Developing an Inductive Stent to Accurately Detect the Occurrence of In-Stent Restenosis

Literature Review

- Restenosis is the reduction of the lumen diameter, hollow structure of an artery post surgery
  - Seen as narrowing
  - Stents are a common solution to this, expanding the diameter of the narrowed area as shown in Figure 1
- Classified as restenosis if the reduction occurs after percutaneous coronary intervention (PCI)
  - Through the skin
  - With or without stent implants
- Restenosis often leads to a reversion back to angina symptoms or symptoms of acute artery syndrome
- Typical treatment is a reintervention post diagnosis of restenosis (Buccheri, Dario)
- Approximately 30% of patients have in-stent restenosis within 6 months of treatment
- Several methods have already tried to combat restenosis
  - Most notably is drug eluting stents (DES)
- DES help prevent plaque buildup
- These are coated with medicine that is gradually released into the bloodstream
- If any complications happen such as restenosis, chest pain, etc., surgery would be needed and in some cases a brand new DES will be needed (Thomas, Liji)
- CAD models have shown effective in determining durability and impact of different stents
  - Everolimus-eluting stent (EES), a type of DES
  - Saurabhi and team Performed finite element analysis on EES (FEA) to compare varying lengths of stents dependent on the length of stenosis
  - Was able to compare performance of each stent at various conditions
    - Stent expansions, comparing mean inner stent diameter
    - Vessel scaffolding, comparing circular cell diameter
    - Exemplified the importance of CAD modelling in stent design (Saurabhi, Samant)

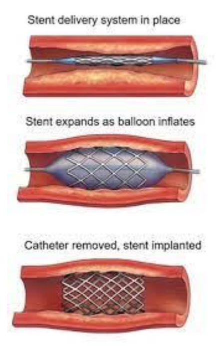

Figure 1

Problem Statement

The purpose of this project is to design a stent to properly diagnose in-stent restenosis prior to the development of pre-surgery severity.

Solution

- Design an inductive stent
  - A stent having the ability to transmit signals
- Inductive stent will be placed in the narrowed area and transmits signals to the doctor through a transmitter
- Transmitter relays to the doctor if the stented area is narrowing post implementation

Criteria & Constraints

- Criteria
  - Must achieve a FOS value of greater than 1
  - Have the magnetic field given off by the transmitter reach the stent
- Constraints
  - Time
  - Inability to test the model in a real surgery

Experimental Design

1. Learned and practiced the foundations of Solidworks, a CAD modelling software, with respect to the part features and flow and static simulations
2. Designed a traditional stent using a variety of tools within a part feature with the dimensions provided by the mentor
3. Ran a flow simulation on the model to determine the pressure distribution of the traditional stent with a constant blood flow and when exposed to body temperature (310.15 K)
4. Imported the flow simulation results into a static simulation to act as external loads, to add blood flow pressure onto the stent
5. Fixed the geometry at the top of the stent to be able to run the static simulation
6. Added a custom material, nitinol, which was applied to the stent, as nitinol is used in biomedical applications due to its expansive properties in body temperature
7. Ran the static simulation and the stress, displacement, strain, and factor of safety (FOS) plots were defined to determine the performance and structural integrity of the design
8. The model was then imported into the Ansys Electronics Desktop software to run conductivity simulations
9. The model was surrounded by a layer of gold to improve its conductive abilities
10. The transmitter was added as an identical stent with a larger diameter and placed 10mm away from the original stent
11. A frequency was added as 13.56 MHz for the design to operate at
12. An excitation was assigned as a lumped port was added with an impedance value of 50 ohms to both stents to act as the capacitors
13. The model was simulated and the magnetic field was plotted to show the conductive ability of the setup

