The design of a double-walled stent graft with a comprehensive gas layer in increased compliance

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Introduction and Background

- Dissection of the aorta occurs when the layers of the aortic wall separate to form a false lumen which can lead to complete rupture and/or decreased
- A stent graft is a tube made of a thin metal mesh covered in a polyester fabric.
- Stent grafts effectively seal the false lumen created by an aortic dissection
- Stent grafts circumferential rigidity inhibit the natural compliance of the aorta.
- It was hypothesized that reintroducing compliance to the aorta in the form of a compressible balloon inside the stent graph will reduce the Mean Arterial Pressure.

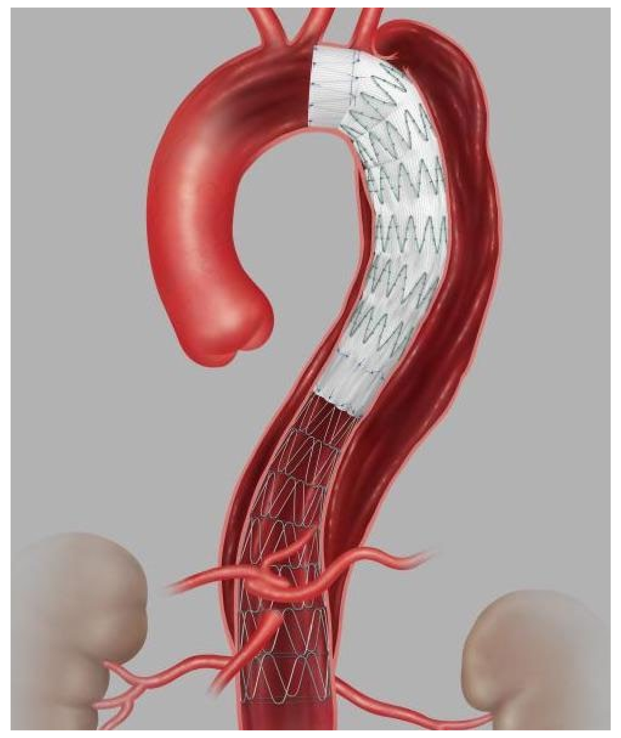

Figure 1: Stent graft placed in descending thoracis aorta

Objective

The goal of this project is to design and build a device that could be fastened to the stent graft that would mimic the native compliance of the aorta. The device when tested in the aorta should lower the downstream pressure compared to an unmodified stent graph.

Materials and Methods

Materials
- 90A Polyether Thermoplastic
- Tabletop Impulse Sealer
- Loctite Light Cure Adhesive 3971
- 4mm medical tubing
- 15cm x 80mm Stent Graft

Methods
- Insert has 5 air pockets that are connected by an air channel 7mm tall
- 10mm section at top and bottom of insert are not pressurized as to allow a space to sew the insert to the stent graft without compromising the balloon
- 7mm opening at the top is where the 5mm medical tubing is inserted

Evolution of design

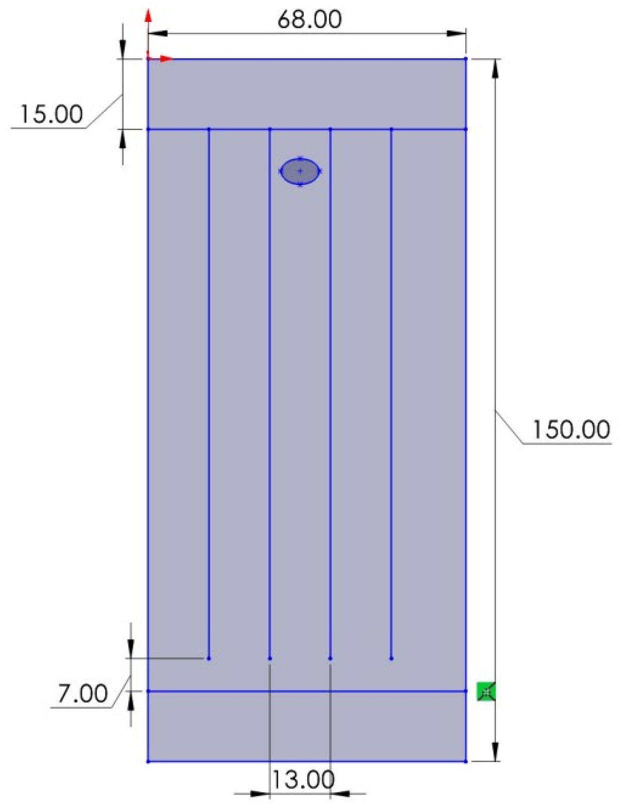

Figure 2: Blueprint of initial design for insert (mm)

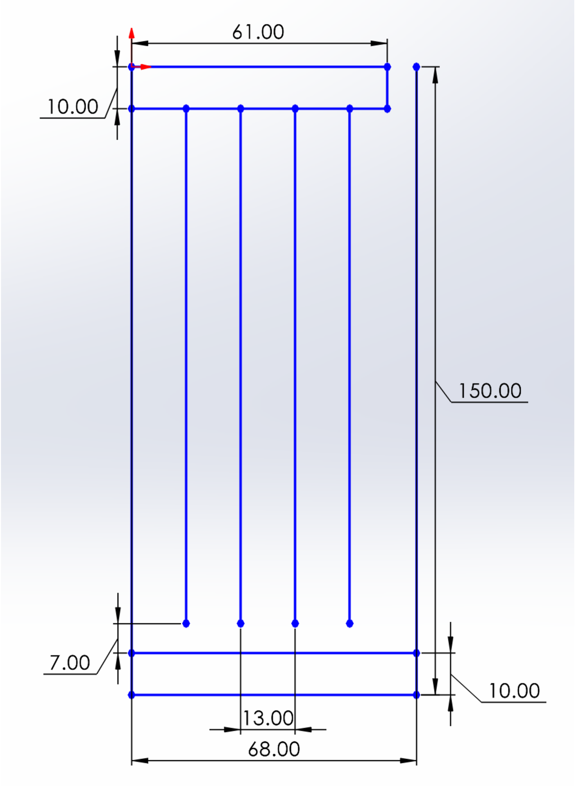

Figure 3: Blueprint of final design for insert (mm)

