Design and Preliminary Testing of an Improved Abdomen Testing Device for use in Hernia Repair Modeling

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Design and Preliminary Testing of an Improved Abdomen Testing Device

for use in Hernia Repair Modeling

by

Alexandra Dunbar

A thesis presented to the School of Engineering of Washington University in St. Louis in partial fulfillment of the requirements for the degree of Master of Science

May 2018

Saint Louis, Missouri
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Alexandra Dunbar

Washington University in St. Louis
May 2018
Dedicated to my father and my brother
for their support through all my endeavors

And to my mom, Katie Keeler, and Emilie Hobbs
Thank you for being here for me, even if you are no longer here.
ABSTRACT

Design and Preliminary Testing of an Improved Abdomen Testing Device for use in Hernia Repair Modeling

by

Alexandra Dunbar

Master of Science in Biomedical Engineering

Washington University in St. Louis, 2018

Research Advisor: Professor Spencer Lake

Commonly used *ex vivo* testing methods for studying surgical techniques and medical devices to repair abdominal hernias are unable to replicate the complex loading conditions present along the abdominal wall. This limits the clinical relevance of the results found using these testing methods. Additionally, *in vivo* testing methods for examining hernia repair, such as human or animal models, are costly, time consuming, and often not feasible. Thus, there is a need to develop an *ex vivo* testing device which can more accurately replicate the physiological loading environment of the abdomen. The goal of this project was to design a system to model the intraabdominal pressures produced in the abdominal cavity and assess the functionality of the system through validating the pressures generated within the device and conduct preliminary abdominal testing.

The device constructed here successfully applied physiological pressures to a porcine abdominal wall. Differences in areal strain across the abdomen were observed between an intact abdomen, a simulated hernia, and a prosthetic mesh repaired defect. Additionally, changes in defect area were observed between herniated abdomens and mesh repaired abdomens. The results found here suggest a prosthetic hernia mesh affects the mechanical behavior of the abdomen under loading. Further testing and development is necessary to improve the reproducibility of the device; however, the initial proof-of-concept design demonstrates improved modeling of the loading environment experienced by an abdominal wall.
Chapter 1

Introduction

An abdominal wall hernia occurs when there is a protrusion of a peritoneal lined sac through the muscular layers of the abdomen. The loss of mechanical integrity of the abdominal wall, increased intra-abdominal pressure, predisposed defects, or a combination of these are involved in the formation of a hernia. Approximately twenty million hernias are repaired each year worldwide. Hernias are repaired either through open surgical repair or laparoscopic surgical repair. There has been debate about the ideal method for repairing abdominal hernias. In comparative studies, it has been found that laparoscopic repair reduces operating time and results in fewer recurrences. Yet, the selection of the ideal approach is determined on a patient by patient basis. However, recurrences after reparative surgery are still of concern. Medical devices and surgical techniques have been developed to reduce the recurrence of hernias after surgery and lower post-operative complications. The most prevalent of these devices is the prosthetic hernia mesh, which will be discussed in further detail in the sections below.

Developing and assessing the efficacy of new devices and surgical techniques is an ongoing challenge. Many ex vivo testing models are unable to accurately replicate the complex physiological loading conditions present in the abdomen. Additionally, animal and human testing is costly, difficult to reproduce, and often not feasible. To develop an ex vivo testing device which can improve reproducibility, decrease cost, and can model physiological loading environments, a functional overview of the anatomy and physiology of the abdominal wall is necessary before proceeding.

1.1 Background

Discussing the anatomy and physiology of the abdominal wall is necessary for understanding the development and treatment of abdominal hernias. The abdominal cavity can be visualized as a cylindrical chamber with a positive internal pressure - referred to intraabdominal pressure. It holds the stomach, intestines, and liver among other abdominal organs. The peritoneum, a serous
membrane, separates the internal viscera from the abdominal wall muscles, fat, and skin. Roughly, the abdominal wall is superiorly bounded by the xiphoid process and inferiorly ends at the iliac crest of the pelvis. The abdominal wall is comprised of complex layers of muscle which function to assist in respiration, urination, and defecation, protect internal organs, maintain abdominal structure, and are involved in flexion, extension, and rotation of the torso. Details regarding the abdominal muscles are discussed below.

1.1.1 Abdominal Wall Anatomy – Abdominal Muscles

The abdominal wall consists of five main muscle groups which are the external oblique, internal oblique, transverse abdominis, pyramidalis, and the rectus abdominis muscles (Figure 1.1). These muscles can be divided into two groups: the midline and the anterolateral groups of muscles. The rectus abdominis and the pyramidalis comprise the midline muscle group, and the external oblique, internal oblique, and transverse abdominis muscles comprise the anterolateral group. In the following sections, the function and organization of these muscles are described. The origin and insertion sites for the muscles will not be discussed in great detail here, as the primary focus is to provide a broad understanding of the anatomy of the muscles and their functions.
1.1.1 Rectus Abdominis

The rectus abdominis muscles (RA) are strap-like muscles oriented vertically on both sides of the midline of the abdomen. They originate from the pubic crest and the ligamentous component of the pubic symphysis and extend upwards to their insertion site at the xiphoid process and the anterior surface of the 5th and 7th costal cartilages. It is important to note that the rectus abdominis is bisected by the linea alba, providing a central anchor point for the muscle (Figure 1.1). These muscles primarily serve to flex the abdominal wall and are involved in increasing intra-abdominal pressure. During
activities such as defecation and exhalation the rectus abdominis is active when the actions are forceful but is typically not involved during normal function.

During abdominal surgeries involving the midline, it is important to return the RA muscles to the midline for recreating the linea alba. This is necessary to restore function of the muscles. For brevity, the other midline abdominal wall muscle, pyramidalis, will not be discussed because it has a variable presence in the population.

1.1.1.2 Transversus Abdominis

The transversus abdominis muscle (TAM) is the innermost muscle of the anterolateral group. It originates from the surfaces of the 7th through 12th costal cartilages, iliac crest, anterior leaflet of the thoracolumbar fascia, and the lateral third of the inguinal ligament. The muscle fibers run towards the midline of the abdomen and insert onto the linea alba, pubic crest, and pectineal line. For rough visualization, TAM fibers can be thought of as running horizontally in the abdominal wall going in a lateromedial direction (Figure 1.1).

TAM is involved in providing circumferential hoop tension when it acts with the internal oblique muscle. This provides rigidity to the abdominal wall and creates tension across the thoracolumbar fascia. The transverses abdominal is often thought of as a corset, which holds and protects the visceral sac.

1.1.1.3 Internal Oblique

The internal oblique muscle (IOM) lies in the middle of the three major muscles of the anterolateral group, ventral to the TAM and dorsal to the external oblique muscle. Its origins are similar to those of the TAM (excluding the costal cartilages), and it inserts on the 10th through 12th ribs and the linea alba. IOM can be pictured as running in a lateromedial direction, but instead of being oriented horizontally, the fibers exhibit a slightly upward trajectory (Figure 1.1).

As mentioned above, the IOM is also involved in creating circumferential hoop tension along the abdominal wall. Additionally, this muscle group works with the external obliques to initiate torsion and rotation of the trunk. During exhalation, the IOM contracts to oppose the motion of the diaphragm to increase intra-abdominal pressure.
1.1.1.4 External Oblique

The external oblique muscle (EOM) is the most superficial of the anterolateral group of muscles. It originates from the surface of the 5\textsuperscript{th} through 12\textsuperscript{th} ribs and inserts on the linea alba, iliac crest, and pubic tubercle\textsuperscript{6}. For visualization, the muscle fibers of the EOM run in a lateromedial direction with a slight downward orientation (Figure 1.1). The EOM works with the other muscles in the anterolateral group to create compression for the visceral sac, and it is involved in creating lateral flexion and rotation of the trunk\textsuperscript{6}.

