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Inguinal Hernia Model

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INGUINAL HERNIA MODEL

Abstract

An inguinal hernia is a protrusion of bowel in the abdominal cavity through the inguinal canal. This condition is very common and its repair is frequent. However, the procedure remains difficult to learn. We will create an inguinal hernia model that allows for the practice of open and laparoscopic surgery as well as teaching medical students and residents the anatomy. Our team considered different materials and ways to assemble the model, as well as client input, while developing a way to accomplish this goal. We evaluated the options giving us the most feasible and realistic design. Successful fabrication of the design will increase the accuracy and improve the learning process of medical students when performing open or laparoscopic surgery on patients.

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Background Information

Motivation

On average 600,000 hernia repairs occur each year and about one third of those are inguinal hernias. Inguinal hernias are very common and their repair has become one of the most frequently performed surgical operations. The chance of a male having an inguinal hernia in his lifetime is 27% while only 3% for females. While these surgeries are so frequent, the learning curve, or the number of times the surgery must be performed by any given doctor for him or her to master the technique, is said to be 250. Medical students, residents, and patients would benefit greatly from an inguinal hernia model that would allow laparoscopic and open surgery simulation with hopes to reduce the learning curve and increase the success rate of these surgeries (Rhodes, 2009).

Inguinal Hernia

An inguinal hernia is a protrusion of the bowel in the abdominal cavity through the inguinal canal. There are two types of inguinal hernias, direct and indirect, which can be identified by their relationship to the epigastric vessels. A direct inguinal hernia occurs medial to the epigastric vessels when contents of the abdominal cavity, or the hernia sac, protrude through a weak point in the abdominal wall. Causes of this type of hernia are often unknown, but lifting, straining, coughing, obesity, pregnancy, or constipation are often thought to increase the risk of occurrence. An indirect inguinal hernia occurs when the hernia sac protrudes through the inguinal ring, lateral to the epigastric vessels. This is the most common type of inguinal hernia and may occur at birth or later in life. Symptoms of an inguinal hernia may be gradual or sudden. They include a bulge in the groin or scrotum, discomfort, pain, and possibly a feeling of heaviness (Bupa, 2008).

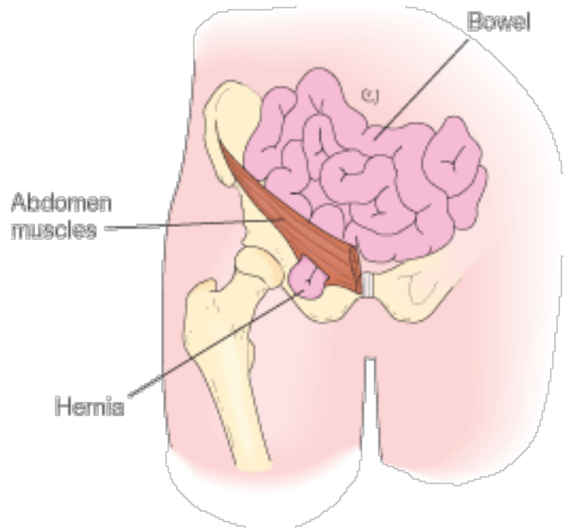

Figure 1. Protrusion of the bowel through the abdomen muscles.

http://drbhandari.com/images/inguinal_hernia.gif

Inguinal hernias do not always require surgery, though it is commonly recommended to avoid complications such as strangulation, or the loss of blood supply to the hernia sac. If a hernia sac in an adult can be pushed back or reduced, surgery can take place at the person's convenience. If it cannot, surgery must take place sooner.

The team's model will focus on two different types of hernia repair procedures, open and laparoscopic. Open surgery is the most common method of inguinal hernias repair. A single cut about 5cm- 10cm long is made in the groin. After the hernia is pushed back into place or removed, a mesh patch is sewn over the weakened area in the abdominal wall.

