FINITE ELEMENT ANALYSIS OF SHAPE MEMORY ALLOY STENTS IN HYPERELASTIC CORONARY ARTERY

[1]AL-ABASSI1, [2]K.KHANAFER, [3]I.DEIAB

[1]School of Engineering, University of Guelph, Guelph, ON, Canada,[2]Mechanical Engineering Department, Australian College of Kuwait, Kuwait,[3]Biomedical Engineering Department, University of Michigan, Ann Arbor, USA

The medical coronary artery stent is a promising technology that treats various coronary diseases. İt is manufactured out of high biocompatible materials. Stent alloys are remarkably promising good clinical outcomes. However, there is threaten of restenosis, stent recoiling, or stent fracture that cause complications in vascular diseases. Stents that are made of Nickel-titanium (Nitinol) can bare extensive plastic deformation and resist restenosis. Thus, studying the behaviors of stents with regards to the contact surfaces of plaque and blood vessel will help to prevent morbidity outcomes. This research analyzes the performance of nitinol Promus Stent using finite elements, in comparison to stainless steel stent. The hyperelastic tissue is selected to resample the plaque layer compared to plaque with high stiffness in coronary artery. The results show the stent bearing with stress and the possibility of dislocation in the treated area.

I. INTRODUCTION

Circulatory system is one of the vital systems of the body that is concerned with transporting blood that carries nutrients, oxygen, vital hormones and neurotransmitters to all parts of the body. Any alteration in the normal functioning of the circulatory vessels leads to circulatory system diseases, which includes both heart disease and vascular disorders that constitutes the leading cause of the death. In North America, diseases of the circulatory system are the most significant cause of mortality. In 2014, Statistics Canada reported that someone dies every 10 minutes in Canada as a result of stroke or heart disease [1]. In addition, more than 610,000 people die in United States annually because of heart disease, and Coronary heart disease considered to kill more than 370,000 patient. Hence, it is the most common fatal heart disease [2]. Stent is the non-surgical treatment of Coronary Artery disease, CAD. Balloon or self-expanding stent are two types of stents that are vital treatments for blocked coronary artery diseases such as angina and myocardial infarction. During angioplasty, stents utilize its scaffolding effect to reduce any pathologic remodeling. Implanting stents in coronary artery can limit the vessel lumen shrinkage and any further restenosis [3].

II. LITERATURE REVIEW

2.1 Coronary Artery And Heart Diseases

Coronary artery diseases are lethal diseases if not treated. Using stents as treatment for blocked arteries lowers the risk of thrombosis or restenosis. Guovanna, et.al presented a comparison study of new and old generation drug-eluting stents after percutaneous coronary intervention. The study indicates that having drug-eluting stent in heart blocked artery is associated with reducing the risk of restenosis by 38%, reducing the stent thrombosis by 43%, and the rate of death by 23% [4].

2.2 Delivery systems of stents

There are two delivery systems of stents. First, self-expanding stents, which has small stent geometry at room temperature, and it expands as shape memory alloy when it exposes to higher temperature in human body. This increases its diameter of the geometry after deployment. Second, ballon-expandable stents that expands once the balloon is inflated against the wall of the artery in order to keep the artery open.

2.3 Key factors that influence stent selection

The stent design should follow specific constrains that determine the operational success to achieve safe delivery. The following table summarizes the key factors that influence the stent selection [5] [6].

Table 1. Key constrain factors of medical stent designs

Key factor	*Relied definition for stent design*
Deliverability	The overall ease of stent delivery to the lesion site.
Trackability	The force needed to move the stent through coronary artery to the lesion.
Radiopacity	Visibility of stent under fluoroscopy (continues X-ray through the body).
Scaffolding	The size of metal supporting the vessel and preventing the plaque from falling.
Conformability	The flexibility of a stent to adapt to blood vessel.
Placement accuracy	Accurately placing the stent in the lesion area. This depends on the stent recoil.
Safety	The ability of stent to avoid restenosis.

