Uterine compression device: a treatment for postpartum hemorrhage

Final Report
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Abstract

Postpartum hemorrhage (PPH) is an obstetrical emergency that can follow vaginal or cesarean delivery. It is defined as blood loss that exceeds 500 ml following vaginal delivery and 1000 ml following cesarean delivery. This emergent situation can arise from many complications such as uterine atony and placenta accreta. PPH affects approximately one in 1000 deliveries and continues to affect more and more women as cesarean deliveries become increasingly prevalent. Due to the inadequacy of the current devices on the market, there is a need for a device or method that will completely compress the uterus in all planes in order to cease bleeding and prevent infection. Dr. Lick, an OB/GYN with UW Health has become aware of this need, and has challenged our team to create a device that will compress the uterus in all planes, and can be absorbed into the body. Our team has developed a device that consists of a solvent-casted PLA film wrapped around the uterus, and sealed on three sides using a heat sealer and simple suture technique. Compression is achieved by the application of suction through a vacuum. Through testing, our device has proven to withstand and exceed the minimum pressure of 100 mmHg that is required to halt PPH. Thus, we are confident that upon further testing and subsequent modifications, it will meet all of the client's needs and be usable by physicians around the world.

Background

Client Description

Dr. Jay Lick is an OB/GYN with UW Health. He performs hundreds of deliveries a year, and has noticed an increase in postpartum hemorrhage stemming from an increased prevalence in cesarean sections. There are three reasons why this occurs. First, performing a cesarean section requires surgically cutting open the uterus, thus there is normally more blood loss in comparison to uterine delivery. Many times, it also causes the woman to be in labor for an abnormally long amount of time, which decreases the uterus' ability to constrict back to its normal volume and shape [1]. Lastly, partially due to the increased amount of time spent in labor, many different hormonal receptors become saturated, which also inhibits the uterus' ability to contract [1]. Due to complications arising from these emergent situations, he and other physicians in his department have been forced to perform many hysterectomies a year. This of course leaves the woman infertile, and is therefore an unpleasant procedure for both patient and physician. In order to address this issue, Dr. Lick has challenged our team to create a device that can be implanted in the body, cease postpartum hemorrhaging and be completely absorbed within one year of delivery. Currently, no methods or devices in use accomplish all three tasks.

Problem Motivation

Today, 20 million women worldwide suffer from acute or chronic disability following immediate postpartum hemorrhage (PPH). PPH is classified as any blood loss over 500 ml following vaginal delivery, and over 1000 ml following cesarean delivery [2]. It is a major cause of maternal mortality and maternal morbidity in both developed and developing countries, where one in 1000 births results in PPH in low income areas [2]. It is also the most preventable cause of maternal mortality, further demonstrating that there is a great need to address this issue.

PPH can result from either uterine atony or placenta accreta. Uterine atony occurs when instead of contracting following delivery, the uterus stays flaccid and the myometrium remains thin. Since the contraction of the thick muscular walls is what normally supplies the necessary pressure to stop bleeding, hemorrhage occurs and can threaten the life of the mother. Placenta accreta occurs when the placenta attaches too deep into the endometrium and myometrium layers, which are visualized in Figure 1. Thus, when the placenta detaches either naturally or manually, it can result in excessive blood loss. This occurs in one in 533 pregnancies [2].

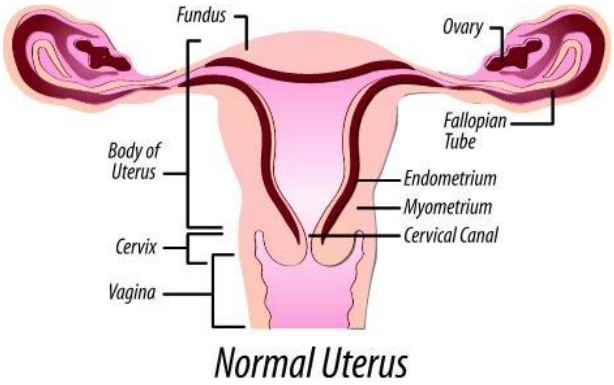

Figure 1: Anatomy of the uterus [3].

There are many problems with the current response methods to situations of PPH. First, none of the methods in use compress the uterus in all planes, thus rendering them insufficient in stopping blood loss. When the bleeding does not stop, the physician is forced to perform a hysterectomy, leaving the mother infertile. Second, there is a major risk management issue with handling PPH. In many cases, there is:

1. A delay in diagnosis and treatment failures resulting from underestimation of blood loss.

2. Lack of easy to use protocols.

3. Lack of adequate education and training.

4. Poor communication between physicians and other staff.

5. Deficiencies in organization within the operating or delivery room [2].

In creating our device, we hope to minimize all of the issues stated above.

Current Methods

There are many methods in use today to help in the management of PPH. One of these methods is the Bakri Balloon (Figure 2). This device is a hydrostatic balloon catheter that is inserted vaginally. The balloon is then filled with sterile fluid via syringe and acts as a tamponade to increase pressure on the uterine walls from the inside while the catheter drains the excess blood out of the abdominal cavity. The balloon is left in for a recommended 24 hours, however bleeding usually ceases within four to six hours after application [2]. It is one of only two devices approved for this use by the United States Food and Drug Administration (FDA) [4]. Some advantages to using this method are that insertion is easy and done rapidly with minimal anesthesia. Additionally, insertion requires minimal technical skill, and removal is painless. If the device should fail, its failure can be identified very rapidly. However, the device has been known to correlate to an increased risk of infection. Overall it has an 84% success rate [2].

Figure 2: A Bakri Balloon is placed into the uterus via catheter and inflated with sterile fluid using a syringe [4].

Another method for management of PPH is arterial embolization. To implement this method, the patient must be physiologically stable. It is most useful for treatment of uterine atony following vaginal delivery, as it does not require surgical opening of the abdominal cavity [5].

Embolization involves placement of gelatin pledgets, coils or glue into the vessels for occlusion [4]. Normally, there is recanalization of blood flow within the organs within a few weeks [4]. Some advantages of this practice are that it allows for selective occlusion of the major uterine and ovarian blood vessels, it preserves the mother's fertility and is associated with minimal morbidity. However, possible complications include: feet ischemia, bladder and rectal wall necrosis, and various sciatic nerve damage [2]. The risk of reoccurrence is also increased. Arterial embolization has a general success rate of 70-100% [2].

Absorbable sutures can also be used to occlude blood flow to the uterus in instances of PPH. One example is the B-Lynch suture technique (Figure 3). It is used to control the bleeding from the placental site by opposing the anterior plane, and is especially useful as it envelopes and compresses the uterus without sewing the anterior and posterior walls together. Since the uterus has to be checked for emptiness, the B-Lynch suture is a convenient method for PPH treatment following a cesarean section, when the patient is already undergoing surgery [5]. There are however some associated complications with this procedure. In some cases, it can result in occlusion of the uterus if the sutures are tied too tightly [2]. The sutures can also slip off of the fundus if they are not tied tightly enough [2]. Recently, many variations of the B-Lynch method have been developed in order to address these issues. Overall, it has a 91.7% success rate [2].

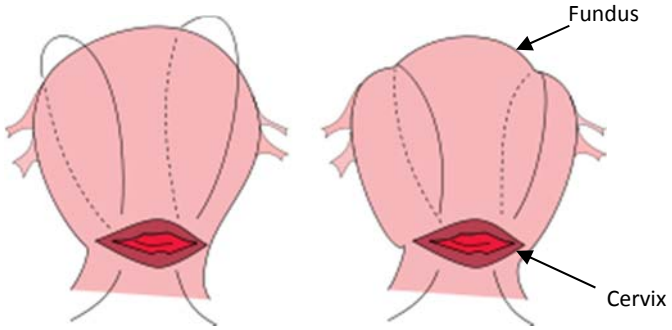

Figure 3: The B-Lynch suture technique [6].

Arterial ligation of the utero-ovarian artery and uterine artery is another treatment option for PPH (Figure 4). This method has been shown to occlude 90% of the blood flow, and can save the uterus by avoiding a hysterectomy [5]. Bilateral ligations are rather simple to perform, however hypogastric ligation is much more challenging and time consuming [4]. This results in complications that can arise from incomplete ligation. Arterial ligation is associated with an 80-96% success rate [2].

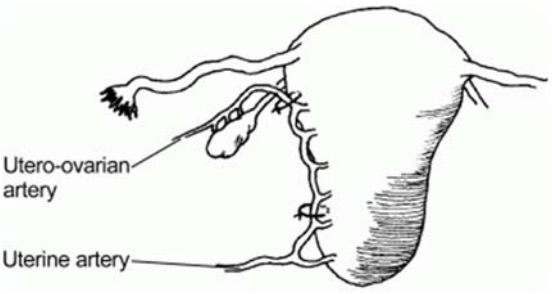

Figure 4: Sites of uterine arterial ligation [7].

Recently, a new method for management of PPH has been developed in low income and developing countries. It is called a tourniquet, and involves a Foley catheter that is tightly tied around the bottom of the uterus (Figure 5). It is than held in place by a clamp. This method occludes both the uterine and ovarian vessels and can be used for short term or long term treatment [8]. Although it is a new method, the complications that have arisen from it are the possible compromise in the viability of the ovaries, and a greater risk of infection [8].

