NUMERICAL STUDY ON MECHANICAL PROPERTIES OF STENTS WITH DIFFERENT MATERIALS DURING STENT DEPLOYMENT WITH BALLOON EXPANSION

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Balloon Expandable Stent

- Percutaneous transluminal coronary angioplasty (PTCA) is a widespread method for treatment of coronary artery disease
- Balloon expandable stents are preferable in treatment of coronary artery stenosis
- Coronary stents are smooth metallic mesh-like structures
- Stents can be either in tubular or in coil shape
- Stents are deployed inside arteries with balloon expander
- Balloon is inflated to expand the stent till it reaches to artery wall
- Finally, balloon is removed, and expanded stent continues to provide mechanical support to the artery wall
Coronary Stents

Stent Inside a Coronary Artery

- Coronary artery
- Plaque
- Stent

A. Coronary artery located on the surface of the heart
B. Closed stent
C. Stent widened artery

Balloon
Expanded stent
Compressed plaque
Increased blood flow
Narrowed artery
Plaque
Closed stent around balloon catheter
Artery cross-section
Compressed plaque
Widened artery
Stent
Different Types of Stents

Clockwise from Top Left:

A. Tubular Mesh
B. Tubular wire
C. Coil
D. Hollow slotted tube with open and closed struts
Stent Materials Used in the Model

- 4 sample stents with different materials are used
- All stents have same geometrical properties
- Same initial deployment pressure applied to all stent
- Materials are chosen which are commonly used in today’s stent manufacturing.
- stent materials:
  1. Stainless steel 316 L Annealed
  2. Nitinol (austenite) – (55% nickel, 45% titanium)
  3. Elgiloy (heat treated at 525 c) – 15.5Ni, 2Mn, 1Be, 0.15C, balance Fe
  4. Tantalum (Pure)
# Stent Materials Properties

<table>
<thead>
<tr>
<th>Metal</th>
<th>Composition, wt%</th>
<th>Elastic modulus, GPa (Msi)</th>
<th>Tensile strength σₑ, MPa (ksi)</th>
<th>Ultimate tensile strength σᵤₐₜ, MPa (ksi)</th>
<th>Elongation, %</th>
<th>Poisson’s ratio</th>
<th>Yield Strength (Mpa)</th>
<th>Isentropic hardness modulus (GPA)</th>
<th>Density (kg/m-3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>316 L Stainless Steel, Annealed</td>
<td>17Cr, 12Ni, 2.5 Mo, &lt;0.03C, balance Fe</td>
<td>193 (28)</td>
<td>260 (38)</td>
<td>550 (80)</td>
<td>50</td>
<td>0.3</td>
<td>300</td>
<td>2</td>
<td>7850</td>
</tr>
<tr>
<td>Nitinol (Austenite)</td>
<td>55 Ni - 45 Ti</td>
<td>83 (12)</td>
<td>195 to 690 (28 to 100)</td>
<td>960</td>
<td>25 to 50</td>
<td>0.3</td>
<td>560</td>
<td>1</td>
<td>6478</td>
</tr>
<tr>
<td>Tantalum</td>
<td>Pure</td>
<td>185 (27)</td>
<td>165 (24)</td>
<td>205 (30)</td>
<td>40</td>
<td>0.35</td>
<td>170</td>
<td>1669</td>
<td></td>
</tr>
<tr>
<td>Co-Cr-Mo Alloy (Elgiloy)</td>
<td>40Co, 20 Cr, 7Mo, 15.5Ni, 2Mn, 1Be, 0.15C, balance Fe</td>
<td>190 (28)</td>
<td>690 (100)</td>
<td>1020 (148)</td>
<td>38</td>
<td>0.226</td>
<td>520</td>
<td>8300</td>
<td></td>
</tr>
</tbody>
</table>
VERSION: COMSOL 3.5a

STRUCTURAL MECHANICS MODULE

Solid Stress-Strain

Static analysis, elasto-plastic material model
Theoretical Background

• The Structural Mechanics model
  – Current model uses Solid Stress Strain application mode
  – it aims to solve for displacement, strain and stress in 3D

• Fundamental Relationships
  – Strain Displacement Relationship
  – Stress Strain Relationship

• Implementation and Analysis
  – Implementation based on weak formulation of the equilibrium equations of stresses
    \[-\nabla \cdot \sigma = F\] (where \(\sigma\) is the stress tensor)
  – Substituting with the fundamental relationships, Naviers’ displacement equation is obtained
  – Analysis types
    • Static
    • Eigenfrequency
    • Transient

• Current model uses static analysis. Solver has been selected accordingly.
Stent Type: Palmaz Schatz (J&J Cordis®)
- Shape: Hollow slotted tube
- Length: 8 mm
- Diameter: 1.37 mm
- Thickness: 0.1 mm
- 6 Identical units are linked with struts
### Modeling Parameters