The most important criteria for ideal stent are: deliverability, efficacy, and safety. These parameters efficiently determine the optimal stent technology [7].

III. MATERIALS AND METHODS

3.1 Stent materials properties

There are many biocompatible materials used for medical stents in various applications. Some of these materials are; Stainless steel, Cobalt Alloy, Platinum alloy, Titanium, and NiTi shape memory alloy. The shape memory alloy is less used however, it is considered to be the best biocompatible material for medical stents. The following sections will explain in details the properties of each bio-material. According to mechanical properties of biomaterials, Nitinol has the highest UTS (ultimate tensile strength), 1400 MPa. Nitinol has advantage over other biomaterials as it has better resistance to corrosions, higher value of elastic modulus compared with other materials, and good ductility [8]

3.2 Top coronary stents geometry designs

A comparison study of multiple stent designs was established for Promus, Cypher, Endeaver, Xience, Nobori, and Taxus stent to compare the efficiency of each stent with respect to its biomechanical properties. Nakazawa, et. al, mentioned that Taxus struts may overlap after 28 days of implementing it [9]. Nobori and Taxux stent have limited advanced perspectives. Conversely, Promus stent has up to 40% less recoil than cobalt alloy stents in bench testing. It has less bending moment, and around 88% less than the cobalt alloy stents [10]. The compression test results of BAE et. al [11], indicate that the radial force values was the greatest for Cypher stent. However, Xience has the lowest level of performance among the relative competitor stent designs. Therefore, the best drug eluting stents are Cypher, Promus, and Endeavor stents. The prototype design of Promus stent was optimized to predict the optimal number of struts and the thickness of each strut. Medical and clinical staff are recommending stents of thinner struts as it is more efficient in reducing restenosis in blood vessels. Moreover, thin struts of stents can reach distal lesions easier as it has smaller profile. Thus, it is required more in medical marketplaces [12] [13]. Figure1 shows the Endeaver stent measurements from end and long axil views.

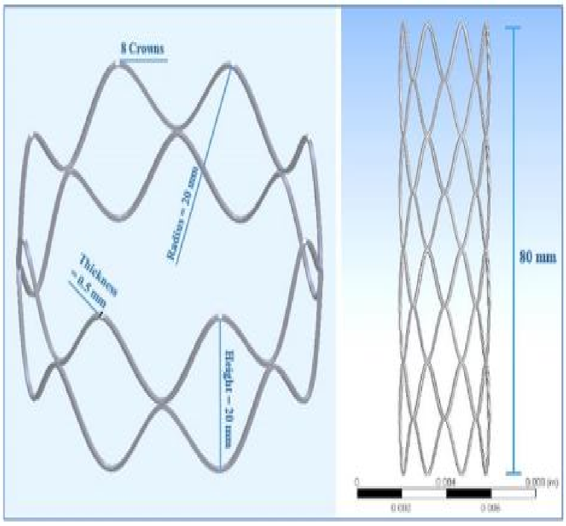

Figure 1. Geometry measurements of Endeaver stent

The dimensions of the coronary artery were adopted from Perry, et. al. [14] where they used high resolution enchocardiography to detect the measurements of the wall thickness and diameter of the coronary artery in patients with CAD. Their validated techniques gave an average coronary artery wall thickness of 1.1 ± 0.2 mm and external diameter of 4.5 ± 0.9mm [16]. These measurements were used to create the tested model.

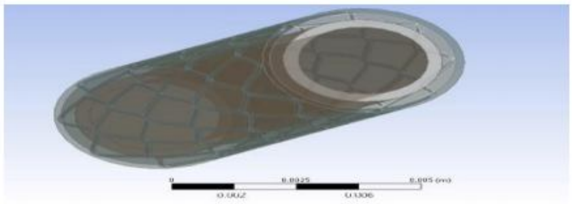

Figure 2. model of stent in a system of coronary artery with plaque layer.