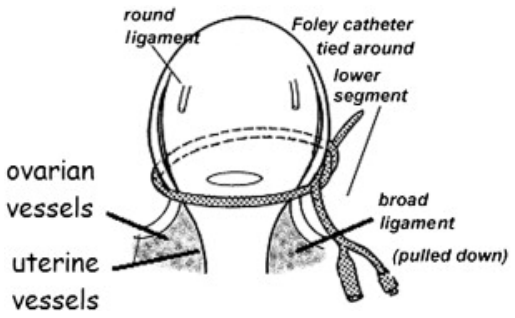

Figure 5: The tourniquet method showing the catheter tied around the lower segment of the uterus [8].

As a last resort, partial or complete hysterectomy can be performed. Whether it is performed early or late within the treatment process depends on the other methods available, as well as the surgeons skill [2]. It is and should always be used as a last resort as it results in the woman's infertility, and can affect emotional recovery of both the patient and family. It has an associated success rate of 94-99% [2].

Design Requirements

The design requirements outlined in the Product Design Specifications of Appendix A are explained in detail here. Requirements for this design revolve around three main focuses: safety, performance standards, and ease of use.

Safety requirements are crucial to the design process in order for the device to be usable and effective. The design must not cause excess discomfort throughout the degradation of the materials following placement of the device into the body. Also, the process of degradation must not expose the patient to a higher risk of infection, hemorrhaging in other areas, or infertility. All materials and devices used in the process of implantation and application of pressure must be easily sterilized for use during surgery. The device must also meet all of the requirements for class one medical devices established by the FDA.

In addition to safety requirements, the device must follow the requirements given to us by our client. First and foremost, as the device will be implanted into the body and will not be removed, all materials used must be bio-absorbable. The device must also supply a minimum pressure of 100 mmHg to the uterus. The minimum blood flow to the uterus is 175 cc. /minute and because this blood flow is so substantial, no maximum pressure threshold has been set as this ample flow makes it unlikely that necrosis would occur in the patient [9]. The pressure must be applied in the anterior, posterior, superior, and lateral planes. Additionally, the pressure must be maintained for a minimum of 24 hours, in order to ensure that bleeding has ceased. Ideally, the device should be absorbed by the body within six to twelve months of implantation, in order to allow the patient to resume her natural menstrual cycle. Furthermore, the device must stop excess hemorrhaging

within a five minute time period, as the less time the uterus is exposed to the external environment, the less likely infection will occur.

As well as the safety and performance requirements, the device must also be easily used and quickly applied by the operating physicians. Post-partum hemorrhaging occurs quickly, thus the faster the excess bleeding can be stopped the more likely the fertility and safety of the patient will not be compromised. Finally, the device should be fairly low-priced in order to ensure that it is competitive with the devices and methods currently being used.

All of these elements were taken into account when deciding upon design options to pursue in development and testing.

Design Alternatives

Throughout the brainstorming process, we determined that the structure and material of our device are both important elements and should be considered independently. Based on this conclusion, we separated our design possibilities into two criterions: the first being the structure of the device, and the second being the materials used to create the structure. First, we will describe three different structural possibilities, followed by three different materials that were considered for each structure.

Corset

The corset design would consist of two sheets of biodegradable mesh, one on the anterior side, and the other on the posterior side. These two sheets would be connected on the lateral sides by a cross-linkage of bio-absorbable sutures around the lateral vasculature of the uterus. This corset-like device would be placed on the uterus and each side would be tightly fastened by pulling the sutures tight. By having a pre-existing linkage, the time and technical expertise needed to fasten the sutures would be greatly reduced. Additionally, this device would have a cinch made of bio-absorbable sutures around the lower segment of the uterus to ensure adequate fastening around the cervix area (Figure 6). Once completely fastened and tightened, the corset device would provide complete compression to the uterus in the anterior, posterior, and lateral directions.

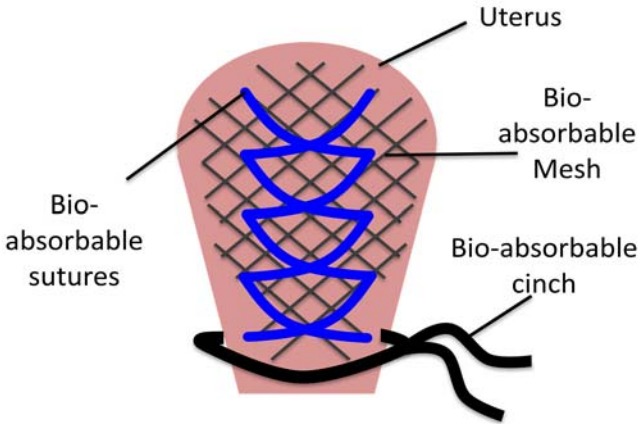

Figure 6: Corset design consisting of two pieces of bio-absorbable mesh connected by cross-linking bio-absorbable sutures.

Vacuum

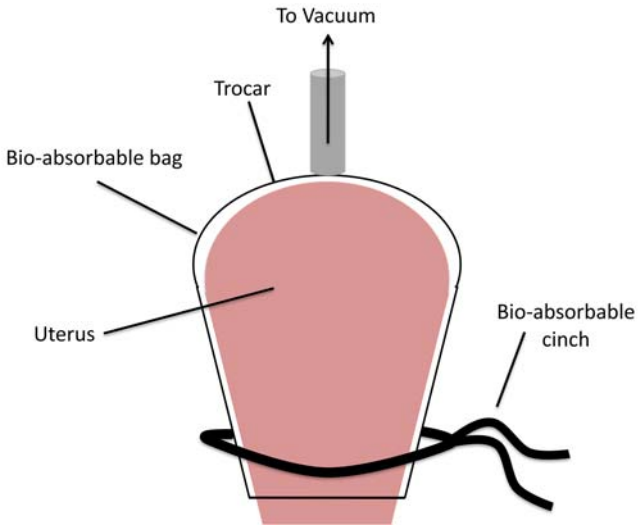

Figure 7: Vacuum Design consisting of a bio-absorbable bag sealed by a medical vacuum.

The vacuum device would consist of a bio-absorbable bag wrapped around the uterus. This bag would completely surround the uterus, including the lateral vasculature, ligaments, fallopian tubes, and ovaries. Like the corset design, the vacuum bag would also involve a cinch made of bio-absorbable sutures around the lower segment of the uterus. At the top of the bag, there would be a segment of tubing connected to a medical vacuum, a device that is readily found in the operating room. Once turned on, the vacuum would completely compress the uterus in all planes, at a minimum pressure of 100mmHg. Ideally, the pressure applied would be as large as possible. Due to the excellent blood supply to the uterus, there is no concern of necrosis as a result of too much pressure [10]. Additionally, there will be a trocar inserted into the fundus of the uterus to expel any air that may be left in the uterine cavity. This trocar would penetrate the uterine wall, but would still be within the limits of the bag (Figure 7). The non-absorbable trocar would be removed vaginally after the patient has recovered from the surgery. Once the vacuum has compressed the uterus, it would be detached from the bag's tubing, and the bag would be sealed by cauterization.

Parachute

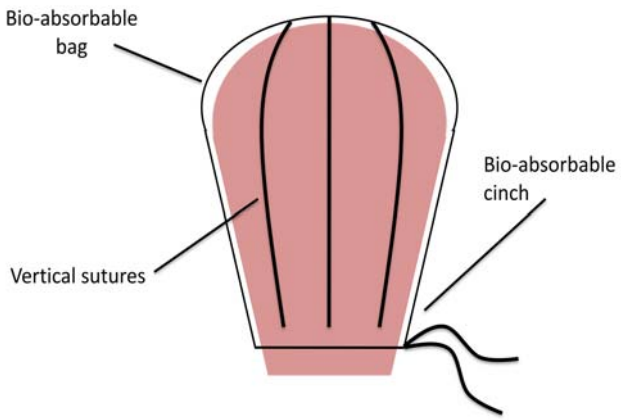

Figure 8: Parachute design consisting of a bio-absorbable sheet fastened by thick, lengthwise bio-absorbable sutures.

This device would consist of a bio-absorbable parachute-like sheet that would be placed over the top and around the uterus. As described in the previous two designs, this device would also have a cinch made of bio-absorbable sutures around the lower segment of the uterus. To provide sufficient compression while avoiding bulging, as observed in the B-lynch suture technique, thick bio-absorbable sutures (approximately 1.5cm in width) would be fastened over the sheet

around the uterus in the lengthwise direction, thus pushing the anterior and posterior walls together (Figure 8).

Preliminary Tensile Testing

In order to generate a list of materials to consider for our design we ran preliminary tensile testing on materials with desirable properties. The ideal polymer would act similar to a plastic bag that is flexible enough to conform to an irregular shape, yet strong enough to withstand stresses during compression. There were three materials tested: a high-density polyethylene (HDPE) bag, a linear low density polyethylene (LLDPE) bag, and a HDPE bag layered with nylon used in vacuum-sealed food storage (Figure 9). Each bag was cut into strips 6.35 cm long and 12.7 mm wide. The remainder of the testing followed the protocol in Appendix B.

Figure 9: Specimen from each material type. From left to right: HDPE, LLDPE, HDPE/Nylon. Strips were cut to 6.35cm x 12.7mm.

The strips were loaded into the grips as seen in Figure 10, and then pulled apart while measuring load and elongation data. Each material was tested three times for an n = 3. Thicknesses for standard HDPE and LLDPE bags were determined through searching current literature [11, 12] while HDPE/Nylon bag thickness was determined experimentally. Using a drop gauge, the HDPE/Nylon bag thickness was recorded at three locations and averaged for use in calculations. Thickness values are displayed in Table 1 with standard deviations for experimental values. Cross-sectional area was determined and used to calculate stress from the measured load data. Stress-strain graphs were generated for each specimen and Young's Modulus (E) was calculated from the linear portion of the graph and recorded in Table 1. Statistical analysis was performed using ANOVA analysis with Tukey HSD post Hoc test and alpha set to 0.05. Appropriate p-values were recorded in Table 2. Average Young's Modulus and standard deviations were recorded in Table 1. From this data we generated a list of three materials to consider with properties that were comparable to those we measured, as seen in Table 3.

