In Silico analysis of stent deployment - effect of stent design

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***Abstract*—Coronary artery disease (CAD) remains the leading cause of death in Europe and worldwide. One of the most common pathologic processes involved in CAD is atherosclerosis. Coronary stents are expandable scaffolds that are used to widen the occluded arteries and enable the blood flow restoration. To achieve an adequate delivery and placement of coronary stents different parameters play a significant role. Due to the strain that the stents are exposed to and the forces they should withstand, the stent design is dominant. This study focuses on investigating the effect of the stent design in two finite element models using two stents with difference in the strut thickness. The *in silico* deployment is performed in a reconstructed patient specific arterial segment. The results are analyzed in terms of stress in the stent and the arterial wall and demonstrate how stent expansion is extensively affected by the scaffold's design.**

I. INTRODUCTION

Atherosclerosis is an inflammatory pathology of the vascular tissue in which the atherosclerotic plaque growth is taking place inside the arteries and the blood flow is occluded. As atherosclerosis progresses, the arterial wall becomes more thick and stiff, while blood flow in coronary arteries is obstructed [1].

The appearance of CAD varies in time and space, whereas for individual patients, it is difficult to predict which plaques will evolve and destabilize. However, genetic predisposition has a key role to the initiation of this disease [2], while the growth is affected by other factors including the obesity, the smoking, the high levels of cholesterol and the high blood pressure [3], [4]. The aforementioned pathologies are initially treated through drug therapies [5]. However, drugs cannot act acutely. Therefore, in case an acute relief of the obstructed atherosclerotic coronary vessel is required, the gold standard treatment approach is mechanical intervention.

Percutaneous transluminal coronary angioplasty (PTCA) concerns the inflation of a catheter inside the narrowed coronary artery towards compressing the plaque, expanding the arterial wall, widening the arterial lumen and restoring the blood flow. Stents are tubular scaffolds that are placed and inflated in the stenotic region through the balloon catheter and provide scaffolding support, preventing this way the arterial recoil [6].

Even if the stent implantation has improved the clinical outcomes in CAD treatment, this interventional process poses certain issues – some related to the stent itself and others to the artery. The arterial injury caused by the stent implantation may result in tissue overgrowth, in-stent restenosis (ISR) as well as stent thrombosis (ST) [7]. Taking into consideration the high number of stent implantation procedures, which are performed worldwide, even a low rate of failure represents a large percentage of patients.

The last years, several stents have been designed and developed with variations in design, material and technology. The Stent Biomedical Industry has highly focused in research and development from the perspective of the stent design. The stent should fulfil specific performance requirements such as: (i) high radial strength, (ii) flexibility, (iii) good fatigue properties, (iv) low elastic radial and longitudinal recoil and, (v) optimum scaffolding. However, after stent implantation, in specific regions, the stents exhibit stress concertation, and it is this area that is subject to a potential stent failure. Today, the evaluation of the stents safety and efficacy is achieved through: (i) *in vitro* tests, (ii) *in vivo* assessment in animals and finally, (iii) clinical trials in humans. Even if this roadmap in the evaluation of the stents has been followed for many decades, a major concern exists related to the ethical issues that arise due to the animal experiments, as well as the issue of increasing variability among patients, since there is a difference between individuals' anatomy and pathophysiology of the arterial disease.

The advent of *in silico* modelling the last decades has enabled the design and development of biomedical products

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with advantages in terms of time and cost [10]. *In silico* technologies are of great importance since they are able to answer a variety of difficult questions, such as "What is the stent performance after implantation?", "How a specific change in the stent design may affect in the short and long term the patient outcomes?" [8]–[10].

Finite Element Analysis (FEA) has become an important tool for evaluating the stent performance and predicting its effect on the arterial morphology. Such models are able to provide useful insights into several different aspects of stent design, towards reducing the arterial wall injury. It provides information for different conditions, making it possible to examine and optimize several stent designs before concluding on the final stent configuration.

