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Simulation of Mechanical Behaviors of NIR Stent in a Stenotic Artery Using Finite Element Method

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Abstract: The implantation of intravascular stent (IVS) is a kind of coronary angioplasty to restore the blood flow perfusion to the downstream of the heart muscle tissue. Since stenting does not require any surgical operation and has less complication, pain and a more rapid recovery compared to the other possible treatments, the use of coronary stents in interventional procedures has rapidly increased in recent years. In order to have the better output of stent implantation, it is necessary to analyze the mechanical behavior of this device before manufacturing and utilizing. One of the most effective methods to investigate the mechanical behavior of the stent is finite element method. As the main objective, this study aims to investigate the expansion characteristics of a stent as it is deployed in an artery containing a plaque and propose a model as close to real conditions of stent implantation as possible. A nonlinear model that contains balloon, stent and vessel with plaque is used and bi-linear elasto-plastic material model for stent and hyperelastic material models for balloon, artery and plaque have been assumed. This model includes the internal pressure of blood. Stress distribution, radial gain, outer diameter changes, dogboning and foreshortening are investigated.

Key words: Atherosclerosis % Coronary stent % Balloon % Plaque % Vessel % Finite element method

INTRODUCTION

Atherosclerosis is one of the most serious and common forms of cardiovascular disease. An atherosclerotic plaque is an intimal lesion that typically consists of an accumulation of cells, lipids, calcium, collagen and inflammatory infiltrates [1]. These plaques can cause artery occlusion leading to a reduction in blood flow. Treatment options include balloon angioplasty and stenting, bypass surgery and atherectomy [2]. A stent is a tubular scaffold which can be inserted into a diseased artery to relieve the narrowing caused by a stenosis. Since stent implantation, namely stenting, does not require any surgical operation and has less complication, pain and a more rapid recovery compared to the other possible treatments, the use of coronary stents in interventional procedures has rapidly increased in recent years. Only in the United States, 1.2 million patients undergo stent implantations each year [3].

A successful stent implantation is dependent on the good understanding of its behavior during its deployment. There are two methods to analyze the behavior of the stent: experimental methods and numerical simulations. In comparison with expensive experiments carried out in hospitals and laboratories, numerical simulations accomplished by computers have advantages in both flexibility and cost. For this reason, the use of numerical methods in analyzing the performance of the coronary stent has increased. In recent publications, different numerical models, with different level of complexity and accuracy, have been proposed to simulate the expansion during deployment of the coronary stent. In the early works, single stent models were used without considering the contact effect [4-8]. Later on, in order to obtain better results, more complicated models have been proposed, such as balloon-stent model [9-13], stent-artery model with plaque [14], balloon-stent-artery model without plaque [15] and balloon-stent-artery model with plaque [16, 17]. Furthermore, different formulations of constitutive models for artery and plaque have been proposed in the literature, including linear isotropic [15, 17] or hyperelastic material models [14, 16, 18]. Moreover, extensive studies were found in the literature that did not consider the blood flow [4, 16, 17, 18],

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although Lally *et al*. [14] and Gervaso *et al*. [19] tried to simulate the blood pressure by applying a constant internal pressure to the artery and plaque.

With attention to the mentioned background, it is necessary to propose a model as close to real conditions of stent implantation as possible. The aim of this paper is to present a more accurate model that contains internal blood pressure, balloon, stent, plaque and vessel. Finite element method is used to simulate the mechanical behavior of the NIR Stent. Moreover, a bi-linear elasto-plastic model was chosen for the stent material while the balloon, artery and plaque were simulated using hyperelastic material model. Stress distribution in the stent and artery, radial gain, outer diameter changes, dogboning and foreshortening are investigated. These results could deserve consideration when designing stents.

MATERIALS AND METHODS

In this section, modeling of various parts used in analysis of mechanical behavior of coronary stent is presented. This part includes the modeling of stent, balloon and vessel with plaque. Commercially available software has been used.

