Uterine compression device: a treatment for postpartum hemorrhage

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Abstract

Postpartum hemorrhage (PPH) is an obstetrical emergency that can follow vaginal or cesarean delivery. It affects approximately 1 in 1000 deliveries and continues to affect more and more women as cesarean deliveries become increasingly prevalent. 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 Polylactic acid (PLA) film wrapped around the uterus. A suction pressure is then applied through the use of a vacuum to compress the uterus in all planes. Our uterine compression device has proven to withstand and apply pressures to the uterus exceeding 250 mmHg, much higher than the minimum pressure of 100 mmHg needed to halt PPH.

Introduction

- PPH is classified as any blood loss over 500 ml following vaginal delivery and 1000 ml following cesarean sections [1].
- In developing countries, 1 in 1000 births results in PPH where it often results in hysterectomy or death [1].
- PPH is the most preventable cause of maternal mortality.
- This complication can arise following placenta accreta or uterine atony.
- Placenta accreta – attachement of the placenta too deep into the endometrium and myometrium.
- Uterine atony – following delivery, myometrium remains thin and uterus remains flaccid.
- Methods and devices currently in use do not successfully halt all blood loss, and many require an additional surgery to remove the substance that was implanted.

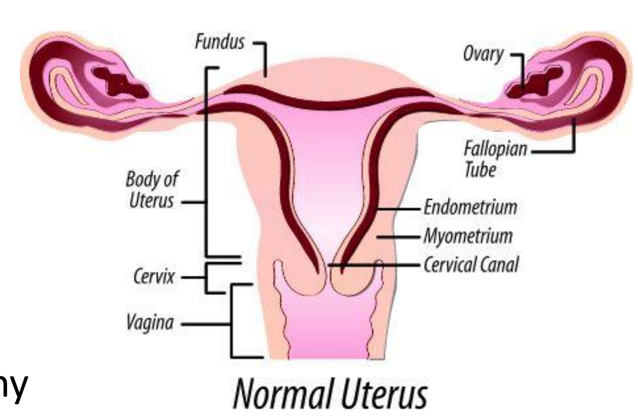

Figure 1: Anatomy of a normal uterus. http://artificialinsemination.wordpress.com/about/reproductive-anatomy/

Design Criteria

- All materials left in body must be FDA approved and 100% bio-absorbable.
- All elements of device must be easily sterilized.
- Device must provide full compression to the uterus for a minimum of 24 hours.
- Device must reach a minimum pressure of 100mmHg.
- Device must be easily handled and implanted.
- All materials must be completely reabsorbed within one year.

Modeling

- Two holes for the vacuum attachment and cervical opening of 10 mm and 25 mm diameters, respectively.
- ρ = 13.332 kPa, t = 0.5 mm, r = 55 mm were used for all stress calculations.
- Using the formula $\sigma = \rho r/2t$ for the spherical model [2], a stress of 733 kPa was found.
- Using the formula $\sigma = \rho r/t$ for the cylindrical model [2], a stress of 1466 kPa was found.
- For the capsule model, stresses found from the cylindrical and spherical models can be used for the separate regions.

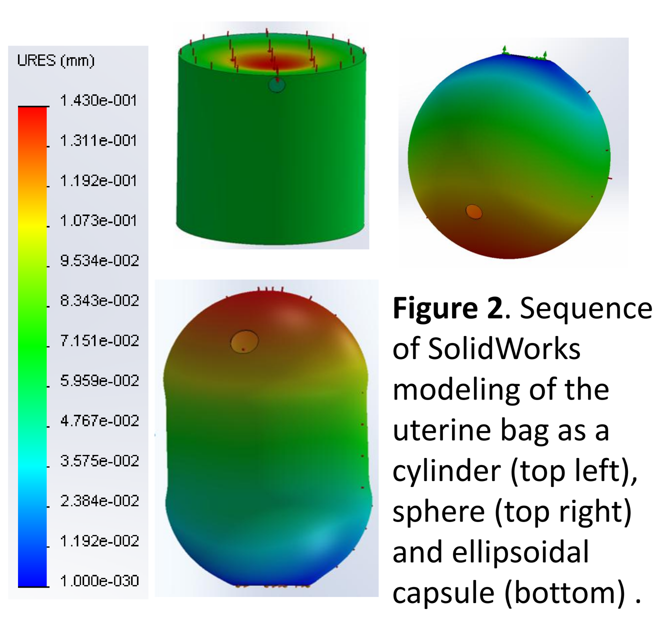

Figure 2. Sequence of SolidWorks modeling of the uterine bag as a cylinder (top left), sphere (top right) and ellipsoidal capsule (bottom).