FEA modelling has been extensively used in the investigation of the stent performance as well as the stent-arterial wall interaction. Early studies were based on free-stent expansion models, in which the arterial geometry was not considered. Indicative studies of such approaches are those by Wu *et al.* [5], Dumoulin *et al.* [6], Tan *et al.* [7], Migliavacca *et al.* [8] and Chua *et al.* [9]. Donnelly *et al.* [11] performed a comparison of the stress/strain contour plots of different stent designs utilizing a unit cell model. The transient stent behaviour within different expansion modelling strategies was followed by De Beule *et al.* [10]. The authors applied three different scenarios: (i) a pressure directly on the inner stent surface, (ii) a displacement-driven condition on the inner balloon surface, (iii) a pressure on the inner surface of the balloon. Roy *et al.* [12] examined six commercial stents: PS stent, Cypher stent, S670 stent, Driver stent, Taxus Express stent and Element stent. Azaouzi *et al.* [13] studied the structural stent behavior and showed the effect of the stent design. More specifically, the stent "bridges" were evaluated in terms of flexibility, torsion and expansion.

To understand the effect of the arterial tissue and the underlying mechanism of stent implantation within a diseased arterial segment, several research teams included in their models the arterial morphology. Initially the 3D arteries were considered as idealised cylinders, whereas as the studies evolved patient-specific arterial geometries were used. Auricchio *et al.* [14] examined the Palmaz–Schatz stent performance in an idealised stenotic artery, focusing on the elastic recoil, the foreshortening and the metal-to artery-ratio surface ratio. Chua *et al.* [15] assessed the deployment characteristics of the Palmaz–Schatz stent in an idealised stenotic artery and investigated the degree of the induced arterial stresses. Ballyk *et al.* [16] focused on the effect of stent oversizing and the subsequent induced arterial stresses leading to neointimal hyperplasia. Capelli *et al.* [17] compared the mechanical performance of five different stent designs. Garcia *et al.* [18] investigated the stent geometrical parameters that influence the radial force and designed a new stent that achieved an improved arterial wall interaction. Imani *et al.* [19] compared two different stent designs in terms of stress, radial gain and foreshortening. Pant *et al.* [20] performed a parameter stent design analysis, which was accomplished by varying the shape of the circumferential rings and links.

In this study, we present the results of an *in silico* analysis that focuses on the effect of stent design during stent deployment in a reconstructed arterial geometry. The developed *in silico* model could be used as a framework for assisting the Stent industry in assessing *in silico* the biomechanical performance of stents and selecting the optimal design characteristics for the stent manufacturing.

II. Materials And Methods

A. 3D reconstruction

For the 3D reconstruction of the right coronary artery, data collected during the routine clinical examination were used. Intravascular Ultrasound (IVUS) and angiographic data were acquired and the methodology suggested by Bourantas et al. [21] was followed. Specifically, a three step process was implemented: (i) detection of the lumen and media adventitia borders of the artery, (ii) placement of the detected borders on the 3D lumen centerline, (iii) extraction of points clouds, that represent the arterial wall and lumen anatomy respectively. Then, based on the two point clouds, the creation of the 3D arterial model, which is utilized in the stent deployment modeling was achieved (Fig.1).

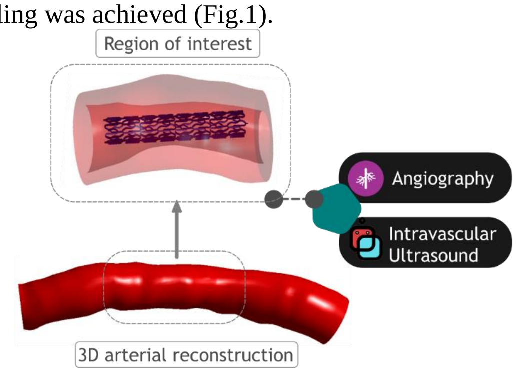

Figure 1. 3D finite element model including the reconstructed artery and the stent (unexpanded configuration).