<table>
<thead>
<tr>
<th>Stent Type</th>
<th>Young modulus</th>
<th>Poisson’s Ratio</th>
<th>Ultimate Tensile Strength</th>
<th>Yield Strength</th>
<th>Density</th>
<th>Length</th>
<th>Diameter (Mounted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stainless Steel</td>
<td>193</td>
<td>0.3</td>
<td>550</td>
<td>300</td>
<td>7850</td>
<td>8</td>
<td>3.681</td>
</tr>
<tr>
<td>Nitinol</td>
<td>83</td>
<td>0.3</td>
<td>960</td>
<td>560</td>
<td>6478</td>
<td>8</td>
<td>1.568</td>
</tr>
<tr>
<td>Elgiloy</td>
<td>190</td>
<td>0.226</td>
<td>1020</td>
<td>520</td>
<td>8300</td>
<td>8</td>
<td>1.483</td>
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<tr>
<td>Tantalum</td>
<td>185</td>
<td>0.35</td>
<td>205</td>
<td>170</td>
<td>1669</td>
<td>8</td>
<td>3.681</td>
</tr>
</tbody>
</table>

**Constant Definition:** Young modulus, poisson’s ratio, Yield Strength, Isentropic Hardness ratio have been given for different

**Sub-domain setting:** Load, Density have been set up in physics mode, sub-domain setting
GOVERNING EQUATIONS

Governing Equations
A normal load applied acting radially outward on stent wall

Equation for load:
\[ \text{Load}_\text{max} \times ((\text{para} \leq 1) \times \text{para} + (\text{para} > 1) \times (2 - \text{para})). \]

Navier’s displacement equation:
\[ -\nabla \cdot (c \nabla u) = F \]

Load
- From clinical study, it is found that standard 0.3 MPa or 2 atm pressure is applied to inflate the balloon.
- In the study, a radially outward pressure is applied on the inner surface of the stent.
- During loading, pressure is increased with the parametric solver to a maximum value of \( p_{\text{max}} = 0.3 \text{ MPa} \).
- Followed by decreasing the load to zero to obtain the final shape of the deformed stent
Boundary Conditions

Boundary Condition
• Symmetry boundary conditions
• Prevents rigid body translation along y and z direction
• Prevents rotation around all axes
• A point constraint along x direction to prevent rigid body translation along x
• Predefined fine mesh size has been chosen in Free mesher parameter
• Tetrahedral elements (Lagrangian-Quadratic)
• Approximately 7300 elements generated
Results

• Outputs
  – Von Mises Stress
  – Diameter deformation in all directions (u,v,w)
  – Integral volumetric deformation (u,v,w)

A Sample Output of Model

• Fully deformed stent after expansion (nitinol material)
• Measure: Boundary deformation (Displacement (m))
• Color legend shown at right
Comparison of Stress Developed

### Max. Von Mises Stress (Mpa)

- **High Stress**
- **Low stress**

#### Sl. No. | Materials     | Max. Von Mises Stress (Mpa) | Maximum Displacement (mm) |
<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Stainless steel</td>
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<tr>
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<td>Elgiloy</td>
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<tr>
<td>4</td>
<td>Tantalum</td>
<td>939.1</td>
<td>3.681</td>
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</tbody>
</table>
Comparison of Volume Deformation

<table>
<thead>
<tr>
<th></th>
<th>Stent</th>
<th>Stainless Steel</th>
<th>Nitinol</th>
<th>Elgiloy</th>
<th>Tantalum</th>
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</thead>
<tbody>
<tr>
<td>Deformation</td>
<td>2.64</td>
<td>0.9</td>
<td>0.67</td>
<td>2.64</td>
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</tbody>
</table>
Stress and Deformation in Stainless Steel

High Stress Concentration Region

Low Stress Concentration Region

Minimum Deformation

Maximum Deformation

Fracture will initiate as stress exceeds the ultimate tensile strength
Stress and Deformation in Nitinol

- High Stress Concentration Region
- Maximum Deformation
- Fully expanded Nitinol Stent
- Dogboning phenomena

Fracture will not initiate as stress does not exceed the ultimate tensile strength.
Deformation Process Monitoring

The plot shows a standard characteristic of mechanical behavior of shape memory alloy Nitinol.

Nitinol is preferable as it remain the shape as predefined (1.3 mm diameter approx. in this case).

Plot of load parameter vs. radial deformation
Detailed Deformation Study of Different Stent

Figure 3: Plot of integrated deformation of stents against parameters – (a) stainless steel, (b) nitinol, (c) elgiloy, (d) tantalum.
Study of Stress developed and Fractures

- Above comparison shows that fracture risk is there in case of Stainless steel and Tantalum stents.

- In case of nitinol and elgiloy, fracture will not occur as their ultimate tensile stresses are higher than the maximum von Mies stress developed.

- Here, the load on stents and stent geometries are kept constant.
Conclusions

• The study of deformation and stress development during the stent deployment process are important for determining the stent efficacy
• Comparison of different stent materials’ mechanical properties during the expansion process is important to decide the preferred material to choose
• The comparison of stress developed during the stent expansion process determines the risk factors of developing fractures inside stents
• The current model results shows that, with constant pressure load on stent wall and constant stent geometry, fracture development risks in nitinol and elgiloy stents are less and that in stainless steel and tantalum are more
Acknowledgement

• We sincerely acknowledge the help we have got from COMSOL® Multiphysics support and documentation set for successfully developing the numerical analysis model in the present study. A big thank to the Comsol team.

• We specially thank to the entire lab team of Jadavpur University School of Bio Science and Engineering for allowing us to use the lab facilities.

• We sincerely thank to the Dept. of Mechanical Engineering, Jadavpur University for the exceptional help in completing this study, especially in theatrical formulation of finite element analysis.

• We sincerely thank to all our colleagues for their kind help and for allowing us to devote extra time in completing the present study.
References

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