Stent: A balloon-expandable NIR stent (Scimed, Boston Scientific Europe, Verviers, Belgium) was modeled in this study. This kind of stent incorporates the presence of two different types of elements: (*i*) tubular-like rings and (*ii*) bridging members (links). The first one function to maintain the vessel opens after the stent expansion and the second one to link the rings in a flexible way during the delivery process. Hence, the tubular-like rings determine the stiffness whilst the bridging members determine the flexibility of the overall structure.

Primary model of stent was produced using commercially available software. Model was constructed on the basis of images from the literature [20]. The stent has an outer diameter of 3 mm, a length of 10 mm and a thickness of 0.05 mm. Fig. 1 shows the stent model in its unexpanded configuration.

The stent was assumed to be made of stainless steel 304. A bi-linear elasto-plastic material model was used to model the behavior of stent material. The material properties were chosen same as those assumed in [1], which are as: Young's modulus = 193 GPa; shear modulus = 75×106 MPa; tangent modulus = 692 MPa; density = 7.86×10^{-6} kg/mm^3; yield strength = 207 MPa; Poisson's ratio = 0.27.

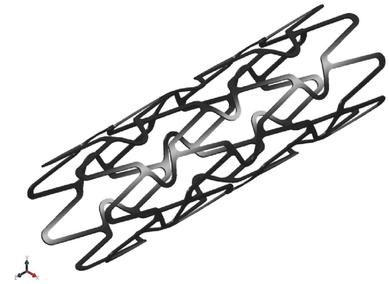

Fig. 1: Geometry of stent model in its unexpanded configuration

Artery with Plaque: With the assumption of homogenous and isotropic material, the coronary artery was modeled as an idealized vessel. The geometrical properties of the vessel and plaque are: vessel's length = 20 mm; vessel's inner diameter = 4 mm; vessel's outer diameter = 5 mm; plaque's length = 3 mm; plaque's inner diameter = 3 mm. The vessel and plaque were modeled as hyperelastic material with Mooney-Rivlin (M-R) description. Using a hyperelastic model of an incompressible isotropically elastic solid, the Cauchy stress, s_{ij}, may be given in terms of the left Cauchy-Green tensor, B_{ij}, as [21]:

$$s_{ij} = -p + 2\frac{\partial W}{\partial I_1} B_{ij} - 2\frac{\partial W}{\partial I_2} B_{ij}^{-1} \tag{1}$$

where W is the strain-energy density function, while I_1, I_2 and I_3 are the invariants of B_{ij} which can be defined in terms of principal stretches of the material, 8_1, 8_2 and 8_3, as:

$$I_1 = l_1^2 + l_2^2 + l_3^2 \tag{2}$$

$$I_2 = l_1^2 l_2^2 + l_1^2 l_3^2 + l_2^2 l_3^2 \tag{3}$$

$$I_3 = l_1^2 l_2^2 l_3^2 \tag{4}$$

The general polynomial form of the strain-energy density function for an isotropic hyperelastic material can be written as [22]:

$$W(I_1, I_2, I_3) = \sum_{i,j,k=0}^{\infty} C_{ijk}(I_1-3)^i (I_2-3)^j (I_3-3)^k \tag{5}$$

$$C_{000} = 0 \tag{6}$$

where C_{ijk} are the material coefficients determined from the experiments. Incompressible nature of vascular tissue was established by Carew *et al*. [23]. For an incompressible

Table 1: Hyperelastic coefficients to describe the arterial tissue and stenotic plaque non-linear elastic behavior

	Arterial wall tissue (kPa)	Stenotic plaque tissue (kPa)
C_{10}	18.90	-495.96
C_{01}	2.75	506.61
C_{20}	85.72	1193.53
C_{11}	590.43	3637.80
C_{30}	0	4737.25

material, the third invariant is given as $I_3 = 1$. The specific hyperelastic constitutive model used to model the arterial tissue in this study is a specific form of Eq. (5) whereby the strain-energy density function is a third-order hyperelastic model suitable for an incompressible isotropic material and has the form given in Eq. (7):

$$W = C_{10}(I_1 - 3) + C_{01}(I_2 - 3) + C_{20}(I_1 - 3)^2 + C_{11}(I_1 - 3)(I_2 - 3) + C_{30}(I_1 - 3)^3 \quad (7)$$

This M-R form constitutive equation is included in several finite element codes and is therefore readily applicable to stent design. Substituting Eq. (7) into Eq. (1), the stress components can be easily obtained. Table 1 summarizes the coefficients used for the hyperelastic constitutive equations of the two material models [14].

