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In Silico Assessment of the effects of Material on Stent Deployment

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Abstract

Coronary stents are expandable scaffolds that are used to widen occluded diseased arteries and restore blood flow. Because of the strain they are exposed to and forces they must resist as well as the importance of surface interactions, material properties are dominant. Indeed, a common differentiating factors amongst commercially available stents is their material. Several performance requirements relate to stent materials including radial strength for adequate arterial support post-deployment. This study investigated the effect of the stent material in three finite element models using different stents made of: (i) Cobalt-Chromium (CoCr), (ii) Stainless Steel (SS316L), and (iii) Platinum Chromium (PtCr). Deployment was investigated in a patient specific arterial geometry, created based on a fusion of angiographic data and intravascular ultrasound images. *In silico* results show that: (i) the maximum von Mises stress occurs for the CoCr, however the curved areas of the stent links present higher stresses compared to the straight stent

segments for all stents, (ii) more areas of high inner arterial stress exist in the case of the CoCr stent deployment, (iii) there is no significant difference in the percentage of arterial stress volume distribution among all models.

Keywords

stent; material; finite element model; mathematical model

I.　Introduction

Atherosclerosis, an inflammatory vascular pathology in which the atheromatous plaque builds up inside the arteries and obstructs blood flow, is the leading cause of mortality in Europe and worldwide [1]. Current pharmacological treatments focus on lipid lowering combined with anti-inflammatory therapies, which slowly over time can reduce lesion burden minimally and modestly prevent progression [2]. More importantly drugs cannot act acutely and as such the gold standard treatment for acute relief of atherosclerotic coronary vessel occlusion is mechanical intervention. Percutaneous transluminal coronary angioplasty (PTCA), inflation of a balloon-tipped catheter within the narrowed coronary artery compresses the plaque and expands the surrounding wall of the artery, widening the arterial lumen and restoring distal blood flow. Once the balloon is deflated and catheter withdrawn, the artery recoils and benefit is lost except if permanent implants are left in place to provide continued support. Stents, tubular metal scaffolds, are such devices which when positioned and expanded in the stenotic region through the balloon catheter provide scaffolding support, preventing arterial recoil [3].

Since the first stent development and implantation, a variety of different stents have been proposed with variations in design, material and technology. Manufacturers have invested heavily in research and development focusing on materials and surface properties [4]. Today, safety and efficacy evaluation of stents involves *in vitro* tests, followed by evaluation in animals *(in vivo)* and then in humans (clinical evaluation/trial). Though this path has increasing clinical relevance there is also increasing variability with natural difference between individuals, anatomy and pathologic manifestation of arterial disease.

In silico modelling has therefore emerged as an important adjunctive evaluator tool to answer difficult questions, such as: "How do stents behave after implantation?", "What design changes and modifications can be implemented in to alter patient outcomes?".

In silico finite element analysis (FEA) e.g. enables the examination and evaluation of virtual implantation of multiple alternative designs in a range of theoretical anatomical and environmental conditions rapidly and cost effectively.

Several studies have been conducted investigating the performance of the stent and the stent-artery interaction through the utilisation of FEA modelling. Early works used free-stent expansion models without considering arterial geometry. Such studies were those presented by Wu *et al.,* [5], Dumoulin *et al.* [6], Tan *et al.* [7], Migliavacca *et al.* [8] and Chua *et al.* [9]. De Beule *et al.* [10] compared the transient behaviour of a Bx-Velocity stent with different

expansion modelling strategies applying: (i) pressure directly on the inner stent surface, (ii) displacement-driven conditions on the inner balloon surface, (iii) pressure on the inner surface of a tri-folded catheter balloon.

The effect of the arterial tissue and its composition was included in later models ranging from model arteries as idealised cylinders to patient-specific arterial geometries. Auricchio *et al.* [11] presented the results from an analysis that investigated the performance of the Palmaz-Schatz stent in terms of elastic recoil, foreshortening and metal-to artery- ratio surface when deployed in an idealised stenotic artery. Chua *et al.* [12] carried out a FEA to assess the deployment characteristics of the Palmaz-Schatz stent within an idealised stenotic artery and evaluated the degree of induced arterial stresses. Ballyk *et al.* [13] evaluated the effect of stent oversizing on the induced arterial stress and examined the "stress threshold" for the development of neointimal hyperplasia. Capelli *et al.* [14] studied the mechanical effect of five different balloon-expandable stent designs. Garcia *et al.* [15] evaluated the influence of the stent geometrical parameters on the radial force and based on the outcomes of the analysis designed a new stent to improve the stent arterial wall interaction.