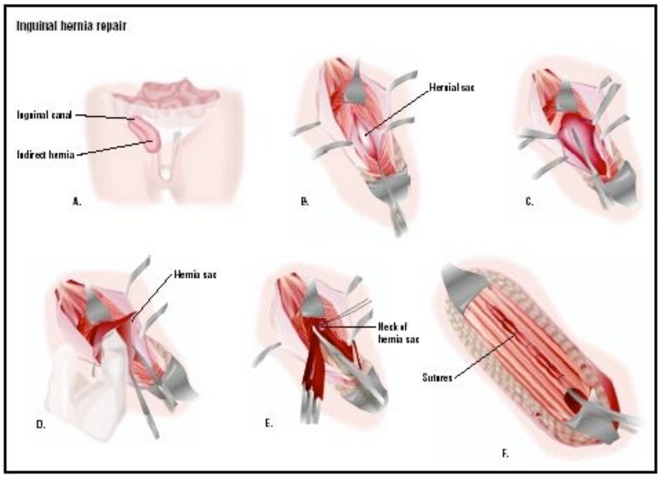

Figure 2. Open inguinal surgery repair.

http://www.surgeryencyclopedia.com/images/gesu_02_img0123.jpg

Laparoscopic surgery has some advantages over open surgery in certain situations. Studies show laparoscopic repair is less painful and allows patients to return to activities more quickly than after the open procedure (Rhodes, 2009). However, this type of surgery has a higher risk for serious complications. During laparoscopic surgery, the surgeon creates a small incision just below the navel. He or she places a balloon into abdomen, which is inflated with carbon dioxide so that the surgeon can see the abdominal organs. A laparoscope is inserted through the incision. The instruments to repair the hernia are inserted through other small incisions in the lower abdomen. After the hernia is pushed back into place, mesh is placed over the weakened area to reinforce the abdominal wall.

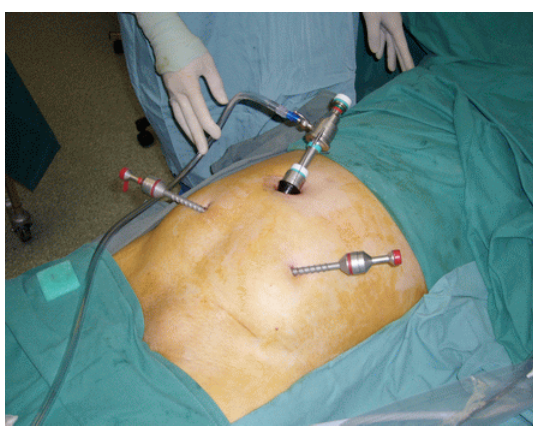

Figure 3. Laparoscopic inguinal hernia surgery repair, external view.

http://urologycentre.com.sg/ports.gif

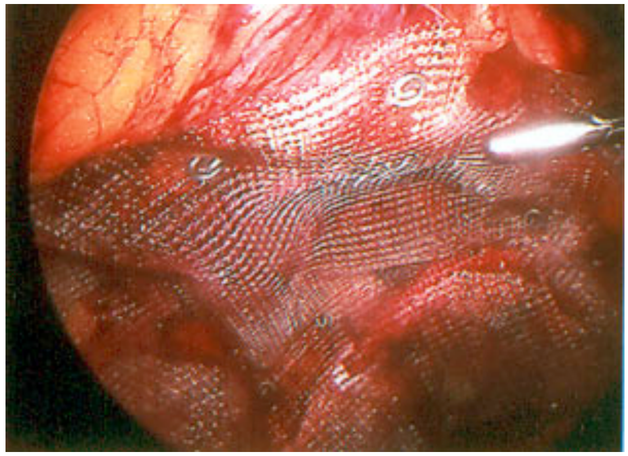

Figure 4. Laparoscopic inguinal hernia surgery repair, internal view.

http://urologycentre.com.sg/hernia_tepp.jpg

Client Information

Our client is Dr. Jon Gould who is an Associate Professor of Surgery at the UW School of Medicine and Public Health**.** He specializes in minimally invasive laparoscopic surgery of the foregut. In addition, he uses advanced minimally invasive techniques to treat acid reflux, obesity, and hernias.

