Analysis of a Medical-grade Material Used in a Cardiac Device

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BIOMEDICAL ENGINEERING
TEXAS A&M UNIVERSITY

CorInnova
Technologies that Lead to Heart Recovery

Introduction

Congestive heart failure (CHF) affects nearly six million people in the U.S.[1] There is a significant unmet medical need for a treatment to extend patients' lives; therefore, a device targeting cardiac function recovery would be beneficial in the medical field. A minimally invasive direct cardiac compression device has been developed that is capable of providing adjustable cardiac support and synchronous active assist after a cardiac episode.[2] A fatigue analysis test was designed to analyze the effect of a crease developing in one of the device's chambers after implantation. The tube was also modeled using finite element method (FE) in Abaqus to investigate stress on the material.

Methodology

- A driver system was set up to generate cyclic air pressure into a tubular chamber made from the device material, Carbothane. Testing ensued for one million cardiac cycles with the chamber submerged in saline.

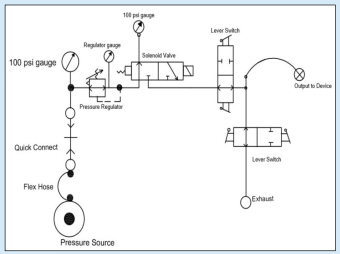

Figure 1. Driver Schematic

Figure 2. Creased tubular chamber

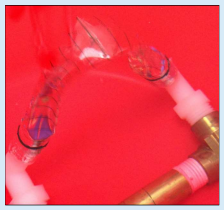

Figure 3. Creased chamber at lowest pressure

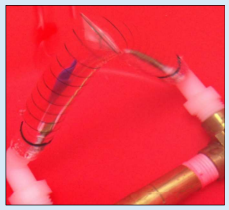

Figure 4. Creased chamber fully pressurized

- A function generator was programmed to signal square waves at a frequency of 2.3158 Hz and an amplitude of 5 V.
- The holes and deformation of the material were analyzed with an AVEN zipScope.
- Abaqus was used to model two tubes- one with rigid attachments on the ends and one with a crease.

Results

Fatigue Analysis

Figure 5. 0.213 mm cut on left end

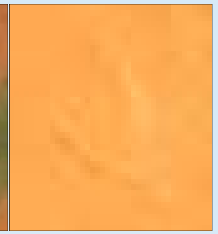

Figure 6. 0.534 mm cut on right end

Figure 7. 1.4195mm cut near the crease

Figure 8. The tubular chamber was reinforced with latex around the attachment area. Holes still developed around the attachments.

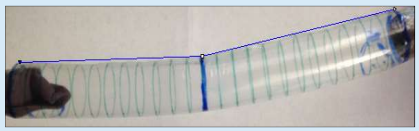

Figure 9. Post-testing deformation: Tube was originally 180 degrees and is now 170 degrees

FEA

Creased tube was generated with 832 quadrilateral elements. Straight tube contained 955 elements.

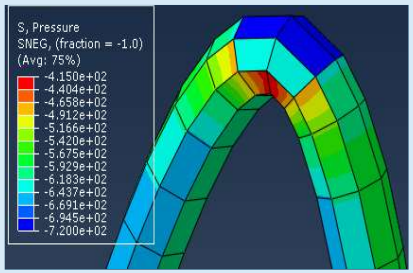

Figure 10. Stress from pressure at the crease of the tubular chamber.

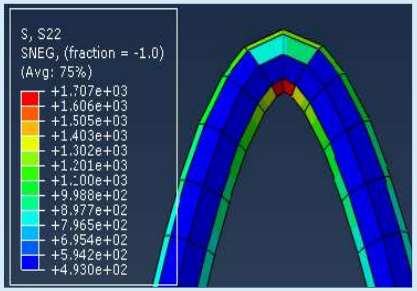

Figure 11. Maximum shear stress in the creased chamber.

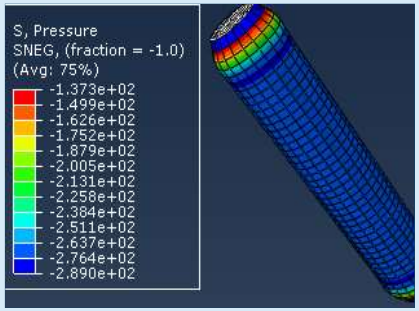

Figure 12. Stress from pressure at the end of a tube with rigid attachments.

Discussion

- After 200,000 cardiac cycles of the fatigue test, a 0.53398 mm hole was found on the right side of the tubular chamber near the base. Two more holes were found after 400,000 cardiac cycles had been completed. One of the two holes was found at the base and measured 0.213 mm. The other hole was 4 mm to the left of the crease and measured 1.4195 mm in length. The creased tubular chamber was permanently deformed after a million cardiac cycles.
- Abaqus FE analysis revealed pressure peaks around the creased area as well as where the rigid tubes are attached to the tubular chamber. The values of shear stress at the crease are comparative to the tensile strength of the Carbothane material.

	Load at Peak (lbf)	Tensile at Peak (psi)	Tensile at Break (psi)	Tensile @ 100% (psi)
1	42	8320	8320	1489
2	44	8574	8574	1469
3	41	8092	8092	1468

Figure 13. Carbothane tensile strength.

Conclusions

- The crease in the tubular chamber had a significant effect on the durability of the chamber.
- When high stress is added to the Carbothane material, it behaves as a plastic.
- Carbothane undergoes elastic deformation and plastic deformation, resulting in fracturing of the material.
- Future iterations of the device should take into account the effect of rigid attachments and the development of a crease after implantation due to the high stress risers they create.
- In the future, a more elastic material should be sought after for device construction.

References

[1] Hosenpud, JH, *J. Heart Lung Transplant*, 2000, 19, pp. 909–31.
[2] Moreno, MR, et al. *J. Med. Devices*. 2011. 5(4): 041008

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