1.1.2 Abdominal Wall Anatomy – Linea Alba

The linea alba is a fibrous structure that runs down the midline of the abdominal wall from the xiphoid process to the pubis symphysis (Figure 1.1). It is composed primarily of collagen and elastin and forms the aponeurosis of the muscles in the anterolateral group (TAM, IOM, and EOM)\textsuperscript{6}. The linea alba is of particular interest in abdominal surgeries, such as hernia repairs, for intra-abdominal access because it is avascular. However, the linea alba also has an inherent weakness since there is a lack of muscle coverage on the posterior side of it\textsuperscript{6}. This makes it a common site for primary ventral hernias\textsuperscript{7}. Additionally, since the linea alba is a common incision site for midline laparotomies, incisional hernias occur at this location as well\textsuperscript{6}.

For reconstructing the abdominal wall after surgery, restoring the linea alba is necessary. This abdominal structure is critically important for understanding the development of ventral hernias, the repair of hernias, and the potential development of incisional hernias. Since the linea alba plays a major role in hernia formation, a defect along this component of a porcine abdominal wall is used in this study to model a hernia.

1.1.3 Intra-abdominal Pressure

Within the abdominal cavity, there is constant positive pressure present which ranges between 5 and 7 mm Hg in healthy adults\textsuperscript{8}. For reference, this is roughly 0.1 – 0.135 psi. The pressure is created because the abdominal cavity is a sealed compartment surrounded by muscles and varies depending on activity of the abdominal wall muscles, the diaphragm, and the glottis. As mentioned previously, activation of the transversus abdominis and internal oblique muscles increases intra-abdominal pressure. The abdominal wall must be able to withstand the pressures generated within the abdominal
cavity. During different activities, this pressure can increase to be as high as 171 mm Hg (~3.0 psi) from maneuvers such as jumping. The effect of activity on intra-abdominal pressure can be found in Table 1.1. There are factors associated with higher intra-abdominal pressures. Increasing BMI and obesity have been shown to increase intra-abdominal pressure, so it is lies between 7 and 14 mm Hg (0.135 – 0.27 psi).

Table 1.1. Average measured intra-abdominal pressures for different maneuvers in healthy adults

<table>
<thead>
<tr>
<th>Maneuver</th>
<th>Mean Intra-Abdominal Pressure (mm Hg)</th>
<th>Standard Deviation (mm Hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supine</td>
<td>1.8</td>
<td>2.2</td>
</tr>
<tr>
<td>Standing</td>
<td>20.0</td>
<td>3.8</td>
</tr>
<tr>
<td>Sitting</td>
<td>16.7</td>
<td>2.9</td>
</tr>
<tr>
<td>Stairs</td>
<td>68.9</td>
<td>17.4</td>
</tr>
<tr>
<td>Abdominal Crunch</td>
<td>26.7</td>
<td>10.7</td>
</tr>
<tr>
<td>Cough</td>
<td>81.4</td>
<td>25.6</td>
</tr>
<tr>
<td>Jumping</td>
<td>171</td>
<td>48.4</td>
</tr>
</tbody>
</table>

As demonstrated in Table 1.1, coughing increases intra-abdominal pressure. Noting this is of particular importance in the scope of hernia repair. To minimize the risk of recurrence after hernia repair surgery, the patient must keep their intra-abdominal pressure to a minimum during the healing phase so as to reduce the load experienced by their abdominal wall. However, with respiratory conditions such as COPD and pneumonia, the patient is predisposed to a significant amount of coughing leading to prolonged increased intra-abdominal pressure. After abdominal surgery, patients who cough a significant amount are at a greater risk for the development of incisional hernias in part because of the increased abdominal pressure. Additionally, vomiting and even sitting up may increase the patient’s intra-abdominal pressure, and increase the risk post-operative hernia formation.

It is important to understand the physiologically relevant intra-abdominal pressures when modeling the abdominal wall and the abdominal cavity. Since patients are not likely to be jumping after abdominal surgery, their intra-abdominal pressure probably will not reach 171 mm Hg (~3.0 psi). However, it is likely intra-abdominal pressures could reach 81.4 mm Hg or slightly higher (~1.6 psi) from coughing. For the abdominal modeling device designed, physiologically relevant pressures that could be produced by coughing were tested.
1.2 Hernia Formation

As mentioned above, a hernia occurs when a peritoneal lined sac protrudes through the muscle and fascial layers of the abdominal wall (Figure 1.2). Traditionally, it has been reported that abdominal hernias occur when there is a weakening of the abdominal wall at a specific location, leading to a drop in the load the site can maintain. Increases in intra-abdominal pressure have been thought of as a contributor in hernia formation pathology because the abdominal wall must withstand increasing load. The biological mechanisms behind the mechanical weakening of the abdominal wall are either due to primary fascial defects or surgical wound failure.

Figure 1.2. Hernia Formation. The graphic above illustrates the process by which a hernia forms. The protrusion through the abdominal wall is visible here.

1.2.1 Primary Hernia Formation

Hernias occurring prior to any abdominal surgery or occurring at a site unrelated to an incision created by surgery will be referred to as primary hernias within this report. Abnormal collagen metabolism has been proposed as a mechanism for fascial weakening leading to the formation of primary and incisional hernias. When the structure of the abdominal wall is compromised – through reduced collagen content – the pressure which can be supported decreases. Smoking and nutritional deficiencies can lead to acquired collagen defects.

Recently, connective tissue disorders have been investigated in relation to hernia formation due to a predisposition to collagen defects. Type I collagen is known to provide improved mechanical strength in comparison to other collagen types. The ratio of type I collagen to type III collagen is
important for the strength of the connective tissue. Altered ratios of Type I/III collagen have been associated with reduced tensile strength and mechanical stability. Matrix metalloproteinases (MMPs) and a lack of inhibitors for MMPs are thought to be the causes of alterations in the collagen ratio. It is still unclear which MMP subtype is primarily responsible shifting the Type I/III ratio; however, multiple studies have found these enzymes are involved in altering the ratio. These finding change the original thinking that hernia formation is caused by a single event but rather is a biological process of decreasing the strength of the abdominal wall.

### 1.2.2 Secondary Hernia Formation

Hernias occurring post-operatively at the site of an abdominal incision will be referred to as a secondary hernia or an incisional hernia within this report. These hernias often occur following wound failure at an incision site. Failed wound healing at incision sites is implicated in the formation of secondary hernias. Wound healing defects or insufficient surgical technique are the main mechanisms behind failed wound healing. Additionally, patient characteristics such as obesity, smoking, diabetes, and post-operative infection all increase the potential for poor wound healing. At the sites of repair, the fascial planes are replaced with scar tissue. Scar tissue is mechanically weaker than the original tissue layers because the collagen fibers are not properly organized.

During the inflammatory response after surgery, tissue strength of the wound is extremely low. Foreign materials, such as suture or prosthetic mesh, are used for abdominal surgeries, which can prolong the inflammatory response. Prolonged inflammation delays the progress of wound healing and increases the risk of recurrence. Collagen is deposited during wound healing to provide structural strength to the tissue. However, abnormal collagen synthesis, delayed collagen synthesis, or increased proteinase activity degrading collagen all can result in wound healing defects. This leads to decreased mechanical strength at the incision site and ultimately, wound failure.

When wound healing mechanisms are not the cause of the wound failure, there may be surgical explanations. Suture pulling through adjacent tissue of the incision is most often the reason for surgical wound failure rather than knot slippage or suture fracture. Mechanical failure in a midline laparotomy leads to disuse atrophy and change in muscle fiber type of the abdominal wall muscles. This can make healing difficult, and there is the potential for developing a recurrent hernia.
Understanding the mechanisms behind hernia formation can help in the treatment and prevention of hernia formation in the future.

1.3 Hernia Repair

Hernias are repaired either laparoscopically or through an open surgical method. There has been debate about which method is the most effective for repairing abdominal hernias with regards to postoperative complications such as morbidity and recurrence rates. The benefits and drawbacks of laparoscopic versus open repair methods will not be discussed in this report. Instead, a basic overview of hernia repair surgery will be described. The main purpose of surgically repairing an abdominal hernia is to open the abdominal wall and either remove the protruding tissue or return it into the abdominal cavity. Prosthetic mesh may be placed in one of several locations of the anterior abdominal wall to reduce the tension on the abdominal tissue. Finally, suture is used to close the incision. The use of mesh will be discussed in further detail below.