Balloon: The balloon as a medium to expand the stent was modeled to be 12 mm in length. The outer diameter and the thickness of the balloon were 2.9 mm and 0.1 mm, respectively. A polyurethane rubber type material was used to represent the balloon. Polyurethane is an incompressible material and was defined by a nonlinear first-order hyperelastic M-R model, in which the strain-energy density function was given as:

$$W = C_{01}(I_1 - 3) + C_{10}(I_2 - 3) \quad (8)$$

The energy function's coefficients used are: C_{01} = 0.710918 MPa, C_{10} = 1.06881 MPa. The material density was equal to 1070 kg/m^3 [10, 11].

Meshing and Boundary Conditions: All of the parts of the model were meshed with eight-node linear 3D block elements. Sensitivity analyses were performed to ensure enough meshing refinement. Stent, balloon, artery and plaque includes 4512, 2040, 3060 and 448 elements, respectively. Fig. 2a demonstrates the finite element model of the stent. Moreover, an automatic surface to surface algorithm approach available in software was selected in order to cope with the nonlinear contact problem among the surfaces.

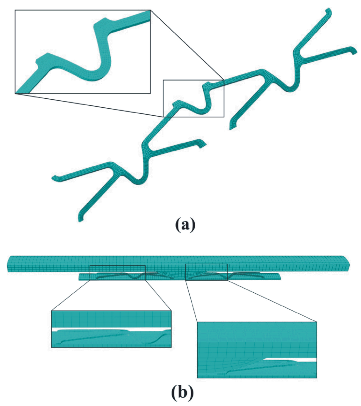

Fig. 2: (a) Finite element model of one-seventh of the stent; (b) 3D meshed model for balloon-stent-vessel with plaque

Due to the symmetrical conditions, only one-seventh of the model was used to simulate the expansion process. Symmetric constraints were imposed to corresponding symmetry nodes of the balloon, stent, vessel and plaque. Both ends of the balloon were considered to be fully fixed. Furthermore, only the movement in radial direction was permitted for the nodes located at the two ends of the vessel and the plaque was attached to the vessel. Fig. 2b shows the final assembled model.

Loading and Solutions: The loading process consisted of two steps. In the first step, without considering the existence of the balloon and the stent, a constant internal pressure equal to 13.3 kPa was applied to the vessel and the plaque. This pressure is equal to the blood pressure of 100 mmHgs [14]. The pressure simulates the internal pressure of the blood and causes the vessel to expand and also, induces an initial stress. This step causes the modeled vessel and the plaque to be as close to the reality as possible. In the second step, by keeping the initial pressure applied to the vessel and plaque, a constant pressure was imposed to the internal surface of the balloon. This pressure was applied with a constant rate in 1.635 seconds and its value was varied from 0 to 0.32 MPa.

RESULLTS AND DISCUSSION

In this section, the results of the finite element analysis of the expansion of the stent inside an atherosclerotic coronary artery are presented. The results include stress distribution, radial gain, outer diameter changes, dogboning and foreshortening. These results could deserve consideration when designing stents

