Modeling Balloon Inflation of Percutaneous Transluminal Coronary Angioplasty for Coronary Stenosis Treatment

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***Abstract*— This project intends to study and simulate the percutaneous transluminal coronary angioplasty (PTCA) using a balloon catheter to treat coronary stenosis treatment. A plastic tube with an inflatable balloon at one end is inserted to the narrowed coronary artery where plaque had built up. Balloon is inflated multiple times to compress the plaque and widen the artery. Selecting the optimal balloon material in different scenarios is crucial to carry out PTCA [1]. The model demonstrates the comparison of various materials' mechanical properties such as inflation pressure and hoop stress applied to the balloon when stretched using COMSOL [2].**

I. Introduction and Background

Coronary artery disease is one of the leading causes of death in the United States and causes over 15 million deaths worldwide every year [3]. It refers to the state when the coronary arteries thicken and narrow from fatty plaque building up, interfering with blood flow. Less blood flow in the coronary arteries decreases delivery of oxygen and nutrients to the heart which can be detrimental to human health causing shortness of breath, chest pain, heart failure, heart attack and even death. Coronary artery disease progresses at a slow pace, over decades, allowing for plenty of time to prevent it from developing into serious health problems. A lot of the prevention methods come from changing lifestyle habits such as not smoking, exercising regularly, keeping the weight at the normal body mass index range, eating less of the saturated/trans fats, salt, and sugar but more of mono-/poly-unsaturated fats and fiber [1][4].

Once the disease has developed where medical intervention is needed, there are two techniques to treat the disease: coronary artery bypass surgery and percutaneous transluminal coronary angioplasty (PTCA). During a bypass surgery, a healthy blood vessel from the chest or leg area is connected below the blocked heart artery. During PTCA, a balloon catheter is inserted into the blocked artery. The balloon inflates and pushes the fatty plaque against the artery wall (Fig.1). The balloon catheter is inflated multiple times for approximately one minute per inflation until blood flows freely. Imaging such as X-ray imaging is done to confirm the artery is open [1][2][6]. PTCA is preferred over bypass surgery thanks to it being an outpatient care, minimally invasive, and allowing fast recovery while bypass surgery is an inpatient care that requires at least 7 days of recovery in hospital. Depending on the severity of the disease and other health conditions of the patient, the doctor decides which treatment to take [5].

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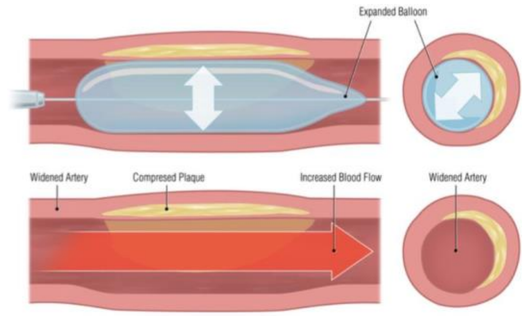

Figure 1. PTCA Procedure [1]

II. Significance and Innovation

The PTCA performance would be different based on various balloon sizes, materials, construction structures, and compliance of the balloon to the artery. Depending on the location and severity of the plaque, PTCA catheter is required to have varied properties and characteristics [7]. Better understanding of the balloon inflation can be beneficial to perform a safe and efficient PTCA procedure that is personalized to suit the patient's disease severity [8].

This project focuses on analyzing and improving the control of balloon inflation during PTCA. In particular, we look into the materials of the PTCA balloons. The relationship between the stretch of balloon versus the inflation pressure and first principal stress applied to the balloon is studied. They reflect the inflation and deflation capabilities and requirements for various materials. We simulated this with different balloon materials, silicone and polyurethane, to evaluate the performances of rubbers that are used for PTCA. The results of this paper's simulation are going to serve the design of the PTCA balloons.

III. Methods

We study the relationship between the stretch of the balloon versus the inflation pressure and first principal pressure. Inflation pressure is the measurement of pressure in units of Pascals required to stretch the material to the desired stretch value. First principal stress is the measurement of stress applied in normal direction to the plane, also in units of Pascals, and typically represents the maximum (tensile) stress applied to the plane [9]. These two variables being measured can show the rigidity and sensitivity of different materials to pressure. In order to do that, we simulate inflation of balloons of different materials using different hyperelastic material models in COMSOL. The balloon simulated is spherically symmetric, and the 45-degree angle sector in a 2D axial symmetry plane is shown below in Fig.2.