Figure 10: LLDPE sample loaded into the grips of the mechanical tester. Distance between the grips is controlled by the remote seen in the lower right hand corner. As the grips move apart, load and elongation data is recorded.

In order to compare the stiffnesses of our materials we calculated the stiffness constant (K) for each. The axial stiffness coefficient is an extensive property that is independent from shape and geometry [13]. This allows us to

compare the stiffnesses of our materials without film thickness confounding the data. To calculate K, we used the equation $K = {}^{AE}/_{L}$ where A is the cross sectional area of the strip (m^2), E is the Young's Modulus (Pa), and L is the axial length of the strip during testing (m) [13]. In our calculations we used a cross-sectional area of the thickness times the width of the strip, 0.0127m. For the Young's Modulus, we used those calculated from our stress-strain data and an axial length of 0.0635 m. Calculated and averaged stiffness coefficients are recorded in Table 1 and visualized in Figure 11.

From the analysis it appears that HDPE and LLDPE have comparable stiffnesses as we expected from visual inspection. However, the HDPE/Nylon layered vacuum bag had a significantly higher stiffness that was approximately six times larger than the other materials. It is important to note that the addition of nylon resulted in a change in the stiffness, suggesting that layering various polymers could be used to fine-tune the Young's Modulus of our final material. The full data set can be seen in Appendix C.

Table 1: Bag thickness found in the literature or measured experimentally using a drop gauge. Young modulus (E) calculated from stress-strain data measurements. Stiffness constant K was calculated from E, area, and length data.

Material	Thickness (mm)	Specimen	E (MPa)	E(Pa)	K (N/m)	Average of K	Standard Dev of K
HDPE	0.025 [11]	1	406.62	406620000	2033.1	**1880.5**	**256.31**
		2	316.92	316920000	1584.6		
		3	404.77	404770000	2023.9		
LLDPE	0.0254 [12]	1	200.42	200420000	1018.1	**1002.8**	**115.66**
		2	218.53	218530000	1110.1		
		3	173.29	173290000	880.3		
HDPE/Nylon	0.762 ± 0.0254	1	92.307	92307000	14067.6	**14662**	**734.98**
		2	94.716	94716000	14434.7		
		3	101.6	101600000	15483.8		

Table 2: P-values calculated using ANOVA analysis with Tukey HSD post Hoc test and alpha = 0.05.

	HDPE	LLDPE	HDPE/Nylon
HDPE		0.1211	<0.0001
LLDPE	0.1211		<0.0001
HDPE/Nylon	<0.0001	<0.0001	

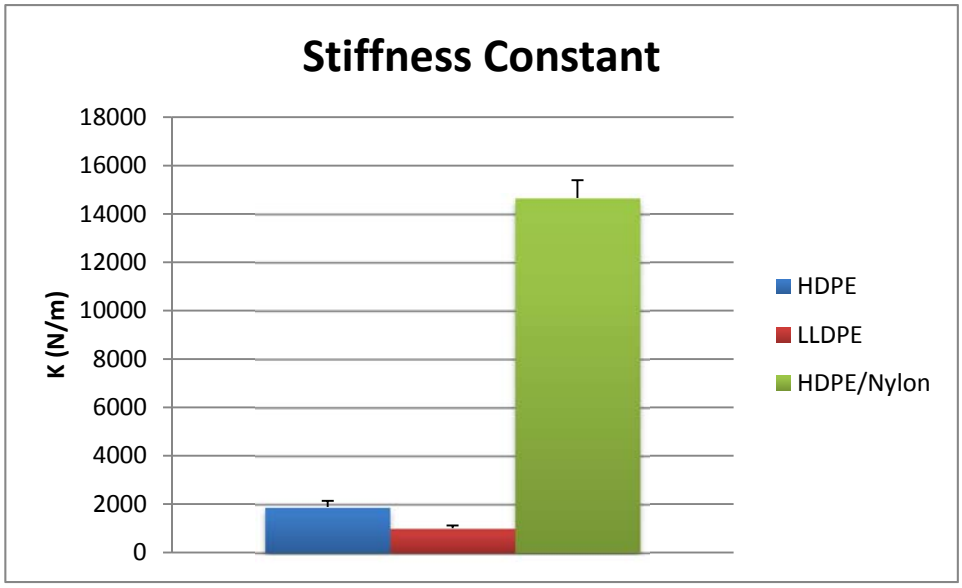

Figure 11: Visual representation of data recorded in Table 1: stiffness coefficients of HDPE, LLDPE and HDPE/Nylon, respectively.

Table 3: Young's modulus of materials found in the literature that are most comparable to the desired values measured in Table 1 [14,15,16].

Material	Young's Modulus (MPa)
PLA	**1500**
PLGA	**3000**
PHB	**1500**

Material Alternatives

Any materials used for the three design structures previously described must be bioabsorbable and FDA approved. There are three different polymer alternatives that we considered implementing, as seen in Table 3. These polymers include Polylactic-glycolic acid, Polylactic acid, and Polyhydroxybutyrate.

Polylactic-glycolic acid (PLGA)

PLGA is a copolymer of Polylactic Acid (PLA) and Polyglycolic Acid (PGA). After spending a certain amount of time in the body, PLGA is broken down by water through various hydrolysis mechanisms. Depending on the ratio of PGA to PLA used, the time for complete hydrolysis is customizable. The higher the ratio of PGA:PLA, the faster the degradation with the exception of the fastest degradation time which is achieved with a 50:50 ratio of PGA:PLA [17]. A ratio of 90:10 is most commonly used for medical applications, such as sutures, due to its higher strength and faster degradation time [18].

Polylactic Acid (PLA)

PLA is a polymer that, like PLGA, is degraded in the body by hydrolysis mechanisms in the presence of water. The degradation time of this polymer is relatively long and variable: it can range anywhere from four to 36 months. Due to the fact that lactic acid is a chiral molecule, PLA can be found in two different forms: Poly(L-lactide) and Poly(D-lactide). Poly(L-lactide) has a tensile strength of 70MPa, while the racemic mixture of the two has a lower tensile strength of 50MPa. Poly(L-lactide) is much more readily used in medical applications due to its significantly higher strength [18].

Polyhydroxybutyrate (PHB)

PHB is the third material we considered for our designs. PHB is also broken down by hydrolysis, however, unlike the previous two materials, PHB is water insoluble. PHB degrades completely within 6 to 12 months. With a tensile strength of 40MPa, polyhydroxybutyrate is the weakest of the three materials listed [18].

Design Matrix

Table 4: Design matrix used to compare design alternatives and choose a final design.

Category	**Weight**	**Design**		
		Corset	**Vacuum**	**Parachute**
Cost	15	13	8	12
Ease of use	25	20	18	23
Effectiveness	35	27	35	25
Manufacturability	25	20	24	15
Total	**100**	**80**	**85**	**75**

To compare our design alternatives we constructed a design matrix to consider design cost, ease of use, effectiveness, and manufacturability. Each category was weighted out of 100 points, and each design received a score with a maximum of the weighted value.

Cost

The category of cost was weighted with 15 points, the lowest weighted category, due to our relatively high budget. The corset scored highest in this category because there are few components to the design. The parachute scored next highest because this design incorporates components that are already on the market, such as the large-width absorbable suture. This would cut down on manufacturing costs. The vacuum design scored the lowest because the design requires the hospital to have access to a medical vacuum, which significantly increases the cost.

Ease of use

Ease of use was weighted with 25 points because it is important that the design be straightforward and quickly applied to the uterus. The corset received 20 points in this category because it would require the surgeon to connect each mesh piece with cross-linking sutures. This would consume time and the quality of the sutures could vary between applications. The vacuum received the lowest score because it would require the surgeon to make an airtight seal around the lower portion of the uterus. This could be technically challenging due to the limited view the surgeon would have. The parachute received the highest score because application of the device would consist of placing the sheet around the uterus, and securing the cinch around the bottom.

Effectiveness

Effectiveness was weighted the highest with 35 points because the device must be able to perform in the high-stakes situation where maternal mortality is in jeopardy. The corset received 27 points because compressive forces will be applied to the uterus in the anterior-posterior planes, medial-lateral planes, but not in the transverse plane. This would allow the uterus to balloon out at the fundus, giving an incomplete compression profile on the surface of the uterus. The vacuum received the highest score because the bag will apply a continuous compressive force to the uterus, ensuring a maximum compressive force in all planes. The parachute received the lowest score because the sutures will apply compressive forces in only the anterior-posterior plane, causing ballooning and incomplete compression in the medial-lateral and transverse planes. The sheet will lessen the ballooning that occurs between stitches, but cannot ensure complete compression.

Manufacturability

Manufacturability was weighted with 25 points because the number of available manufacturing options will inherently affect the cost of the final product. The corset received 20 points because the design would require a mesh to be formed from our polymer of choice. This relatively complicated shape will require a more technically involved manufacturing process. The vacuum received the highest score because the manufacturing process needed to make a thin-film bag is well established. The parachute received the lowest score because this design would require multiple sizes in order to account for variations in uterine size. This would complicate the manufacturing process.

After totaling the scores in each category, the vacuum design received the highest score with 85 points, with the corset in second and the parachute last. Thus, we decided to proceed through the remaining design course pursuing the vacuum design.