The full model in Figure 16 is imported into static structural analysis in ANSYS, where materials are selected for each body, meshing size is identified for surfaces and edges, loads are applied, and contact surfaces formulation is set to represents the physical reality of the the model. FEA Simulations is applied using this stent in order to predict its performance in a system of blood vessel with plaque layer.

3.3 Finite Element of Artery Hyperelasric Tissue

3.3.1 Energy Potential function of Mooney-Rivlin hyperelastic tissue

In this study, the Mooney-Rivlin model is used as an elastic material for the vessel tissue and plaque layer. Mooney-Rivlin is one of the Phenomenological Models that has polynomial form of 1st and 2nd Strain Invariants. The density function or strain energy potential function are defining the constitutive hyperelastic models [15]. The strain energy potential is denoted as W, it is a function of principal stretch ratios λJ

W (λ1,2,λ3) (1)

The strain energy function is used to calculate stresses and strains

Sij= $dWdEij$ (2)

- where Eij are components of the strain tensor

The strain energy potential function has a polynomial form that is based on strain invariants. It is a phenomenological model of the form

W= $\Sigma ci(\bar{I1}-3)Ni+j=1i(\bar{I2}-3)j+\Sigma 1dkNk=1(J-1)2k$ (3)

I defines the Strain invariants in the energy potential function. The material properties define the values of cij and di from the curve fitting of the material test data to predict the bulk modulus and shear modulus. Equation 4 shows the nonlinear polynomial form of five-term Mooney Rivlin constants.

$W=c10(\bar{I1}-3)+c01(\bar{I2}-3)+c20(\bar{I1}-3)2+c11(\bar{I1}-3)(\bar{I2}-3)+c02(\bar{I1}-3)2+1d(J-1)2$ (4)

Mooney-Rivlin material constants of vessel tissue and plaque layer are used as input in the simulation for the material properties required in the stent system.

Table 2. Mooney–Rivlin hyperelastic constitutive equation material properties

Material Property	Density (kg/mm^3)	Elastomer Constants of Polynomial energy function					
		C10 (Pa)	C01 (Pa)	C20 (Pa)	C11 (Pa)	C02 (Pa)	d1 (Pa^-1)
Mooney-Rivlin (vessel)	1.07E-6	6.79E-3	0.54	-1.11	10.65	-7.27	1.63
Mooney-Rivlin (plaque)	1.45E-6	2.38E-3	0.19	0.39	3.73	-2.54	0.57

3.3.2 loads, meshing and contact surfaces

This model is solved in three load steps to simulate the actual physical model of stent during crimping, deploying, and expanding stages in the coronary artery.

(1) The first load step would compress the stent to the inner surface of the plaque. The contact elements between stent and plaque would be killed prior to solving the first load step. In the first load step, neither the vessel nor the plaque will move or be loaded. The stent only is compressed depending on the alloy modulus of elasticity.

(2) Then activate the elements of the contact pair. This is done in one load step to take advantage of the no-interference condition with the contact pair alive and the stent compressed. The initiation of applying loads happens at this load step.

(3) In a third load step, the stent expands slowly, letting the stent contact and expand the plaque. Let the substeps increase in size while applying pressure and temperature conditions. As the stent expands, it contacts the inner face of the plaque, causing the plaque to expand and to touch the inner face of the "vessel" on the way out.

The boundary conditions are applied to prevent the inner bodies from siding and rotating about Y, given that there is no friction in the model. And the model can be more stable when symmetry boundary conditions are applied.

Various meshing is required to enhance the computation of results, and accommodate the complex geometry. Therefore, adaptive meshing is added to adapt the complexity of the geometry. Various meshing types were selected for specific faces and edges in the stent model. Face meshing method is used for the upper and lower surfaces of the vessel and plaque layers. And body sizing for the sheath with 0.3 mm as element size. In addition, automatic meshing type of quadrilateral dominant method is used for the sheath surface. Edge sizing however, is used for vessel and plaque circumferences with various numbers of divisions. The vessel can have a much more coarse mesh of high-order elements

Contact surfaces settings between parts of the simulated model should be selected as following: (1) a contact pair between the outside of the stent and the sheath surface which compresses it, (2) between the outside of the stent and the inside of the plaque after the first load step, and (3) between the outside of the plaque and the inside of the vessel. In a contact pair, a penalty-based contact model is required to build up the reaction force where contact elements touch target elements. The accurate model should have the minimal amount of penetration. And the Augmented Lagrange method can control the amount of penetrations, although extra iterations are required with Augmented Lagrange formulation.