Final Design

Key Design Components of Uterine Compression Device:

- Solvent casted PLA film: 5% PLA in CCl_4.
- Dimensions of PLA sheet: 140mm x 350mm x 0.65mm.
- Sheet is folded in half and heat-sealed on one lateral edge [Figure 4, A].
- Hand-held impulse heat sealer to fasten film around uterus and cervix.
- PLA sutures to fasten near cervix.
- Trocar inserted through fundus to expel any excess air (Figure 3).

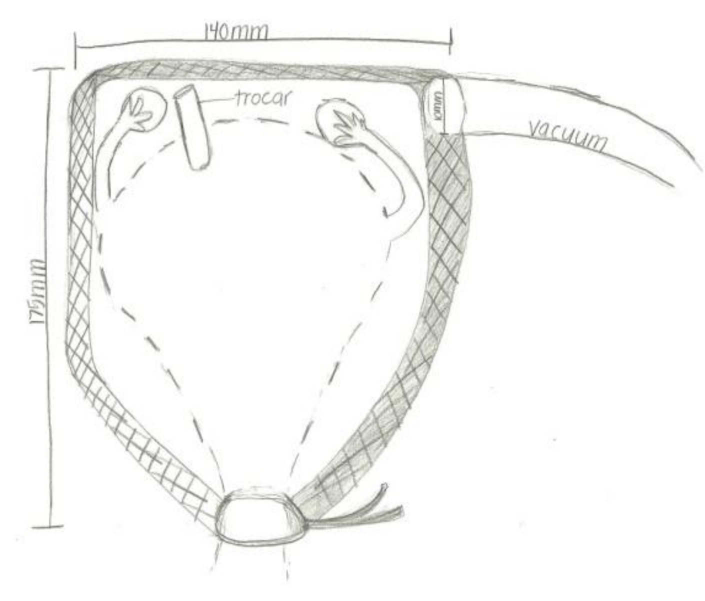

Figure 3. Sketch of final design with final dimensions and all aspects labeled.

Device Implantation and Application of Uterine Compression:

- Insert small trocar into fundus of uterus [Figure 4, B].
- Place PLA film over the top of the uterus [Figure 4, C].
- Heat seal unsealed lateral edge, leaving small opening for vacuum insertion [Figure 4, D].
- Heat-seal bottom edge [Figure 4, D].
- Apply 2-3 PLA sutures around cervix [Figure 4, E].
- Insert vacuum and expel air [Figure 4, F].
- Once all air has been expelled, remove vacuum and heat seal final segment of film.
- Place compressed uterus and PLA film back into abdominal cavity.

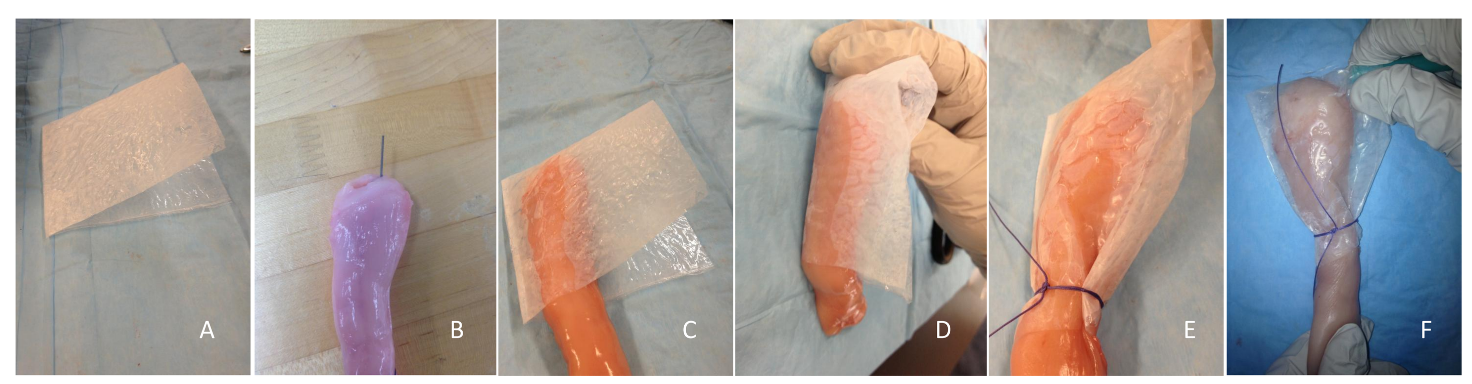

Figure 4. Sequence of device implantation and uterine compression as detailed above.