1.3.1 Prosthetic Hernia Mesh

Before the design of prosthetic mesh, surgical repair of hernias was conducted under tension. The edges of the incision were pulled and sutured together creating tension within the tissue. Tension along the incision site increased the likelihood of secondary hernia formation. To address this problem, prosthetic mesh was designed. As mentioned above, the mesh is placed along the abdominal wall to reduce the tension within the tissue and re-enforce weakened the abdominal wall. Incisional hernias are reported to occur after 2-20% of abdominal surgeries. When sutures are used in the hernia repair, the recurrence rates range from 12-54%. With the use of prosthetic mesh, the rates are lower, falling between 2-36%. There is still a large amount of variation in recurrence rates, but overall, prosthetic meshes have led to a reduction in secondary hernias formation.

1.3.1.1 Hernia Mesh Characteristics

There is much debate about the “ideal” mesh to use for hernia repair. Hernia meshes can be synthetic, biological, or a composite, and they can be permanent or resorbable or coated. Meshes exhibit a range of the following properties: weight, elasticity and strength, pore size, and isotropy. There are numerous meshes currently on the market for use in hernia repair. Determining the optimal mesh is
difficult because of the variation in physical and mechanical characteristics of the mesh and the size and the location of the hernia require different considerations.

Synthetic meshes are composed of polymers, typically polypropylene (PP), polytetrafluorethylene (PTFE), Dacron, polyethylene, and mylar. To reduce the foreign body response caused by implanted mesh, coatings are often used to encourage tissue integration and decrease adhesion formation with abdominal contents. Permanent meshes remain in the patient’s abdomen; whereas, the resorbable meshes are designed to be degraded while the abdominal wall heals. Risk of infection, impaired range of motion, and chronic pain have been associated with the permeant meshes. In contrast, absorbable meshes minimize the amount of foreign material in the abdominal wall and are designed to disappear over time, so the problems listed above are not seen. Biological meshes are decellularized extracellular matrices derived from living tissue. Since they are derived from a biological source, they contain collagen networks and provide bioactive signals that synthetic meshes cannot.

The pore size of the mesh is important for the tissue incorporation. Meshes with pores larger than 75 μm allow for infiltration of blood vessels, collagen, and macrophages. Large pore size helps aid in soft tissue ingrowth, and the meshes are more flexible because granuloma bridging is not achieved. The large pore size helps to inhibit granulomas from becoming confluent and surrounding the mesh. When the pore size is larger, there is a risk for adhesion to the internal viscera if the mesh is not coated. Pores smaller than 800 μm are not able to inhibit granuloma bridging. The mesh can become encapsulated, which leads to the development of a scar plate and decreased flexibility. Small pore size also makes it more difficult for collagen ingrowth. Recently, composite meshes have been designed with a macroporous surface to expose to the parietal side of the abdominal wall, so tissue ingrowth can occur. The other surface of the mesh is microporous to expose to internal organs, so adhesion formation is prevented.

Hernia mesh weight is characterized as being ‘lightweight’ or ‘heavy weight’. Heavy weight meshes contain a significant amount of material with small pore size and high tensile strength. These meshes reduce abdominal wall compliance because they can be very stiff. Since there is more material present with heavy weight meshes, the foreign body response is much greater and can possibly lead to increased chronic pain for the patient and fibrosis. In contrast, lightweight meshes have less material and are more elastic. There is a lesser foreign body response associated with the use of lightweight meshes, which results in less pain for the patient, increased abdominal compliance, and better tissue
incorporation. The use of lightweight hernia mesh is preferred for these reasons; however, the high tensile strength of heavy weight meshes is a benefit to reinforce the incision site.

The elasticity and strength of the mesh are also important properties to consider when determining an appropriate mesh to use in hernia repair. First, acknowledging the loading in the abdominal wall is necessary. The horizontal forces generated by the contraction of the anterolateral muscle group are significantly greater than the vertical forces, so the vertical direction exhibits greater elastic behavior. The anisotropic loading conditions here are important to consider in the material properties of the hernia mesh. Additionally, as described in the intraabdominal section above, the pressure in the abdominal cavity varies with different maneuvers. Prosthetic meshes must have the structural integrity to withstand these physiological stresses. The strength of the mesh is important; however, the natural elasticity of the abdomen must also be taken into consideration. The flexibility of the abdominal wall ideally would be mimicked in the hernia mesh to maximum the comfort and natural movement of the patient. Assessing all the mesh characteristics is important for choosing an optimal mesh for the hernia size, the location, and the healing and comfort of the patient.

1.3.1.2 Biological Response to Hernia Mesh

When the hernia mesh is implanted, a foreign body response is triggered. Initially proteins adsorb to the surface of the mesh, and the immune system attempts to isolate the foreign body. The adsorbed proteins can change their conformation when they adhere to the surface and interact with phagocytes. Through these interactions with phagocytes, inflammatory and wound healing responses are initiated. The inflammatory response causes an increase in cytokine and immune cells concentration at the site of the mesh leading to the development of an early stage granuloma. Over time, the granulate matures to a late stage.

The last step of the biological response to the mesh is synthesis of connective tissue. Fibroblasts secrete collagen for approximately 21 days, and following this, there is a decrease in immature collagen and an increase in mature, Type I collagen. The connective tissue grows around and through the mesh. Over 6 months, the mechanical strength of the incision increases, but only reaches 80% of its original strength. The biological response to the mesh is affected by the pore size, weight, and material of the prosthetic.
1.3.2 Hernia Mesh Fixation

Hernia mesh is often fixed to the abdominal wall to prevent migration and recurrence. There are three major devices and techniques: tacks, transfascial sutures, and adhesives\textsuperscript{18}. Tacks can be absorbable or nonabsorbable. Both are designed to grip the abdominal tissue and hold the mesh in place. They can take on numerous configurations with the goal being to minimize adhesion formation and ensure there is no mesh displacement. The designs of different tacks can be seen in Figure 1.3. The effectiveness of these designs has not been thoroughly investigated. A double crown arrangement of tacks is often used by surgeons to secure a mesh to the abdominal wall (Figure 1.4). An outer ring and an inner ring of tacks are laid along the mesh with the outer ring being approximately 0.5 cm from the edge of the mesh and the tackers in the inner ring are placed 1 to 2 cm apart\textsuperscript{6}. Tacks are a commonly used fixation method because of the strength and ease of use.

![Figure 1.3 Hernia Mesh Tacks. Six different hernia mesh tacks are displayed above, illustrating the differences in the design of each\textsuperscript{6}.](image)

Adhesives cause minimal damage to the surrounding tissue and can be broken down into three main categories: synthetic, biological, and genetically engineered polymer protein glues\textsuperscript{6}. Some of these glues are designed to be hydrolyzed and degraded to allow for tissue ingrowth. Others are designed to mimic the generation of fibrin and can serve as a fixator to the mesh\textsuperscript{6}. There is a range of polymerization reactions and adhesion properties with glues. There is no penetration of the abdominal wall tissue with the use of adhesives; however, the strength of the adhesion may be lower than other methods\textsuperscript{19}.
Figure 1.4 Double Crown Fixation. The image above illustrates the double crown fixation pattern used to secure a prosthetic hernia mesh with tack\textsuperscript{6}.

Similarly to tacks, sutures can be absorbable or nonabsorbable. They are often applied transfascially as illustrated in Figure 1.5. In addition to the transfascial sutures, sutures are used to close the incision upon completion of the repair. The bite size, suture material, barbed or knots are some of the factors that must be taken into consideration when applying sutures.

Figure 1.5. Transfascial Suture Application\textsuperscript{20}. The figure above illustrates the application of a transfascial suture through the abdominal wall and prosthetic mesh.