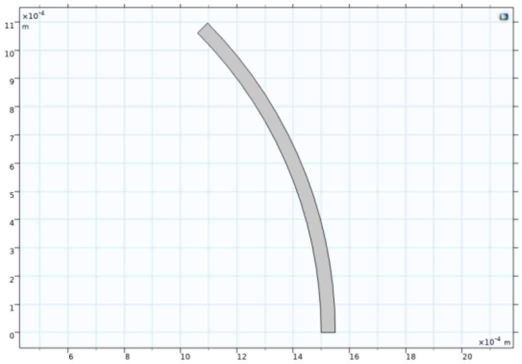

Figure 2. 2D Axisymmetric Mesh

PTCA balloon catheters are typically made of polyurethane or silicone. These materials stretch from 100 % to 800 % and are often used in applications that require the balloon to fully conform to the anatomy [10].

For each material, the following characteristics are used: density, bulk modulus, shear modulus, and Poisson ratio (Table 1). The bulk modulus is the ability of the material to withstand compressions from all directions that cause an overall volume change. The shear modulus is a measurement for rigidness: the ability of the material to withstand deformation due to forces applied parallel to the material surface. The Poisson ratio is a measure of the ability of the material to withstand deformations in directions perpendicular to the direction of force.

TABLE I. MATERIAL PROPERTIES

Material/ Property	Density (kg/m3)	Bulk Modulus (GPa)	Shear Modulus (GPa)	Poisson Ratio
Silicone [11]	1700	1.75	0.0102	0.27
Polyurethane [12]	975	4.65	0.00105	0.39

Two hyperelastic material models used are Neo-Hookean and Ogden, which typically result in a nonlinear stress-strain relationship. By defining the elastic strain energy density expressions, one can create corresponding hyperelastic material models. In COMSOL, the Nonlinear Structural Materials Module offers a variety of pre-established material models. These models allow users to input parameters for the elastic strain energy density expressions [13].

For Neo-Hookean, bulk modulus and shear modulus are entered. For Ogden, shear modulus and parameter beta, which is derived from the Poisson ratio, are entered. The Neo-Hookean model is known to model the experimental data at high accuracy at low to moderate strains levels, but fail at high strains. The Ogden model is adapted from the Neo-Hookean model, and is suitable at modeling hyperelastic deformation at high strains.

IV. RESULTS

Our COMSOL simulation results show that silicone requires more pressure to inflate than polyurethane. Silicon requires 300-400 MPa while polyurethan requires about 50 MPa. The result aligns with the fact that silicone has a greater, approximately 10 times larger, shear modulus than polyurethane, which makes silicone much harder to inflate than polyurethane. Different models result in slightly different results since they use different material properties and equations, but they still show similar trends for the same materials (Fig.3, Fig.4).

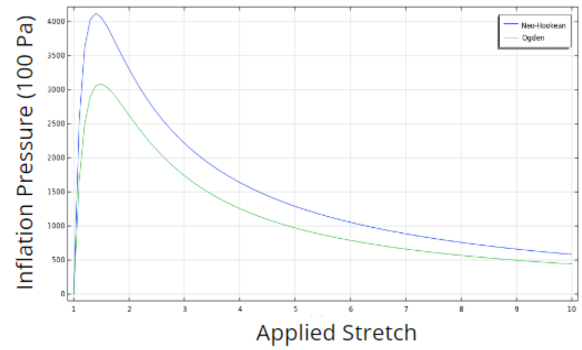

Figure 3. Inflation Pressure Profile of Silicone

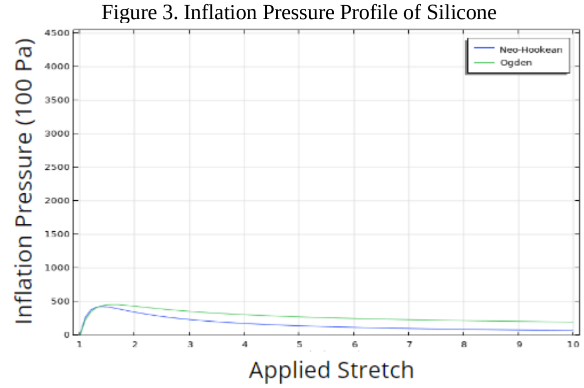

Figure 4. Inflation Pressure Profile of Polyurethane

The first principal stress required for a silicone balloon is higher than that of a polyurethane balloon for both models. This result aligns with the inflation pressure profiles obtained above. Silicone is much more rigid, so it makes for it to require higher tensile stress to expand in the normal direction to the surface. Again, there are slight differences in the exact stress values for each material, but they show similar trends. The difference results from the different approximations, equations, and parameters used for the different models (Fig.5, Fig.6).

