Modeling stent deployment in realistic arterial segment geometries: the effect of the plaque composition

Georgia.S. Karanasiou¹, Antonios.I. Sakellarios¹, Evanthia.E. Tripoliti¹, Euripides.G.M. Petrakis¹, Michalis.E. Zervakis¹, Francesco Migliavacca², Gabriele Dubini², Elena Dordoni², Lambros.K. Michalis³, Dimitrios.I. Fotiadis⁴

Abstract— Stents are medical devices used in cardiovascular intervention for unblocking the diseased arteries and restoring blood flow. During stent implantation the deformation of the arterial wall as well as the resulted stresses caused in the arterial morphology are studied. In this paper we study the effect of the composition of the atherosclerotic plaque during the stent deployment procedure, using Finite Element modeling. The stenting procedure is simulated for two different cases; in the first the presence of the plaque is ignored whereas in the second a three dimensional (3D) stiff calcified plaque is located in the stenotic area of the artery. Results indicate that in the second case the von Mises stresses in the arterial wall are higher than the stresses occurred in the first case. In addition, the distribution of the arterial von Mises stress depends on the plaque composition.

I. INTRODUCTION

A THEROSCLEROSIS is one of the most common cardiovascular diseases, that affects more than 26% of the human population. It is observed that elderly people are most likely to suffer from atherosclerosis; however, the start and the progress of atherosclerosis may begin earlier. The development of the atherosclerotic plaque leads the arteries to become hardened and narrowed. As a consequence, the blood flow is obstructed or even totally blocked. The complications vary and depend on the severity of the artery occlusion and may cause hypertension or stroke episodes [1]. Regarding the

G.S. Karanasiou, is with the Department of Electronic and Computer Engineering, Technical University of Crete, Chania, Crete, Greece (phone: +302651007702, fax: +302651008889, email: <u>g.karanasiou@gmail.com</u>)

A.I. Sakellarios, E.E. Tripoliti, E.G.M. Petrakis, Michalis. E. Zervakis is with the Department of Electronic and Computer Engineering, Technical University of Crete, Chania, Crete, Greece

(ansakel@cc.uoi.gr,etripoliti@gmail.com,petrakis@intelligence.tuc.gr, michalis@display.tuc.gr).

F. Migliavacca, G. Dubini, E. Dordoni is with the Laboratory of Biological Structure Mechanics (LaBS), Department of Chemistry, Materials and Chemical Engineering "Giulio Natta"

(email: <u>francesco.migliavacca@polimi.it</u>, <u>gabriele.dubini@polimi.it</u>, <u>elena.dordoni@polimi.it</u>).

L.K. Michalis is with the Department of Cardiology, Medical School, University of Ioannina, Ioannina, Greece (email: <u>lmihalis@cc.uoi.gr</u>).

D.I. Fotiadis is with the University of Ioannina, Department of Materials Science, Unit of Medical Technology and Intelligent Information Systems, Ioannina, Greece (email: <u>fotiadis@cc.uoi.gr</u>).

treatment, this can be done employing balloon angioplasty, stent placement and artery bypass [2]. In angioplasty a balloon catheter is inserted into a narrowed artery, its expansion reduces the blockage, compresses the plaque against the arterial wall and restores blood flow. Depending on the severity of the artery occlusion and in order artery's narrowness to be prevented, stenting procedure is often utilized. In the stenting procedure, a tiny metal stent is placed across the arterial wall [3]. Initially the stent is in contact with the balloon catheter and the balloon-stent device is inserted in the narrowed artery. After the balloon's expansion, the stent remains in place keeping the arterial wall open and pushing the plaque. The stent must be positioned accurately into the diseased artery. It should be in direct contact with the arterial wall in order to avoid potential complications such as in stent restenosis. Stenting has become increasingly popular and it is superior to balloon angioplasty for chronic occlusion diseases [4]. This is due to the fact that during angioplasty there is a high risk of an excessive healing process in the arterial wall leading to the arterial re-narrowing [5].