Results

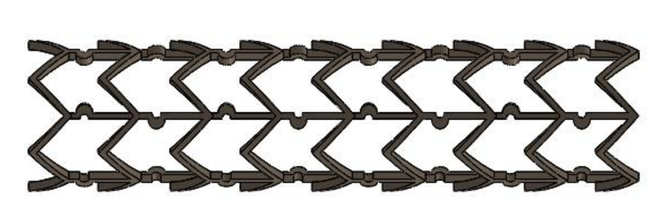

Figure 2: Design of the traditional stent
Diameter = 3.0 mm

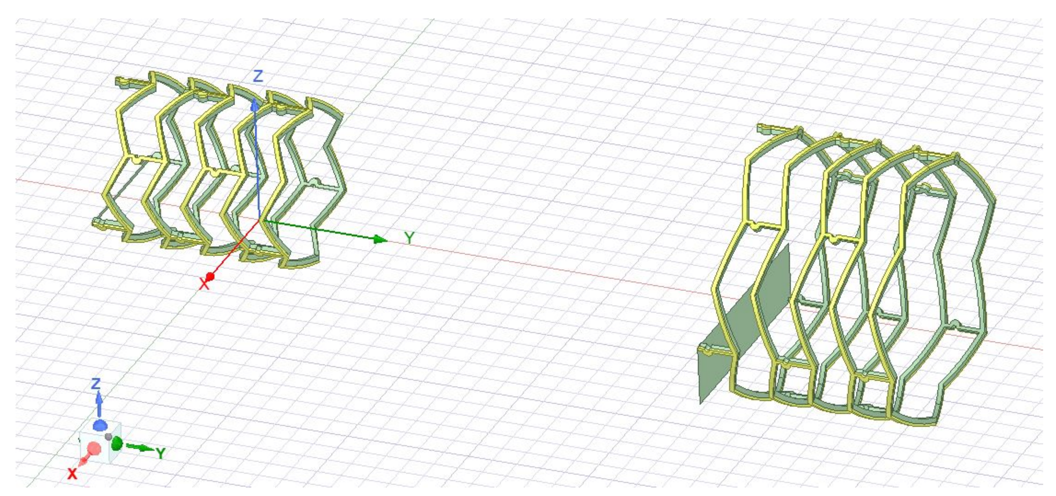

Figure 4: Setup for conductive simulations

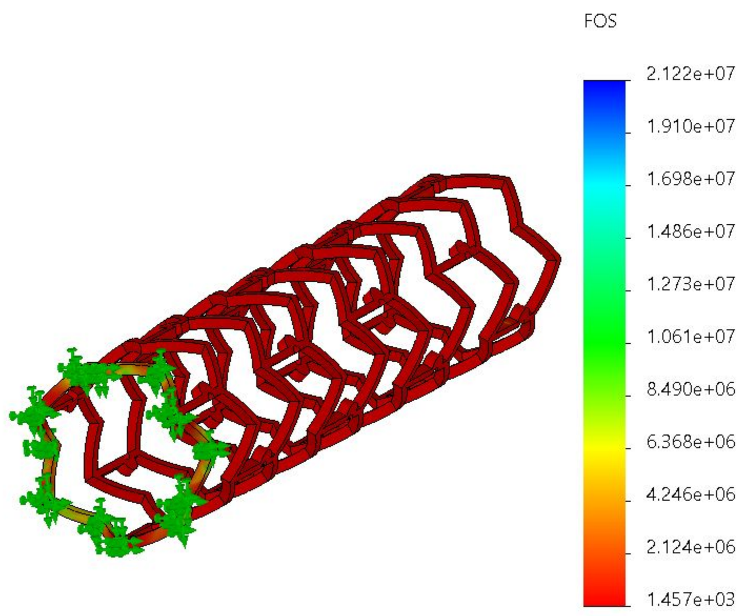

Figure 3: Defined Factor of Safety (FOS) plot
Shows the min FOS = 1.5e03

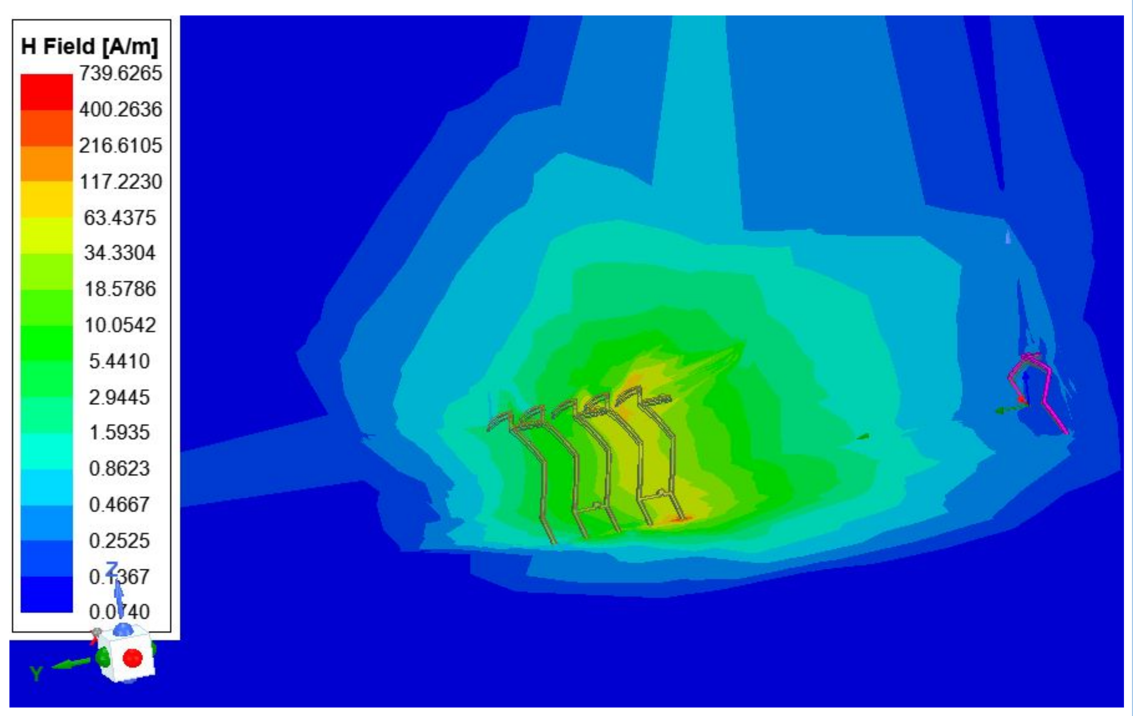

Figure 5: Plot of the magnetic field

Conclusions

- Design of the inductive stent shows structural stability
  - Structural stability dictated by the factor of safety (FOS)
  - FOS is calculated as tensile yield strength divided by the von mises force
  - A structure is stable if the minimum FOS is greater than 1
  - FOS simulation ran on this project's design calculates a minimum FOS as 1.5e03 as shown in Figure 3
  - Stability is further shown in the simulation as almost all of the model is experiencing the maximum force provided
    - Shown as the model contour is red throughout, representing the minimum FOS which is minimized at the maximum von mises force
- As the structural stability of this model is verified, it can now be used as the base for the addition of capacitors and the transmitter
- From Ansys Simulations
  - Model shows to have a magnetic field which reaches the stent as shown in Figure 5
    - Seen as the blue field reaching the stent
  - Shows viability of the design and can be further optimized by varying the number of connectors and rings
- Limitations of this project
  - Time for completion of the project
  - Materials needed to be manually added to software material libraries
  - Unable to test the performance of the design in an experimental setting to verify the results of the online simulations

Future Steps & Implications

- Further Optimization
  - Vary connectors and rings to manipulate the length and structure
  - Run the same conductivity simulations to find the strongest design
  - Goal is for the red field to encompass the stent
- 3D Printing
  - Print the physical model of the design and test the model under the same conditions in a real life setting
  - Would verify the models structural integrity and establish how the transmitter would work for the doctor's point of view
- Implications
  - Detects in-stent restenosis before a reversion to pre-surgery complications
  - Removes the need of open intervention
  - Removes the risks associated with open intervention or relapse to the previous condition

Works Cited

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