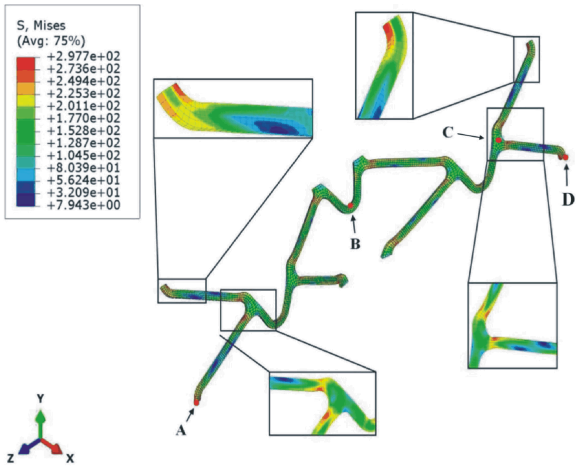

Fig. 3: Distribution of von Mises stress in the stent

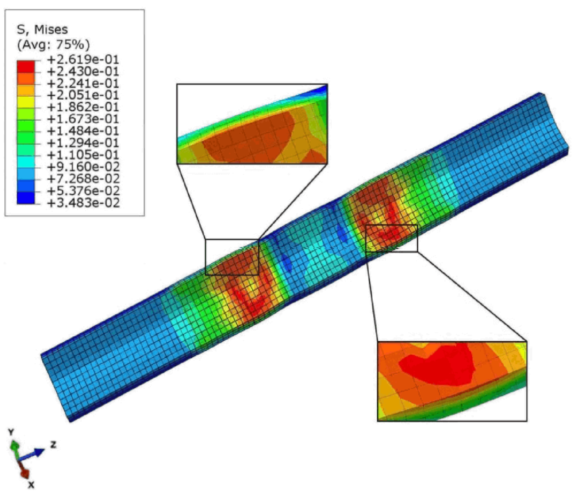

Fig. 4: Distribution of von Mises stress in the expanded vessel at maximum expansion.

Stress Distribution: The distribution of von Mises stress in the stent is shown in Fig. 3 at maximum expansion instant. As can be seen in this figure, the value of maximum von Mises stressin the stent is 297.7 MPa. Furthermore, it is possible to observe the effect of considering the plaque on the deformed configurations reached by the stent model.

Von Mises stress in the expanded vessels is depicted in Fig. 4. The highest arterial stresses are in the areas where maximum changes occurred in stent diameter. The value of maximum von Mises stress in the vessel is 0.262 MPa. A possible damage to the artery might occur at these critical points. Furthermore, because of the presence of the plaque, the stress distribution in the vessel is different from the study by Walke *et al*. [15]. This shows the importance of considering the plaque in finite element simulating of mechanical behaviors of coronary stent. Moreover, the von Mises stresses show a considerable gradient from the internal to the external surface of the arterial wall.

Radial Gain and Outer Diameter Changes: Radial gain (RG) is one of the most important parameters to evaluate the performance of the stent, which is defined as follow:

$$RG = R_{expansion} - R_0 \tag{9}$$

where $R_{expansion}$ and R_0 are the outer radius of the stent, after and before the expansion, respectively. RG is measured at the middle of the stent. Note that the value of RG represents the final radial deformation and greater value of RG is more appropriate in practical applications. In this model, the value of RG is 0.361 mm.

For a better understanding of the expansion behavior of the stent, Fig. 5 plots the outer diameter of stent against the expanding pressure. As can be seen in Fig. 3, because of the existence of the plaque and the pressure applied by it, different positions of stent have different diameters. Here, in order to verify the behavior of the model, the outer diameter changes of points B, C (as shown in Fig. 3) were derived and shown.

Fig. 5 shows that the rate of increment of stent diameter at points B and C is almost identical as pressure changes from 0 MPa to 0.14 MPa. From the pressure 0.11 to 0.25 MPa, because of the contact between point B and the plaque, stent diameter increases with a low rate at point B, while at point C, the rate of increment of the diameter grows significantly. Finally, for pressures larger than 0.25 Mpa, because of the contact between the stent and the vessel, the variation of diameter at point C becomes small.

Dogboning: When the stent expands, because of different distribution of circumferential stress between the free ends and the central part, it bends on edges that causes the diameter at the end sides becomes larger than that of the middle of the stent. This phenomenon is called "dogboning". According to the findings of the clinical studies, a stent is expected to have the low dogboning [24, 25]. The dogboning is defined as:

$$dogboning_{distal} = \frac{R_{distal} - R_{central}}{R_{central}}, distal = left, right \tag{10}$$

$$dogboning = \sum_{distal} \left| dogboning_{distal} \right|, distal = left, right \tag{11}$$

