



Uterine compression device: a treatment for postpartum hemorrhage

Mid-Semester 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. It can be caused by many complications such as uterine atony and placenta accreta. PPH affects approximately one in 533 deliveries and continues to affect more and more women as cesarean deliveries become increasingly prevalent. The uterine compression device would mimic normal uterine response by simulating smooth muscle contraction and 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.

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. 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.

Problem Motivation

Currently, 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 [1]. 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 [1]. 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. Thus, when it detaches either naturally or manually, it can result in excessive blood loss. This occurs in one in 533 pregnancies [1].

There are many current problems with the response methods to instances 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 doesn't 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]:

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.

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 1). 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. 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 [1]. It is one of only two devices



Figure 1: A Bakri Balloon is placed into the uterus via catheter and inflated with sterile fluid using a syringe [2].

approved for this use by the United States Food and Drug Administration (FDA) [2]. 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 [1].

Another method for management of PPH is arterial embolization. To implement this method, the patient must be stable. It is most useful for treatment of uterine atony following vaginal delivery, as it does not require surgical opening of the abdominal cavity [3]. Embolization involves placement of gelatin pledgets, coils or glue into the vessels for occlusion [2]. Normally, there is recanalization of blood flow within the organs within a few weeks [2]. 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 [1]. The risk of reoccurrence is also increased. Arterial embolization has a general success rate of 70-100% [1].

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 2).

It is used to control the bleeding from the placental site by opposing the anterior and posterior walls together [1]. This method 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 use for PPH following cesarean sections, when the patient is already undergoing surgery [3]. 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 [1]. The sutures can also slip off of the fundus if they are not tied tightly enough [1]. Recently, many variations of the B-Lynch have been developed in order to address these issues. Overall, it has a 91.7% success rate [1].

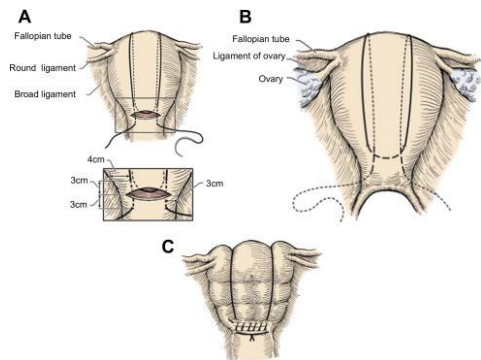


Figure 2: The B-Lynch suture technique [2].

Arterial ligation of the major uterine vessels and myometrium is another treatment option for PPH (Figure 3). This method has been shown to occlude 90% of the blood flow, and can save the

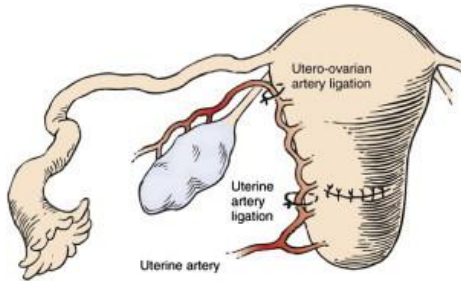


Figure 3: Uterine arterial ligation [2].

uterus by avoiding a hysterectomy [3]. Bilateral ligations are rather simple to perform, however hypogastric ligation is much more challenging and time consuming [2]. This results in complications that can arise from incomplete ligation. Arterial ligation is associated with an 80-96% success rate [1].

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 4). It is then 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 [4]. Although it is a new method, the complications that have arisen from its use are the eventual need for a hysterectomy, the viability of the ovaries can be compromised and there is also a greater risk of infection [4].

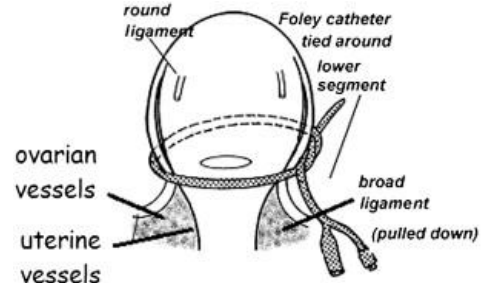


Figure 4: The tourniquet method showing the catheter tied around the lower segment of the

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 [1]. 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% [1].

Design Requirements

The design requirements outlined in the Product Design Specifications in the 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 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 included must be bio-absorbable. The device must also supply a minimum pressure of 100 mmHg to the uterus. There is no set maximum pressure threshold because the minimum blood flow to the uterus is 175 cc./minute [5]. Because this blood flow is so substantial, it is unlikely that necrosis would occur in the patient. This 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 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 are 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 criteria: 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 structural consideration.

