Fatigue behaviour of Nitinol peripheral stent: finite element analyses of *in vivo* loading conditions

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Abstract - Fatigue resistance of Nitinol peripheral stents implanted into femoropopliteal arteries is a critical issue due to the particular biomechanical environment of this district. Hip and knee joint movements, combined with the cyclic loading due to the arterial blood pressure, expose the superficial femoral artery (SFA), and therefore the implanted stents, to quite large and cyclic deformations that may influence the fatigue resistance of the device. In this study, simulations of angioplasty, stenting and subsequent in vivo loading conditions (cyclic pressure, axial compression and bending) have been developed in a stenotic vessel models, using the commercial code ANSYS (Ansys Inc., Canonsburg, PA, USA). A finite element model of a stent, resembling the geometry of the Maris Plus peripheral stent (Medtronic-Invatec), has been reconstructed. A stenotic vessel model has been developed. The results, analyzed in terms of amplitudes (ε^1_a) and mean values (ε^1_m) of the first principal strain through the stent, showed that the cyclic pressure is the less critical loading condition: the maximum alternating strain in this case is one order lower than in others loading conditions. Moreover, this study reveals the importance of replicating a realistic vessel morphology, since plaque shape could affect fatigue resistance of the stent.

Keywords - Numerical modeling; Nitinol peripheral stent; Fatigue.

I. INTRODUCTION

Peripheral Arterial Disease (PAD) is one of the major manifestations of systemic atherosclerosis that involves the presence of a partial or total occlusion of peripheral arteries. At the present, self-expandable Nitinol stents are one of the most common treatments for PAD: clinical studies[1,2] report high rates of technical success of the stenting procedure and higher vessel patency rates in the medium to long-term follow-up than that obtained with traditional intervention techniques. Although Nitinol stent implant has proved to be valid in the treatment of PAD, some studies[3,4,5] reported high fracture rates of these devices. Fatigue resistance of Nitinol stents is a critical issue due to the cyclic loading conditions characteristic of peripheral districts. Since the small and complex geometry of the stents often does not allow to carry out all the tests required for a standard medical device, the use of finite element analysis (FEA) for the investigation of complex physical phenomena, such as stents implantation and their response to biomechanical forces that characterize the femoropopliteal district, is a valid method to have a surrogate for the testing of these devices. In the present study, a computational approach was used to investigate the fatigue resistance of a commercial peripheral stent, subjected to physiological cyclic loads, after the insertion in a stenotic vessel. The aim of this study is to investigate how the *in vivo* loading conditions influence the fatigue behaviour of Nitinol peripheral stents using finite element analyses.

II. MATERIALS AND METHODS

A. Stent model

The stent geometry resembling *Maris Plus* peripheral stent (Medtronic-Invatec, Roncadelle, BS, Italy) was reconstructed. The stent had an external diameter of 8 mm and a length of 45.8 mm. The Nitinol material properties required for the ANSYS material model[6], were obtained averaging typical values taken from literature. The reconstructed peripheral stent is depicted in Fig. 1.

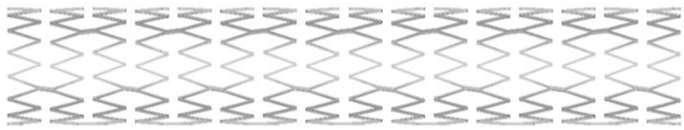

Figure 1. 3D model of *Maris Plus* peripheral stent, which consist of open cell design, peak to peak connections and 3 links for each crown.

B. Stenotic vessel model

A model of a stenotic vessel was developed, resembling the distal SFA-proximal PA. It was modelled as an hollow cylinder with an inner diameter of 5.6 mm, a thickness of 0.56 mm and a length of 100 mm.

A concentric atherosclerotic plaque with a single peak was considered; the stenosis rate was equal to 80% of the healthy vessel diameter.

The non-linear behaviour of the artery was described using a nine parameter Mooney-Rivlin hyperelastic constitutive equation[7] . The plaque was modelled with an elasto-plastic material: the yielding point was identified from experimental data of tensile tests on plaque samples[8].