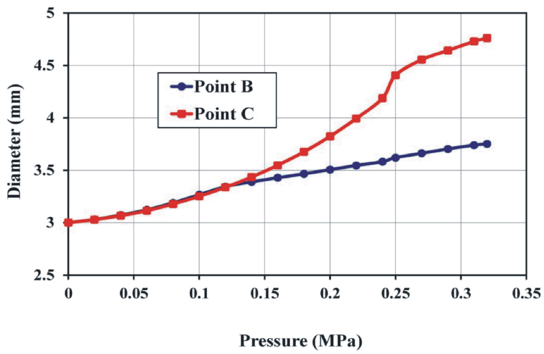

Fig. 5: The relation between the outer diameter of the stent and expanding pressure

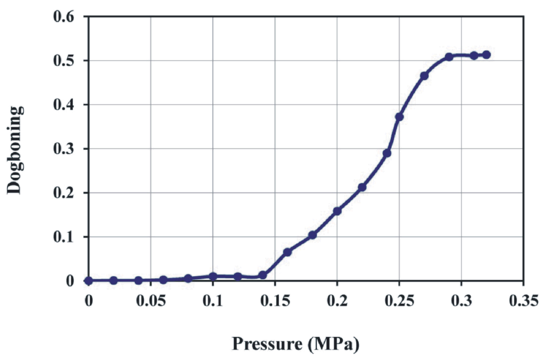

Fig. 6: The relation between the dogboning and expanding pressure

where subscripts (*distal* = *left*, *right*) indicate where the deformed structure is measured. Here, Points *A* and *D* are *left* and *right*, respectively.

Fig. 6 plots the relation between the dogboning and the expanding pressure. As shown in this figure, in pressures of 0.14 MPa and 0.25 MPa, the rate of dogboning is changed because of the contact of stent to the plaque and vessel.

Foreshortening: As mentioned above, because of the dogboning phenomenon, the diameter at the end sides of the stent becomes larger than that of the middle of the stent. This results a reduction in the stent length which is called "foreshortening". In fact, foreshortening defines the effective length of the stent and according to the findings of the clinical studies, a stent is expected to have a low value of foreshortening [24, 25]. The foreshortening is defined as:

$$foreshortening = \frac{L_0 - L}{L_0} \times 100\% \tag{12}$$

where L_0 and L are the initial and final length of the stent, respectively.

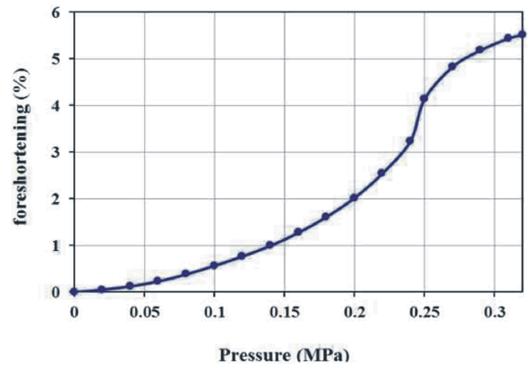

Fig. 7: The relation between the foreshortening and expanding pressure

Table 2: Comparison between the results obtained in this study and other researches

	Maximum stress in the stent (MPa)	Difference (%)
Present study	261.5 MPa	-
Chua *et al.* [10]	250 MPa	4.6
Ju *et al.* [12]	288. 2	10.2

Fig. 7 plots the relation between the foreshortening and the expanding pressure. As expected, in pressures of 0.14 MPa and 0.25 MPa, the rate of dogboning is changed because of the contact of stent to the plaque and vessel.

Verification: To validate the present method, the models same as those presented in [10, 12] were constructed and the obtained results compared in Table 2. The comparison indicates that the results are in a good agreement in terms of maximum von Mises stress in the stent.

CONCLUSION

The paper presents a methodology for modeling the expansion of coronary stents used in the treatment of blood vessel stenosis. In order to achieve a more realistic description of the stent implantation procedure, the model includes internal pressure of blood, balloon, stent, vessel and plaque. A commercially available stent model was analyzed in this study. According to the analysis, the critical points of the arterial wall are in the areas where maximum changes occurred in stent diameter. Thus, using this kind of stent would tend to damage vessel at these points. Moreover, after inflation, the length of the stent reduces about 5.5 %. The analysis performed and the results obtained could be used in design and optimization of geometrical and material properties of the stents as well as in evaluation of their performance at real conditions.

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