IV. RESULTS AND DISCUSSION

The model solves slowly on a computer with large CPU capability. Thus cyclic symmetry is implemented to increase the computational efficiency and reduce the running time of the simulation. Cyclic symmetry is beneficial as it decreases model size, and allows for increasing the meshing density in the stent and the vessel. Thus, a segmental model is used for simplicity. Figure 3 shows the difference between 14 model, 18 model, and 116 model. The results of the stent-artery model simulation will be presented and two case studies will be analyzed. The study cases are:

1. Case I: Study of hyper-elastic artery for a patient with CAD
2. Case II: Study of hyper-elastic artery and plaque layer with Nitinol stent

4.1 Case I: Study of hyperelastic artery for a patient with CAD

The normal blood pressure is called systolic blood pressure, which represents the ventricular contraction in the heart. The highest over lowest pressure in Millimeters of mercury is 120/80 mmHg. Patients with Coronary Artery Disease (CAD) may be at risk of lower blood pressure (80 to 100 Hgmm) and this is associated with increasing mortality due to the limited coronary perfusion [15]. The pressure applied is equivalent to 0.008 – 0.01 Mpa. In addition, thermal condition of human body was presented as temperature of 38 °C.

4.1.1 Stress Analysis of coronary artery for a patient with CAD

Blood pressure of a patient with CAD was applied, and Von-Mires stress is depicted as it predicts yielding of the materials under loading of blood pressure and thermal condition. The stress values are depicted corresponding to max, intermediate, and min diastolic pressure of patient with CAD. The maximum stress values at the model during the first time step, second time step, and third time step are 3.12E-09 Mpa, 3.53E-09 Mpa, and 3.94E-09 Mpa respectively. When blood pressure load increases, the stress increases in the inner wall of the vessel and plaque layer till it reaches the maximum stress at the highest pressure applied. From a physical perspective, these results are required to study the difference between stress analysis of coronary artery with and without stents of different mechanical properties.

4.1.2 Strain and deformation analysis of the system for a CAD patient.

The strain analysis is important to predict when the vessel will rapture and to prevent cardiovascular risks. In addition, it is critical to observe the deformation to prevent any dislocation of the stent in the vessel. The strain and deformation in this analysis are obtained at different pressure loads. Figure 5 shows the equivalent elastic strain of the vessel and plaque model when pressure is applied. The maximum strain is shown at the inner wall of the plaque layer, and the lowest strain appears at the outer surface of the vessel.

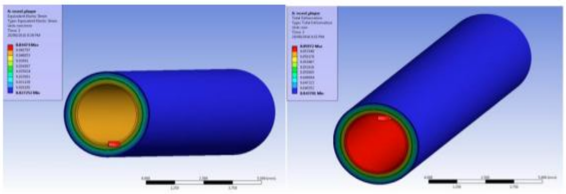

Figure 3: Thefigure at left shows the strain contour and the one at the right shows the total deformation of a plaque-artery system.

The strain values vary at each layer, and upon applying different pressure loads. The following table shows the strain values for each layer of the model separately at 8e-003 Mpa and 1e-002Mpa.

Table 3. Strain and deformation results of vessel and plaque at BP 8e-003 Mpa and 1e-002 Mpa

Blood Pressure of CAD patients	8e-003 MPa	1e-002 MPa
Strain of the Vessel	2.46E-02 mm/mm	2.73E-02 mm/mm
Strain of the Plaque	3.00E-02 mm/mm	3.32E-02 mm/mm
Deformation of the Vessel	3.95E-02 mm	4.38E-02 mm
Deformation of the Plaque	4.60E-02 mm	5.10E-02 mm

The plaque has a higher strain than the vessel as it is in direct contact with the blood pressure.