Materials Matrix

Table 5: Materials matrix used to determine the most effective polymer for use in our final design.

Category	Weight	Material		
		PLA	PLGA	PHB
Cost	10	10	2	5
Biocompatibility	30	26	28	12
Mechanical properties	25	22	18	22
Degradation time	15	10	15	10
Manufacturability	20	18	10	18
Total	100	86	73	67

To determine the most effective polymer for use in the final design we constructed a materials matrix to consider cost, biocompatibility, mechanical properties, degradation time, and manufacturability. Each category was weighted out of 100 points, and each design received a score with the maximum of the weighted value.

Cost

Cost was weighted at 10 points. PLA received the highest score because the well-established polymer is readily available priced at $1.50 per pound. PLGA received the lowest score, priced at $65 per gram. PHB received a score of five points, priced at $9.44 per gram.

Biocompatibility

Biocompatibility was weighted with 30 points because the polymer will be placed within the body, and should not cause a foreign body response that could harm the patient. PLA scored 26 points because it is broken down into lactic acid, a molecule found naturally in the body. PLGA scored the highest because it is broken down into lactic acid and glycolic acid. The concentrations of each break down product will be half that of PLA because it is a co-polymer, and thus more easily managed by the body. PHB scored the lowest because chemical additives may be needed to achieve our desired material properties, which will be harmful when broken down inside the body.

Mechanical properties

Next, mechanical properties was weighted with 25 points because optimal properties will be needed to allow the bag to be flexible enough to conform to the unique shape of the patients uterus while still maintaining the strength needed to deliver the desired compressive pressure. PLA and PHB scored equally with 22 points because the Young's Modulus (Table 3) is closest to our obtained value from the preliminary testing (Table 1). PLGA scored lowest because the E is further from our desired E, approximately 3000MPa.

Degradation time

Degradation time was weighted with 15 points because the material must maintain its mechanical properties until the hemorrhaging can be effectively stopped, defined by the client as a minimum of 24 hours. However, the material must also degrade within six to twelve months, as defined by the client. PLGA scored the highest in this category because the degradation time can be customized by varying the ratio of lactic acid: glycolic acid within the polymer. PLA and PHB tied for the lowest score because their degradation times are set anywhere from four to 36 months.

Manufacturability

Manufacturability was weighted with 20 points because the material we choose must be capable of forming into a thin-film bag. PLA and PHB scored highest with 18 points each because each polymer has well defined manufacturing processes that could be used to form a thin bag. PLGA scored the lowest with 10 points because manufacturing processes are less well defined and formation of a thin bag could require time consuming processes such as electrospinning.

After totaling the scores in each category, PLA received the highest score with 86 points, with PLGA in second and PHB in last. Therefore we chose to proceed through the remaining design process with PLA.

Final Design

Using Poly-Lactic Acid (PLA) obtained from Poly-Med, Inc., solvent casting was used to produce a thin film of PLA. A 5% solution of PLA in chloroform was made and stirred continuously at room temperature for 24 hours [18]. Once the PLA had completely dissolved, the solution was poured into a glass Pyrex dish and left to dry for at least 24 hours. Then once the solvent had completely evaporated, the film was carefully peeled off of the glass mold using sterile tweezers, yielding a thin film measuring 140mmx350mmx0.65mm (Figure 12).

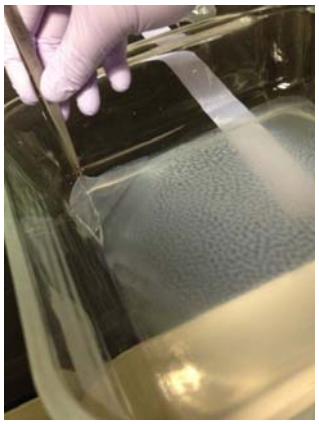

Figure 12: Dried PLA film being removed from mold following solvent-casting.

The protocol for solvent casting can be found in Appendix D.

Next, the film was folded in half and heat-sealed on one lateral edge with an impulse heat-sealer (Figure 13, A). In the field, once these steps are completed and the material has undergone ethylene-oxide sterilization, it will be ready for use in the operating room [19].

The process for inserting the uterine compression device is as follows. Following a cesarean section, when the uterus has been removed from the abdominal cavity, the OB/GYN will first insert a small trocar into the fundus of the uterus (Figure 13, B). Once the trocar is in place, the PLA film will be placed over the top and around the uterus (Figure 13, C). Using a hand held impulse heat-sealer, the second lateral side of the film will be sealed, leaving a small opening where the vacuum hose is to be placed. The film will also be sealed at the bottom, near the cervix (Figure 13, D). In addition to this, 2 to 3 PLA sutures will be tied around the cervix, acting as a cinch to increase the seal's reliability (Figure 13, E). Once the film has been properly placed around the uterus with effective air-tight seals, a medical grade vacuum hose will be placed inside of the bag to expel all air (Figure 13, F). Once all air has been removed and complete compression has been achieved, the hose will be removed and the final portion of the film will be sealed. A sketch detailing these design elements and characteristics can be found in Figure 14.

Once completely compressed by the vacuum-sealed PLA film, the uterus will be placed back into the abdominal cavity for continued compression. The PLA will then gradually degrade over a period of approximately six to twelve months. Removal of the trocar will be performed vaginally approximately one week following device implantation.

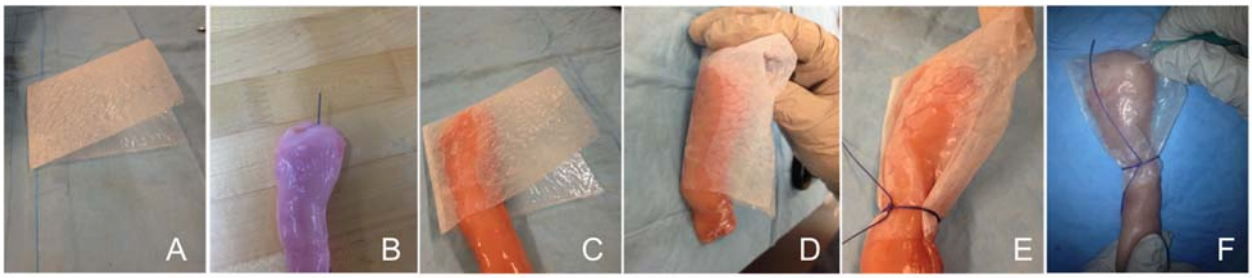

Figure 13: Sequence of application of device and vacuum compression of the uterus, as detailed above.

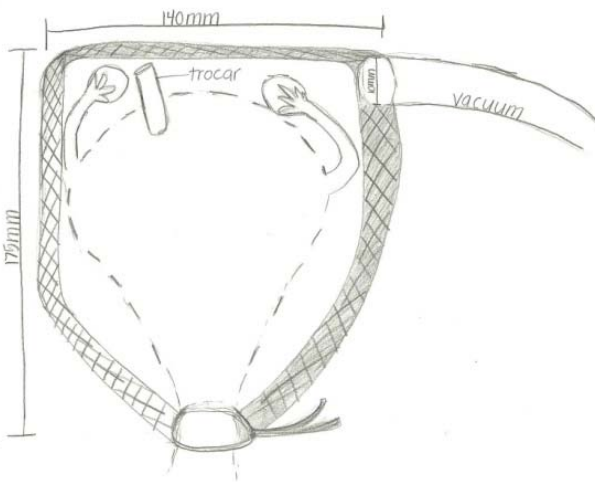

Figure 14: Sketch of final design consisting of PLA film, heat sealed edges, trocar, PLA sutures, and a vacuum device.

Modeling

In order to determine the stresses that would be applied to the material when a pressure of 100 mmHg is applied, the bag was idealized as three different polygonal figures: a cylinder, a sphere, and an ellipsoidal capsule. All models used for calculations were assumed to be closed vessels, without the holes that are present in the final design. Dimension values for the models were based on a 93mm anterior/posterior diameter of the uterus post-partum [20]. For all stress calculations, the values for wall thickness, pressure, and radius remained constant (t = 0.5 mm, $p = 13332$ Pa, and $r =$ 55 mm). The stresses in the sphere were found using the simple equation:

$$\sigma = {}^{pr}/_{2t} \qquad (1)$$

This mathematical statement is known to be true for all thin walled pressure vessels of this shape [21]. Using the values previously stated, the stress on the material was found to be 733 kPa. The tensile strength of the film should be at least twice as strong as this value, since pressures greater than 200 mmHg will likely be placed on the uterus by the vacuum device.

In the cylindrical model, a radius of 55 mm and a length of 110 mm were used, in order to be consistent with the spherical modeling. To find the stress in the cylindrical model, an equation very similar to that of the spherical model was used [21].

$$\sigma = {}^{pr}/_{t} \qquad (2)$$

Stress was then computed using the values previously stated, resulting in a value of 1466 kPa. Thus, if modeled as a cylinder, the material must be able to resist a stress twice as large as when modeled as a sphere, having a tensile strength of at least 3 MPa.

In the ellipsoid model, the hemi-spherical ends on each side had a consistent radius of 55 mm, and the total length of the model was 150 mm. The stresses at the hemispherical ends of the ellipsoid capsule model were found to be equal to the stresses in the spherical model. The center of the ellipsoid can be modeled as a cylinder. Thus, by combining the stresses calculated in the cylindrical model with those of the spherical model, total stress for the ellipsoid was found. This model was determined to be the most physiologically accurate in representing the shape of the bag around the uterus. It is an advantageous combination of both the spherical and cylindrical models: having less concentrated stresses than the cylindrical model, and more accurate stresses than the spherical model.

