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Computational Approach for Evaluating the effect of Stent Materials on Biomechanical Properties

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Abstract: one of the most important cardiovascular diseases is atherosclerosis. In the case of coronary arteries, may block the flow of oxygen-rich blood and access to the heart muscle leading mostly to heart attacks, often normal blood flow is restored via narrow arteries by the introduction of a mechanical structure called stent. The Stent is an expandable slotted tube is inserted into narrow blood vessels to be expanded due to the accumulation of plaque in them. The aim of this thesis is to provide a computational approach for evaluating the effect of stent materials on biomechanical properties outcomes at the deployments of stents, by applying stainless steel SS316L. Finite Element Analysis procedure was carried nonlinear out using ANSYS Workbench in the stent geometry, to predict quantitative calculation of the effect of mechanical properties such as density, stress and strain of these biomaterials on Stent behavior during the deployment. A quantitative comparison is made for exploring the effect of different materials at the deployment of stents. This study is important in understanding the role for stent materials effect on the biomechanical responses to the coronary stenting.

Keywords: biomechanics, stent implants, stent failure, deformation, in-stent restenosis, cardiovascular diseases, balloon-expandable stent, cardiovascular disease

I. INTRODUCTION

The Finite Element Method has become a particularly useful tool in analyzing the stresses in structures of complex shapes, material behavior and loading, enables a great variety of loading conditions and design variables to be changed easily but it is only an approximate method of solution, it represents the model being modelled as a finite number of materials using ANSYS Workbench 2019. The model will not converge to the solution of the physical structure under consideration however, unless the model is a precise representation of the structure as in Figure 1. The accuracy of a finite element model depends on the type of elements and materials used in the model and the fineness of the mesh, and is best evaluated by observing the convergence of the solution as the number of elements defining the problem is increased. In this part details the modelling procedures by FE a balloon catheter is used as a medium to the stent expansion to obtain a more realistic results into the expansion process, also in deformation behaviour[1,2]. In such a case, the balloon has to be modelled with stent, so the whole expansion process of the stent is simulated by the dynamics module of ANSYS Workbench 2019must be taken into consideration its design and contact conditions between the stent and balloon, will the results from the simulations are presented and analysed below[3].

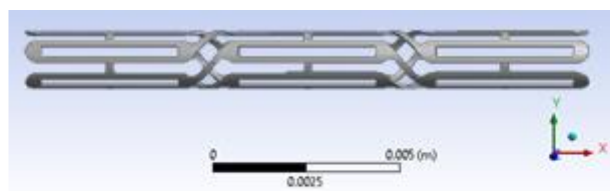

Figure 1: Stent geometric model.

II. F.E. MODEL OF CARDIAC STENT IMPLANT

Finite Element method FEM is a numerical technique in which approximate solutions based on differential equations are found and applied to boundary value problems. The ANSYS Workbench 2019 program was used to produce stable solution and minimize an error function. The stent geometries are designed from the available data of their respective manufacturing companies and also from literature. For modeling and drawing a finite element analysis tool is used (COMSOL Multiphysics V4.3a). Initially, the stent dimensions are drawn in the two-dimensional work plane and then extruded to their respective thickness in the Z direction, to give a three dimensional (3D) for stent model. The stent considered for analysis are Palmaz Stent, Driver Stent (Medtronic USA). S670 Stent, Element Stent (Natick, Boston Scientific USA), Taxus Express Stent. A representative unit cell of the stent with suitable boundary conditions is used for simulation to reduce the computational time. Where the stent contains 15 slots (cells)or expandable rings, 15 groups of wavy connecting elements, which are equally spaced throughout the entire model. The properties and dimensions of the stent simply are shown in the Table 1 below:

Table 1: The most important properties and radial directions of stent.

Parameters	Values
Number of Cells	15
Strut thickness	0.001 mm
Length of Stent	7.4 mm
Inner Diameter of Stent	0.685 mm
Outer Diameter of Stent	0.686 mm
Strut width	0.001 mm
Stent Surface Area	15.8 mm^2
Volume	2.1242e-010 m^3
Mass	1.6675×10^{6}kg

Most stent designs viewed as a lattice; cell unit design is repeated in the axial. It has been shown that the mechanics of a unit cell can be analyzed and extrapolated to describe the mechanics of the entire lattice due to the symmetrical geometry of the stent [4].One particular benefit from this model is that the computation time of the problems was greatly reduced, it is herein assumed that these struts expand in a repeatable way such that analysis of a strut can be expanded to describe the mechanics of the unit cell. Then, the mechanics of the unit cell can be used to describe the entire stent of rapid simulation of stents expansion [5]. Accordingly, a representative unit cell of the stent with suitable boundary condition was used for simulation in this project work, as shown in Figure 2.