Results

Figure 3: Intermediate insert design unpressurized

Figure 4: Intermediate insert design pressurized

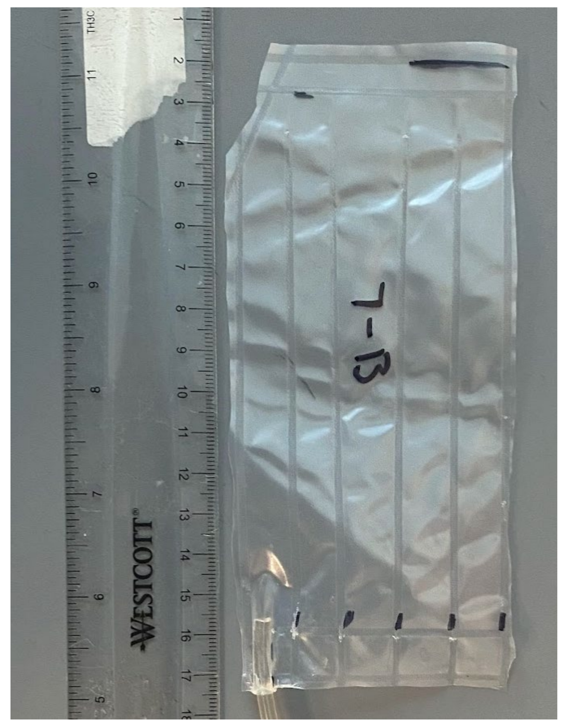

Figure 5: Final insert design unpressurized

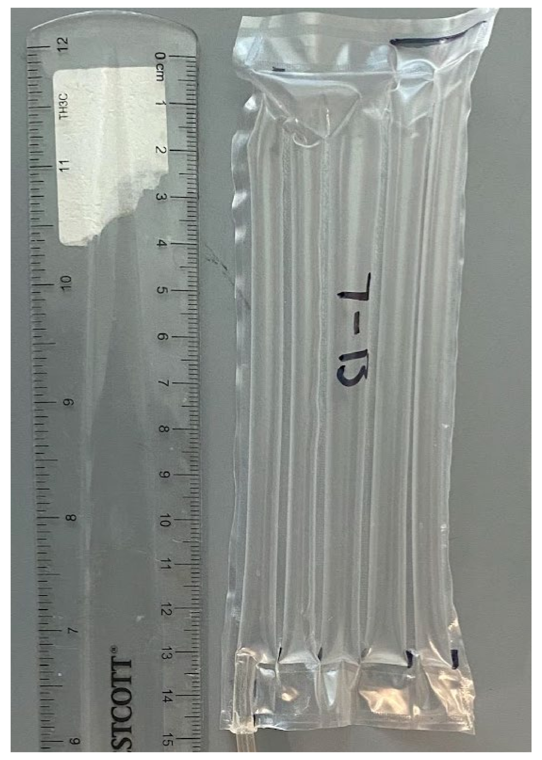

Figure 6: Final insert design pressurized

Success and Failures:

The intermediate design featured two plastic molded pieces to fit the inside pockets at the top and bottom of the stent graft. In this design, the insert was held onto the stent graft by only the friction made by these pieces. This design proved troublesome as the friction was not enough to offset the shear force caused between the blood flow and the insert. During the flow loop test, the insert dislodged causing the experiment to fail. In the final design, the pocket which held the plastic piece was left empty and was used as the anchoring point for the suture that was between the insert and stent graft.

The intermediate design featured the medical tube protruding from a slit cut into the center of the 3rd air pocket as seen in Figure 2. This was a point of failure for many inserts as the glue that sealed the tube to the insert was subjected to high levels of forces over a small surface area. These inserts often leaked which led to inconclusive data as it was not known the exact amount of air in the insert during the experiment. In the finale design, the air tube was moved to the fifth pocket (as seen in Figure 5) and was sealed by gluing the air tube in-between the layers of the insert drastically increasing the surface area for the glue to hold. After these improvements to the design, the study could proceed as the insert was properly pressurized and secured to the stent graft.

Discussion

- The final iteration of the design was used in the most recent flow loop experiment and preformed well. The insert remained firmly attached to the wall of the stent graft.
- The insert was able to handle the intense pressures of the systolic phase of the pump without rupture.
- The new method of sealing the air tube by gluing in-between the layers of the insert has proven to be effective as air no longer leaks from the seal.
- Utilizing the thermoplastic 90A Polyether has increased the durability of the insert so much so that the same insert was able to be used in consecutive experiments. This eliminated the results of both studies to be directly compared to each other
- Future improvements to the design could include adding a polyester fabric to the luminal side of the insert to mimic the stent graft and reduce shear force between blood flow and insert.

References