After all stress calculations were performed, a SolidWorks rendition of all three models was made and analyzed. In these models, the shape was punctured by two holes, being 10 mm and 25 mm in diameter. The 10 mm diameter hole, on the superior side, is representative of where the vacuum tube will be inserted into the bag. The 25 mm diameter hole, on the inferior side, represents the opening for the cervix. The model was fixed at this point and treated as a rigid

body. Then, a 100 mmHg (13.332 kPa) pressure was applied inwards from the all planes. After selecting a material to model with properties similar to those of the PLA film (a Low Density Polyethylene film with elastic modulus of 1.29 GPa and tensile strength of 17 MPa), an analysis was run to determine stresses and deformation. Maximum stresses found in the modeling were consistent with those that were calculated previously, and the deformation of the models can be seen in Figure 15, 16 and 17. Most deformation occurred in the area furthest from the cervix. This can be explained through reasoning that the largest force generated by the pressure would be applied furthest away from the cervix, thus causing the largest deformation. These models aided in simulating a realistic force generation on the uterus expected in the finished design.

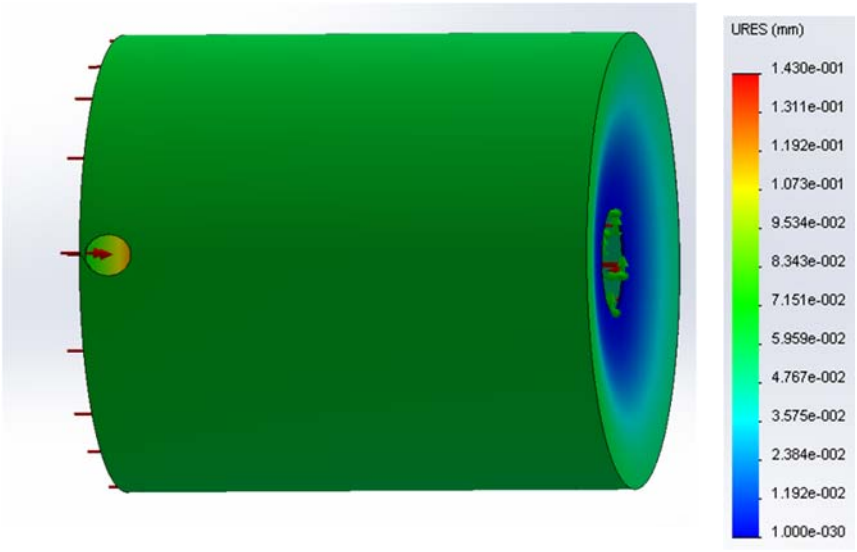

Figure 15: Displacement of bag modeled as a cylinder having a radius of 55 mm and a length of 110 mm. The gradient on the right depicts deformation from largest (red) to smallest (blue).

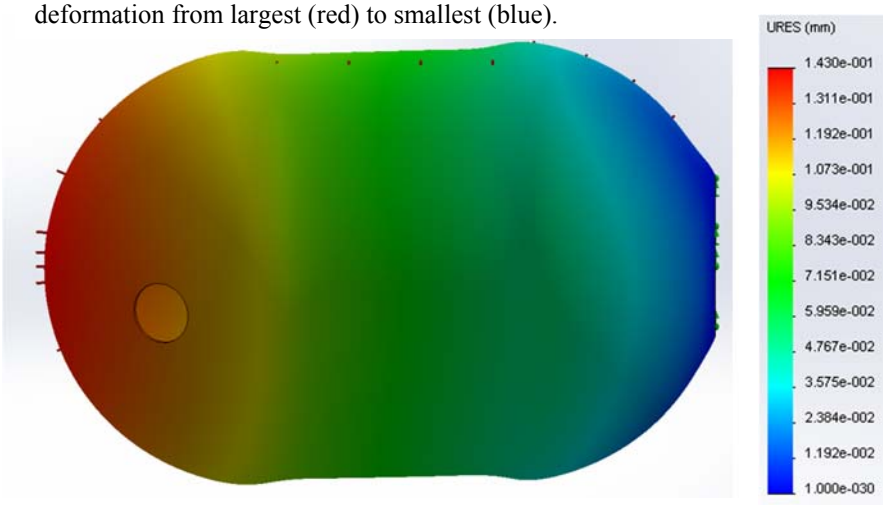

Figure 16: Displacement of bag modeled as an ellipsoid capsule having a length of 150 mm and a height of 55 mm. The gradient on the right depicts deformation from largest (red) to smallest (blue).

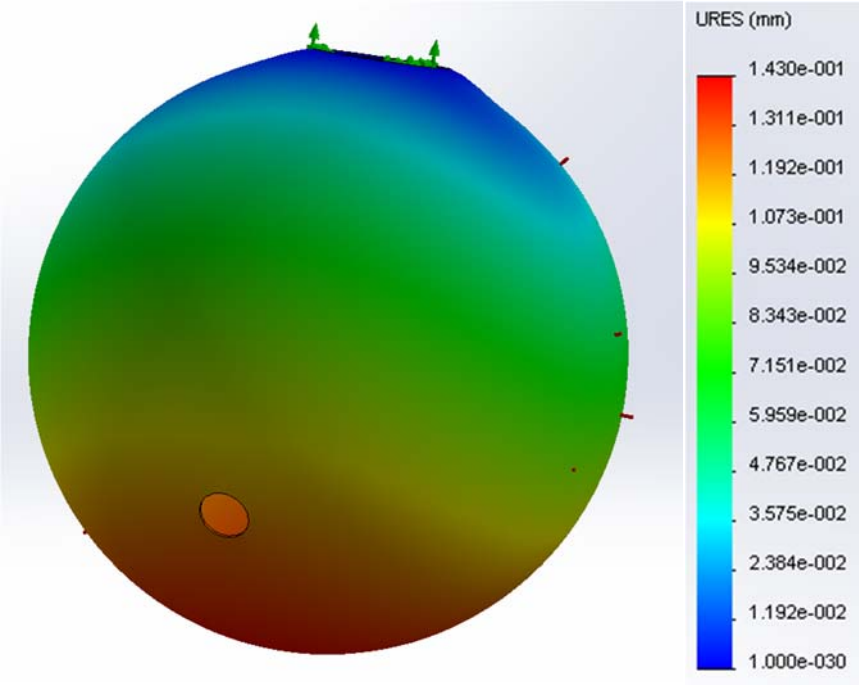

Figure 17: Displacement of bag modeled as a sphere having a radius of 55 mm. The gradient on the right depicts deformation from largest (red) to smallest (blue).

Testing

PLA Film Tensile Testing

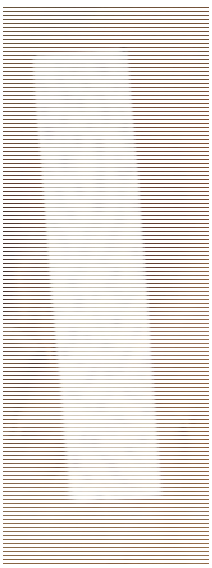

Figure 18: PLA film cut in to a strip in preparation for mechanical tensile testing.

Tensile testing was performed on our solvent-casted PLA film for comparison to the previously tested materials HDPE, LLDPE, and HDPE/Nylon. The PLA film was cut into three strips 6.35 cm long and 12.7 mm wide as seen in Figure 18. It was then loaded into the grips, and pulled at either end to generate load and strain data. The full protocol can be seen in Appendix B.

In order to calculate stress values from the measured force data, the thickness of the film needed to be measured. For this, a drop gauge was used to measure thickness at eight randomly chosen locations. These values were recorded in Table 6 and the average thickness was used to calculate the cross sectional area of the strip, as well as stress values. Stress-strain graphs were generated for each specimen, and Young's Modulus was calculated from the linear portion of the graph. Average Young's Modulus and standard deviations were recorded in Table 7. Data from HDPE, LLDPE, and HDPE/Nylon trials are from the previously discussed preliminary mechanical testing. Stiffness constants were also calculated using methods previously mentioned in Preliminary Mechanical Testing. These results are recorded in Table 7 and visualized in Figure 19. Statistical analysis was performed using ANOVA analysis with Tukey HSD post Hoc test and alpha set to 0.05.

Appropriate p-values are recorded in Table 8. The full data set can be seen in Appendix C.

Table 6: PLA film thicknesses measured using a drop gauge.

Trial	Thickness (in)	Thickness (mm)	Average (mm)	St Dev
1	0.021	0.5334	**0.65405**	**0.14416438**
2	0.019	0.4826		
3	0.026	0.6604		
4	0.02	0.508		
5	0.035	0.889		
6	0.029	0.7366		
7	0.031	0.7874		
8	0.025	0.635		

Table 7: Bag thickness found in the literature or measured experimentally using a drop gauge. Young modulus (E) calculated from stress-strain data measurements. Stiffness constant K was calculated from E, area, and length data.