Many computational studies, based on the Finite Element Method (FEM) have been conducted regarding the stent deployment procedure. The stent can be made of metal mesh or fabric. There are some stents coated with drugs (drug eluting stents) that slowly release a drug to block the cell proliferation and prevent the arterial wall to be blocked again [6]. The stent design [7], [8] and the material of the stent [8], [9] determine the behavior of the arterial wall. Also self-expanding stents made of shape memory alloy materials are used for the treatment of diseased arteries [10], [11]. The stents under different loading conditions present different mechanical behavior [12]. There is also a dependency on other parameters like the composition of the arterial wall and the plaque [13], as well as the type of the balloon used [14]. Many different techniques were used concerning the modeling of the balloon expansion [15], [16]. The finite element method is also used to investigate the interaction between the involved components during the stent deployment [15], [17]. Other studies take into account the plaque existence [15] whereas others ignore it [18].

Although, stent deployment procedure has been routinely and successfully used, it is scientifically interesting to focus on the biomechanical factors that affect

Manuscript received July 30, 2013. This work is part funded by European Commission (Project "RT3S: Real Time Simulation for Safer vascular Stenting" FP7- 248801).

the effectiveness of this procedure and minimize the longterm failure. The aim of this study is to examine the effect of the existence of a calcified plaque component in a realistic reconstructed diseased artery during the stent implantation procedure. In particular, the differences in the resulted stresses of the involved components with and without the plaque component are studied. The results indicated that FEM was suitable and effective in predicting and evaluating the effect of the existence of the plaque component in stent implantation.

II. MATERIALS AND METHODS

A. 3D reconstruction

The reconstruction of the three dimensional artery (3D) is based on the fusion of angiographic and intravascular ultrasound (IVUS) data which are collected from a 62 year old patient, affected by symptoms of arterial hypertension and hypercholesterolemia. The method introduced by Bourantas *et al.* [19] is adopted for the reconstruction of the stenotic arterial segment. The detected lumen and media adventitia borders were positioned on the 3D catheter path and the generated point cloud depict the arterial wall and lumen geometry. Regarding the reconstruction of the plaque geometry, an automated plaque characterization method, introduced by Athanasiou *et al.* [20], is employed.

B. Computational modeling

In order to perform the stent deployment simulation, the FEM requires the input of the geometry and the material properties of (a) the artery, (b) the plaque, (c) the stent and (d) the balloon, as well as, appropriate boundary conditions. A 3D finite element model in its unexpanded configuration is developed and the software ANSYS 12.1 (ANSYS, Canonsburg, PA) is used for the pre- and postprocessing. The atherosclerotic artery, with length 17.54mm, and the plaque, with length 3.27mm and thickness range from 1.05-1.40mm, were in contact during the whole stenting procedure. For the generation of the stent geometry, the OPEN STENT design is selected [21] and formed appropriately for this specific reconstructed artery. Regarding the balloon geometry, it is designed in its unfolded state and modeled as a cylindrical plane, being initially attached to the stent inner surface. The simulation of the stenting procedure is performed for the following cases:

a. *First model:* consists of the artery and the stentballoon device, ignoring the presence of the plaque component.

b. *Second model:* consists of the artery and the stentballoon device, including a calcified plaque component.

These cases are studied in order to investigate the importance of the existence of the plaque component in the stenting simulation. The 3D finite element geometries for both stenting models are presented in Fig.1.

Concerning the modeling approach, the stenting

procedure introduced by Gervaso *et al* [16] is followed. A uniform radial displacement is imposed in the cylindrical balloon surface, simulating balloon inflation and therefore the forthcoming stent expansion. The FEM models are discretized using 27360 and 29315 tetrahedrons elements, respectively, except the balloon which is discretized using hexahedron elements. The mesh density, used in the analysis, is defined on the basis to ensure the minimum penetration between the involved contact pairs during the stent deployment and optimize the simulation.