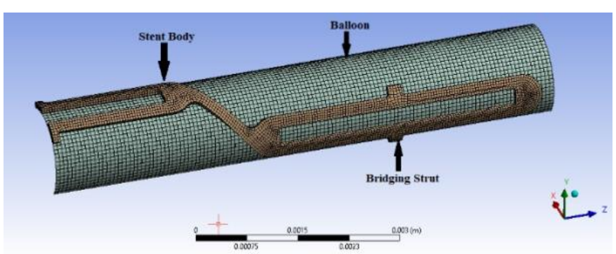

Figure 2: Finite element model of a cell of the stent (selected discretized geometry).

The finite element model of the stent was meshed to properly model the geometry, also designed to apply a radially outward force of avoid migration of the device and to open a stenosis the artery. The stent comprised stainless steel 316L of 4116 elements and 25614 nodes, a 3-D elastoplastic material model was assumed for the stent material. The material properties were chosen previously to approximately represent stainless steel 316L stent, this expansion can be modeled through analytical methods to insight into stent through the effect of the stent materials on the biomechanical properties.

The balloon was modelled as cylinder placed inside the stent as the expansion tool of the stent, from the outside diameter of the balloon equal to the inside diameter of the stent[6]. Hyperelastic material was used to represent the balloon, by Mooney-Rivlin 2 Parameter model was used in this simulation with C (10) $=1.06\times 10^{6}$Pa and C (01) = 1.14×10^{5}Pa, the balloon as a medium to expand the stent. The balloon was modelled using three-dimensional dynamic elements to be 7.7 mm in length, the finite element model at the balloon consists of 3712 elements and 26772 nodes for best distortion in the radial direction, Table 2 below explains the properties of the balloon simply:

Table 2: The most important properties of balloon.

Parameters	Values
Length of Balloon	7.7×10^{3}m
Balloon Surface Area	17.1 mm^2
Volume	1.3363×10^{11} m^3
Mass	0 kg

III. Material Properties

The simulation was carried out for stent materials stainless steel (SS 316L) in order to study and observe the biomechanical properties changes that occur on the stent after expansion, so that it is at the beginning of its expansion flexible with the possibility of returning to the first shape (elastic), to the point of distortion in which the shape changes in addition to change to the situation inflexible (plastic)[7]. Table 3 below showing type of material and its mechanical properties:

Table 3: Material data used for material model.

Stainless Steel 316L [8][7]	Material Properties
Density	7850 Kg/m3
Young's Modulus	193 GPa
Shear Modulus	82 GPa
Tangent modulus	1.93 GPa
Poison's Ratio	0.3
Yield Strength	190 MPa
Failure Stress	558 MPa
Failure Strain	40 %

IV. BOUNDARY CONDITIONS AND LOADING

Due to the symmetry of the stent only a unit cell was developed to simulate the expansion process, and hence the stent nodes at the symmetry edges were restrained in the appropriate directions by using frictionless supports, as Figure 3:

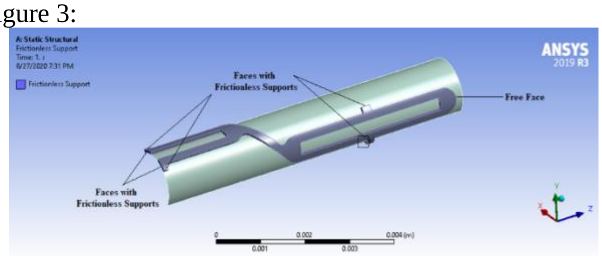

Figure3: Free Face and Faces with Frictionless Supports used in axisymmetric analysis.

The applied load strain was imposed on the inner balloon surface, as in Figure 4, expanding the stent radially past its elastic limit to a maximum diameter before failure stress was reached. Boundary conditions were simulated as a step-controlled displacement. It entailed two steps, step 1; inflation of balloon that expands the stent radially until the onset of plastic deformation and reach the ultimate tensile strength of the material. Step 2; deflation of balloon leaving the stent in its deformed state [9]. The balloon was gradually deformed within one second, to enable a realistic simulation of the stent deployment, from 0 to 0.3 mm in the first step and then from 0.3 mm to 0 in the second step[10], as shown in Figure 5. Table 4 shows the displacement boundary condition applied for the inner surface of the balloon in the cylindrical coordinate system.