The evaluation of stents, composed of different materials, has also gained great interest [16]. Schiavone *et al.* [17] examined four stents, two each of Stainless Steel (SS316L) and Cobalt-Chromium (CoCr). The Co-Cr stents presented higher stresses compared to SS316L stents; however, all stents experienced the dog-boning effect provoking higher stress concentration to the ends of the plaque. A similar study was the one performed by Zhao *et al.* [18], who compared the performance of five balloon-expandable and a self-expanding stent. This study demonstrated that larger strain was induced on the arterial walls by the SS316L stents compared to Co-Cr stents, performance that can be attributed to the higher stiffness of the Co-Cr stents and corresponding thinner struts. The Ni-Ti stent induced less arterial stress and strain, which could be caused by the lower stiffness of the Ni-Ti alloy. Tamaredi *et al.* [19] performed a computational analysis focusing on the effect of four different stent materials (SS316L, CoCr alloy, titanium alloy (Ti6Al4V), unalloyed annealed tantalum) based on the Palmaz-Schatz stent design. Tantalum and the SS316L stents required less pressure (0.564 and 0.6 MPa) to reach the target arterial diameter of 3 mm than Titanium and CoCr stents (1.2 and 1.32 MPa), attributed to differences in yield strengths.

As informative as these studies have been, there remains an imperative need at including more realistic 3D patient-specific arterial morphology. Kiousis *et al.* [20] investigated which is the optimal stent design for specific clinical criteria. This study, improved the numerical results of stenting by including the interaction of stents with the atherosclerotic lesions. Gijsen *et al.* [21] performed stent deployment in a 3D reconstructed coronary artery based on fusion of biplane angiography and intravascular ultrasound (IVUS). The stent strut thickness varied and authors investigated stent stresses and induced stresses on the arterial wall. Mortier *et al.* [22] compared different second generation stents and assessed their effect on the arterial wall of a coronary bifurcation with a (highly) curved main vessel. A new method was used for the creation of the 3D bifurcation model using *in vivo* patient-specific angiographic data. The different layers of the arterial wall and the anisotropic behavior of these layers were modelled through the utilisation of a novel algorithm. The proposed simulation strategy deployed the stent in the curved main branch through the insertion of a

folded balloon catheter. Zahedmanesh *et al.* [23] focused on investigating the mechanics of balloon-stent interaction and shed light on the difficulties of folded balloon geometries creation. Gervaso *et al.* [24] simulated three different modelling approaches to assess the stent-free expansion and the stent expansion inside an idealised artery by: (i) applying a uniform pressure on the inner stent surface, (ii) expanding a cylindrical surface with displacement control (iii) including a deformable balloon.

For a particular stenotic artery, the optimal intervention strategy varies and depends on several factors, such as the stent type, the strut thickness, the stent cell geometry, as well as the stent-arterial wall radial mismatch. Holzapfel *et al.* [25] proposed a methodology in which several parameters varied, to evaluate the difference within the arterial wall before and after implantation of Multi-Link-Tetra™ (Guidant), NIROYAL™ Elite (Boston-Scientific), and InFlow™-Gold-Flex (InFlow Dynamics) stents. These models were parameterized to allow creation of new designs by varying stent geometry.

We now present a study of the effect of material on stent deployment in a reconstructed arterial morphology. A unique *in silico* model is developed to assist industry in evaluating *in silico* the performance of stents and optimal material for the stent manufacturing, and to guide healthcare professionals in selecting the most appropriate stent and implantation procedure for a specific patient lesion.

II. Materials And Methods

A. 3D reconstruction

The reconstruction of the right coronary artery in 3D was based on data acquired during routine clinical examination and a conventional methodology proposed by Bourantas *et al.* [26] was followed. The centerline methodology utilized angiographic data and IVUS images. The following process was implemented: (i) the lumen and media adventitia borders of the artery were initially detected, (ii) the detected borders were placed on the 3D lumen centerline, (iii) two points clouds were extracted, representing the arterial wall and lumen anatomy. Then, the 3D arterial model was utilized for the stent deployment modeling (Fig. 1).

B. Computational Model

ANSYS 14.5 (Ansys Canonsburg, PA) was used for finite element model development and post processing of the results [27]. The three finite element models consisted of the arterial geometry and the stent, both in unexpanded configurations. The models include arterial geometry with three different stents of CoCr, SS316L and PtCr based on designs of the commercially available Leader™ Plus CoCr PTCA stent system stent (Rontis Corporation S.A., Zug, Switzerland, Table I) [28].