Fig. 1. The FEM model (a) without the plaque component, (b) with the plaque component (green component).

C. Material properties

The stent is assumed to be made of Stainless Steel (SS304) with Young Modulus 193GPa, Shear Modulus 75×10^6 MPa, Tangent Modulus 0.692GPa, Yield Stress 207MPa and Poisson's ratio 0.27. The mechanical behavior of the stent is modeled using the bi-linear elastoplastic material model [22], [23]. This material model approaches the permanent deformation that stent displays after the stent deployment. The arterial wall consists of three layers: the intima, media and adventitia, even though in most computational studies the arterial wall is simplified and treated as homogenous, isotropic and incompressible [24]. The non-linear behavior of the arterial wall, between stress and strain, can be described through a hyperelastic material model. The hyperelastic material theory assumes that the loading and unloading stress-strain response is based on the same curve, which depicts the basic mechanical behavior that the human soft tissues have. The hyperelastic material model used is the five parameter third order Mooney-Rivlin model, defined by a polynomial form in Eq.(1) and described by Eshghi et al. [22] :

$$W = C_{10}(I_1 - 3) + C_{01}(I_2 - 3) + C_{20}(I_1 - 3)^2 + C_{11}(I_1 - 3)(I_2 - 3) + C_{30}(I_1 - 3)^3.$$
(1)

The hyperelastic constants of Eq.(1) are summarized in Table I.

T ABLE I Arterial Wall Hyperelastic Coefficients

Coefficients	C ₁₀	C ₀₁	C ₂₀	C ₁₁	C ₃₀	
Artery	0.0189	0.00275	0.08572	0.5904	0	

A linear isotropic elastic description is employed for the calcified plaque with Young Modulus 2.7MPa and Poisson's ratio 0.4913. Furthermore, the polyurethane balloon is described by a Mooney Rivlin hyperelastic material model using C_{10} =1.0318MPa and C_{01} =3.6927 MPa [25].

D. Boundary conditions

The reliability of the stent deployment analysis depends on the assumptions and the hypotheses adopted. In order to avoid the rigid body motion of the FEM, the artery is fully tethered at its ends while the stent is allowed to move only in the radial direction. Additionally, a radial displacement of 0.8mm is imposed on the inner surface of the balloon. The outer surface of the balloon is initially in contact with the inner surface of the stent. The penalty contact algorithm, available in ANSYS, is selected to model all the contact pairs. Frictional contact is adopted for the interface among the stent, balloon and the stent, artery components with friction coefficient 0.1. The other contact bodies are defined as frictionless. The non-linear behavior of the materials and the contact analysis, is solved, using the iterative Newton-Raphson's algorithm. Moreover factors such as stiffness and penetration are crucial and specific attention must be taken.

III. RESULTS AND DISCUSSION

The arterial von Mises stresses, for both models, in three different cross sections along the longitudinal axis are shown in Fig 2. More specifically, for each cross section, both models in the undeformed state are presented, as well as, the obtained von Mises stresses after stent deployment. The distribution of the arterial von Mises stresses is examined in three different cross sections near the region of the stenosis; a) before the maximum stenosis, b) in the maximum stenosis, and c) after the stenosis. The model consisted of the artery and the stentballoon device, ignoring and taking into account the presence of the plaque component, is depicted in the first row and second row, respectively. We obtain differences in the von Mises stress in the arterial wall for these two cases; in the second case we observe higher stresses than in the first one especially in the region where the stenosis and the stiff plaque exists. Thus, the calcified plaque affects the consequential von Mises stresses in the plaque, where the maximum stresses appear. In order to evaluate the effect of the stent deployment in the lumen of the arterial wall, a vertical cross section is made as well and it is shown in Fig. 3.

Fig. 3 shows that, in the area where the stent expands and the struts contact the arterial wall, higher stresses are presented for both cases. Also, the stress in the arterial wall is reduced from the lumen to the outer arterial wall surface. However, it is noticed that stent deployment affects these models in a different way, regarding the area where high stresses appear. The FEM analysis indicates that the maximum von Mises stress in the arterial lumen varied with the presence or absence of the plaque component.