Tensile Testing

- Drop gauge to measure film thickness.
- Stiffness constant K is an extensive property.

$$K = {AE}/{L}$$

Material	HDPE	LLDPE	HDPE/Nylon	PLA
Thickness (mm)	0.025[3]	0.0254[4]	0.762	0.654

Figure 5: Thickness of material tested as found in the literature or measured using a drop gauge

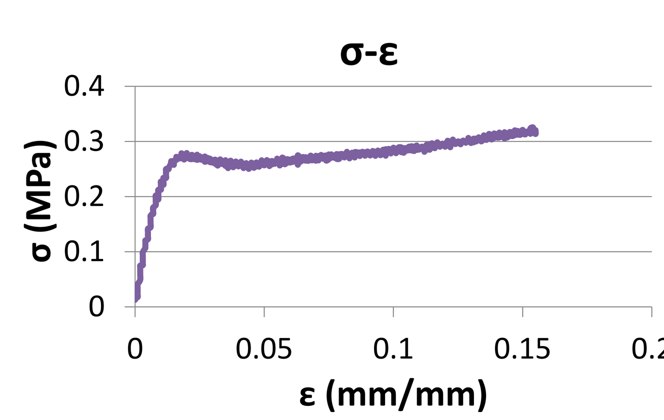

Figure 6: σ-ε curve for our PLLA film

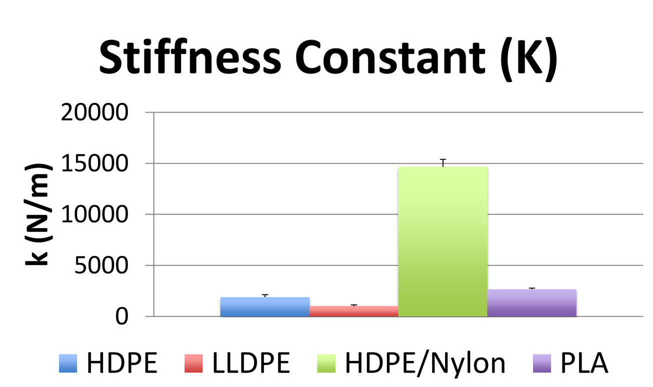

Figure 7: Calculated stiffness constant for various materials

Pressure Testing

- Goal: reach at least 100mmHg.
- Pressure sensor relates voltage to pressure.
- Calibration curve used to calculate values.

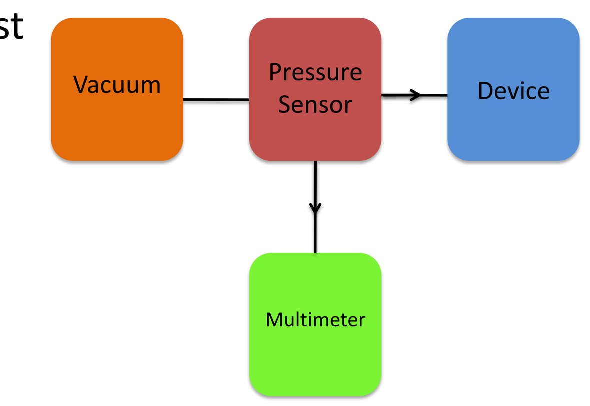

Figure 8: Schematic of the pressure testing.

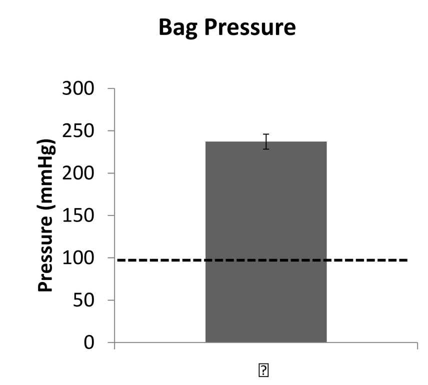

Figure 9: Average maximum pressure reached in the bag in relation to 100mmHg goal.

Discussion

PLA Tensile Testing

- Larger, more distinct elastic region in PLA stress-strain curve.
  - Can withstand larger stresses before plastic deformation.
- Stiffness of PLA similar to HDPE and LLDPE, all lower than currently used vacuum-sealing bag.

Pressure

- Maximum pressure reached surpasses our 100mmHg goal.

Budget

- Currently, well under estimated budget of $1,000.
- Projected costs of PLA, CCl_4, trocar and heat-sealer: $286.

Limitations

- Film used for testing was on a smaller scale than the final product.
- Performed testing using a horn-shaped uterus.

Future Work

- Create appropriate mold.
- Order solvent casting materials, trocar, impulse heat sealer and absorbable sutures.
- Construct a full size sheet (140mm x 350mm x 0.65mm).
- Test completed prototype on cow uterus.
- Perform additional testing on cow uterus to characterize uterine musculature.
- All team members obtain Research Animal Research Center (RARC), Food and Drug Administration (FDA) and Institutional Review Board (IRB) certification.
- Test device in a sheep lab.
- Eventually test device on human subjects.

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[2] Parnas, Levend, & Katriciv, Nuran (2002). Design of Fiber-reinforced Composite Pressure Vessels under Various Loading Conditions. *Composite Structures* 58(1) 83-95.

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