Tetrahedral lower-order 4-node elements (SOLID285) and higher order 10-node elements (SOLID187) were selected for the stent and artery mesh generation. A mesh-independence study was conducted to define mesh. For this purpose, the arterial von Mises stress was used after stent expansion of mesh densities over a 4-fold range of 65202, 129645, 203557, and 258373 elements. The von Mises arterial stress difference between the latter two meshes was

less than 5%, therefore the 203557 element mesh was selected for the further analysis. The arterial geometry was divided in three parts to achieve a refined mesh in the area of stent deployment, while for the stent the element thickness of 0.05mm was chosen (Fig. 2).

C. Material properties and Boundary Conditions

Arterial tissue was assumed homogeneous and a hyperelastic material model proposed by Mooney-Rivlin *et al.* was used, defined by a polynomial form [29]. The strain energy density function W was as described by Maurel *et al* [30]:

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

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} is the hyperelastic constants, λ_1, λ_2, λ_3, are the principal stretches of the arterial wall (Table II). Three different stent materials were used (Table III) and modeled with an elastoplastic stress strain relationship.

For stent expansion, the boundary conditions imposed on the stent were those suggested by Gervaso *et al.* [24]. More specifically, a pinned boundary condition was applied at the arterial ends, while three nodes (middle section) of the stent were allowed to expand only radially to avoid rigid movement. For the stent-artery contact, a surface-to-surface frictional contact was selected. To achieve stent expansion, 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).

III. Results And Discussion

The results of the *in silico* analysis are presented in terms of stress distribution in the stent and the inner arterial wall and stent radial change. These results could be taken into account in the phase of material selection during the stent design process.

In Fig. 3, the pressure vs. the radial deformation is shown for node 2 of the central stent cross section. For this node, a similar expansion performance with a small difference between CoCr vs. SS316L and PtCr stents is observed. The radius maintains a peak value during the holding phase, while the stent contracts when the load decreases.

The stress distribution for the stents (Fig. 4, end of phase III) suggests that the percentage of stent volume is almost equal for the stress range of 0–200MPa and 200–400MPa for all models. High von Mises stresses (>400MPa) exist: 5.2% in the CoCr stent, 3.8% in SS316L and, 4.2% in PtCr stents. The von Mises stress of the three stents (Fig. 5) show similar expansion performance with a maximum diameter achieved at 1.8MPa. It should be noted that the maximum von Mises stent stress of ~ 736 MPa occurs in CoCr stent, while the relevant stent stresses are 659 and 709MPa for the other stents. For all models, the curved areas of the stent links present higher stresses compared to the straight stent segments. The high stresses in these regions could indicate a risk for potential failure during stent expansion.

All stents followed a similar pattern of inner arterial stresses after unloading. The maximum von Mises stresses were 0.65MPa for CoCr, and 0.62MPa for both the SS and PtCr stents (Fig. 6). In each model, the peak arterial stress is concentrated in the same region, which is mainly the region of stenosis. More areas of high arterial stress exist in the CoCr stent compared to the other two models. However, the following observations are made regarding the stress percentage volume distribution for the arterial wall, only in the region of interest, for all models: (i) 83% of the arterial tissue has a von Mises stress in the range 0–0.15 MPa, (ii) 13% of the arterial tissue has a von Mises stress in the range 0.15–0.30 MPa, (iii) 4% of the arterial tissue has a von Mises stress over 0.30 MPa.

The above mentioned observations denote that only the inner arterial layer is mainly affected by the stent expansion.

IV.   Conclusions

In this study, the effect of the different stent materials was investigated by *in silico* FEA in an arterial model reconstructed from patient specific clinical imaging data. In particular, three different materials were used CoCr, SS316L, and Pt-Cr, and different key performance indicators were evaluated.

The investigation of the arterial stresses showed that a similar pattern is followed for latter two materials, whereas a small increase in the arterial stress is obtained for the first. The results confirm the differences obtained by the expansion of different stents, while the analysis of the von Mises stress for the stents are in agreement with the results obtained by Schiavone *et al.* [17] and Pant *et al.* [31].

A comparison among *in silico* studies, modelling the full stent deployment, with a focus on the effects of stent materials, is presented in Table IV. In most studies the arterial geometry is idealised and not based on patient specific data [17], [18], [19]. More specifically, only the study of Mortier *et al.* [22] and the current study utilised patient-specific angiographic and IVUS data to accurately reproduce the *in vivo* characteristics of the arterial segments. The

atherosclerotic plaque component is included in [17], [18], however it is modelled as an idealised cylinder with an axisymmetric stenosis. To the best of our knowledge, this study is the first attempt to compare the effect of SS316L, CoCr, PtCr materials during stent deployment in a 3D reconstructed artery.