### 1.3.3 Hernia Recurrence

The development of a post-operative hernia can occur for multiple of reasons. The mechanisms behind secondary hernia formation has been described in previous sections. The majority of hernia recurrences occur at the implant-tissue interface when there is inadequate wound healing\textsuperscript{21}. If the mesh is unable to integrate with the abdominal wall appropriately, then the likelihood of recurrence is much higher. Dislocation or failure of the mesh can be caused from insufficient mesh overlap, mesh shrinkage, improper placement, mesh protrusion, and inadequate fixation among other problems\textsuperscript{22}. These problems with the mesh impede its ability to reduce the tension at the incision site. Late
recurrence can occur from collagen metabolism defects that leads to thinning of the scar tissue as the patient ages\textsuperscript{33}.

### 1.4 Development of Project Scope

Understanding the loading environment, the mechanical properties, and the material properties of the abdominal wall is important for understanding the formation of hernias and reducing the rate of recurrence after hernia repair. The abdominal wall supports the body and withstands intraabdominal pressure and forces generated through abdominal muscle contraction. As described above, the abdominal muscles are arranged in different orientations leading to complex loading environment. Additionally, depending on location along the abdominal wall, there is variation in the muscle layers and connective tissues present. This also contributes to the complexity of loading along the abdominal wall. The stresses the abdominal wall experiences are still not well understood and accurately modeling said stresses is challenging. Developing a method for created physiologically relevant abdominal wall loading conditions would improve testing for analysis of tacker, suture, and mesh performance among other things.

Also adding to the complexity of the abdominal wall, are the mechanical and material properties of the different tissue structures. Mechanical testing of the linea alba has demonstrated anisotropic properties. There is greater compliance in the longitudinal direction of the linea alba compared to the transverse direction, and transverse stresses have been found to be significantly greater than the longitudinal stresses\textsuperscript{21}. Non-linear, viscoelastic properties of the linea have also been reported\textsuperscript{24}. Through mechanical testing, the rectus sheath and the transversalis fascia both demonstrated anisotropic behavior as well\textsuperscript{21}. There have been very few studies examining the abdominal wall musculature. A complete understanding of the structure-function interactions of the abdominal wall is still missing. Development of mathematical and computational models have attempted to address this; however, there are significant shortcomings. Assumptions such as uniform thickness of the abdominal wall and isotropic and linear behavior of tissues have all limited the applications of these models\textsuperscript{21}.

For testing new medical devices to be used in hernia repairs, it is necessary to mimic the \textit{in vivo} conditions as closely as possible. From examining the information currently available concerning the loading along the abdominal wall and the mechanical and material properties of the tissue, there are
numerous factors that must be accounted for to appropriately model the abdominal wall. The goal of this project was to design a testing setup that could model the loading environment of the abdominal wall and could account for the mechanical and material properties of the abdominal wall. With this model, different technologies for aiding in hernia repair could be tested and their functionality evaluated.
Chapter 2

Abdominal Modeling Device

Studies assessing new methods and technologies for hernia repair are often performed with animal experiments and clinical trials. Both require ethical approval, significant monetary investment, and time to collect results. Preclinical testing for development of new surgical methods and treatment technologies is mainly done in animal models before clinical trials can be pursued. Ethical approval and the cost of animal studies can be limiting factors for creating and testing innovative surgical techniques and technologies. Constructing a device to model the function of the abdominal wall under physiological pressures can allow for testing new ideas without the constraints of *in vivo* models.

2.1 Evaluation of *Ex Vivo* Hernia Testing

To circumvent the constraints of *in vivo* testing for hernia repair methods, numerous *ex vivo* testing methods have been used. Some of these testing methods and apparatuses will be discussed and evaluated below. The pitfalls from these testing models aided in the development of the abdominal modeling device discussed within this thesis.

2.1.1 Ball Burst Testing

A commonly used method for testing hernia repair devices is known as the ball burst method. Briefly, this testing method uses square sections of material – either tissue or synthetic material – that are secured into place by clamping onto the sides of the material. Then, a metal sphere fixture is designed to attach to the end of a universal testing machine (Figure 2.1). The ball is pushed against the section until failure, and the tensile strength is determined. The tensile strength of the hernia mesh and the effect of tacks on the strength of the mesh among other mesh characteristics can be tested with this method.
A benefit of the ball burst testing method is that standard testing protocols exist. The test setup and the testing method can be designed to conform to the American Society for Testing and Materials (ASTM) specifications, which allows for comparison between acquired results. Testing parameters can be consistently controlled and measured with ball burst testing. However, there are limitations to this testing method. Only small sections of material can be tested. One study used 7.5 x 7.5 cm sections. With this specimen size, the size of the mesh tested cannot be clinically relevant. Using small sections also cannot replicate the behavior of the entire abdominal wall. Additionally, although the stress applied may be physiologically relevant, the application of it is not. The complexity of the forces generated along the abdominal wall cannot be replicated through this testing method. Examining the shortcoming of the ball burst method illustrates there is room for improvement in designing an \textit{ex vivo} testing device.

2.1.2 Uniaxial Testing

Uniaxial testing is another testing method widely used for hernia repair device research. Stress is applied along one direction of the sample to yield the tensile strength of the specimen. In uniaxial testing, specimens can either be biological or synthetic. The sections used are often small in size, comparable to the ball burst testing. One study used abdominal samples of 5 x 7 cm. For testing
with hernia mesh, a portion of the mesh is removed from the tissue. Each end is placed into clamps and pulled in opposing directions (Figure 2.2). A dynamometer or universal testing device is used to displace the material, and the failure of the mesh can be analyzed.

![Figure 2.2. Uniaxial Testing Setup](image)

Conducting uniaxial testing has some of the same benefits as ball burst testing. Since a universal testing device is used, the stress and strain of the system can be monitored precisely and with consistency. Uniaxial testing is a common method, which makes comparing results between studies possible. However, there are limitations to uniaxial testing similar to those of the ball burst. The forces generated and the size of the samples with uniaxial testing do not reflect physiological abdominal loading. It is only capable of generating forces along one direction of the tissue. The curvature of the abdomen is not accounted for with uniaxial loading. For designing a testing device, these concerns should be addressed.

### 2.1.3 Planar Biaxial Testing

Biaxial testing is conducted to address some of the shortcomings of uniaxial testing. Instead of pulling the sample in one direction, the sample is pulled in two directions (Figure 2.3). The tension applied in each direction can be different to reproduce an anisotropic loading environment, or the tension applied can be the same depending on the desired testing\(^\text{29, 30}\). Anisotropic testing is an improvement at attempting to model the loading of the abdominal wall. The sample sizes with biaxial testing remain small, however. One study used 40 x 40 mm sections with this test setup\(^\text{30}\). When conducting planar biaxial testing, the displacement along each axis is controlled, and the force output can be recorded. This testing method allows for measuring the anisotropy, nonlinearity, and hysteresis of the sample.
Biaxial testing allows for control over the displacements applied, and precise force values can be collected. Compared to uniaxial testing or ball burst testing, biaxial testing is better at modeling physiological stresses on the sample. However, the small size of the specimens tested is a limiting factor. Additionally, the shear forces and intraabdominal pressure cannot be modeled through biaxial testing. Thus, improvements of *ex vivo* testing for hernia repair devices and surgical techniques are possible.

