefore cannot simulate lateral prolapse. Our model could be more accurate if the support system of the tube were changed, thus allowing our model to accurately display forms of lateral prolapse. Another way to improve our design is to make the organs more life-like in feel through the silicone. One idea to do this includes putting cotton or some other soft material into a stretchy fabric casing and attaching these to the clay organs.

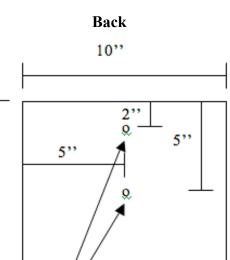
Appendix-Part A

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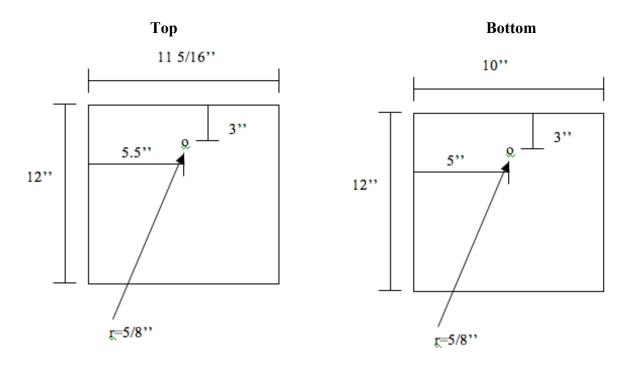




r=5/8"

2"





Rods: Top and bottom rods are 14'' long, holes are 0.8'' (2cm) apart Back rod is 24''

Angles of Rods: Top and bottom enter at 35°

Back rods enter at 65°

Part C-

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

(November 21, 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, rectum, vagina, and cervix.
- Model must show different stages and types of central prolapse.
- 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 must display structural support as well as the bladder, cervix, 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 (30-40°C) 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 two 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: \$150.

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.