V. Limitations And Future Work

To reduce the required computational time, the arterial wall was modelled as homogeneous and the different plaque components were not included in the current analysis. The presence of the media, the fibrous and calcifications could result in a more sophisticated model. In addition, the analysis ignored the presence of the balloon component that could provide valuable information regarding the injury caused on the arterial wall during stent expansion.

Acknowledgment

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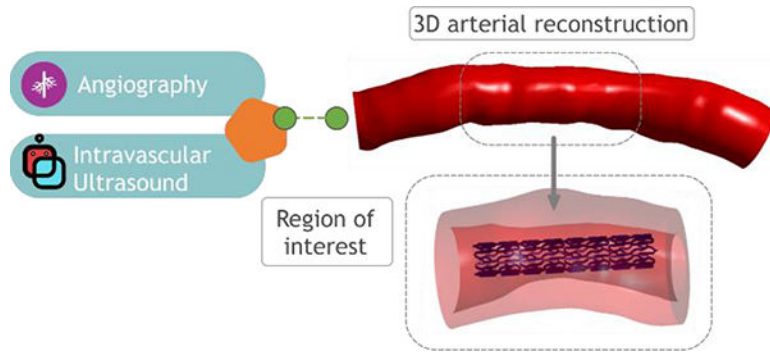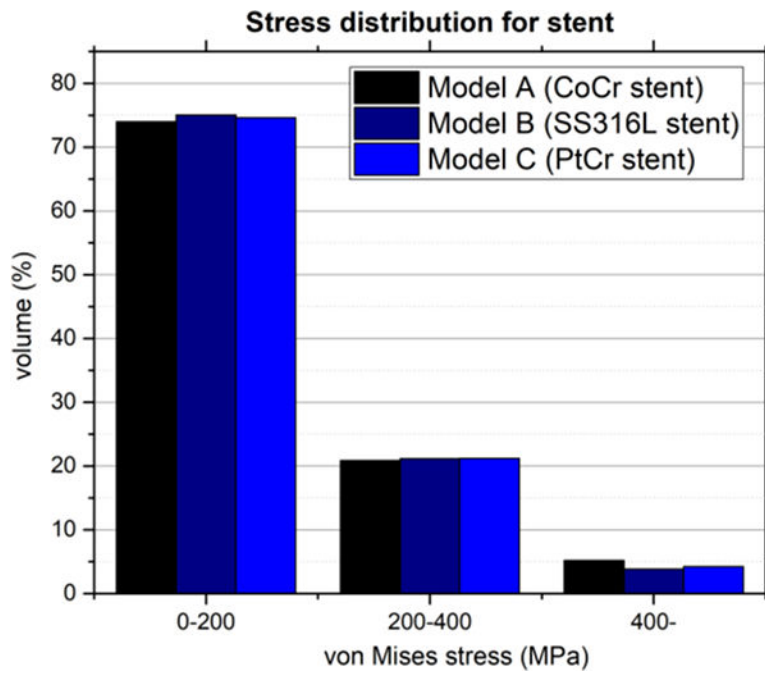
Figure 1.
Fusion of IVUS and angiography medical data for the 3D arterial reconstuction. The finite element model pre-simulation (unexpanded configuration).
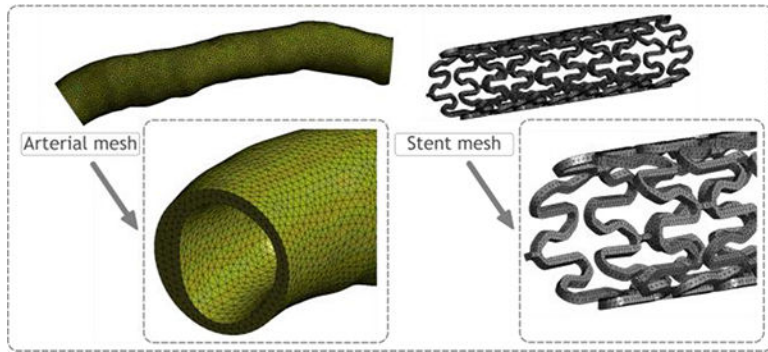
Figure 2.
Model design and mesh in the: (i) artery (left), (ii) stent (right).
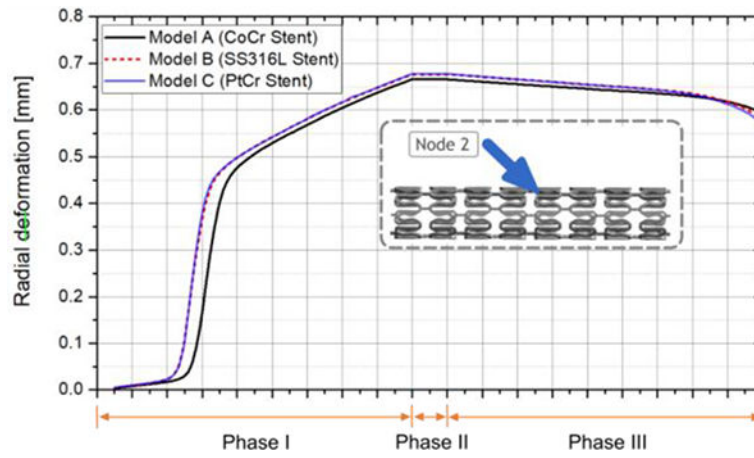
Figure 3.
Plot of pressure vs radial deformation for node 2 (node existing in the stent middle cross-section) for different stents
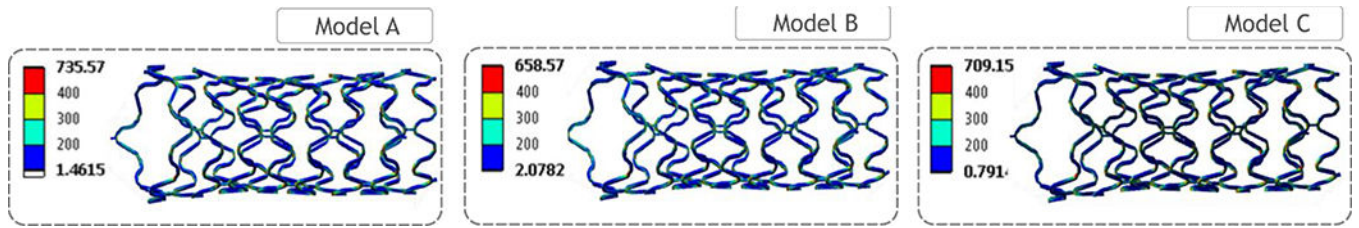
Figure 4.
Von Mises stress percentage volume distribution for stents of Models A, B and C.
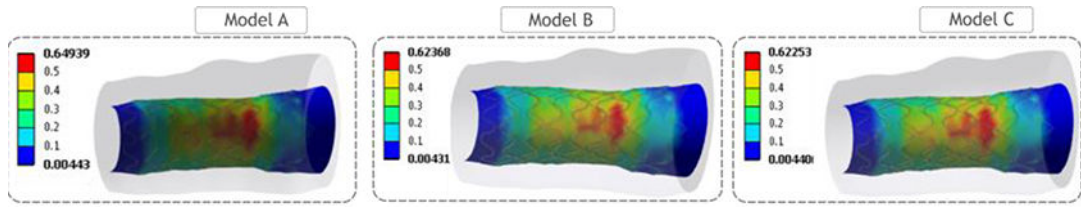
Figure 5.
Von Mises stress distribution for the CoCr, 316L SS and CoCr stents (at the end of the unloading phase).