4.2 Case II: Study of hyper-elastic artery and plaque layer with Nitinol stent

In this case study, the Mooney-Rivlin model is used as an elastic material for the vessel tissue and plaque layer, while Nitinol (shape memory alloy NiTi) is used as a material for the self-expanding stent to obtain the following results.

4.2.1 Stress analysis of Coronary artery with plaque and Nitinol stent

stress distribution of CAD patient carries the stent is at its least values along the flat surfaces of the stent, and it increases as the curvature is more tilted towards the curves connecting the struts of the stent. This is corresponded to how the stent behaves under blood pressure. The maimum, intermediate, and minimum stress evaluation of each part for the model shows that the stent deployment is increasing the stress at the artery wall by 3.86e-8 as the artery extends.

Table 4: Hyperelastic vessel plaque and Nitinol stent equivalent stress

Stress at:	Vessel (Mpa)	Plaque (Mpa)	Stent (Mpa)
Max	4.25e-8	0.323	625.82
Intermediate	2.68e-8	0.127	208.61
Min	1.10e-8	0.062	1.31

The equivalent stress of plaque in Figure 6 shows the highest stress at the lining of the struts. When the stent expands, the stent causes stress on the plaque wall as the struts push it back. The maximum stress caused by the Strut curvature lines is shown as light green color and it is equal to 0.3888 Mpa. The stress is decreasing throughout the plaque layer and the least would be at the vessel as the plaque is separating it from the stent. The expansion of the stent is causing stress on the plaque and the highest will be at the inner wall, and the least will be at the contact surface between plaque and vessel. The variation of the stress color in the figure shows the darkest color at the outer surface of the plaque.

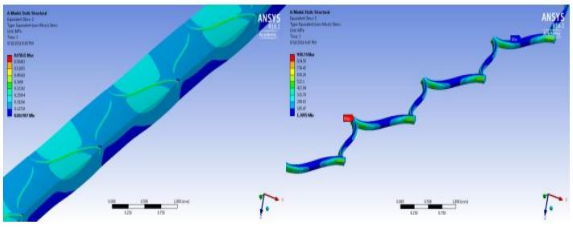

Figure 4: The Equivalent Von-Mises stress of plaque layer, and the shape memory alloy Nitinol stent

The stress variation of sent is caused by the expansion of the shape memory alloy as a result of changing the temperature and pressure inside the coronary artery. Figure 6 shows contours of what the stress analysis looks like in 1/16 of a stent under the same loads that are applied to the full model. The variation in stress is pattered in each strut and gives similar stress distribution in each strut curvature. The maximum stress value is equal to 626.26 Mpa and it shows up in connection areas between each strut pairs. However, the straight surfaces responds to the pressure with less stress along the strut waves, this gives the minimum stress, 1.3095 Mpa.

The directional deformation of the plaque shows a pattern of deformed areas along the axial direction of the plaque. The maximum deformation is 0.176 mm where the struts of the stent touch the plaque.

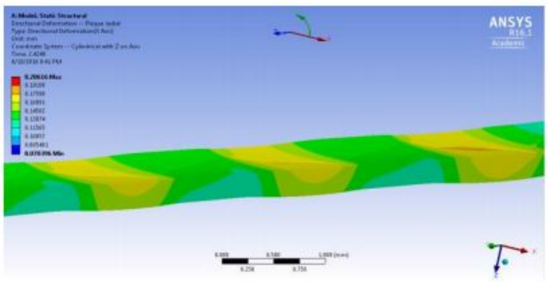

Figure 4: Directional deformation of plaque layer as a result of expanding the Nitinol stent

The middle section of the vessel is deformed more than the ends as the stress is concentrated where the stent locates, and the artery deforms less at the free ends of the stent. As the stent expands, the plaque extends more along the touching surface with the stent, which increases the diameter of the vessel by 0.01mm. The stent does not dislocate.