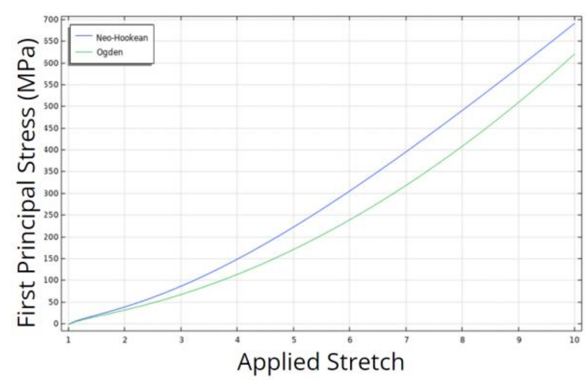

Figure 5. First Principal Stress Profile of Polyurethane

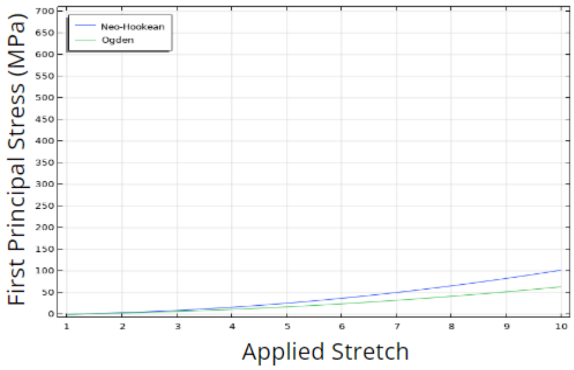

Figure 6. First Principal Stress Profile of Polyurethane

From these results we concluded that a polyurethane balloon is more efficient to operate since it requires significantly less pressure to inflate than silicone. It also requires less pressure change to inflate to different degrees. In contrast, a silicone balloon is more suitable for procedures that do not require significant inflation. Also, it is more applicable to situations that require fine tuning of the balloon size since large pressure change is required to inflate the balloon to different degrees.

To explore the application of silicone and polyurethane balloon catheters specifically to PTCA, other properties affecting the PTCA procedure are researched. Based on the performance of catheters already existing in the market, polyurethane has high resistance to tension and breaking loads and allows for increased fluid flow given the same size of expansion. Silicone has high resistance to bacterial adhesion but has a low mechanical stability due its rigidness and brittleness. Some common mechanical failures of silicone balloon catheters are dislocations, ruptures, and tip migration. If the silicone balloon is ruptured during the PTCA procedure, it can lead to even more complicated and detrimental problems in the artery. Both materials have risks of infection and thrombosis caused from the insertion of catheters, but these problems can be reduced by drug coating the catheters and taking antibiotics, regardless of the balloon material choice [14][15]. Considering all these aspects, it is concluded that polyurethane is more suitable for PTCA in general.

V. Conclusion

Based on the COMSOL simulation results and properties of silicone and polyurethane catchers, it can be concluded that polyurethane is more suitable for PTCA in general. Polyurethane balloons can be expanded with significantly less pressure and are more durable than silicone balloons. Silicone balloons require much higher pressures to inflate, so they may be applicable for extremely fine tuning the balloon size, but are fragile, posing safety concerns. Silicone catheter is recommended for specific cases where only a small degree of inflation is required so not as high pressure is required so that risk of mechanical failure is decreased.

Further work in modeling balloon inflation is to try using other hyperelastic material models to confirm the results from the Neo-Hookean and Ogden models. In addition, if experimental data of silicone and polyurethane balloon inflation can be obtained, comparing those data to the model simulation results can be helpful in determining which model depicts the experimental data the best, meaning it is the most suitable model for simulating inflation of silicone and polyurethane balloons.

Acknowledgment

Chu and Kim thank Dr. Siyang Zheng and Teaching Assistant Vaishak Harish for their support and feedback during the course and the project.

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Appendix. COMSOL instructions

Protocol [16]:

1. Open a new COMSOL File and define the following:
    a. Model Wizard > **2D Axisymmetric**
    b. Select Physics > Structural Mechanics > **Solid Mechanics (solid)**
    c. Study > General Studies > **Stationary**
2. Define Parameters:
    a. Model Builder > Global Definitions > **Parameters 1**

Name	Expression	Value	Description
Ri	1.5[mm]	0.0015 m	Inner radium
H	50[um]	5E-5 m	Thickness
stretch	1	1	Applied stretch
mu	0.00105[GPa]	1.05E6 Pa	Shear modulus
kappa	4.65[GPa]	4.65E9 Pa	