![Figure 2.3 Biaxial Testing Setup](image)

2.2 Device Collaboration

A biomechanical abdominal wall model was designed by Lyons et al. from the Trinity Centre for Bioengineering at Trinity College in Dublin, Ireland\(^2\). The project presented in this thesis was designed in collaboration with Lyons et. al. with initial inspiration coming from the device described in “Biomechanical abdominal wall model applied to hernia repair.” The device described within the paper is illustrated in **Figure 2.4**. Briefly, a rectangular box containing an oversized balloon and surrogate small intestine was created to model the abdomen, internal organs, and intraabdominal pressure. A porcine abdominal wall was laid over the top of the box and balloon and held in place with a lid secured with suture and pulleys\(^2\). Using this device, a mesh overlap study was conducted. This device offers multiple benefits not offered by other *ex vivo* testing. Rather than using a small piece of the abdomen for testing, a larger, more realistic section of abdomen can be tested. The balloon offers a method for applying uniform pressure to the entire section of abdominal wall, and the application of pressure is more realistic than the forces applied from other *ex vivo* testing methods.
Through discussion with the researchers from the Trinity Centre for Bioengineering, further details about the biomechanical surrogate abdomen device were gathered. From descriptions, it was suggested that multiple features of the device could use improvement. The pulley system applied uniform compression to the porcine abdomen; however, stringing the pulleys with suture was time consuming and tedious. The lid used was described as being thick (exact dimensions were not specified) and created bulging when the pressures were high. Along the edges of the box, nutmeg graters were used to grip the tissue. Even with this, tissue slippage was still reported when pressure was applied to the balloon. Lastly, the onset of a hernia in the paper by Lyons et. al. was monitored by extrusion of a surrogate intestine material through the defect created. The surrogate intestines were created from reconstituted powdered potatoes (RPP). Through discussion, it was clear that maintaining the consistency of this mixture was extremely difficult and messy. It was recommended to pursue other options for measurement. Each of these issues was considered and attempted to be improved in the design of the abdominal model created here.

2.3 Device Design

Based on the discussions with the researchers from the Trinity Centre for Bioengineering, an initial abdominal modeling device was designed (Figure 2.5). From the computer-aided design and drafting (CAD) model, the shape of the box remained similar. The dimensions of the box were changed, so abdomen testing with hernia meshes could be more physiologically relevant. The aforementioned biomechanical surrogate abdomen model tested defect sizes with a maximum diameter of 50 mm and

![Figure 2.4. Biomechanical Abdominal Wall Model](image)
prosthetic meshes with a maximum size of 100 mm in diameter\textsuperscript{25}. The dimensions of the device used were roughly 6.5 x 8.5 inches. In clinical settings, a 5 cm defect is the smallest that normally gets repaired with the placement of a mesh, and the mesh size in this case is normally 15 cm. The dimensions of the original device design limited the size of the defect, incision, or mesh that could be tested. To address this concern, the dimensions of the device described here were increased, so a more physiologically relevant defect size could be examined. The final construction was 8 x 9 inches (Appendix A). The radius of curvature of the box was approximately 200 mm to model the circumferential curvature of the abdomen\textsuperscript{32}.

![Figure 2.5. CAD Model of the Abdominal Model Device.](image)

The original tissue clamping design employed the use of pulleys along the edge of the box. Since this was reported to be tedious, time consuming, and tissue slippage was still an issue, it was modified in the final design. Instead of using pulleys, a combination of nylon straps and bolts were used (Figure 2.6a). It should be noted that it has been assumed the downward force applied by the straps and bolts onto the tissue is significantly greater than the upward forces generated by the pressure applied by the balloon. Bolts and nylon straps were selected because they reduce the time required to set up, the force applied can be adjusted, and tissue samples of different thicknesses can be placed in the device. The bolts aid in aligning the lid in the appropriate position over the open face of the box.
Figure 2.6. Abdomen Gripping Strategy. A) Bolts and nylons straps used to clamp an abdominal wall into the device. B) Visualization of the graters and mending plates.

Originally, nutmeg graters were placed along the edge of the device to hold the tissue in place. To improve slippage of the tissue, a combination of graters and mending plates were used to grip the tissue (Figure 2.6b). Through preliminary porcine abdominal wall testing, slipping of tissue was not observed with these changes.

A balloon was used to contain compressed air to apply pressure to the abdominal wall. A chimney balloon was reportedly used originally; however, upon further inspection of the chimney balloons available in the United States, there were numerous concerns. At the top of the balloon, there was a plastic piece to hold a group of rubber bands inside of the balloon. The rubber bands and plastic piece on the surface of the balloon would interfere with the abdominal wall and the pressure applied. A vinyl balloon with a diameter of 17 inches was selected instead. An oversized balloon was chosen, so energy was not used to expand the walls of the balloon.

Additionally, cost considerations were important for the development of this project. Since this project did not have any funding sources, cost-effective materials were chosen. Components, such as the air pump and force sensor among others, were primarily selected based on budgetary considerations. Thus, the goal was not only to design a testing system to replicate the physiological loading conditions of the abdomen, but also to construct the device in a cost-effective manner.
2.4 Construction Details

The box of the abdominal modeling device was made of acrylic with the sides being $\frac{1}{2}$ inch thick and the base being 1 inch thick (Appendix A). The lid was made of $\frac{1}{4}$ inch acrylic and heated to allow it to conform to the curvature of the box. Holes for the bolts and slots for the nylon straps were machined into the lid, and ledges were attached to the sides of the box for the nylon straps and bolts to feed through. The oversized vinyl balloon was placed inside of the box with a tube leading out to allow for compressed air to be supplied to the balloon. A schematic of the air supply system can be seen in Figure 2.7. It should be noted that there is room for improvement with this part of the abdominal modeling device, which will be discussed in further detail below. To account for budgetary constraints of the project, a Husky 120-volt Inflator was purchased to supply the compressed air to the balloon. The air pump was used to send compressed air to the balloon along a line of plastic tubing. A network of valves was placed along the line to allow for filling the balloon, for holding the pressure in the balloon, and for releasing the pressure in the balloon (Figure 2.7). A low-pressure gage was placed in the line, close to the balloon to measure the pressure inside of the balloon (MGI-5-A-9V-R, SSI Technologies).

![Air Pressure System Schematic](image)

Figure 2.7. Air Pressure System Schematic. Valves 1 and 3 are adjustable flow valves. Valve 2 is a directional control valve. The air flow could be directed towards the balloon, could be sealed, or could be exhausted out of the system through path 5. Marker 4 represents the low-pressure gage placed in the line.

2.5 Device Operation

The device was designed to hold an abdominal wall and apply pressure to the abdomen using the balloon. For the preliminary studies conducted here a porcine abdominal wall was used. The following steps were followed to setup the device for testing:
1. The balloon was fully deflated in the device, and inlet of the balloon was connected to the tubing that fed outside of the device.

2. The abdominal wall was placed upon the device and pulled taut, so the middle of the abdomen did not sag. (Note: this took two people to successfully achieve)

3. The lid was placed over the abdomen and secured. The bolts were placed through the lid first to align the lid properly over the abdomen. Before the bolts were tightened with hex nuts, the nylon straps were threaded through the slots. Tightening the bolts first, followed by tightening the nylon straps was found to work best for holding the abdominal wall.

4. Once the abdomen was secured in the device, the pressure gage and the air pump were turned on. When the pressure reached the desired value, the air pump was turned off, and the valves was closed to seal the pressure in the balloon.

To avoid using RPP to evaluate the performance of the abdomen, strain across the abdomen was investigated instead. Markers were placed on the abdominal wall in a grid pattern before it was loaded on the device. A camera placed above the abdomen recorded video while pressure was supplied to the balloon. The deformation of the marker locations was tracked and used to calculate the area strain along the abdomen in two dimensions.

2.6 Pressure Validation Testing

2.6.1 Previous Pressure Validation

Initial pressure validation was performed by Lyons et. al. with porcine intestines, RPP, and porcine abdominal wall. Using a trocar port, a 10-mm defect was created in the abdominal wall through the umbilicus. The defect was left open, and the pressure was increased until the porcine intestines or RPP extruded through the defect. Extrusion was intended to model the formation of a hernia. This was repeated at defect sizes from 10 mm to 50 mm. For validation of the system, the onset of hernia for all the tests fell within physiologically relevant pressures.
2.6.2 Revised Pressure Validation

More rigorous pressure validation was attempted here to ensure the pressure recorded from the pressure gage was the pressure the abdomen would be experiencing. This testing was also conducted to verify that the pressure applied was uniform across the abdomen. A flexible, resistive force sensor (Flexiforce, Tekscan) was used to record the pressure applied (Figure 2.8). The sensor specifications can be found in Appendix B. As the sensing area is compressed, the resistance of the sensor changes. This corresponds to a voltage output, which was collected and converted into a force using a measured calibration curve. The force from the sensor was then converted to a pressure using Equation 2.1. The sensing area of the force sensor was used in Equation 2.1.

\[
\text{Pressure} = \frac{\text{Force}}{\text{Area}} \quad (2.1)
\]

![Figure 2.8](image)

**Figure 2.8.** Pressure Validation System. A Flexiforce sensor was placed on the underside of the sheet metal and connected to an Arduino Uno to monitor the pressure applied by the balloon when inflated.

