Cardiovascular disease is the leading cause of death worldwide and is projected to remain so for decades according to the World Health Organization. Surgical intervention, including the use of balloon angioplasty and stent insertion, continues to be a lifesaver for many patients.

In patients with coronary heart disease caused by buildup of plaque, stents are used to open arteries and help reduce symptoms such as chest pain (angina) or to help treat a heart attack. Stents are small expandable tubes made of metal mesh that are deployed in narrowed coronary arteries by balloon angioplasty. The durability of a stent is of great importance since damage to a stent can lead to restenosis or an embolism. Stents are meant to be a permanent implant in the artery where it is expected to perform while the anatomy heals.

The SIMULIA Living Heart Human Model provides a unique testing environment where a stent can be deployed virtually in coronary arteries and deformed mechanically during the cardiac cycle. Once the mechanical deformation results are obtained, the long-term durability of the stent can be assessed. The virtual nature of the test provides a physiologically accurate methodology to test new and existing devices without exposing patients to unnecessary risk.

1. GEOMETRY AND MODEL

A generic coronary stent design was created in Generative Shape Design App on the 3D EXPERIENCE platform. First, one strut section and the associated connector geometry was created (Figure 1a), this same parametric geometry was repeated and wrapped cylindrically to form the stent geometry. The sweep mesh tool was used to create a hexahedral mesh for the stent (Figure 1b). Two cylinders, concentric to the stent geometry, were created. One cylinder acts as a crimping tool (Figure 1c-gray component) and the other as an expansion tool (Figure 1c-blue component).

Coronary arteries, which are available as part of the SIMULIA Living Heart Human Model package, were added to the model. The stent, crimping tool, and expansion tool were then aligned with the coronary artery and added to the heart model, as shown in Figure 2. The proximal end of the coronary artery tree was tied to the left coronary ostia. One-third of the coronary arteries’ surface (closest to the ventricles) was tied to the ventricles and the atrium; this ensured that the coronary arteries followed the heart motion during the cardiac cycle. This approach provides more realistic deformation of arteries compared to the traditional approach of modeling artery as a fixed cylinder.
Figure 2: Coronary arteries (blue) and stent added to the SIMULIA Living Heart Human Model. Zoomed-in view shows the stent aligned with the coronary arteries.

2. MATERIAL AND GEOMETRIC PROPERTIES

The stent was modeled as stainless steel, and the crimping and expansion tools were modeled as rigid. The geometric parameters and material properties of the stent are listed in Table 1.

Table 1: Geometric and material properties of the stent

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
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<tr>
<td><strong>Geometry</strong></td>
<td></td>
</tr>
<tr>
<td>Length</td>
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<tr>
<td>Radius</td>
<td>~1.25 mm</td>
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<tr>
<td>Wall Thickness</td>
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<td><strong>Material Properties</strong></td>
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<tr>
<td>Density</td>
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<tr>
<td>Young’s Modulus</td>
<td>193000 MPa</td>
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<tr>
<td>Poisson’s Ratio</td>
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</tr>
</tbody>
</table>

3. ANALYSIS PROCEDURE

The mechanical portion of the heart model simulation utilized Abaqus/Explicit. In the first step, the stent was compressed to simulate the process of crimping the stent onto the delivery balloon (Figure 3b), and then the stent was expanded into the artery to simulate the balloon deployment (Figure 3c). Because the initial state of the remainder of the heart model is at 70% diastole, in the next step, the pressure in the arteries was increased gradually to a consistent state. Next, three cardiac cycles are simulated to reach a cyclic steady-state response.

4. BOUNDARY CONDITIONS AND LOADS

During the crimping process, a radial displacement boundary condition was applied to the crimping tool (gray cylindrical component in Figure 1c), which resulted in compression (Figure 3b) of the stent. Then, a radial displacement boundary condition was applied to the expansion tool (blue cylindrical component inside stent in Figure 1c), which resulted in expansion of the stent into the artery (Figure 3c). Arterial blood pressure during cardiac cycle was computed as difference between Ventricle pressure and Atrium pressure in Heart model. Blood pressure changes during the cardiac cycle were then applied to the inside surfaces of the coronary arteries.

5. INTERACTIONS

During the stent crimping and deployment processes, general contact was specified between (i) the stent and the coronary arteries, (ii) the stent and the crimping tool, and (iii) the stent and the expansion tool. During the cardiac cycles, contact surfaces were activated between (iv) the coronary arteries and the ventricles and (v) the coronary arteries and the atrium to ensure realistic deformation of the arteries.

6. RESULTS AND DISCUSSION

The stent is a thin metal mesh that undergoes significant elastic deformation during the cardiac cycle. Since it is not possible to measure the stent deformation in vivo, the SIMULIA Living Heart Human Model provides a tool to quantify the stent deformation during the cardiac cycle. The primary output quantities of interest are the stent displacement and stresses. Figure 4a shows the undeformed configuration of the stent as well as three element sets (proximal—blue, middle—green, and distal—red) created for post-processing of the results. Figure 4b and Figure 4c show the deformed stent with the contour plot of von Mises stress at the diastolic and systolic states of the cardiac cycle, respectively. It can be observed from the images that the distal portion of the stent experiences the maximum deformation and stress during the cardiac cycle.
A fatigue assessment was carried out by a Goodman analysis, shown in Figure 5. For this assessment, an ultimate tensile strength of 860 MPa and a fatigue limit of 250 MPa were used. The mean and alternating stresses for three regions of the stent (Distal, Middle, and Proximal) were plotted using colors consistent with Figure 4a. While the proximal region of the stent tends to stay under the Goodman limit, indicating a longer fatigue life, the distal region of the stent exceeds the Goodman limit, indicating that stent is more likely to fail due to fatigue in this region.

The results of this simulation indicate that a stent’s durability can be significantly influenced by the bending and twisting motion of the vasculature (depending on the stent placement) as opposed to just by the pulsatile radial loading the stent undergoes, and leads one to conclude that traditional modeling approaches that account for pulsatile loading may be insufficient to accurately estimate the long-term durability of coronary stents.

Figure 5: Fatigue evaluation of the stent by Goodman’s plot. The distal region of the stent (red) is more likely to fail than the proximal region of the stent (blue).

7. SUMMARY

In this technology brief, we demonstrate that the SIMULIA Living Heart Human Model can be used to enhance the state of the art in simulating the behavior of a stent during cardiac cycles. The virtual nature of the simulation allows you to evaluate stent designs in a safe and efficient manner.

For additional information, please contact SIMULIA.Living-Heart-Project@3ds.com.
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