Problem Statement

Dr. Jon Gould has requested a life-like anatomical simulation of inguinal hernia anatomy that can be used to train medical students and residents for both laparoscopic and open hernia surgical repair.

Hernia models that Dr. Gould has previously used did not have enough anatomical landmarks that are used to find specific nerves. The team's model will be made with materials that best imitate the appearance and feel of the body while having correct anatomy and including important anatomical landmarks.

Competition

Several models depicting inguinal hernias are currently on the market. Most models represent the defect in order to inform patients about their conditions, but there are few companies who make models that medical school students can practice the procedure of inguinal hernia repair.

Figure 5. Inguinal hernia model manufactured by Simulab (Simulab Corporation, 2010).

Simulab markets a model that is the most similar to this design project. This model, as shown in figure 5, shows students and doctors the anatomical landmarks used in laparoscopic repair while also showing the etiology of hernias. The trunk is covered with a removable skin, which has premade incisions that the procedure utilizes. This product also includes the following anatomical structures: pectineal ligament, transversalis fascia, external iliac vessels, inferior epigastric vessels, peritoneum, spermatic cord, and testicles. They have also created simulated bone landmarks including the anterior superior iliac spine and pubic symphysis. All layers can reflect to show deeper anatomy. This model depicts all three cases of inguinal hernias: direct, indirect, and femoral. Students can practice mesh placement multiple times on the various hernias. However, this model does not replicate the appearance of a human body. The model appears very stiff with unrealistic texture. In addition, medical students cannot create incisions, especially the cut through the fascia, an important aspect of the procedure. (Simulab Corporation, 2010).

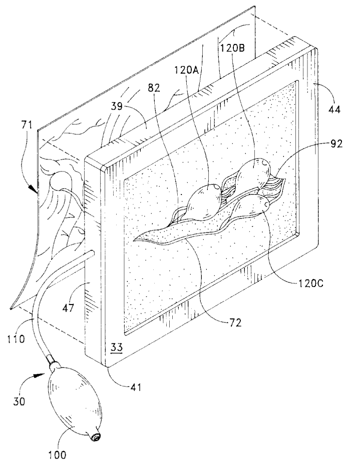

Figure 6. Inguinal hernia model patented by Goldfarb (1999).

The Goldfarb's patented hernia model, as shown in figure 6, is used to inform patients about hernias and the surgical operation to repair them. It uses three balloons to show indirect, direct, and femoral hernias enclosed in a frame suspending four layers—the epidermis, external oblique fascia, and transverse muscle. This relatively low cost model depicts the external oblique fascia, the transverse abdominis, the spermatic cord, and illustrated epigastric vessels. However, this model appears inadequate for teaching medical students as the model lacks structural landmarks and anatomical features, including the ilio-inguinal nerve and pectineal and inguinal ligaments (Goldfarb, 1999).

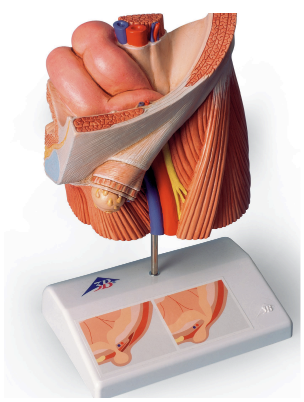

Figure 7. Inguinal hernia model manufactured by 3B Scientific (3B Scientific, 2002).

American 3B Scientific, as shown in figure 7, also produces a model directed toward patient education. The model depicts and compares indirect and direct hernias while also showing the major muscles in the pelvic region. In addition, the model shows the layers of the hernia sac and musculature. However, this model contains no removable parts as it is made from one solid piece of plastic, only showing deep anatomy by reflecting layers in the plastic. The texture and appearance are not realistic and would be of little help to a medical school student attempting to master the inguinal hernia repair procedure (3B Scientific, 2002).