Material	Specimen	E (MPa)	E(Pa)	K (N/m)	Average K (N/m)	Standard Dev of K
HDPE	1	406.62	406620000	2033.1	**1880.51**	**256.31**
	2	316.92	316920000	1584.6		
	3	404.77	404770000	2023.9		
LLDPE	1	200.42	200420000	1018.1	**1002.85**	**115.67**
	2	218.53	218530000	1110.1		
	3	173.29	173290000	880.3		
HDPE/Nylon	1	92.307	92307000	14067.6	**14662.04**	**734.98**
	2	94.716	94716000	14434.7		
	3	101.6	101600000	15483.8		
PLA	1	19.454	19454000	2544.77774	**2657.75**	**105.01**
	2	21.041	21041000	2752.37321		
	3	20.458	20458000	2676.11098		

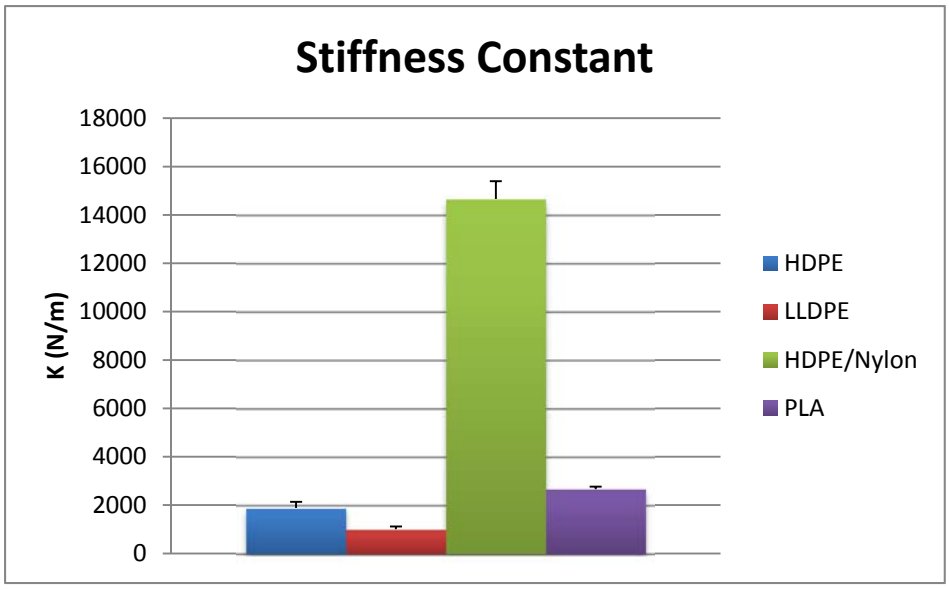

Figure 19: Experimentally determined stiffness constant K of various materials in comparison to our PLA film.

Table 8: P-values calculated using ANOVA analysis with Tukey HSD post Hoc test and alpha = 0.05.

	HDPE	LLDPE	HDPE/Nylon	PLA
HDPE		0.1211	<0.0001	0.1548
LLDPE	0.1211		<0.0001	0.0041
HDPE/Nylon	<0.0001	<0.0001		<0.0001
PLA	0.1548	0.0041	<0.0001	

From the analysis it appears that the stiffness of our PLA film is comparable to the HDPE bag, statistically stiffer than the LLDPE bag, and less stiff than the HDPE/Nylon layered vacuum bag. From these results we see that our PLA film is less stiff than the HDPE/Nylon bag, which is desirable because from visual inspection the vacuum bag is so stiff that when folded over makes sharp and stiffer corners. This is undesirable for our film because we wouldn't want a material that could potentially cause internal damage due to sharp corners. Furthermore, the properties of our PLA film suggest that it will have properties similar to HDPE stiffness, in that it is able to withstand tensile stresses while maintaining flexibility. This is ideal for our design because the surgeon must be able to easily wrap the film around the uterus and then take on the relatively irregular shape of the uterus.

Additionally, representative graphs of the stress-strain curve generated from the load-strain data measured for the HDPE bag and our PLA film can be seen in Figures 20 and 21, respectively. The HDPE bag has a non-distinct elastic region where most of the graph is in plastic deformation. However, the PLA curve has a very distinct transition between elastic and plastic deformation. Since the elastic deformation region of the PLA film is larger, this suggests that our film will be able to withstand greater stresses before plastically deforming. This is ideal for our application because our PLA bag will be able to withstand larger stresses before plastically deforming. If the PLA bag remains within the elastic deformation region when applied to the uterus it will be able apply forces to the slowly shrinking uterus until the film reaches a strain of zero.

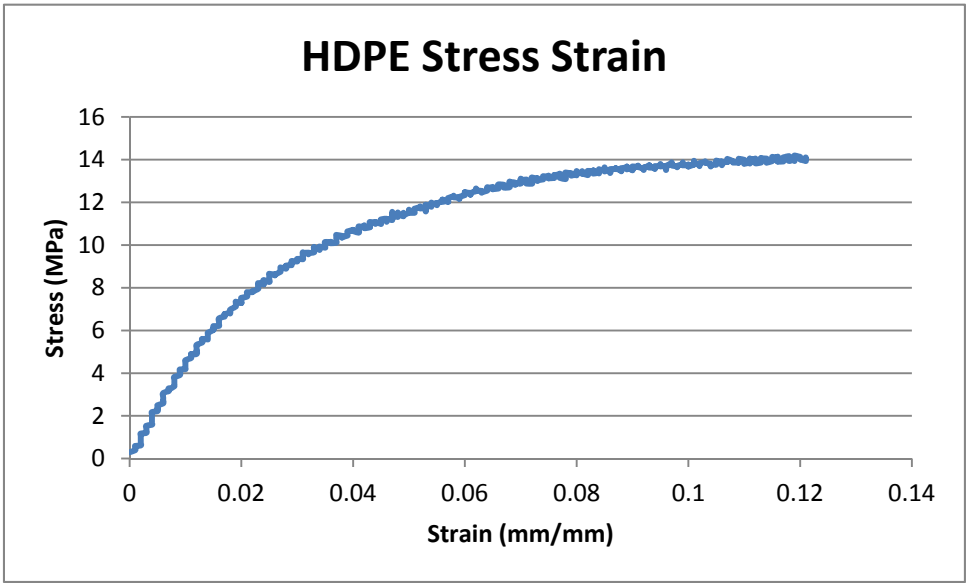

Figure 20: Stress-strain curve of HDPE generated from tensile testing.

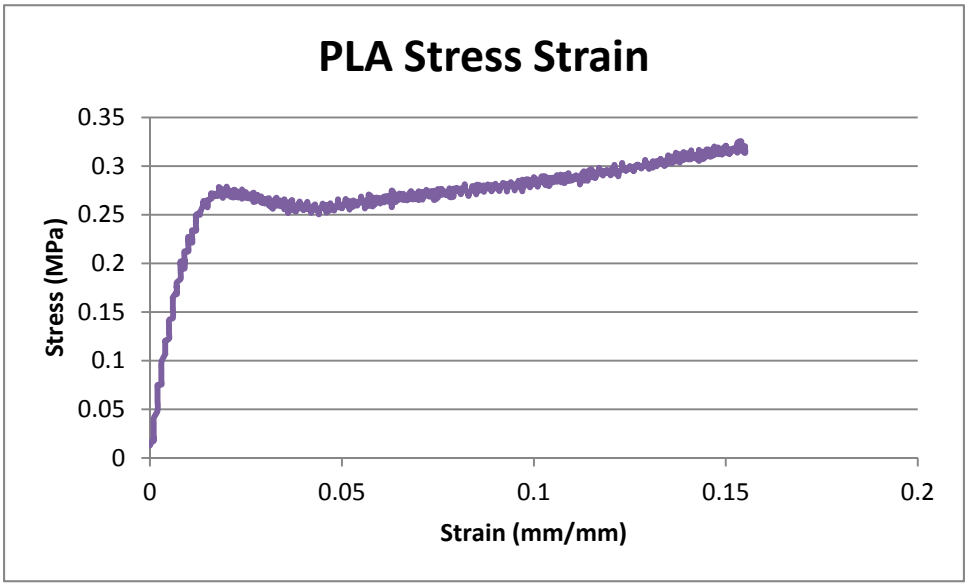

Figure 21: Stress-strain curve of PLA film generated from tensile testing.

Pressure Testing

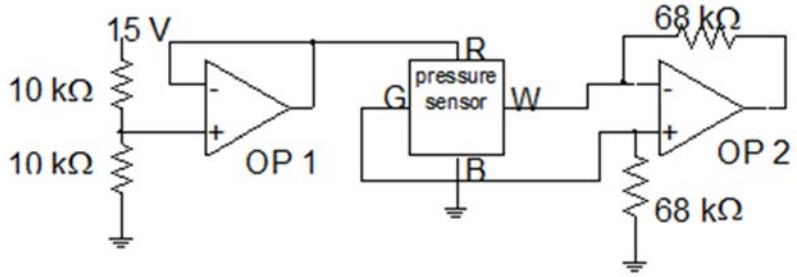

Figure 22: Circuit set-up to read voltage output of sensor at certain obtained pressures. OP 1 provides the excitation voltage at terminal R. The 68 kΩ resistors and OP2 form a differential amplifier. R: red, B: black, G: green, W: white [22].

In order to confirm that the PLA film bag can withstand and supply pressures over 100 mmHg to the uterus, a pressure sensor (DPT-100, Utah Medical Products Inc.) was used that could measure pressure ranges from 0-300 mmHg. The pressure sensor itself gives an electrical output when supplying a force, thus a calibration curve had to be found in order to translate these voltage outputs into pressure values in mmHg [22]. Pressure calibration was performed as explained in Appendix E and is overviewed here. Using the pressure sensor, a power supply, a multimeter (Mastech M8268), an LF747 op amp, resistors, and wires arranged (Figure 22), voltage output was found at a certain pressure. One valve of the pressure sensor was connected to a pressure gauge and the other valve was connected to a blood pressure arm cuff (Figure 23). The cuff was then wrapped around a solid cylindrical paper roll, and pressures were applied to it in increments of 20 mmHg. These increments then gave a voltage output and a calibration curve was found for the values of pressure supplied (Figure 24).

