Fatigue Testing of Transcatheter Heart Valve Commissures

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Background

Fatigue testing of new heart valve designs is performed to verify the valve's capability of withstanding stresses that it will endure during millions of heart cycles. Professor Tranquillo's lab in the Biomedical Engineering Department is developing transcatheter heart valves that use a nitinol wire frame, nitinol stent, and engineered tissue. In order to optimize anchoring sutures between engineered tissue and wire frames, fatigue testing is conducted on entire valves in accelerated wear testers, which can be time consuming and costly.

Because a patient's heart goes through millions of cyclic stresses and changes throughout life, it is important to create engineered valves that can undergo the varying levels of repeated stress and force. One current testing method is conducted post-implantation with the use of exercise and heart monitoring (Piérard & Lancellotti, 2007). However, sometimes the stress testing post-implantation can be too late, which may be dangerous for the patient.

Therefore, there are also up to 50 different inspections and tests conducted on manufactured heart valves, that include microscopic analysis, size analysis, and fatigue testing (M. Sheppard, 2016). The main method used for fatigue testing currently involves a pressurization fixture that tests the entire heart valve in order to determine if the heart valve fails at certain stress levels. The valves are then monitored for cracks, tears, and other issues (M. Sheppard, 2016). This test can be inefficient because an entire valve is needed in order to conduct testing, and each valve can be costly to create.

Materials/Methods

In order to create an efficient and simple system for conducting fatigue testing on the commissures of the heart valve, a linear actuator was used to simulate the pulsing movement of the valve cycle. The linear actuator is a device that converts energy into motion in a straight line. By utilizing the linear actuator to pull the tissue back and forth, the leaflet motion of the heart valve was simulated.

In order to simplify the fatigue testing chamber, instead of testing the entire valve, only a small section of the engineered valve tissue was tested. This involved sectioning the tissue and cutting the wireframe into segments so one commissure post could be tested at a time, as shown in Figures 1 and 2. Sutures were used to attach the wireframes to the tissue, along with mesh fabric for some samples. The tissue was held using plastic grips. The black dashed line in Figure 2 displays where the wire frame and sutures would be located.

Testing was conducted with three different tissue samples, during three different weeks. Each test ran for 7 to 8 days, and the linear actuator moved 5 mm in each direction. The linear actuator completed 90 cycles per minute. Therefore the tissue samples and wireframes were tested for about 907,200 cycles to 1,036,800 cycles. Videos were recorded for each of the tissue samples and measurements were taken. Post-test analysis was also conducted in order to examine any tissue damage that occurred.