Materials

Selecting the correct materials has proven to be one of the most challenging aspects of this design project. The model should consist of durable material yet exhibit the qualities of human tissue, including texture and color. After performing research, silicone, polyurethane, polyvinyl chloride, and latex seem to be the most effective materials to complete the design of the model.

Silicone is a polymer containing silicone, carbon, hydrogen, and oxygen (Greenwood & Earnshaw, 1997). Because this compound seems highly inert, medical devices and implants commonly use silicone (Shin-Etsu Silicone, 2005). Silicone also shows flex fatigue resistance, which seems ideal for this application as students could practice multiple times on the same model (Shin-Etsu Silicone, 2005). The ease of fabrication is another benefit to this material, as silicone can be formed into virtually any shape. Dr. Greg Gion of The Medical Art Prosthetics Clinic, works with silicone because of its versatility and ease of fabrication.

Polyurethane is another type of polymer that is commonly used in models. Because polyurethane remains durable and relatively inexpensive, it is commonly found in muscles and cartilage of many anatomical models. Polyurethane also comes in various textures, all exhibiting different properties (McMaster-Carr, 2010). However, this creates the problem of finding the correct type of polyurethane to get the desired texture. This also creates the problem of fabrication as the compound’s properties vary, making polyurethane difficult to handle.

Polyvinyl chloride (PVC) is yet another polymer found in anatomical models. This material is an inexpensive and durable material (McMaster-Carr, 2010). However, because of its hardness, PVC becomes difficult to mold and get the correct texture of the human body (Gion, 2010).

Latex is another polymer used in modeling that is normally filled with another material to achieve the proper texture. Because of this, the appearance of the anatomy could easily be replicated. Latex also proves to be tear resistant with high abrasion resistance (Hygenic

Corporation, 2008). This material is relatively inexpensive. However, allergic reactions to latex are relatively common; occurring in about one in one thousand people. Allergic reactions range from mild to severe (Asthma and Allergy Foundation of America, 2010). Our model will come in contact with many people, eliminating latex in the final design.

Design Matrix

In order to compare the advantages and disadvantages of the materials, we have developed a design matrix. The design matrix evaluates four different types of materials: silicone, latex, polyurethane, and polyvinyl chloride. The categories that we used to evaluate the materials were determined from our client specifications.

Design Matrix for Materials

	Weight	Silicone	Latex	Polyurethane	Polyvinyl chloride
Cost	0.25	1	3	3	4
Durability	0.85	3	3	4	4
Appearance	1	4	4	2	1
Realistic texture	1	4	4	2	1
Feasibility	0.5	4	3	2	1
Safety	0.75	4	1	4	4
Diverse application	0.45	4	3	3	1
TOTAL		17.6	13.9	13.5	10.35

Table 1: Design Matrix.

The material design matrix is shown in Table 1. The categories chosen to evaluate the materials include cost, durability, appearance, realistic texture, feasibility, safety, and diverse application. We weighted these categories by ranking them on a scale from 0 to 1, with 1 being the most important. Each material was given a score from 1 to 4 relative to each other, with 0 being the worst and 4 being the best. Silicone was the rated the best material with a total of 17.6 points. The runner up was latex with 13.9 points.

The cost category was weighted 0.25 because we have a budget of $500 with potential for larger funds if necessary. Durability was weighted 0.85/1 because our model needs to be able to be used multiple times to teach many students. All of the materials that we looked at were relatively durable. The next category was appearance. Appearance is a very important category and was given the full weight. Silicone and latex were both received a 4 for appearance because these materials are easily manipulated into different colors, textures, and consistencies.

Realistic texture is also an important aspect of the design. Many other models have a realistic appearance but not texture (i.e. composed of hard plastic). Our challenge is to use durable materials that have a realistic texture so that the medical students and patients using the model can understand what the organs look and feel like. Again, silicone and latex were both ranked at 4 because they can be easily manipulated and patterned to get the different textures to mimic the different organs of the body.