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 bioabsorbable 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 bioabsorbable sutures around the lower segment of the uterus to ensure adequate fastening around the cervix area (Figure 5). Once completely fastened and tightened, the corset device would provide complete compression to the uterus in the anterior, posterior, and lateral directions.

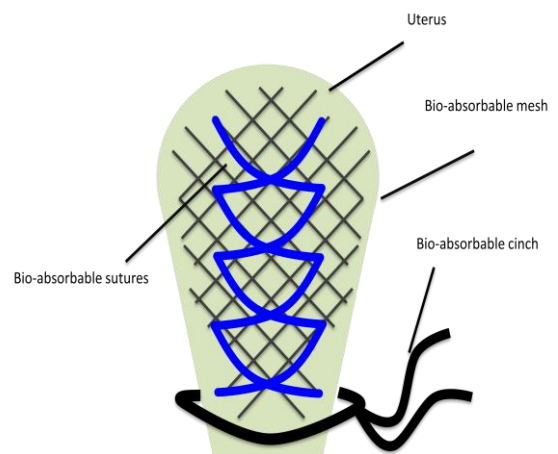


Figure 5: Corset design consisting of two pieces of bioabsorbable mesh connected by cross-linking bioabsorbable sutures.

Vacuum

The vacuum device would consist of a bioabsorbable 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 bioabsorbable 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 [6]. 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 6). 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.

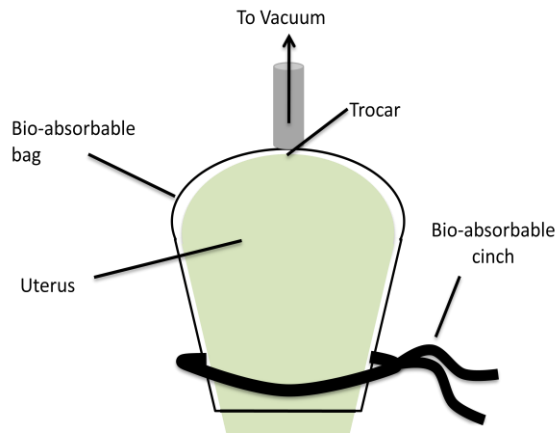


Figure 6: Vacuum Design consisting of a bioabsorbable bag sealed by a medical vacuum.

Parachute

This device would consist of a bioabsorbable 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 bioabsorbable sutures around the lower segment of the uterus. To provide sufficient compression while avoiding bulging, as observed in the B-lynch suture technique, thick bioabsorbable 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 7).

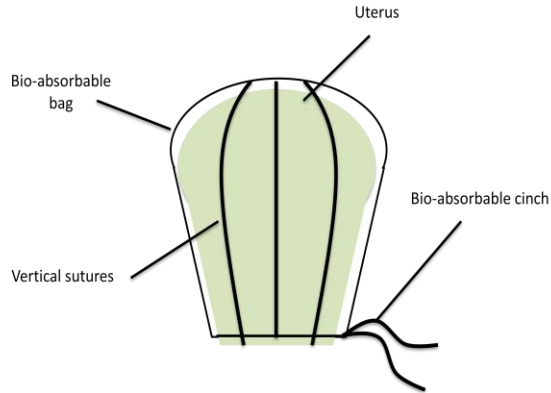


Figure 7: Parachute design consisting of a bioabsorbable sheet fastened by thick, lengthwise bioabsorbable sutures.

Preliminary Testing

Tensile Testing

In order to generate a list of materials to consider for our design we ran preliminary tensile testing on materials that had 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 linear low density polyethylene (LLDPE) bag, a high density polyethylene bag (HDPE 1), and another high density polyethylene (HDPE 2) bag as pictured in Figure 8. Each bag was cut into strips 8 cm long and 20 mm wide. The remainder of the testing followed the protocol in Appendix B.

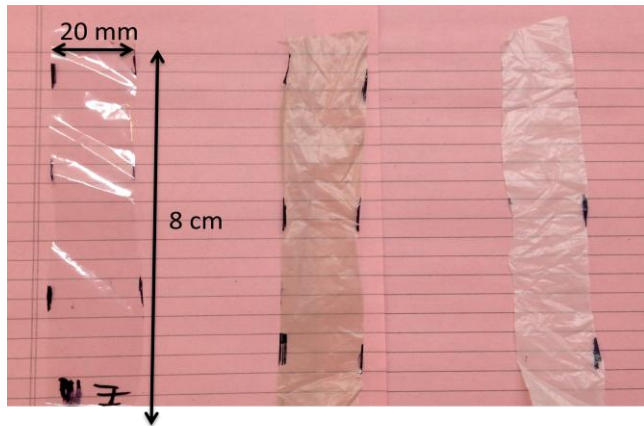


Figure 8: Three polyethylene bags were tested, LLDPE, HDPE 1, and HDPE 2.