Fig. 2. Von Mises stresses for three section areas (a, b, c). The FEM model: (1) without the plaque component, (2) with the plaque component.



Fig. 3. Von Mises stresses for both models in the vertical cross section (1) The FEM model without the plaque component, (2) The FEM model with the plaque component.

Particularly in the first model, the maximum von Mises stress appears in two different arterial locations whereas in the second one the maximum von Mises stress appears to be concentrated in one region. For these two models, even if the difference in the maximum arterial von Mises stress is insignificant; 0.38375MPa for the first model and 0.39601MPa, respectively, in the plaque area the difference in the resulted von Mises stress ranges from 58-87%.

IV. CONCLUSIONS

In the present work we can demonstrate that the Finite Element Method is a reliable and valuable method for estimating the performance of stent deployment and revealed that the presence of the calcified plaque differentiates the von Mises stresses occurred in the arterial wall.

Furthermore, it was presented that stress concentration occurs when the stiff plaque is taken into account. Different plaques may behave differently to the same stenting procedure. Moreover the injury of the arterial wall may depend on the plaque properties. Plaque rupture is most likely to occur in regions associated with high stress. It is thus concluded that, more accurate data, of plaque composition, can be significant for the doctors in order to predict regions with higher risk for plaque rupture. Experimental studies have been presented for hemodynamics after stent placement; however it has been difficult to measure accurately the flow characteristics.

For future work, different models regarding the plaque composition could be modeled in order to examine the effect of the material stiffness in the underlying arterial stresses. Also, the behavior of the hemodynamic parameters on a 3D reconstructed patient artery, pre and post stenting procedure, could be examined.

ACKNOWLEDGMENT

This work is part funded by European Commission (Project "RT3S: Real Time Simulation for Safer vascular Stenting" FP7- 248801).

REFERENCES

- H. Rana, J. Andrews, B. Chacko, K. Hansen, P. Levy, "Mortality in patients with premature lower extremity atherosclerosis," Journal of Vascular Surgery., pp. 28-36, Jan. 2013
- [2] R. Mehta, K. Harjai, J. Boura, J. Tcheng, S. Dixon, G. Stone, C. Grines, "Short-term outcomes of balloon angioplasty versus stent placement for patients undergoing primary percutaneous coronary intervention: Implications for patients requiring early coronary artery bypass surgery," American Heart Journal., pp.1000-1007, June 2013
- [3] D. Fischman, M. Leon, D. Baim, R. Schatz, M. Savage, I. Penn, K. Detre, L. Veltri, D. Ricci, M. Nobuyoshi et al., "A randomized comparison of coronary-stent placement and balloon angioplasty in the treatment of coronary artery disease. Stent Restenosis Study Investigators," N Engl J Med., pp. 496-501, 1994
- [4] P. Rubartelli, E. Verna, L. Niccoli, C. Giachero, M. Zimarino, G. Bernardi et al., "Coronary stent implantation is superior to balloon angioplasty for chronic coronary occlusions: Six-year clinical follow-up of the GISSOC trial," Journal of the American College of Cardiology., pp. 1488–1492, 2003,
- [5] C. Macaya, P. Serruys, P. Ruygrok, H. Suryapranata, G. Mast et al., "Continued benefit of coronary stenting versus balloon angioplasty: one-year clinical follow-up of Benestent trial. Benestent Study Group," J Am Coll Cardiol., pp. 255-261, Feb. 1996
- [6] W. Khan, S. Farah, A. Domb, "Drug eluting stents: Developments and current status," Journal of Controlled Release., pp. 703–712, July 2012
- [7] Boyle, Colin, Lennon, Alex, Prendergast, Patrick, "Application of a mechanobiological simulation technique to stents used clinically," Journal of Biomechanics., Volume 46, pp. 918-924, March 2013