3. Create the Geometry:
    a. Model Builder > Geometry1 > Unit > **m**
    b. Model Builder > right click Geometry > circle (In the "Setting Window", set the following values)
        i. Rename as r1
        ii. **Radius** = Ri+H, **Sector angle** = 45
        iii. **Layers**:

Layer name	Thickness (mm)
Layer 1	H

    c. Model Builder > right click Geometry > **Delete Entities** (In the "Setting Window", set the following values)
        i. Entities or Objects to Delete > Geometric entity level list > **Domain**
        ii. Object c1 > Domain 1 only
4. Define Material Models:
    a. Model Builder > Component 1 (comp1) > right-click Solid Mechanics (solid) > Material Models > Hyperelastic Material
        i. Label text field > type Neo-Hookean
        ii. Domain Selection > Selection list > All domains
        iii. Hyperelastic Material > Compressibility list > Nearly incompressible
        iv. κ text field > type kappa
        v. μ list > User defined > type mu
    b. In the "Definitions" toolbar > Domains > Hyperelastic Material
        i. Setting > Label text field > type Ogden
        ii. Domain Selection > e Selection list > All domains
        iii. Hyperelastic Material > Material model list > Ogden
        iv. Add twice
        v. κ text field > type kappa
        vi. Ogden parameters table

p	Shear Modulus(Pa)	Alpha parameter (1)
1	6.3e5	1.3
2	0.012e5	5
3	-0.1e5	-2

5. Define Domains and Boundaries:
    a. In the "Physics" toolbar > Boundaries > **Roller**
        i. In the "Settings window" set Input Entities: Boundaries 1 and 2
    b. In the "Physics" toolbar > Boundaries > **Boundary Load**
        i. In the "Settings window" set Input Entities: Boundary 3
        ii. In the "Settings window" set Force: choose **Pressure** from the Load type list
        iii. p text field > p_f
    c. In the "Definitions" toolbar > Nonlocal Couplings > **Integration**
        i. In the "Settings window" set Geometric entity level list > **Point: Point 3**
        ii. In the "Settings window" set Source Selection > Advanced: choose **Material (R, PHI, Z)** in Frame list
        iii. Clear the Compute integral in revolved geometry check box
    d. In the "Definitions" toolbar > Local Variables > **Variables 1**
        i. In the "Settings window" set Variables section

Name	Expression	Unit	Description
ub	intop1(u)	m	Radial displaceme nt

    e. Model Builder > Show More Options > select the physics > Equation-Based Contributions check box
    f. Click OK
    g. In the "Physics" toolbar > Global >

Global Equations

i. In the "Settings window" set the Global Equations

Name	f(u,ut,utt,t) (1)	Initial value (u_0) (1)	Initial value (u_t0) (1/s)	Description
p_f	ub-u_appl	0	0	

ii. Units > Click Select Dependent Variable Quantity
iii. Physical Quantity > type pressure
iv. Click Filter
v. Select General > Pressure (Pa)
vi. Click OK
vii. In the "Settings window" for Global Equations, click Select Source Term Quantity
viii. In the Physical Quantity > type displacement
ix. Click Filter
x. Select General > Displacement (m)
xi. Click OK

h. Model Builder > Component 1 (comp1) > Definitions > **Variables 1**

i. In the "Settings window" put in the expression

Name	Expression	Unit	Description
p_Ogden	2*(H/Ri)*(mu1*(stretch^(alpha1-3)-stretch^(-2*alpha1-3))+mu2*(stretch^(alpha2-3)-stretch^(-2*alpha2-3))+mu3*(stretch^(alpha3-3)-stretch^(-2*alpha3-3)))	Pa	Pressure
sp1_Odgen	mu1*(stretch^alpha1-stretch^(-2*alpha1))+mu2*(stretch^alpha2-stretch^(-2*alpha2))+mu3*(stretch^alpha3-stretch^(-2* alpha3))	Pa	Hoop stress

i. Mesh > Mapped > Mapped 1 > Distribution

i. Select Boundary 2
1. Settings > Distribution > enter 3 for number of elements

ii. Select Boundary 3
1. Settings > Distribution > enter 50 for number of elements

iii. Right-click **Mesh 1** and click Build All

6. Add Models to Study

a. Build Neo-Hookean: Model Builder > Study 1 > Step 1: Stationary > Physics and Variables Selection

i. Check the box for "Modify model configuration for study step"
ii. Select and disable the following: Component 1 (comp1) > Solid Mechanics (solid), Controls spatial frame > Mooney-Rivlin, Component 1 (comp1) > Solid Mechanics (solid), Controls spatial frame > Ogden, and Component 1 (comp1) > Solid Mechanics (solid), Controls spatial frame > Varga
iii. Set the applied stretch from 1 to 10: Study Extensions > Auxiliary sweep > enter the following values to the table