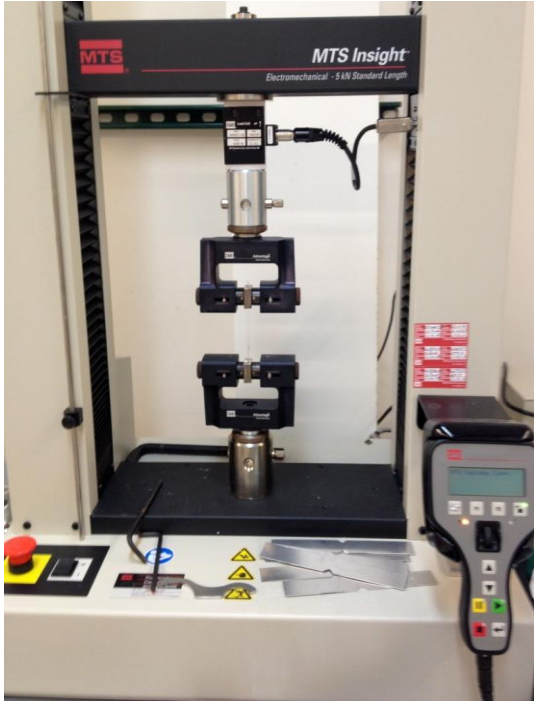


Figure 9: LLDPE sample loaded into the grips of the mechanical tester. Distance between the grips is controlled by the remote seen in the lower right hand corner. As the grips move apart, load and elongation data is recorded.

Briefly, strips were loaded into the grips as seen in Figure 9, and a program was run to pull the ends apart. This generated load and elongation data. To analyze this data, cross sectional area was determined and used to calculate stress from the measured load data. Stress-strain graphs were then generated for each polymer and ultimate tensile strength and young’s modulus were recorded in Table 1. The full data set can be seen in Appendix C. From this table, we generated a list of three materials to consider with properties that were comparable to those we measured, as seen in Table 2.

Material	Young’s Modulus (MPa)	UTS (Mpa)
LLDPE Bag	134.84	7.21
HDPE Bag #1	378.25	23.87
HDPE Bag #2	483.21	28.15

Table 1: Mechanical properties calculated from the tensile testing.

Material	Young's Modulus (MPa)	Ultimate Tensile Strength
PLA	1500	50
PLGA	3000	20
PHB	1500	40

Table 2: Mechanical properties of materials found in the literature that are most comparable to the desired values measured in Table 1 [9, 10, 11].

Material Alternatives

Any materials used for the three design structures described above must be bioabsorbable and FDA approved. There are three different polymer alternatives that we considered implementing. 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 [7]. A ratio of 90:10 is most commonly used for medical applications, such as sutures, due to its higher strength and faster degradation time [8].

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 [8].

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 [8].

Design Matrix

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

Table 3: Design matrix used to compare design alternatives and choose a final design.

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. We will proceed through the remaining design course pursuing the vacuum design.

Materials Matrix

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

Table 4: Materials matrix used to determine the most effective polymer for use in our final design.

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 strength. PLA and PHB scored equally with 22 points because the Young's Modulus (E) is closest to our desired E, as defined by our preliminary mechanical 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 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 a well defined manufacturing processes that could be used to form a thin bag. PLGA scored the lowest with 10 points because manufacturing process are less well defined and formation of a thin bag would 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. We will proceed through the remaining design process with PLA.

Testing

Blown Film Extrusion

In moving forward with PLA, we performed preliminary testing to determine the optimal manufacturing technique. Using a blown film extrusion machine, we tested the polymer's ability to be blown into a thin-film bag.

Briefly, polymer pellets are fed into an extruder, where frictional heat causes the polymer to melt. The melted polymer is then fed up into a basin where the polymer can continue in the shape of a cylinder to the top of the machine where rollers provide a constant upward motion. Air is blown into the center of the cylinder to expand the polymer before it cools into a thin film bag. This process is represented in Figure 10.



Figure 10: Film extrusion blower used to expand melted polymer into a flexible thin-film bag.
<http://www.esrf.eu/UsersAndScience/Experiments/CRG/BM26/pictures/BM26B/LDPE-film-blowing.jpg>

Ethical Considerations

The patient's safety is the primary concern of this device; therefore we must ensure that it does not make the patient more susceptible to infection, further hemorrhaging, or infertility. Since the device will be used in conjunction 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 [12]. 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 price of our device will most likely exceed the budget available in developing countries with a less advanced healthcare system, 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).