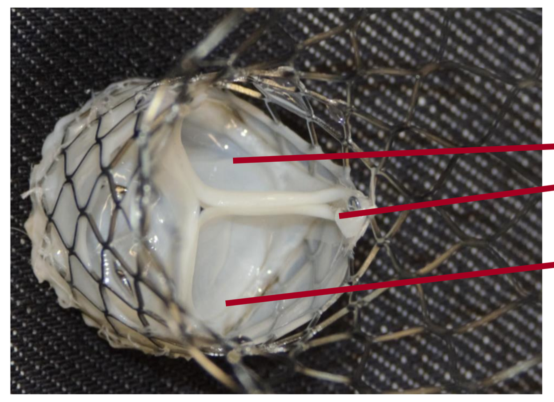


Figure 1: Full valve in a stent

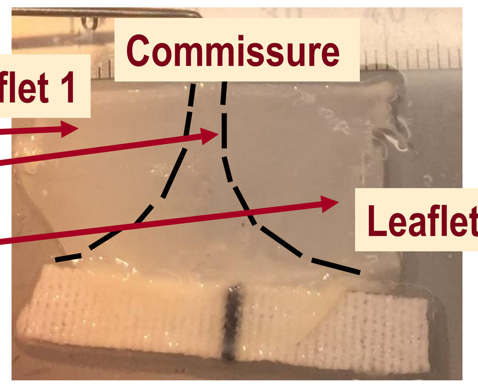


Figure 2: Sectioned tissue

Fatigue Testing Chamber Mechanism

The fatigue testing chamber works by using the linear actuator to convert energy into a linear motion. The linear motion of the actuator was used to pull on the tissue. One end of fishing wire was attached to screws that connected to the moving base of the linear actuator, and the other end was attached to a plastic clip. The red arrow shown on Figure 3 displays the direction of the movement of the base of the linear actuator. The plastic clip was then used to clip onto the leaflets of the tissue sample. The base of the tissue sample and the wireframe were also attached to another plastic clip that was fixed, in order to hold the tissue in place. The linear actuator was then able to pull the clip back and forth, which in turn pulled the tissue back and forth.

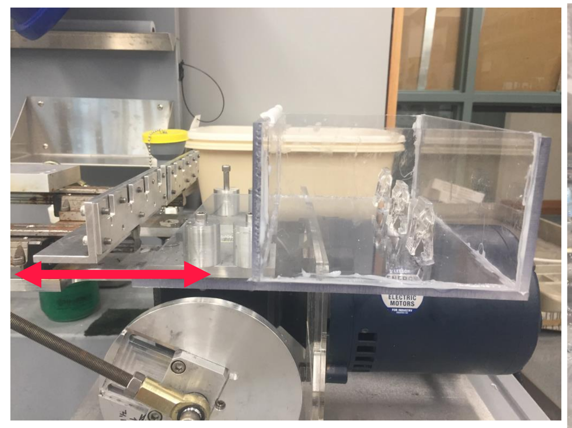


Figure 3: Design 1, side view

Figure 4: Tissue attachment, Design 2

Fatigue Testing Chamber: Design 1

The first design that was created utilized plastic clips glued to the base. A fishing wire was attached to the second plastic clip, which attached to the tissue as shown in Figures 5 and 6 (below). However, when using the linear actuator, the tissue was pulled by an upward force. This is the opposite of what occurs at a leaflet in the body, so the design had to be changed.

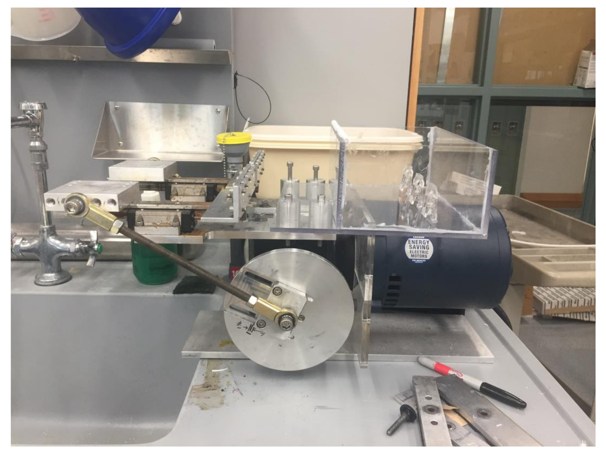


Figure 5: Design 1, side view

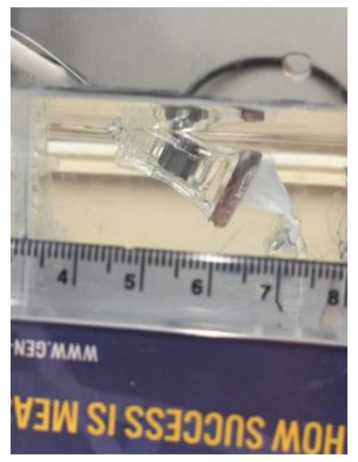


Figure 6: Tissue attachment

Fatigue Testing Chamber: Design 2

The second design created was a modification of the first design. The plastic clips were attached to a bar so that the clips could be hung upside down. This way, the tissues could be held upside down as well, and therefore, when the linear actuator pulled the on the second clip in an upward motion, it was actually pulling the tissue in a downward motion. This motion was more similar to the actual motion of leaflets in heart valves. Figures 7 and 8 display the new design.