C. Simulations and Boundary Conditions

Appropriate boundary conditions were used to simulate stent crimping and expansion into the 3D model of the stenotic vessel, after a procedure of percutaneous transluminal angioplasty (PTA). After that, physiological loading conditions of blood pressure, axial compression and bending of the artery were simulated. The simulation of the PTA requires the definition of an angioplasty balloon model: this was considered as a cylindrical rigid body, placed into the vessel (Fig. 2a) and then expanded in the radial direction until a diameter ensuring the suppression of the atherosclerotic plaque (Fig. 2b). After that, the balloon was deflated, allowing the elastic recoil of the plaque and the vessel (Fig. 2c). In the same time of the plaque pre-dilatation, the crimping of the stent was performed, using a cylindrical rigid body under displacement control conditions (Fig. 2b). Following the PTA procedure, the stent was released into the vessel (Fig. 2d). The cyclic blood pressure was simulated applying systolic and diastolic pressure to the inner surface of vessel and plaque. The axial compression was simulated applying 5% stretching at plaque ends, carrying them back to their original position and stretching them again: as a result of the friction at the interface between stent and plaque, the device was subjected to cycles of axial shortening of about 5%. The bending of the stent was obtained using two rigid bodies controlled by pilot nodes in displacement control, located at both plaque ends, including stent extremities. Applying a rotation to these pilot nodes (corresponding to 20°) and then moving them back to zero, a cyclic bending of the device was obtained. Displacement values applied for each loading condition were taken from literature[9].

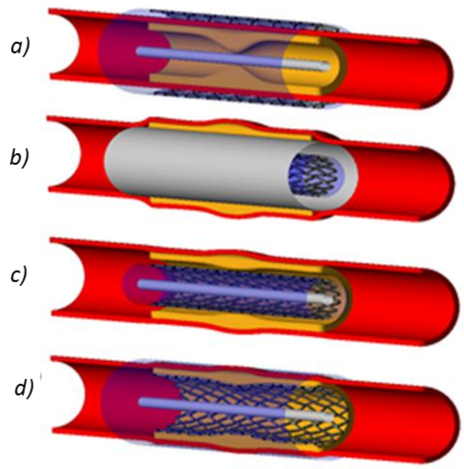

Figure 2. Stenting procedure: initial configuration (a), end of stent crimping and expansion of the balloon for angioplasty (b), after the release of the angioplasty balloon (c), after stent self-expansion (d).

III. Results And Discussion

The analysis of different loading conditions shows that ε^1_m values are comparable as determined by the oversizing ratio between stent outer diameter and plaque/vessel inner one: the maximum values in each case corresponds to the plaque peak, where the oversizing is higher. On the contrary, the maximum value of ε^1_a is located at the ends of the plaque, where its thickness is less. The vessel/plaque system has a non-uniform thickness in longitudinal and radial directions, that implies a non-uniform stiffness of the vessel/plaque system. As a consequence, the stent undergoes a higher loading in relation to the low radial and axial stiffness of the vessel-plaque wall. As regards the maximum ε_a values, the strain induced by cyclic pressure is one order of magnitude lower than the strain induced by the axial compression and bending (0.031% vs. 0.24% and 0.17%, respectively). Figure 3 shows a representation of the pairs of values ($\varepsilon_{m;}\ \varepsilon_a$) resulting from cyclic pressure, axial compression and bending on the stent deployed in the SFA model; they are compared with the fatigue limit for 10^7 cycles[10]. Considering that the material parameters of the Nitinol used to obtain the fatigue limit curve[10] are not known and hence they might not correspond to those used in the finite element simulations, in Figure 3 the limit curve obtained from literature (continuous line) was shifted up and down (dot lines) in order to represent a lower or greater risk of fatigue failure for the material. This representation was made to take into account a possible variability in the material fatigue properties. For each loading condition, it can be noted that the most stressed points are below the curve that defined the fatigue limit of the material: however, it must keep in mind that this is only a qualitative comparison, because the fatigue characterization of the stent material is not available.