Parameter name	Parameter value list	Parameter Unit
stretch (Applied stretch)	range (1, 0.1, 2) range(2.3, 0.2, 10)	

iv. Click Study 1 and name it Neo-Hookean
v. De-select the Generate default plots check box
vi. Click Study > Show Default Solver > Solution 1 > Dependent Variables 1 > Scaling > Methods > choose Manual
vii. Model Builder > Neo-Hookean > Solver Configurations > Solution 1 > Stationary Solver 1 > Direct > General > Solver > choose PARDISO
viii. Model Builder > Neo-Hookean > Solver Configurations > Solution 1 > Stationary Solver 1 > Parametric 1 > Continuation > Predictor > choose Constant
ix. Model Builder > Neo-Hookean > Solver Configurations > Solution 1 > Stationary Solver 1 > Fully Coupled 1 > Method and Termination > Nonlinear method > Choose Constant

(Newton)

x. Click Compute from the Study tool bar

b. Add another study: Study > Add Study > Studies > Select Study > General Studies > Stationary > Add Study

c. Build Ogden: Model Builder > Ogden > Step 1: Stationary > Physics and Variables Selection

   i. Check the box for "Modify model configuration for study step"

   ii. Select and disable the following: Component 1 (comp1) > Solid Mechanics (solid), Controls spatial frame > Neo-Hookean, Component 1 (comp1) > Solid Mechanics (solid), Controls spatial frame > Mooney-Rivlin, and Component 1 (comp1) > Solid Mechanics (solid), Controls spatial frame > Varga.

   iii. Set the applied stretch from 1 to 10: Study Extensions > Auxiliary sweep > enter the following values to the table

Parameter name	Parameter value list	Parameter Unit
stretch (Applied stretch)	range (1, 0.1, 2) range(2.3, 0.2, 10)	

   iv. Click Study 2 and name it Ogden

   v. De-select the Generate default plots check box

   vi. Click Study > Show Default Solver > Solution 2 > Dependent Variables 1 > Scaling > Methods > choose Manual

   vii. Model Builder > Ogden > Solver Configurations > Solution 2 > Stationary Solver 1 > Direct > General > Solver > choose PARDISO

   viii. Model Builder > Ogden > Solver Configurations > Solution 2 > Stationary Solver 1 > Parametric 1 > Continuation > Predictor > choose Constant

   ix. Model Builder > Ogden > Solver Configurations > Solution 2 > Stationary Solver 1 > Fully Coupled 1 > Method and Termination > Nonlinear method > Choose Constant (Newton)

   x. Click Compute from the Study tool bar

7. Compute results: plot the inflation pressure plot and first principal stress plot

   a. Add predefined plot: select the model you want to get plots of > select the corresponding solution > Solid Mechanics > Stress (solid) > click Add Plot > click Add Predefined Plot

   b. Results for Stress (solid): Model Builder > Results > Stress (solid) > click Plot

      i. 2D Plot Group > Settings > Plot Settings > Frame > choose Material (R, PHI, Z)

   c. Results for Surface 1: Model Builder > Stress (solid) > Surface 1 > Settings > Expression > enter "solid.sp1" > select MPa for units

   d. Results for Deformation: Model Builder > Surface 1 > Deformation > Settings > Scale > Scale factor > enter "0.05" > click Plot

   e. Plot the inflation pressure vs stretch plot: Home > Add Plot Group > 1D Plot Group > Settings > Label > enter "Inflation Pressure" > Plot Settings > enter title and axes titles as you want

      i. Right click Inflation Pressure > Point Graph > Settings > Data > Dataset > choose the model you want to generate the plot of > select Point 3

      ii. y-Axis Data > Expression > enter "p_f"

      iii. x-Axis Data > Replace Expression > Global definition > Parameters > stretch - Applied Stretch

      iv. Legends > Show legends > Legends > Manual > label it as the model name

      v. Inflation Pressure > click Plot

      vi. Repeat for the other model

   f. Plot the first principal stress vs stretch plot: Model Builder > Inflation Pressure > Duplicate > 1D Plot Group > Settings > Label > enter "First Principal Stress" > Plot Settings > enter title and axes titles as you want

      i. Axis > Manual axis limits > y maximum > enter "40"

      ii. Model Builder > First Principal Stress > click the model you want the plot of (Point Graph #) > Settings > y-Axis Data > Expression > enter "solid.sp1"

      iii. First Principal Stress > click Plot

      iv. Repeat for the other model