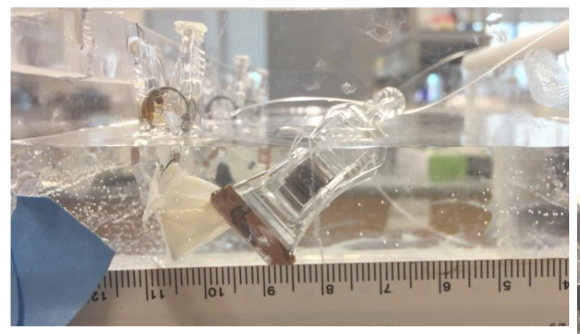
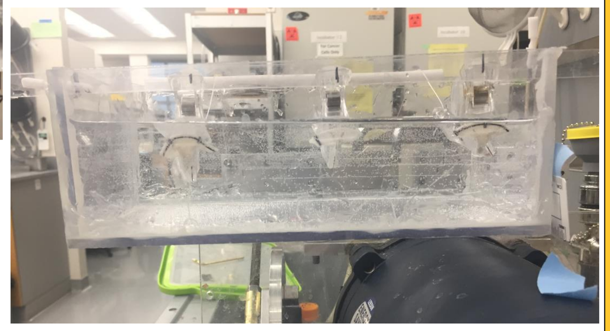


Figure 7: Tissue attachment

Figure 8: Design 2, back-view



Dynamic Strain Measurements

Three main measurements were collected from the videos of the different samples placed in the testing chamber, total tissue length when flexed, total tissue length when not flexed, and deflection. The total tissue length measurements were then used to calculate tissue strain. The tissue strain values, which were found to be in the range of 2-6% were then converted into maximum stress values, which were found to be in the range 16-77 kPa.

Design/Week	Tissue	Total Tissue Length (not flexed) (mm)	Total Tissue Length (flexed) (mm)	Tissue Strain	Deflection (mm)
1-1	1, mesh skirt	9.184	9.692	0.054	0.758
2-2	1, mesh skirt	11.408	10.876	0.048	0.899
2-2	2, mesh skirt	10.759	10.954	0.018	0.795
2-3	3, mesh skirt	8.818	8.946	0.014	1.804
2-3	3, no mesh skirt	10.772	11.025	0.023	0.525
2-3	2, no mesh skirt	8.897	9.445	0.060	1.819
	Average	9.973	10.156	0.063	1.10
	Standard Dev.	1.035	0.826	0.055	0.515

Table 1: Strain and deflection values for each tissue sample

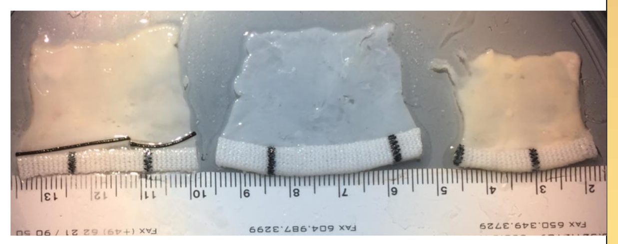


Figure 9 and 10: The images above show the tissues analyzed post-test from the third week of testing. From left to right: Tissue 3 with mesh, Tissue 2 without mesh, and Tissue 2 without mesh.

Further Testing

Further testing can be done using the chamber in order to confirm the benefits of using a mesh skirt. Further testing can also be done on suture patterns that are used to attach the mesh skirt or the wire frame. The mesh skirt was able to protect the tissue, but there could still be tears in the tissue later on if the suture pattern put too much stress in one location of the tissue. This could be tested with different suture patterns, and running the fatigue testing for longer periods. In order to improve the fatigue testing chamber, the tissue could be fixed more securely by fixing the back of the tissue to the clip or the base of the testing chamber. This would allow for more strain on the tissue because the tissue would not be able to bend and flex as much as in the previous two designs.