For the pressure validation testing, a piece of sheet metal was formed to match the curvature of the box, placed over the balloon, and secured in the device with the lid (Figure 2.8). To successfully measure the forces generated, the sensor needed a solid backing to compress the resistive sensing element, which is why the piece of sheet metal was used. Additionally, since the sensor was designed for point loads, a puck was placed over the sensing area to focus the pressure onto that location.

The force sensor was placed at different locations on the lid to measure the pressure along the device (Figure 2.9). The sensor was setup with a microcontroller (Arduino Uno, Arduino) and a MATLAB program to record voltage changes from the sensor. A conditioning step was necessary to improve
reproducibility of the sensor before each use. With standard weights of known mass, a calibration curve of the voltage versus force was established (Figure 2.10). Equation 2.2 is the linear regression calculated from the calibration curve.

$$\text{Voltage (V) } = 2.432 \cdot \text{Force (lbf)} - 0.009755 \quad (2.2)$$

Figure 2.9. Pressure Sensing Locations. The schematic above illustrates the locations where the force sensor was placed on the underside of the sheet metal. Note the representation is not drawn to scale.

Figure 2.10. Sensor Calibration Curve. Calibration of the Flexiforce sensor using a standard weight set from 40 g to 100 g. Error bars illustrate the standard deviation between three trials. A linear regression was performed (see equation on plot) with an $R^2$ value of 0.9924.
Following calibration, the pressures at different locations along the device were probed. The arrangement of locations can be seen in Figure 2.9. For each location, voltages were collected at approximately 0.5 psi, 1.0 psi, and 1.5 psi. This was repeated three times for statistical significance. The voltage values were converted to force values and then to pressure values. A comparison between the applied pressure and the calculated pressure for each location is depicted in Figure 2.11. The important conclusions from this testing are the trends observed.

![Figure 2.11](image_url)

**Figure 2.11.** Pressure at Locations along the Device. The calculated pressure from the sensor is plotted as a function of the applied pressure measured by the pressure gage at approximately 0.5 psi, 1.0 psi, and 1.5 psi. Error bars represent the standard deviation in the applied pressure and calculated pressure for three trials.

### 2.6.2.1 Interpretation of revised pressure validation

The results illustrate that as the applied pressure increases, the pressure at each location increases. One-way ANOVA and Bonferroni multiple comparisons tests were performed to support the conclusion that each location experiences the same pressure. The significance level used for this analysis was 0.05. Upon initial analysis, there appeared to be a dependence on location as the pressure increased (Table 2.1). During testing, it was observed that location 3 was close to the edge of the box, making it difficult to fully apply the load onto the sensing area. By removing this location from the analysis, there only appears to be a dependence on location at the highest pressures examined (Table 2.2). This helps to support the conclusion that there is not a strong dependence on location in this setup. Overall, the pressures an abdomen will be exposed to are increasing linearly as expected, and
there does not appear to be a significant dependence of pressure on location, at least until higher pressures.

**Table 2.1.** Summary of One-Way ANOVA and Bonferroni comparison analysis performed on the calculated pressure

<table>
<thead>
<tr>
<th>Pressure (psi)</th>
<th>One-Way ANOVA (Significant Difference)</th>
<th>p-value from ANOVA</th>
<th>Multiple Comparisons (Number of Significant Differences)</th>
</tr>
</thead>
<tbody>
<tr>
<td>~0.5</td>
<td>Yes</td>
<td>0.0488</td>
<td>0</td>
</tr>
<tr>
<td>~1.0</td>
<td>Yes</td>
<td>0.0014</td>
<td>3 (All from Location 3)</td>
</tr>
<tr>
<td>~1.5</td>
<td>Yes</td>
<td>&lt;0.0001</td>
<td>18</td>
</tr>
</tbody>
</table>

**Table 2.2.** Summary of statistical analysis performed on the calculated pressures with location 3 removed

<table>
<thead>
<tr>
<th>Pressure (psi)</th>
<th>One-Way ANOVA (Significant Difference)</th>
<th>p-value from ANOVA</th>
<th>Multiple Comparisons (Number of Significant Differences)</th>
</tr>
</thead>
<tbody>
<tr>
<td>~0.5</td>
<td>No</td>
<td>0.1056</td>
<td>0</td>
</tr>
<tr>
<td>~1.0</td>
<td>Yes</td>
<td>0.0499</td>
<td>0</td>
</tr>
<tr>
<td>~1.5</td>
<td>Yes</td>
<td>&lt;0.0001</td>
<td>12</td>
</tr>
</tbody>
</table>

**2.6.2.2 Issues with revised pressure validation**

There are concerns related to this pressure validation attempt. Clearly, the values recorded from the sensor are all higher than those expected based on the pressure gage output, and there is variation between the locations. There are a few explanations which may account for these problems. The sensor was designed for point loads directed over the sensing area. The use of this sensor for determining pressures may be inaccurate because trying to direct the load over the sensing area may not be trivial. The measurement differences at the locations may also be caused by the curvature of the sheet metal. It is possible that the sensing area is being differentially compressed because of the curvature. As mentioned previously, location 3 was not exposed to the full loading of the balloon because the sheet metal effect the behavior of the balloon. Alignment of the sensing area with the puck could impact the measurements as well. The puck was placed over the sensing area; however, ensuring exact alignment consistently was difficult because tape had to be placed over the puck. All these factors contributed to the uncertainty of the measured sensor values. Additional discussion concerning the accuracy of the force sensor will be discussed in Chapter 3 which could also account for the issues observed with the pressure validation.
2.7 Preliminary Abdomen Testing

Proceeding force sensor testing, preliminary abdomen testing was conducted with porcine abdominal walls extracted from pigs weighing 80 – 90 kg from the University of Illinois Urbana-Champaign (UIUC) Swine Research Center. The skin and subcutaneous fat were removed from the porcine abdominal walls leaving the abdominal muscles and the peritoneum for testing. Due to time constraints and availability of abdomens, only preliminary testing was conducted, so conclusive results were not gather. The following three abdomen conditions were tested: intact abdominal wall, simulated hernia defect, and mesh repair over the simulated hernia. A hernia was modeled in the abdominal wall by cutting a 5 cm diameter hole centered on the linea alba (Figure 2.12a). For defect repair, a 15 cm square of polypropylene mesh (Bard) was placed over the hernia on the side of the peritoneum and secured in a double crown pattern with tacks (SorbaFix, Bard) (Figure 2.12b). A 5 cm defect was chosen because this defect size is the smallest for which a mesh is used in human abdominal hernia repair. A 15 cm square mesh was selected because this sized mesh is used clinically to repair a 5 cm defect. Markers were placed in a grid pattern along the surface of the porcine abdominal wall, and additional markers were placed around the defect. These were used for strain tracking to determine the areal strain change across the abdomen before and after pressurization.

![Figure 2.12. Preparation of Porcine Abdominal Walls. A) Hernia defect created in the porcine abdominal wall. B) Mesh placement on the peritoneum of the porcine abdominal wall secured with tacks in a double crown pattern.](image)

One camera was placed above the abdomen in the testing device to observe the planar spatial changes of the markers while the balloon was pressurized. Another camera was placed at the side of the device.
to monitor the vertical change while the balloon was pressurized. Images of the abdomen were collected from before and after pressure was applied to the balloon (Figure 2.13).

**Figure 2.13.** Preliminary Abdomen Testing Setup. As the balloon was inflated, the abdominal wall expanded, which can be visualized above. The markers on the surface of the abdomen were used for strain tracking.