B. Computational Model

The three-dimensional (3D) finite element model, that was used in the *in silico* analysis, included the reconstructed 3D arterial geometry and the stent configuration, both, before the stent deployment. The analysis was based on the Finite Element Method (FEM). ANSYS 14.5 (Ansys Canonsburg, PA) was the software that was used for the creation of the Finite Element model and the pre- and post- processing [22]. Two finite element models (Model A, Model B) were created, in which the only difference was in the stent design and more specifically in the stent struts. The stent design was based on the LeaderTM Plus CoCr PTCA stent system (Rontis Corporation S.A., Zug, Switzerland, www.rontis.com, Table I). The details of the stent dimensional characteristics are depicted in Table I.

TABLE I. Details on the Stent Design of Model A and Model B.

Model	***Stent Length (mm)***	***Stent Inner Diameter (mm)***	***Stent Strut thickness (mm)***
Model A	7.55	1.26	0.0810
Model B	7.55	1.26	0.0702

For the the stent and artery mesh generation, tetrahedral lower-order 4-node elements (SOLID285) and higher order 10-node elements (SOLID187) were selected. A mesh-independence analysis was followed to define the mesh that is adequate for the current analysis. Four different mesh densities were tested: (i) Mesh A: 65202 elements, (ii) Mesh B: 129645 elements, (iii) Mesh C: 203557 elements and, (iv) Mesh D: 258373 elements. The von Mises arterial stress between Mesh C and Mesh D was less than 5%, therefore Mesh C was selected. For the stent struts, in both models, the element thickness of 0.05mm was selected (Fig. 2).

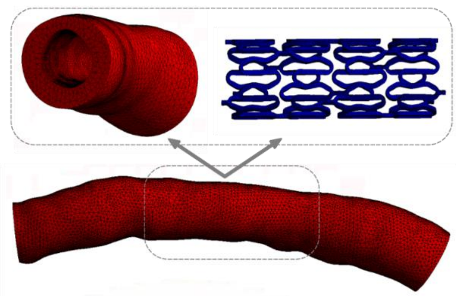

Figure 2. Mesh in the: (i) artery (left), (ii) stent (right).

C. *Material properties and Boundary Conditions*

The arterial tissue was assumed to consist of a single layer and homogeneous. From the biomechanical point of view, for the representation of the mechanical performance of the arterial wall, the hyper-elastic material model proposed by Mooney-Rivlin *et al.* was adopted [23].

The strain energy density function W and the strain invariants were defined as proposed by Maurel *et al*. [24]:

$$W\left(I_1,I_2,I_3\right)=\sum_{p,q,r=0}^{n} C_{pqr}\left(I_1-3\right)^p\left(I_2-3\right)^q\left(I_3-3\right)^r, \quad (1)$$

where the strain invariants $I_{1,}I_2,I_3$ are defined as:

$$I_1=\lambda_1^2+\lambda_2^2+\lambda_3^2, \quad (2)$$

$$I_2=\lambda_1^2\lambda_2^2+\lambda_1^2\lambda_3^2+\lambda_2^2\lambda_3^2, \quad (3)$$

$$I_3=\lambda_1^2\lambda_2^2\lambda_3^2. \quad (4)$$

$C_{000}=0, C_{pqr}$and $\lambda_1,\lambda_{2,}\lambda_3$ are the hyperelastic constants and principal stretches of the arterial wall, respectively. The arterial wall and stent materials properties are shown in Table II. For the stent, a bi-linear elasto-plastic material model was used. Details on the material properties of the arterial wall and the stent are depicted in Table II.

TABLE II. ARTERIAL WALL AND STENT MATERIAL PROPERTIES.

Arterial material properties				
C_{10}	C_{01}	C_{20}	C_{11}	C_{30}
0.0189	0.00275	0.08572	0.5904	0
Stent material properties				
Elastic modulus (MPa)	**Yield strength (MPa)**	**Tensile strength (MPa)**		**Poisson's ratio**
232000	414	738		0.32

III. BOUNDARY CONDITIONS

Both Finite Element Models are in their unexpanded configuration. The stent was placed in the region of stenosis. The artery was constrained at its ends and was not allowed to move/rotate in any direction. In the stent nodes, appropriate boundary conditions were selected, so as the movement in the axial and radial directions was allowed.