Post-Test Tissue Analysis

Post-test tissue analysis was conducted in order to determine if there was any tissue damage. The following images display tissue samples that were put through testing with and without mesh, in order to compare damage done. The important features are shown.

With Mesh	Without Mesh

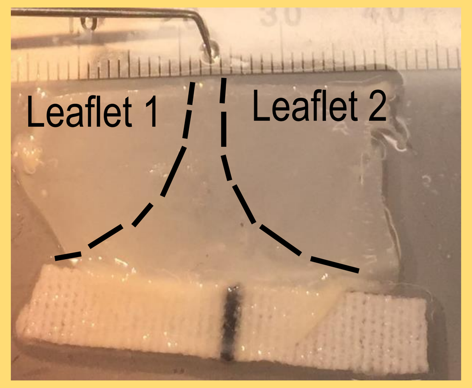


Figure 11: Tissue 2, Design 2, Week 2, with mesh

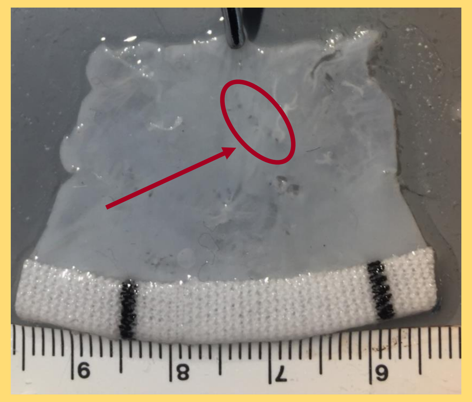


Figure 12: Tissue 2, Design 2, Week 3, without mesh

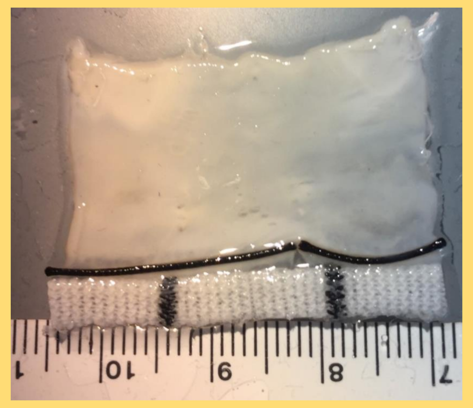


Figure 13: Tissue 3, Design 2, Week 3- with mesh

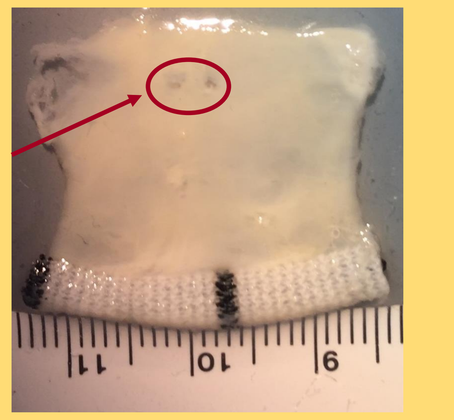


Figure 14: Tissue 3, Design 2, Week 3- without mesh

Conclusions

Using the post-test analysis it was determined that the mesh skirt provided sufficient protection to the tissue (Figures 11-14). Both tissue samples that used the mesh skirt showed no damage (Figures 11 and 13), and both tissue samples that did not use a mesh skirt showed damage, including holes and tears, where the wire frame was attached or touched the tissue (Figures 12 and 14). The range of tissue strain values was found to be 2-6%, as shown in Table 1. These values for strain that was applied to the tissue corresponded to 16-77 kPa of stress applied to the tissue. These values can be used to determine if the fatigue testing chamber accurately applied the correct amount of strain on the tissues, and thus determine if the fatigue testing chamber is an effective way to test tissue samples and commissures of heart valves.

Acknowledgements

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References

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