Figure 6.
Von Mises arterial stress after unloading (end of Phase III) for Models A, B and C.

TABLE I.

Arterial Geometry And Stent Dimensional Characteristics.

Arterial Geometry	Dimensional characteristics		
	Max Inner Diameter (mm)	Min Inner Diameter (mm)	Length (mm)
	4.40	2.26	30
Stent Geometry	Inner diameter (mm)	Thickness (mm)	Number of rings
	1.26	0.081	8

TABLE II.

Arterial Wall Properties.

Arterial Material Properties	Arterial hyperelastic coefficients				
	C_{10}	C_{01}	C_{20}	C_{11}	C_{30}
	0.0189	0.00275	0.08572	0.5904	0

TABLE III.

Material Properties Of Stents.

Stent Material Properties	Table Column Head		
	MODEL A	MODEL B	MODEL C
Elastic modulus (MPa)	232000	193000	200000
Yield strength (MPa)	414	360	355
Tensile strength (MPa)	738	675	834
Poisson's ratio	0.32	0.3	0.32

TABLE IV.

Comparison Of *In Silico* Studies Focusing On Stent Material.

| *In silico Studies* | *Artery* | | *Plaque* | *Stent material* | *Balloon* |
	Idea-Used	*Recon-structed*			
Schiavone *et al.* [17]	✓		✓	SS316L, CoCr, other	
Zhao *et al.* [18]	✓		✓	SS316L, CoCr, other	
Tamaredi *et al.* [19]	✓			SS316L, CoCr, other	
Mortier *et al.* [22]		✓		SS316L, CoCr,	✓
Our study		✓		SS316L, CoCr, PtCr	