To achieve stent expansion, a pressure-driven approach was followed. Specifically, pressure was applied in the inner stent surface in three distinct phases: (i) loading (P=0 to 1.8MPa), (ii) holding (P=1.8MPa constant) and, (iii) unloading (P=1.8 to 0MPa). A frictionless contact was taken for the inner arterial wall-stent contact pair. Specific parameters, including the time step and the surface to surface contact algorithm, were selected to address the non-linearity of the contact problems.

IV. RESULTS

The results of the current analysis show that the stent design characteristics and especially the strut thickness influences the resulting stress field imposed on the arterial wall. Higher arterial stresses are located behind the region where the stent was expanded and more specifically in the region of stenosis. Specifically, it is observed that the inner arterial wall of Model B (1.0 MPa) exhibit higher stresses compared to the inner arterial wall of Model A (0.65MPa) (Fig. 3).

The distribution of the arterial stress in different stress ranges demonstrates that: (i) the percentage of arterial stress in the stress range of 0-0.15MPa is much higher for Model A (84%) compared to Model B (63.8%), (ii) the percentage of arterial stress in the stress range of 0.15-0.45MPa is lower for Model A (16.15%%) compared to Model B, (iii) the percentage of arterial stress in the stress range over 0.45 is higher for Model B (3.7%) compared with Model A (0.5%) (Fig. 4).

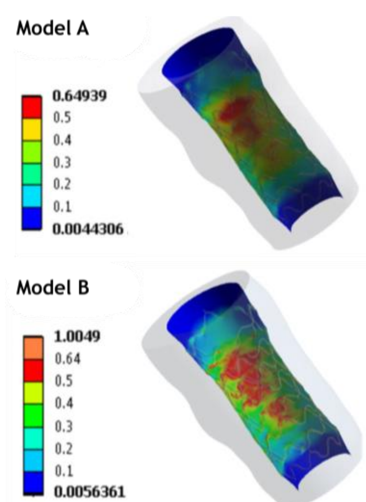

Figure 3. Von Mises stress (MPa) distribution in the inner arterial wall for Model A and Model B.

The percentage volume of each stent model belonging to different stress ranges is shown in Fig. 5. Specifically: (i) 74% percentage of the total von Mises stress belongs to the stress range of 0-200MPa for Model A, whereas the relevant percentage is 62.5% for Model B, (ii) the highest percentage in the stress range over 200MPa belongs to Model B (37.5%) followed by Model A (26%).

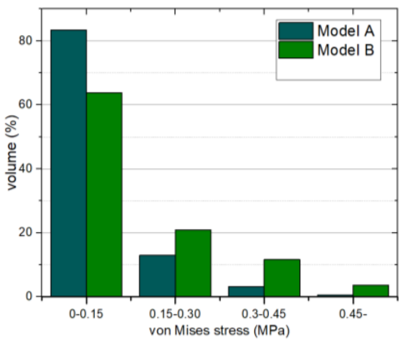

Figure 4. Von Mises stress volume distribution for the arterial wall (region of interest) (Model A and Model B).

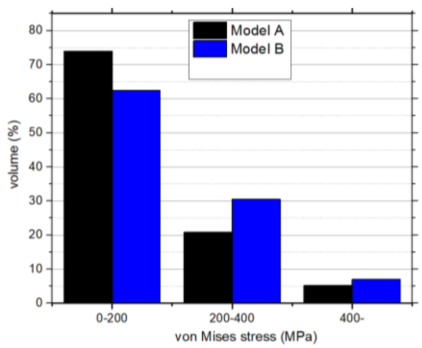

Figure 5. Von Mises stress volume distribution for the stent (Model A and Model B).

V. Conclusion

In the current study, an *in silico* analysis was performed towards evaluating the effect stent design during stent deployment. Specifically, two different stent geometries were used with changes in the strut thickness. The results demonstrated that stent expansion is extensively affected by the scaffold's design.

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