### 2.7.1 Preliminary Abdomen Testing Results

Using the images gathered, two-dimensional areal strain was tracked. The location of the markers was gathered using ImageJ (FIJI) and used in a strain tracking MATLAB program written by Dr. Rouzbeh Amini. Tracking the markers in two dimensions introduced error in the analysis because the deformation of the markers occurred in three dimensions. However, the strain tracking is used to illustrate a proof of concept for the created device, so for this purpose, two-dimensional analysis was performed. A sample image of marker tracking can be seen in Figure 2.14. The areal strain color maps generated help to visualize the behavior for each abdomen conditions. Three representative areal strain images at approximately the same pressure can be seen in Figure 2.15.
Figure 2.14. Representative Marker Tracking Image. The location of the markers on the surface of the abdominal wall were identified with ImageJ and used in a MATLAB strain tracking code.

Figure 2.15. Representative Images of Strain Tracking. The color map on the far left is from an intact abdomen tested at 0.774 psi. The color map in the middle is from an abdominal wall with a hernia defect tested at 0.8 psi. The color map on far right had a mesh repaired defect tested at 1.01 psi.

From examination of the intact abdomen color map, it appears that the highest strain on the abdomen occurred around the center with a steady decrease towards the periphery of the abdomen. The areal strain for the hernia appears to have a greater amount of high areal strain around the location of the defect with a sharp decrease towards the edge of the tissue. In comparison to the mesh condition, there does not appear to be as many locations with the highest strains around the defect with the mesh applied. It is difficult to compare, however, because of how the mesh was generated. Examining the preliminary strain images roughly illustrates some of the expected behavior between the groups. In an attempt to develop a more quantitative understanding of the preliminary abdominal testing, the areal strain as a function of distance and defect area were analyzed further.

To best examine the areal strain on the abdomen quantitatively, the calculated strains were plotted as a function of distance from the center of the defect. Linear regressions were fit to each of these to
understand the behavior of the areal strain across the abdomen. For the intact abdominal wall, it was hypothesized there would be the smallest slope, demonstrating a more uniform distribution of strains across the abdomen. On the other hand, it was expected the hernia would demonstrate the highest areal strains close to the defect and would have the largest decreasing slope. This would illustrate the defect was impeding the ability of the abdomen to distribute the load uniformly across it. With the application of the mesh, it was predicted there would be a decrease in the magnitude of the slope and lower areal strains close to the defect compared to the hernia condition. Theoretically, the mesh would provide mechanical support for the abdominal wall at the site of the defect and improve the abdomen’s response to loading.

The response of an intact abdomen under two loading conditions is illustrated in Figure 2.16. Under both applied pressures, the areal strains close to the abdominal wall are highest with a steady decrease towards the periphery. The high pressure loading condition undergoes higher areal strains close to the midline with a greater decrease towards the edges of the tissue compared to the lower pressure. This trend is also observed for the hernia condition (Figure 2.17). Interestingly, the mesh did not exhibit this trend and the behavior of the abdomen at both abdomens was fairly similar (Figure 2.18). This could potentially mean the mesh is providing mechanical support for the abdominal wall.

The behavior of areal strain as a function of distance is reasonable for the intact and hernia the conditions. It is expected that lower pressures would result in smaller areal strains close to the defect, and by extension, there would be less of a decrease in areal strain towards the periphery. The mesh conditions are more surprising, however, not unrealistic since the mesh could be contributing to the mechanical behavior of the abdominal wall.

![Figure 2.16. Intact Abdomen Testing. High pressure (1.45 psi) and low pressure (0.774 psi) responses for an intact abdominal wall are illustrated as a function of distance from the center of the abdomen. The parameters of the linear regression are provided in the table.](image)

<table>
<thead>
<tr>
<th>Pressure</th>
<th>Slope</th>
<th>Intercept</th>
<th>R²</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>-0.3608</td>
<td>2.0609</td>
<td>0.7427</td>
</tr>
<tr>
<td>Low</td>
<td>-0.2264</td>
<td>1.6910</td>
<td>0.6507</td>
</tr>
</tbody>
</table>
When comparing between conditions, the results become a more difficult to interpret. Due to the very limited number of tests performed, concerns with the mesh generated from the strain tracking program, and difficulty consistently regulating the pressure, drawing meaningful conclusions between groups is limited. No clear trends could be observed between groups for an intact abdomen, a hernia simulated abdomen, and mesh repaired abdomen (Figure 2.19). To compare between low-pressure and high-pressure conditions, specimens from different abdomens are depicted in the plots below. This is a source of error since each abdominal wall has inherent anatomical differences. Further studies are needed to examine the differences between the three abdomen conditions at varying pressures.
Figure 2.19. Areal Strain comparison of different abdomen conditions. The plot on the left illustrates low pressure loading where the pressures applied ranged from approximately 0.75 – 1.0 psi. The plot on the right illustrates high pressure loading where the pressures applied ranged from approximately 1.75 – 2.5 psi.

The height change between each of the abdomen conditions was examined as well. As previously mentioned, a camera was placed on the side of the box to monitor the changes in height as compressed air was supplied to the balloon. As expected, the height increased as the pressure was increased, but no other meaningful differences were found (Table 2.3). This is likely because the balloon and abdomen are expanding as the pressure is increasing. The height increase does illustrate that change in the vertical direction is an important factor in the deformation of the abdomen between a loaded and unloaded state. For future analysis, tracking markers in three dimensions will be necessary to appropriately understand the strain along the abdomen.

Table 2.3. Height Increase of Abdomens under pressure.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Pressure (psi)</th>
<th>Height Increase (in)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>0.774</td>
<td>1.14</td>
</tr>
<tr>
<td>Hernia</td>
<td>0.8</td>
<td>1.24</td>
</tr>
<tr>
<td>Mesh</td>
<td>1.01</td>
<td>1.38</td>
</tr>
<tr>
<td>Intact</td>
<td>1.738</td>
<td>1.50</td>
</tr>
<tr>
<td>Hernia</td>
<td>1.85</td>
<td>1.54</td>
</tr>
<tr>
<td>Mesh</td>
<td>2.50</td>
<td>1.58</td>
</tr>
</tbody>
</table>

The area of the defect was analyzed before and after loading with ImageJ (FIJI). Although the pressures are not identical, there appears to be a difference in the increase in defect area between the simulated hernia and the defect repaired with the mesh (Figure 2.20). The increase in area was found by determining the ratio of the defect area after loading to the area before loading. At comparable
pressures, the increase in area was greater for the abdomen with the defect compared to the abdomen with the defect and mesh.

![Figure 2.20. Defect Area Analysis. The area of the defect was measured before and after loading. The ratio of the area between the two states was determined and reported in the table above.](image)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Pressure (psi)</th>
<th>Defect Area Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hernia</td>
<td>0.8</td>
<td>2.00</td>
</tr>
<tr>
<td>Mesh</td>
<td>1.01</td>
<td>1.66</td>
</tr>
<tr>
<td>Hernia</td>
<td>1.85</td>
<td>1.72</td>
</tr>
<tr>
<td>Mesh</td>
<td>2.5</td>
<td>1.46</td>
</tr>
</tbody>
</table>

### 2.7.2 Concerns with Preliminary Testing

There are a few concerns with the preliminary abdominal testing. As described above, tracking the markers in two dimensions has inherent error. As the balloon expanded, the markers were deformed in three dimensions. Losing the vertical displacement of the markers greatly affects the information contained in the strain tracking analysis. The differences between the three conditions may be much more pronounced if the markers were tracked in three dimensions.

The mesh created with the MATLAB program was missing elements for some of the tests. Adjusting the program to include all the elements led to unrealistic strains calculated from some of the locations. For this reason, the data presented above was gathered from the generated mesh with elements missing. When the mesh is missing elements, information about the behavior of the strain is lacking at that location. For future testing, constructing the desired mesh by defining the nodes by hand may provide the most accurate strain calculations for the system.