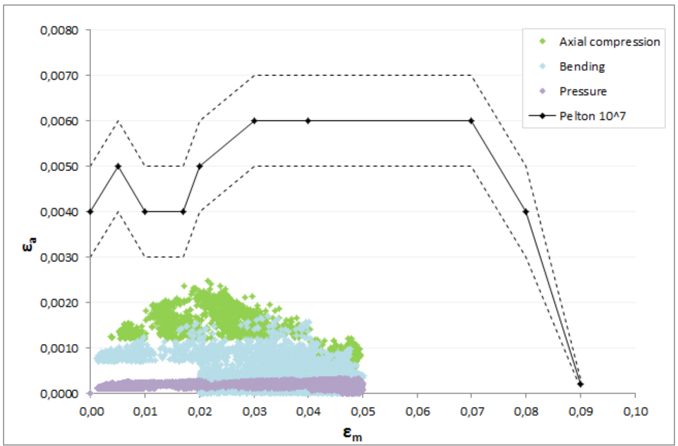

Figure 3. Constant-life diagram for cyclic pressure, axial compression (5%) and bending (20°) loads applied to the stent after its deployment in the atherosclerotic SFA model. The data represented refer to mean and alternating strain in the most stressed areas of the stent.

IV. Conclusions

From the computational simulations the following results were obtained:

i) the cyclic axial pressure is the least critical loading condition; regarding the maximum values of ε^1_a, it is evident that the strain induced by cyclic pressure is of one order of magnitude lower than the strain induced by axial compression and bending conditions.

ii) the non-uniform longitudinal and radial thickness of vessel-plaque system influences the location of the most stressed zones of the stent, that undergoes a higher loading in relation to the low radial and axial stiffness of the vessel-plaque wall.

iii) the distribution of pairs of strain values on the constant-life diagram show that each loading condition is reasonably safe for the considered stent design.

A computational model taking into account vessel and plaque features is useful for the prediction of the fatigue resistance of the device. However, in order to predict correctly the risk of failure of the device under cyclic loading conditions, a fatigue characterization of the stent material need to be performed.

Acknowledgments

This work is within the project ''RT3S - Real Time Simulation for Safer vascular Stenting'' partially funded by the European Commission under the 7th Framework Programme, GA FP7-2009-ICT-4-248801

References

[1] H. Krankenberg, M. Schlüter, H. Steinkamp, K. Bürgelin, D. Scheinert, K. L. Schulte, "Nitinol Stent Implantation Versus Percutaneous Transluminal Angioplasty in Superficial Femoral Artery Lesions up to 10 cm in Length: The Femoral Artery Stenting Trial (FAST)", Circulation. 2007; 116:285-292.

[2] J. R. Laird, B. T. Katzen, D. Scheinert, J. Lammer, J. Carpenter, M. Buchbinder, "Nitinol Stent Implantation Versus Balloon Angioplasty for Lesions in the Superficial Femoral Artery and Proximal Popliteal Artery. Twelve-Month Results From the RESILIENT Randomized Trial", Circ Cardiovasc Interv. 2010; 3(3):267-276.

[3] D. E. Allie, C. J. Hebert, C. M. Walker, "Nitinol stent fracture in the SFA", Endovascular Today, 2004; 22-34.

[4] D. Scheinert, S. Scheinert, J. Sax, C. Piorkowski, S. Braunlich, M. Ulrich, G. Biamino, A. Schmidt, "Prevalence and clinical impact of stent frctures after femoropopliteal stenting", Journal of the American College of Cardiology, 2005; 45(2):312-315.

[5] O. Iida, S. Nanto, M. Uematsu, "Effect of exercise on frequency of stent fracture in the superficial femoral artery", Am J Cardiol 2006; 98:272-274.

[6] F. Auricchio, R. L. Taylor, "Shape-memory alloys: modeling and numerical simulations of the finite-strain superelastic behavior", Computer Methods in Applied Mechanics and Engineering, 1997, Vol. 143: 175-194.

[7] P. J. Prendergast, C. Lally, S. Daly, A.J. Reid, "Analysis of prolapse in cardiovascular stents: a constitutive equation for vascular tissue and finite element modeling", J. Biomed. Engin., 2003, Vol. 125: 692-699.

[8] R.T. Lee, "Atherosclerotic lesion mechanics versus biology", Z. Kardiol., 2000, Vol. 89 (II): 80-84.

[9] A. Nikanorov, S.B. Smouse, K. Osman, M. Bialas, S. Shrivastava, L.B. Schwartz, "Fracture of self-expanding nitinol stents stressed in vitro under simulated intravascular condition", J Vasc Surg. 2008; 48:435-440.

[10] A.R. Pelton, V. Schroeder, M.R. Mitchell, X.Y. Gong, M. Barney, S.W. Robertson, "Fatigue and durability of Nitinol stents", Journal of the Mechanical Behavior of Biomedical Materials I. 2008; 153-164.