Future Work

Testing

After extensive research, we have found that PLA is likely the best material for our purposes; however it is crucial that we experiment with the material at various temperatures, pressures, concentrations, etc. Any observations made about optimal conditions for use of PLA will allow us to make any necessary adjustments to our design. As stated above, our team has begun to test PLA and has attempted to mechanically characterize its properties. This work must continue in order to ensure the material can withstand a pressure of 100 mmHg or higher. Thus, our next step is to order film-blowing grade PLA, since we have been experimenting with extrusion grade PLA. Once we are more familiar with the properties of PLA and are able to film-blow a sheet that may fit around the uterus, testing upon an excised cow uterus obtained from Dr. Lick's laboratory would be necessary in order to see the effect upon uterine tissue.

If testing upon the excised uterus deems a positive result, our client and team would like to pursue live animal testing with the possibility of a sheep lab. Thus, all of members of the group will need to obtain Research Animal Resource Center (RARC) certification. This certification will allow the team to handle the sheep, and eventually test our design using these sheep.

Following animal testing, there is the possibility of human subject testing, which would most likely not occur within the year. However, if the project is advanced to a level that would allow us to do so, all group members would need to receive FDA and IRB certification [13].

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, 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. The purchase of a trocar would increase our total expense by a maximum of \$80; therefore we expect to be well under the proposed budget by our client.

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								
Client		X			X	X								
Team	X	X	X	X	X	X								
Product Development														
Research	X	X	X	X	X	X								
Brainstorming		X	X	X	X	X								
Design Matrix				X	X	X								
Design Prototype						X								
Order Materials														
Fabricate Prototype														
Testing														
Deliverables														
Progress Reports	X	X	X	X	X	X								
PDS		X	X											
Mid Semester PPT						X								
Mid Semester Report						X								
Final Report														
Final Poster														
Website Updates	X	X	X	X	X	X								

Figure 11: Timeline for the semester. Completed tasks are noted by an ‘X’.

As seen in Figure 11, we have been on schedule with the development of our prototype and design, 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 had hoped to have a bag formed out of PLA at this time; however this has not yet become a reality. Nevertheless, we have the material to be ordered ready for purchase, and adequate access to facilities and machinery needed to produce this bag.

Conclusion

In an effort to address the major complication of postpartum hemorrhage during the increasing number of cesarean sections performed each year, we hope to develop a completely bio-absorbable device that will provide complete 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 concluded that a vacuum device made of poly-lactic acid will best meet the design requirements of the client while still providing the patient with maximum comfort and a minimal number of complications.

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Appendix

Appendix A: Preliminary Design Specifications

Uterine compression device: a treatment for postpartum hemorrhage

Product Design Specifications

10/24/12

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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 over twenty-four hours. This could be used in conjunction with a currently used device such as the Bakri Balloon. All aspects of the uterine compression device that are inserted into the patient should be absorbed within six months.

Client Requirements:

- Provide complete compression of the uterus in all direction.
- Ligaments surrounding uterus should be compressed within the hugger.
- Provide constant compression for at least 24 hours.
- Bioabsorbable material that is both durable and absorbable
- Trocar instrument to remove air from uterine cavity.
- Device must be easily and quickly inserted 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 when 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 caused 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 be within the range of 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 of a hysterectomy.

D. Life in Service:

The device must maintain constant pressure for at least 24 hours, and be completely degraded within six 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 must be sterilizable, hemocompatible, and biocompatible. It must also be stored at a range of 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 5cm x 8cm x 4cm with a volume of 80-200mL. 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 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 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 mid-portion 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.
 - a. If compression clamps are installed, switch them out for tension clamps
 - b. Ensure the 1000N load cell is installed and not 500N load cell
2. Tightly secure specimen in the clamps using an L-wrench
 - a. Make sure when securing the specimen, they stay centered within the clamp
 - b. The specimen should cover at least half of the clamp area, and should not hang over the edges
3. Ensure the correct standards are set with a maximum load for -900N to 900N to prevent damage to the machinery.

4. Using the clamp controls, move the head up until the specimen is taught and the load reads positive but small.
5. Press the green arrow to begin the test. It will run until the maximum load is met, or until you stop it.
6. Export Load and Strain data to into excel
7. Convert Load values to Stress values by dividing by the cross sectional area
8. Graph Stress vs. Strain
9. Fit linear portion of the graph with a linear regression to yield the Young's Modulus

Appendix C: Preliminary Testing – Tensile Test Results

See attachment