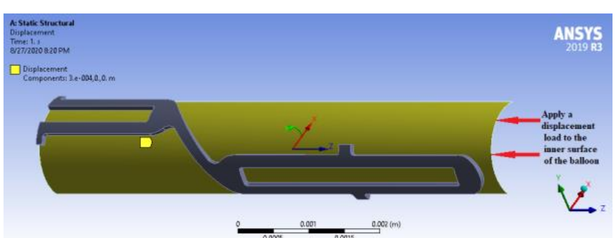

Figure 4: The dilatation of the stent a certain amount of radial displacement was applied to the inner surface of balloon was by 0.3mm.

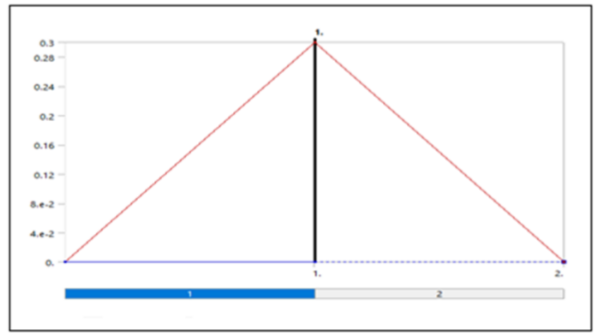

Figure 5: This graph shows the amount of displacement force applied to the balloon to expand the stent associated with time.

Table 4: The displacement phases in load steps linked with time.

Steps	Time [s]	X [mm]	Y [mm]	Z [mm]
1	0	0	0	0
	1	0. 3		
2	2	0	0	0

V. RESULTS AND DISCUSSION

In order evaluate the mechanical characteristics of the present stent, the stent is radially expanded until the onset of plastic deformation is observed and the ultimate tensile strength of the material is reached. For the stent, maximum equivalent stresses are used for the direct comparison with ultimate tensile strength of the material. Figure 6 shows the maximum equivalent von-Mises stress (at 1 sec) and residual stress (at 2 sec). The stent experiences maximum equivalent von Mises stress of326.17 MPa when the balloon expands completely as shown in Figure 6:

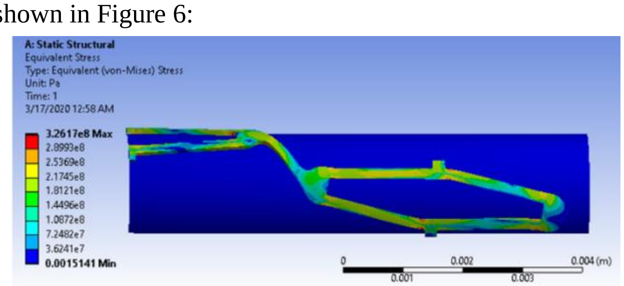

Figure 6: Maximum equivalent von Mises stress when the balloon is fully expanded.

The material reaches plasticity and does not regains its original shape when the balloon deflates. Then unloading occurs, because the maximum equivalent stress is greater than the yield strength, the stress experienced by the stent drops and the contact between the stent and balloon also. The stent undergoes some amount recoiling and retains a maximum of 321.14MPa in a form of residual stress as shown in Figure 7:

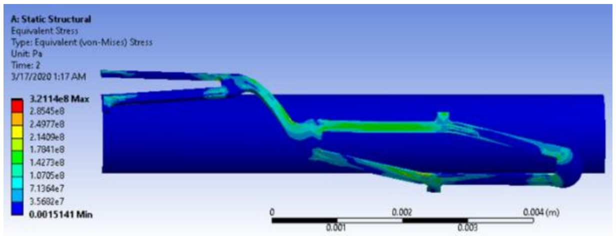

Figure 7: Residual stress retained by the stent after deflation of balloon.