Other potential concerns existed with the testing system and the abdomens. There was difficulty consistently controlling the pressure while inflating the balloon, which made comparisons between trials problematic. Improvements to the device can be made to improve the pressure system, as discussed in the following section. Comparisons could also be affected by the variation present between the porcine abdomens. Variation between tissue specimens is always a concern when using animal tissue particularly with the low number of abdomens tested. The difficulty acquiring abdomens,
the cost, and time constrains did not make a full study feasible at this point. Limitations to the preliminary abdomen testing conducted are present; however, interesting patterns was observed. From visual observation of the areal strain color maps, there appears to be differences in the distribution of the strain across the abdomen conditions. Additionally, differences were observed in the defect area between the hernia and the mesh conditions. The mesh is likely affecting the mechanical behavior of the abdominal wall as it expands under pressure. Unfortunately, clear differences were not observed between the intact, hernia, and mesh groups; however, the concerns described above likely obscure any trends present. Further abdominal wall testing is necessary to understand the behavior of an abdominal wall in this test setup.
Chapter 3

Recommendations and Conclusions

3.1 Device Recommendations

The abdominal testing device developed here illustrates a starting point for an improved *ex vivo* abdominal wall testing method. That being said, there are concerns to address with the device. As described above, regulating the applied pressure was more difficult than anticipated. Originally when designing the device, it was planned to use a laboratory compressed air supply. The pressures supplied from a central air system to a laboratory is well regulated with specific flow rates and pressure requirements. A laboratory air supply offers pressure consistency, and the air coming out of the outlet can be controlled through the valve. Unfortunately, the lab did not have a compressed air supply, so the use of an air pump was required. To stay within the budgetary constraints of the project, a Husky 120-volt inflator air pump was purchased and used throughout the testing. However, an air compressor designed to provide regulated, low pressure would be more appropriate for use with this device. This would make controlling the pressure to the balloon more repeatable and improve testing.

The pressures and flow of the compressed air supplied from the air pump used here fluctuated significantly. Thus, it is recommended to change the compressed air supply for device to improve in the repeatability of the results.

Along the same lines with the pressure irregularity, changes in the compressed air line could improve the performance of the device. There was an air leak present in the system, which was difficult to identify. Zip ties were used at the connections to ensure an air tight seal, and the nozzle to the balloon was sealed using silicone sealant. It is possible that the plastic valves used to seal the pressure in the balloon were unable to completely seal the system and produced a small air leak. Immediately after turning off the air pump, there was a logarithmic drop in pressure until the pressure loss leveled off. Using metal valves would improve sealing and potentially prevent the air leak observed.
The force sensor used for the pressure validation could also use improvement. This sensor did have initial appeal for multiple reasons. It was selected because its load capabilities are within the range of interest for this project, it has a low profile thanks to the resistive sensing element that would not interfere with the inflation of the balloon, its flexibility allows it to conform to the curvature of the device, and it is low cost. Although there were benefits to using this sensor, it is not an ideal sensor. Some of the limitations have been described above – its small sensing area and it is designed for point loads. Additionally, this sensor’s accuracy is not particularly high. It was found that the Flexiforce sensor only have 64.1% accuracy at 30.5 mmHg (0.59 psi)\textsuperscript{33}. This accuracy is problematic; however, for the cost, it was an appropriate place to start. Other sensors options with greater accuracy would improve the confidence in the pressure validation results. With the improvements laid out, the performance of this \textit{ex vivo} testing device would increase and help provide more conclusive results.

3.2 Device Conclusions
The goal of this project was to develop a testing device to improve modeling the physiological loading conditions in the abdominal wall. The forces generated from the abdominal wall musculature, intraabdominal pressure, and the size of the abdomen are all important factors replicate for testing focused on the abdomen. Other \textit{ex vivo} testing methods, such as the ball burst method and uniaxial testing, are unable to accurately model these features. Testing a small section of the abdominal wall is commonly seen. However, anatomical features of the abdominal wall are missing when examining a small portion of the abdominal wall. The fascial layers, connective tissue, and complex musculature are not represented in other testing devices. In the abdominal testing device discussed here, a 9 x 9-inch section of a porcine abdominal wall can be tested. The linea alba, abdominal muscles, fascial layers, and the peritoneum are all included in the sections tested, which improves the clinical relevance of the data gathered from a device such as this. Although muscle contraction cannot be replicated in this testing device, the intraabdominal pressure can be created much more realistically than other methods. Instead of modeling pressure by applying tension to the edges of the sample, this device applies air pressure to the abdominal wall.

Researching new surgical techniques and medical devices for hernia repair is often conducted in animal or human models. These are cost prohibitive, time consuming, and often not feasible for some research interests. Developing an \textit{ex vivo} testing method allows for testing without the restrictions of
in vivo studies. The abdominal testing device described here addresses some of these concerns and is able to more realistically replicate the physiological loading conditions found along the abdominal wall.
Appendix A

Engineering Drawings of Abdominal Testing Device
Note: holes are 1" in length and have a width of 0.25".

Note: all slots are 1" in length and 0.25" in width.
Appendix B

Flexiforce Sensor Specifications

### SENSOR PROPERTIES

**Standard FlexiForce Sensor (Model A201)**

<table>
<thead>
<tr>
<th>Sensor Properties</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thickness</td>
<td>0.005 (0.203 mm)</td>
</tr>
<tr>
<td>Length</td>
<td>6' (203 mm)</td>
</tr>
<tr>
<td></td>
<td>6&quot; (152 mm)</td>
</tr>
<tr>
<td></td>
<td>4&quot; (102 mm)</td>
</tr>
<tr>
<td></td>
<td>2&quot; (51 mm)</td>
</tr>
<tr>
<td>Width</td>
<td>0.55&quot; (14 mm)</td>
</tr>
<tr>
<td>Sensing Area</td>
<td>0.375&quot; (9.53 mm) diameter</td>
</tr>
<tr>
<td>Connector</td>
<td>3-pin male square pin (center pin is inactive)</td>
</tr>
</tbody>
</table>

**Typical Performance**

| Force Ranges       | 0-1 lb (4.4 N)                                                       |
| Operating Temperature Range | 15°F to 140°F (-9°C to 60°C)                                      |
| Linearity (Error)  | +/- 3%                                                               |
| Repeatability      | +/- 2.5% of full scale (conditioned sensor, 50% force applied)      |
| Hysteresis         | +/- 4.5% of full scale (conditioned sensor, 50% force applied)      |
| Drift              | <5% per logarithmic time scale (constant load of 90% sensor rating)  |
| Response Time      | <5 microseconds                                                      |
| Output Change/Degree F | Up to 0.2% (~0.36%/°C)                              |
|                    | Loads <10 lbs, operating temperature can be increased to 165°F (74°C).|

**High-Temperature FlexiForce Sensor (Model HT201)**

<table>
<thead>
<tr>
<th>Sensor Properties</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thickness</td>
<td>0.008&quot; (0.203 mm)</td>
</tr>
<tr>
<td>Length</td>
<td>7.75&quot; (197 mm)</td>
</tr>
<tr>
<td></td>
<td>Optional 6&quot; (152 mm)</td>
</tr>
<tr>
<td></td>
<td>Trimmed 4&quot; (102 mm)</td>
</tr>
<tr>
<td></td>
<td>Lengths 2&quot; (51 mm)</td>
</tr>
<tr>
<td>Width</td>
<td>0.55&quot; (14 mm)</td>
</tr>
<tr>
<td>Sensing Area</td>
<td>0.375&quot; (9.53 mm) diameter</td>
</tr>
<tr>
<td>Connector</td>
<td>3-pin Male Square Pin (center pin is inactive)</td>
</tr>
<tr>
<td>Substrate</td>
<td>Polyamide (ex: Kapton)</td>
</tr>
</tbody>
</table>

**Typical Performance**

| Force Ranges       | 0-30 lbs (133N)                                                       |
| Operating Temperature Range | 15°F to 400°F (-9°C to 204°C)                                        |
| Repeatability      | +/- 3.5% of full scale                                                |
| Linearity          | +/- 1.2% of full scale                                                |
| Hysteresis         | 3.6% of full scale                                                    |
| Drift              | 3.3% per log time                                                    |
| Output Change/Degree F | 0.18%                                                               |
References


Abdomen Modeling Device, Dunbar, M.S. 2018