- [8] J. Tambaca, S. Canic, M. Kosor, R. Fish, D. Paniagua, "Mechanical Behavior of Fully Expanded Commercially Available Endovascular Coronary Stents," Tex Heart Inst., pp. 491–450, Jan.2011
- [9] F. Migliavacca, L. Petrini, P. Massarotti, S. Schievano, F. Auricchio, G. Dubini. "Stainless and shape memory alloy coronary stents: a computational study on the interaction with the vascular wall," Biomech Model Mechanobiol., pp.205-217, Mar 2004
- [10] M. Azaouzi, A. Makradi, S. Belouettar, "Deployment of a selfexpanding stent inside an artery: A finite element analysis," Materials & Design., pp.410-420, Oct. 2012
- [11] M. Azaouzia, N. Lebaalb, A. Makradia, S. Belouettara, "Optimization based simulation of self-expanding Nitinol stent," Materials & Design., pp. 917–928, Sept. 2013
- [12] M. Azaouzi., A. Makradi, S Belouettar, "Numerical investigations of the structural behavior of a balloon expandable stent design using finite element," Computational Material Science., pp. 54-61, May 2013
- [13] I. Pericevica, C. Lallyb, D. Tonerb, "The influence of plaque composition on underlying arterial wall stress during stent expansion: The case for lesion-specific stents," pp 428–433, May 2009
- [14] D. Pamplona, P. Gonçalves, S. Lopes, "Finite deformations of cylindrical membrane under internal pressure," pp. 693-696, June 2006
- [15] H. Zahedmanesh, J. Kelly, C. Lally, "Simulation of a balloon expandable stent in a realistic coronary artery — Determination of the optimum modelling strategy," Journal of Biomechanics., pp. 2126-2132, Aug. 2010
- [16] F. Gervaso, C. Capelli, L. Petrini, S. Lattanzio, L. Virgilio, F. Migliavacca, "On the effects of different strategies in modelling balloon-expandable stenting by means of finite element method," Journal of Biomechanics., pp. 1206–1212, 2008
- [17] K. Takashima, T. Kitou, K. Mori, K. Ikeuchi. "Simulation and experimental observation of contact conditions between stents and artery models," Med Eng Phys., pp. 326-35, May 2006
- [18] F. Gijsen, F. Migliavacca, S. Schievano, L. Socci, L. Petrini, A. Thury et al., "Simulation of stent deployment in a realistic human coronary artery," Biomed Eng Online., pp. 7-23, 2008
- [19] C. Bourantas, I. Kourtis, M. Plissiti, D Fotiadis, C Katsouras, M Papafaklis, L Michalis. "A method for 3D reconstruction of coronary arteries using biplane angiography and intravascular ultrasound images," Comput Med Imaging Graph., pp. 597-606. Nov 2005
- [20] L. Athanasiou, P. Karvelis, V. Tsakanikas, K. Naka, L. Michalis, C. Bourantas, D. Fotiadis, "A novel semiautomated atherosclerotic plaque characterization method using grayscale intravascular ultrasound images: comparison with virtual histology,"IEEE Trans Inf Technol Biomed., pp. 391-400, May 2012
- [21] C. Bonsignore, Open Stent Design at: http://www.nitinol.com
- [22] M. Imani, A. Goudarzi, M Hojjati, "Finite Element Analysis of Mechanical Behaviors of Multi-Link Stent in a Coronary Artery with Plaque," World Applied Sciences, pp. 1597-1602, 2013
- [23] Mechanics of Materials, R. Hibbeler, Macmillan, New York, 1994
- [24] A. Valencia, F. Solis, "Blood flow dynamics and arterial wall interaction in a saccular aneurysm model of the basilar artery," Computers & Structures., pp. 1326–1337, August 2006
- [25] D. Chua, B. MacDonald, M. Hashmi, "Finite element simulation of slotted tube (stent) with the presence of plaque and artery by balloon expansion," pp 1772–1779, Nov. 2004