The pressure force of the prototype bag was then tested using the pressure sensor, the same circuit used to characterize the sensor, a lab aspirator vacuum, and the PLA film prototype wrapped around a section of pig uterus. All steps in pressure testing are explained in Appendix F and summarized here. The aspirator tube was attached to one valve of the pressure sensor, and an air vacuum tube was attached on the other valve of the sensor, which lead to the PLA bag to supply pressure. The electrical leads from the sensor were then attached to the circuit as in the calibration set-up, and the voltage output difference was found through the readings of the multimeter. These voltage outputs were then translated to pressure output through the use of the linear equation obtained from the calibration curve.

$$pressure = (voltage - 0.9846)/0.0143$$

The pressures obtained reached up to 238.83 mmHg (Figure 25), more than doubling the minimum pressure required for the device to cease PPH. Therefore, the film has proven to sustain a pressure exceeding 230 mmHg without failing or loosing vacuum seal, further validating its use for our purposes.

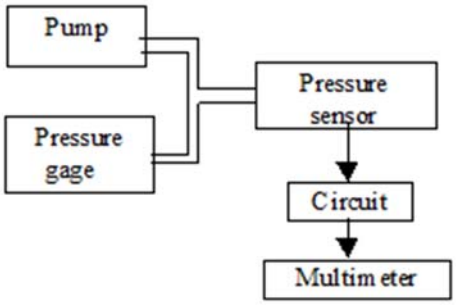

Figure 23: Connection of the pressure sensor to the gage, arm cuff pump, circuit, and multimeter for obtaining calibration curve [22].

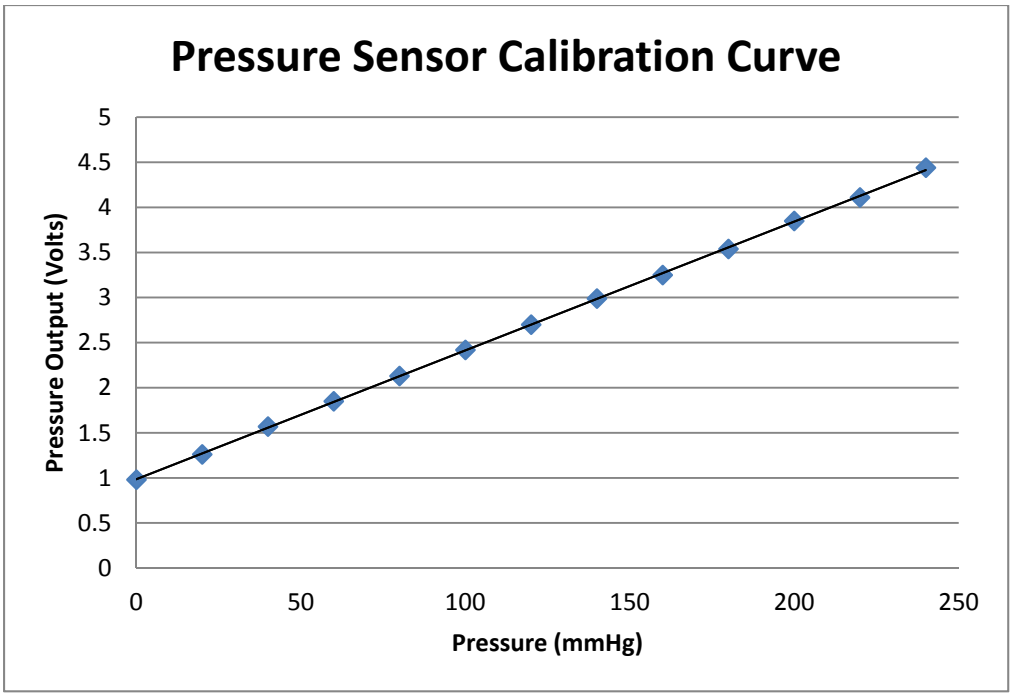

Figure 24: Calibration curve obtained for the pressure sensor relating voltage output to pressure being applied.

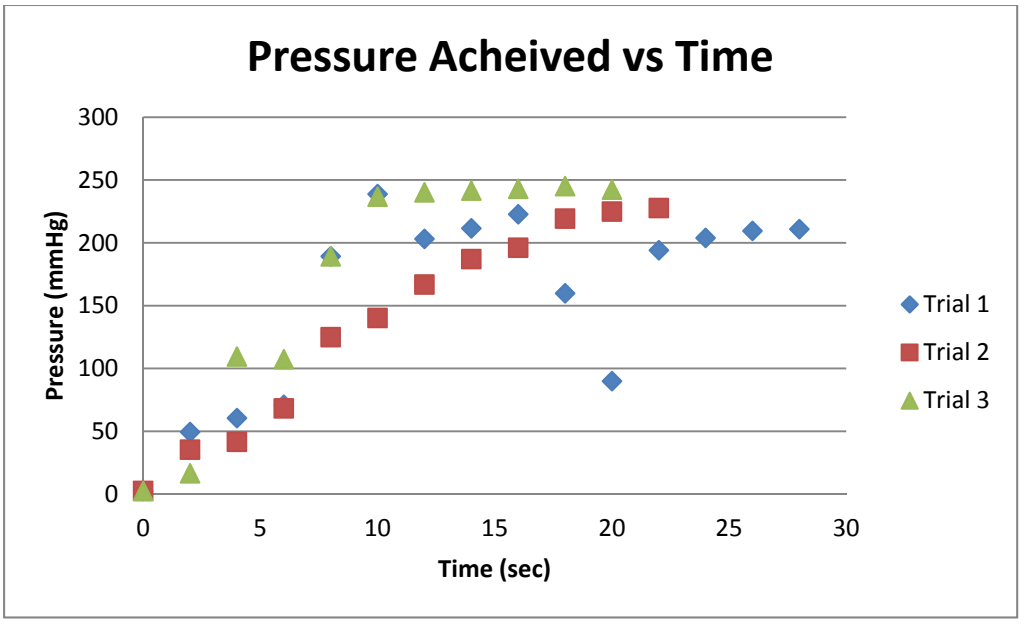

Figure 25: Pressure values obtained in three trail runs with use of aspirator, pressure circuit and prototype bag.

Ethical Considerations

The patient's safety is the primary concern of this device; therefore we must ensure that it does not cause the patient to be more susceptible to infection, further hemorrhaging, or infertility. Any materials that will remain around the uterus must be FDA approved, and the device must either be disposable or easily sterilized to ensure that a clean device is used for each patient. Since the device will likely be used in conjuncture with many other medical devices readily available in the field, such as the Wound-Vac (medical vacuum) and bio-absorbable sutures, we must be certain that the use of these devices or materials is in no way infringing upon the intellectual property of these existing materials [23]. Given that the price of our device will most likely exceed the budget available in developing countries with less advanced healthcare systems, we must consider if it is ethical to design a device that would be less readily available to patients in such countries. Finally, careful consideration must be made when testing the proposed device. Use on live animals and human subjects must follow all guidelines that are required by the Institutional Animal Care and Use Committees (IACUC), the Food and Drug Administration (FDA), and the Institutional Review Board (IRB) [24].

Future Work

Though a model prototype has been created and tested, more testing needs to be performed in order to verify that our design meets all of the required design criteria. First, a full-sized prototype must be developed in order to fit a human uterus. The full sized prototype will then be tested with trocar insertion. We must evaluate the trocars' ability to puncture the uterine wall and release air inside of the uterine cavity upon application of vacuum pressure. The heat sealing of the PLA bag will also be further tested. To do so, we will first perform time trials for the sealing of the bag using a handheld impulse heat sealer, as it will be performed in the clinical setting. Next, tensile testing on and around the point of the seal will need to be performed to validate that these areas are strong enough to withstand the pressures applied by the vacuum.

After formation of a full sized prototype and performance of individual component testing, pressure testing on an ex vivo cow uterus will provide us with more physiological accurate properties of the human uterus than the pig uterus used in the testing detailed above [25]. Preferably, this testing will be done using a vacuum device found in the operating room, such as the Wound-Vac, which will be used in the final device. The pressure following removal of the vacuum and subsequent sealing of the vacuum hole will need to be recorded using a pressure sensor, to assure that necessary pressures are sustained. To perform this test, a more robust pressure sensor should be used: the sensor used on our small prototype is only accurate up to 300 mmHg, and pressures with a full sized prototype will likely exceed this value.

To proceed to animal and human subject testing in the more distant future, all team members need to obtain Research Animal Research Center (RARC), Food and Drug Administration (FDA) and Institutional Review Board (IRB) certification. Animal testing to evaluate in vivo

bodily reaction in a large mammal directly post-partum would then be performed. This would employ a sheep lab, which our client Dr. Lick's colleague, Dr. Magness, has access to. This sheep testing would provide a means to observe the physiological reaction to the breakdown of PLA and to test the effectiveness of the pressure in limiting blood flow to the uterus within living tissue. After multiple successful animal testing trials, when the safety and reliability of the device can be assured, human subject testing is to be performed.

Projected Cost

As determined by our client, the final budget for the device is over $1,000. The major component of the final expense report will be the materials used to create the bag and the hand-held impulse heat sealer, as other components of the design are readily available in a clinical setting already. The cost of PLA is rather low, at $1.50 per pound. In order to create the thin film, our team will need to order additional chloroform, which will increase our expenses by around $100. A handheld impulse heat sealer costs around $89 and the purchase of a trocar will further increase our total expense by a maximum of $80; therefore we expect to be well under the proposed budget, with a total projected cost of about $300.

Expense Report

As seen in our expense report in Table 9, our team is currently well under budget. We expect this to grow to a larger number as we begin to order a larger quantity of solvent casting materials, a trocar, and an impulse heat sealer. However we do not expect to exceed our budget.