We defined the feasibility category as how readily available the material is, how well it molds, and how easy it will be to manufacture. Feasibility was weighted 0.5 because it is important to select well-known materials, but not as important as the appearance of the model. Silicone scored highest in this category since Dr. Greg Gion, a materials expert, has offered to help us acquire the materials. He has also provided his knowledge to assist us in making different textures and shapes out of silicone.

Safety is very important for our model. Surgeons will be using sharp scalpels to cut through different layers of the model. All of the materials were ranked 4 for safety except latex since it elicits potentially severe allergic reactions.

Diverse application was ranked 0.45 because it will be useful and more convenient to make many different parts out of the same material. Silicone is the most versatile because we are able to manipulate the material to alter the flexibility, hardness, texture, and color.

Overall, silicone won as the material to use in our model because of its appearance, realistic textures, feasibility, and safety.

Final Design

Many properties of silicone are easily manipulated, which allows the material to be used in many diverse applications. This makes it the clear choice for the final design of the inguinal hernia model. Other key features include thermal stability and low levels of chemical reactivity and toxicity. The flexible synthesis of silicone will be useful for the replication of the various anatomical features of the hernia model. For example, small fibers such as fishing wire or dental floss can be embedded in the silicone as it cures to replicate the appearance and texture of muscle and fascia.

To realistically simulate the anatomy, a skeletal model of the pelvis will be used as a base for the final design. By using a realistic bone structure, the relative positioning of key components of the anatomy will be more accurate. The bone structure provides an accurate portrayal of the pubic symphysis and anterior superior iliac spine (ASIS), which are both crucial landmarks for the initial incision of the open repair. Furthermore, by using a skeletal base, the anchorage and suspension of the model's components will be more life-like.

The method of attaching anatomical components to the pelvis skeleton has not yet been determined. However, the use of elastic and Velcro are being considered. Also, securing the components by threading them onto a system of rods is another potential method of attachment. Both Velcro and rod attachment would be useful for easily interchanging the replaceable components of the model. In the end, a combination of these methods may be employed.

The simulation of the interstitial fluid of the internal anatomy can be accomplished with silicone gel. This will also reduce the friction attributed to silicone making the model's surfaces more realistic.

As mentioned before, the model will feature replaceable parts. During the open surgical repair, the surgeon must descend and cut through the external, internal, and transverse abdominal oblique muscles. However, in doing so, the ilio-inguinal nerve must be avoided. As this is the most commonly encountered nerve in open hernia repair, care must be taken to leave it unharmed. This surgical skill requires practice and repeated use of the model. Replaceable silicone abdominal oblique muscle layers will be used to accommodate this need. Molds of these silicone components will be made to allow the repeated synthesis of replaceable parts.

The most crucial feature of the model is the replication of the actual hernia. Thin, tubular silicone will be used to recreate the herniated bowel. Replicating both direct and indirect hernias will involve several small openings in the abdomen wall through which the silicone bowel may pass. Including several hernia sites replicates the variability of actual hernias. Furthermore, the amount of protruding bowel will also be variable. Together these facets will allow the replication of many potential hernia conditions.

Surgical simulation requires the attachment of mesh to reinforce the weakened part of the abdominal wall where the hernia occurred. The actual procedure uses small sutures to secure the mesh; however, this may damage the model. To extend the longevity of the model as well as limit the number of parts requiring replacement, a system of magnets will be used to secure the mesh in the model. This seems to be a very realistic alternative since the placement of sutures is not very critical in the actual procedure. Finally, the simulation of the laparoscopic repair requires three points of entry for the various instruments. Therefore, these laparoscope ports will be included in the model.

Potential obstacles

There are a few potential obstacles that our group may encounter. The protrusion of the bowel through the inguinal ring may be hard to simulate because the inguinal ring expands and stretches. In addition, suspending the different pieces of anatomy proves to be a challenge. Our last potential obstacle is designing the mechanism to make the hernia protrude out of the inguinal ring after every use.

Ergonomics

Although the realistic representation of hernia anatomy will be the most critical design requirement, the model should ideally be easy to maintain. Limited maintenance is necessary for the user to enjoy repeated use. Therefore, attention will be given to the process of interchanging replaceable parts.