The maximum total displacement and total displacement after recoiling during inflation and deflation of balloon is also shown. When the balloon is fully expanded, the unconstrained edges of the stent model undergo a maximum total deformation of 531.5mm and the minimum total displacement is 0 m, Figure 8:

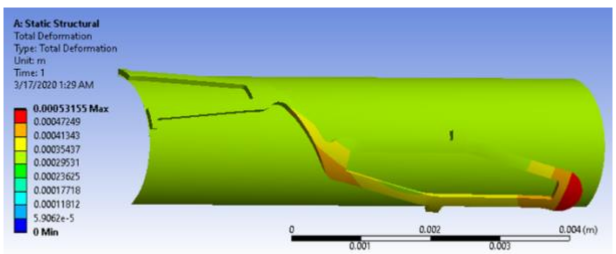

Figure 8: Maximum total deformation at fully expanded condition.

The total deflection deceases due to recoiling as the balloon deflates as shown in Figure 9:

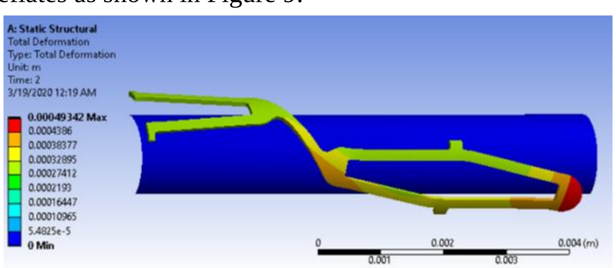

Figure 9: Total deformation due to recoiling when the balloon deflates.

The directional deformation of a point along X direction in the stent gives idea about how the stents expands and recoils. In same Figure 4.5 e, the maximum displacement (at 1sec) and displacement after recoil along the X direction (at 2sec) is shown. The stent reaches a maximum displacement of 3169.5 mm along X direction at fully expanded balloon condition as shown in Figure10:

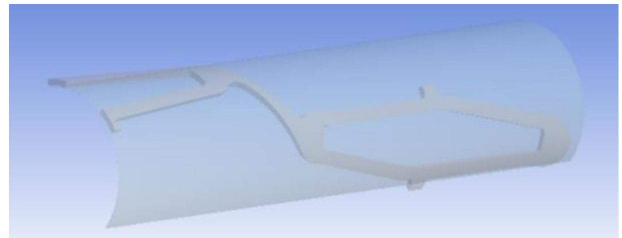

Figure10: Maximum displacement along X at fully expanded balloon.

When the balloon deflates the stent recoils and reaches 3002.3mm as shown in Figure 11 therefore the stent recoils about176 mm along X direction.

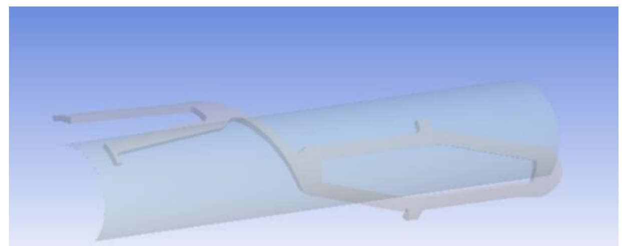

Figure 11: Displacement along X after recoiling.

VI. Discussions

Using ANSYS 2019 Workbench the computational FEM analysis was done. It has been designed the stent with a hyperplastic balloon for the analysis. Experimentally determined mechanical properties of were assigned to a stent model, also mechanical properties of stainless steel 316L. Structural analysis was carried out in two steps to simulate the distension and deflation of balloon. The equivalent von Mises stress, the recoiling and total deformation of the stainless steel 316L were determined. From the computational FEM analysis and the experimental for stainless steel 316L, it was found that SS 316L has great potential to be used as stent materials. Because the rust tolerance limit is high, this infers that the fatigue life of the stents will improve considerably when stainless steel 316L are used as base materials. Table 5 shows the results generated from the computational analysis of SS 316L.

Table 5: Summary of the highest results from mathematical analysis.

Material	max Von mises stress [MPa]	Max residual stress [MPa]	Max total deformation	Recoil percentage [mm]
SS 316L	326.17	321.14	5.3115 $\times 10^{-4}$	3.1695$\times 10^{7}$

The results from it turned out that the Stainless steel 316L is flexible material. This allows it to be used as a successful stent material. The future work will concentrate more and broader on computational fatigue analyses of stent when subjected to cyclic loads, because the stent when implanted in artery undergoes cyclic load due to the diastolic and systolic pressure caused by heartbeat. Structural and fatigue of stent analysis will be conducted by considering these the balloon expansion and also cyclic pressure acting on the stent due to heart beat.

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