Table 9: Up-to-date expense report

Item	Purchased from	Item #	Price	Quantity
8in x 8in square Pyrex dish	Target	070021172	$12.99	1

Timeline

Tasks	September			October				November					December	
	14	21	28	5	12	19	26	2	9	16	23	30	7	14
Meetings														
Advisor	X	X	X	X	X	X	X	X	X	X		X	X	
Client		X			X	X						X		
Team	X	X	X	X	X	X	X	X	X	X	X	X	X	
Product Development														
Research	X	X	X	X	X	X	X	X	X	X	X	X	X	
Brainstorming		X	X	X	X	X								
Design Matrix				X	X	X	X							
Design Prototype						X	X		X	X	X	X	X	
Order Materials								X	X		X		X	
Fabricate Prototype												X	X	
Testing										X			X	
Deliverables														
Progress Reports	X	X	X	X	X	X	X	X	X	X		X	X	
PDS		X	X				X							
Mid Semester PPT						X	X							
Mid Semester Report						X	X							
Final Report												X	X	
Final Poster												X	X	
Website Updates	X	X	X	X	X	X	X	X	X	X		X	X	

Figure 26: Timeline for the semester. Completed tasks are noted by an 'X'.

As seen in Figure 26, we have been fairly on schedule with the development of our prototype and design throughout the semester, as filled boxes are our projected timeline and the checks are the actual progression, with the team either completing or in the process of completing these tasks. We have been able to develop a prototype and test it on an animal model.

Conclusion

In an effort to address the major complication of postpartum hemorrhage due to the increasing number of cesarean sections performed each year, we hope to develop a completely bio-absorbable device that will provide total compression of the uterus in all planes while minimizing the foreign body response of the abdominal cavity. After extensive brainstorming, preliminary testing, and matrix evaluation, we have developed a vacuum device consisting of a heat sealed solvent-casted PLA film, PLA sutures, and a trocar. Using a small prototype on a pig uterus, we performed both tensile and pressure tests. The results of our testing leave us confident

that our design effectively meets the design requirements of the client. With further prototype development and animal testing, we expect to find that this device will provide the patient with maximum comfort and a minimal number of complications, all while ceasing post-partum hemorrhage.

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Appendix

Appendix A: Preliminary Design Specifications

DRAE Hugger uterine compression device: a treatment for postpartum hemorrhage

Product Design Specifications
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Function:

Postpartum hemorrhage is an obstetrical emergency that can follow vaginal or cesarean delivery. It is a major source of maternal morbidity and maternal mortality. The uterine compression device would mimic normal uterine response by simulating smooth muscle contraction by compressing the uterus in all planes, thus preventing uterine atony. The device could also be used in the setting of placenta accreta, allowing for manual removal of the placenta followed by compression using the device. The device would have to compress the uterus in all planes and suppress hemorrhaging for a minimum of twenty-four hours. All aspects of the uterine compression device that are inserted into the patient should be absorbed within six to twelve months.

Client Requirements:

- Provide complete compression of the uterus in all directions.
- Ligaments surrounding uterus should be compressed within the device.
- Provide constant compression for at least 24 hours.
- Bio-absorbable material that is both durable and absorbable
- Trocar instrument to remove air from uterine cavity.
- Device must be easily and quickly interested into the abdominal cavity.
- Pressures sustained after suction should stay in physiological range: minimum of 100mmHg.

1. Physical and Operational Characteristics

A. Performance Requirements:

The DRAE Hugger must stop excess Post-Partum Hemorrhaging bleeding, caused by either uterine atony or placenta accreta. The device must mimic normal uterine response post-partum by simulating smooth muscle contraction and compressing the uterus in all

planes, thus halting uterine atony. The device must also stop bleeding post removal of the placenta in cases of placenta accreta. The device would only be used once, and must be a safe absorbable material so that device removal would not be necessary. The material, in addition to being absorbable, must be able to withstand pressures normally produced by the smooth muscle cells after birth.

B. Safety:

The absorbable material itself must be sterilizable, hemocompatible, and biocompatible. The suction provided by the vacuum device should be at least 100mmHg. There is no maximum pressure due to the excellent blood supply to the uterus.

C. Accuracy and Reliability:

The hugger should meet normal physiological pressure: a minimum of 100mmHg for at least 24 hours. It must also completely halt the progress of postpartum hemorrhage, thus preventing the need for a hysterectomy.

D. Life in Service:

The device must maintain constant pressure for at least 24 hours, and be completely degraded within six to twelve months.

E. Shelf Life:

The hugger should be stored in a dry environment to prevent material break-down. The ideal temperature for storage is -20 degrees Celsius in order to preserve the absorbable materials for extended periods of time.

F. Operating Environment:

The device will be placed in the body, so it must be sterilizable, hemocompatible, and biocompatible. It must also be stored at near 20 degrees Celsius when in the operating room, and at body temperature (37 degrees Celsius) when in use within the abdominal cavity. The absorbable material must be able to withstand a minimum of 100mmHg of pressure during vacuum suction.

G. Ergonomics:

Materials used in the device must not negatively affect the tissue surrounding the uterus and the device should be positioned around the uterus easily.

H. Size:

The device will be 140mm x 350mm x 0.65mm. Furthermore, the device must be portable.

I. Weight

The hugger must be very lightweight as it will be placed within the body.

J. Materials

All components of materials used must be FDA approved, biocompatible and absorbable.

K. Aesthetics

As the product will be placed within the body, it will not be visible and therefore aesthetics is not the most important component of the design process. However, the device must be easy to use and put in place.

2. Production Characteristics

A. Quantity

Multiple units must be available in each hospital that uses the product, therefore the quantity of units that must be produced is not yet known. The client would like to end this design process with one "proof of concept" model.

B. Target Product Cost

Current devices range in cost from $1500 to over $3000. Although there is no set budget for this device, we have set the budget around $1000.

3. Miscellaneous:

A. Standards and Specifications:

All absorbable materials must be biocompatible and FDA approved

B. Customer:

Complete compression of the uterus must be obtained: especially laterally. The device should reach optimal pressure rapidly. Absorbability in six to twelve months is optimal.

C. Patient-related concerns:

Materials must be easily sterilized and cause minimal discomfort to the patient. The device must quickly and effectively stop postpartum hemorrhaging with little to no side effects.

D. Competition: Some existing methods to prevent postpartum hemorrhage include:

i.Bakri Balloon: Device inserted into the uterus and filled with sterile fluid to provide compression of the endometrium in the medial/lateral and posterior/anterior directions.

ii.B-Lynch Suture: Insertion of sutures to compress the midportion of the uterus.

iii.Hypogastric Artery Ligation: Hypogastric artery is surgically tied up or closed off.

iv.Hysterectomy: Surgical removal of the uterus.

Appendix B: Mechanical Testing Protocol

1. Ensure the specimen clamps are correctly installed.
2. If compression clamps are installed, switch them out for tension clamps
3. Ensure the 1000N load cell is installed and not 500N load cell
4. Tightly secure specimen in the clamps using an L-wrench
5. Make sure when securing the specimen, they stay centered within the clamp
6. The specimen should cover at least half of the clamp area, and should not hang over the edges

7. Ensure the correct standards are set with a maximum load for -900N to 900N to prevent damage to the machinery.

8. Using the clamp controls, move the head up until the specimen is taught and the load reads positive but small.

9. Press the green arrow to begin the test. It will run until the maximum load is met, or until you stop it.

10. Export Load and Strain data to into excel

11. Convert Load values to Stress values by dividing by the cross sectional area

12. Graph Stress vs. Strain

13. Fit linear portion of the graph with a linear regression to yield the Young's Modulus

Appendix C: Tensile Test Results

See attachment

Appendix D: Solvent Casting Protocol

EVERTYHING IS DONE IN A CHEMICAL HOOD

1. Measure out 33.03 mL of chloroform and place into appropriate beaker

2. Place sterile stir bar into beaker

3. Put beaker onto stir plate

4. Measure out 1.65 g of PLA and slowly add to beaker

5. Turn stir plate on to medium

6. Wait for 24 hours for PLA to be completely dissolved into the solvent

7. Pour onto an 8inX8in Pyrex glass baking dish

8. Let dry for around 24 hours

9. Once completely dry, peel film off of bottom of glass dish using tweezers

10. Clean all glassware

Appendix E: Pressure Sensor Calibration Protocol

1. Formulate circuit in accordance to the schematic shown in Figure #.
2. Attach power supply to circuit beginning applying 15 volts to the OP amplifiers
3. Attach blood pressure cuff pump to one open input of the pressure sensor
4. Attach pressure gage to opposite input of pressure sensor
5. Place multimeter leads to the beginning and end of circuit formed in step 1
6. Wrap blood pressure arm cuff around solid cylindrical object (i.e. wire spindle)
7. Pump cuff up to a reading 240 mmHg on the pressure gage
8. Close the seal of pump locking the pressure value and record voltage reading from multimeter.
9. Decrease pressure in cuff by 20 mmHg and close pump seal to maintain constant pressure
10. Record new voltage reading from multimeter
11. Repeat steps 8 and 9 until pressure is decreased all the way down to 0 mmHg

Appendix F: Pressure Testing

1. Attach power supply unit to the same circuit used in pressure sensor calibration, supplying 15 volts through it
2. Attach aspirator tube to one input of the pressure sensor
3. Attach tube leading to vacuum bag prototype to other open input on pressure sensor
4. Attach multimeter to beginning and end of circuit
5. Turn on vacuum power
6. Record multimeter voltage reading every two seconds