V. LIMITATIONS AND CHALLENGES

Strugles were found in modeling and simulating this system. Some of the problems occurred were due to excessive element distortion, contact element issues, computational time, and rigid body motion. And to solve these technical issues, the geometry was modified, cyclic symmetry was applied, stabilization techniques were set while using sparse solver, and memory size was increased. The simulation was complex, yet it converged after many adjustments.

CONCLUSION

In summary, the expansion of stent causes a pressure on the plaque layer, this results in deformation of the plaque to widen up the blockage in the artery. In addition, the artery expands to a diameter that is 0.01mm wider than the diameter of the original artery without stent. The plaque holds up the highest stress as the stent expands, leaving the artery with less stress. As a result, the presentation of hyperelastic vessel and Nitinol stent gave a realistic representation of the physical model.

The stent purposely retracted the plaque without causing huge stress on the artery and safely expanded it without penetrating it. Further studies are required to present more study cases of stent designs within a system of hyperelastic artery with the plaque. The results presented may help the medical staff to make a desicion regarding the stent used and further clinical experiments may support this simulation to apply the proper stent safely and prevent any dislocation within the treated area.

REFERENCES

[1]. C. Health, "Stroke Report 2014: Together against a rising tide," Heart and Stroke Foundation, June 2014.

[2]. CDC, "Underlying Cause of Death 1999-2013. Vital Statistics Cooperative Program" NCHS, 10 Augest 2015.

[3]. S. Saito, "New horizon of bioabsorbable stent," Catheter. Cardiovasc. Intery, vol. 66, pp. 595-596, 2005.

[4]. S. Giovanna, "Lower risk of stent thrombosis and restenosis with unrestricted use of ‘new-generation’ drug-eluting stents," European Heart Journal, vol. 33, no. 5, pp. 606-613, 9 January 2012.

[5]. R. Barik, "The story of coronary stent," 12 Jan 2014.

[6]. A. Sharma, "Different Coronary stent design," in Department of Cardiology, Pgimer&DR Rml Hospital, New Delhi, 2013.

[7]. A. Junya, "Design Criteria for the Ideal Drug-Eluting Stent," The American Journal of Cardiology, vol. 100, no. 8, p. S3–S9, 2007.

[8]. B. AL-Mangour, "Coronary Stents Fracture: An Engineering Approach," Scientific Research, vol. 4, no. 10, 2013.

[9]. G. Nakazawa, "Drug-eluting stent safety: findings from preclinical studies" Expert review of cardiovascular therapy, vol. 6, no. 10, pp. 1379-1391, 2008.

[10]. Scientific, "Everolimus-Eluting Platinum Chromium Coronary Stent System," PROMUS Element™ Plus, April 2014. Available: http://www.bostonscientific.com/en-US/products/stents--coronary/promus-element-plus-stent-system/promus-element-plus-stent-strength.html. [Accessed 15 October 2015].

[11]. I.-H. Bae, "Mechanical behavior and in vivo properties of newly designed bare metal stent for enhanced flexibility," Journal of Industrial and Engineering Chemistry, 25 January 2015.

[12]. C. Briguori, "In-stent restenosis in small coronary arteries: impact of strut thickness," J Amer Coll of Cardiology, vol. 40, no. 3, p. 403–409, 2002.

[13]. J. Pache, "Intracoronary stenting and angiographic results: strut thickness effect on restenosis outcome," J Amer Coll of Cardiology, vol. 41, no. 8, p. 1283–1288, 2003.

[14]. R. Perry, "Coronary artery wall thickness of the left anterior descending artery using high resolution transthoracic echocardiography--normal range of values" PubMed Echocardiography, vol. 30, no. 7, pp. 59-64, 2013.

[15]. ANSYS, ANSYS Mechanical Advanced Nonlinear Materials. Appendix 4A: Hyperelasticity, Toronto: ANSYS Inc., 2015.

★★★