Ethical Considerations

In choosing our final material for our model we accounted for some ethical considerations. Latex is very durable and can be molded into many different shapes and textures. It also comes in many different colors and densities. However, we chose silicone as our final material because not only is it durable and moldable like latex, it is also inert and non-toxic. As many people are allergic to latex, we did not want to include it in our final design.

Future Work

The design that we will pursue for the rest of the semester is a model made out of silicone. In the future, our group will use the measurements we have taken in the cadaver lab to make models out of modeling clay. Once we have replicated the parts from modeling clay, we will use them to fabricate the actual pieces of anatomy from silicone. We will do this by covering the modeling clay with silicone and then drawing on patterns to simulate the different textures of the parts. We will construct a mechanism for the hernia sac so that it will automatically protrude out of the inguinal ring after every use. In the future we will be purchasing the silicone, magnets to simulate tacking, and materials to hold the parts in place.

Item	**Cost**
Modeling clay	$21.37
Model Magic	$10.49
Model of Pelvis	$56.38
Total	$88.24

Table 2: Cost of materials.

Our team purchased clay to make a rough model of the anatomy involved in the inguinal hernia surgery. The clay did help as a tool to determine how much space we have and how many parts we have to make, but it wasn't very durable. The clay fell apart and was not an effective material to make a rough model that could be molded repeatedly. Since the clay failed, we purchased Model Magic by Crayola. This material worked much better to create molds out of because it was lighter and kept its shape. Our team purchased a plastic male pelvis bone from Nasco in order to have an anatomically correct pelvis bone to work off of.

Conclusion

The creation of an inguinal hernia model will allow medical students and residents practice the procedure of an inguinal hernia repair, increasing their awareness of the anatomy involved in the surgery, and therefore increasing their confidence and skill. Not only will this be to the benefit of medical schools, doctors, and residents, but to their future patients as well.

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Appendix A

Project Design Specifications

#24- Life-like Anatomical Simulation of Inguinal Hernia Anatomy

March 1, 2010

Team: Carmen Coddington, Bryan Jepson, Laura Platner, Taylor Powers

Client: Dr. Jon Gould

Advisor: Professor Thomas Yen

Function:

Dr. Gould has requested a life-like anatomical simulation of inguinal hernia anatomy that can be used to train medical students and residents in anatomy, for laparoscopic surgical simulation, and for open hernia surgery simulation.

Client Requirements:

- Life- like internal and external appearance
- Interactive learning model
- Male model
- Life- size
- Materials realistically replicate anatomy
- Indirect and direct hernia
- Open and laparoscopic surgery

Design Requirements:

1) Physical and Operational Characteristics

a) *Performance requirements*

i. Interactive model.

b) *Safety*

i. No negative biological effects.

c) *Accuracy and Reliability*

i. Must accurately portray inguinal hernia and surrounding anatomy

d) *Life in Service*

i. Daily use for 5- 10 years

e) *Shelf Life*

i. 15-20 years

f) *Operating Environment*

i. In contact with surgical tools and hands.

ii. Must operate from 15^{o} to 30^{o} C

g) *Ergonomics*

i. Easily maintained.

h) *Size*

i. Dimensions of an average male from lower abdomen to upper thigh

ii. 14 x 10 x 10 in.

i) *Weight*

i. 15lbs- 30lbs

j) *Materials*

i. No latex

ii. Silicone

k) *Aesthetics*

i. Must naturally portray hernia and anatomy

2) Production Characteristics

a) *Quantity*

i. One model.

b) *Target Product Cost*

i. $500- $1,000

3) Miscellaneous

a) *Standards and Specifications*

i. FDA approval is required if placed in the market

b) *Customer*

i. Medical schools

ii. Hospitals

c) *Patient-related concerns*

i. Not applicable.

d) *Competition*

i. Inguinal Hernia Model (Patent number 5,908,302)

ii. SimuLab Product number HTM- 30

iii. American 3B Scientific Inguinal Hernia Model