Comparison of different in vitro testing conditions for peripheral Nitinol stents: a computational study

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Abstract – Fatigue resistance of Nitinol peripheral stents implanted into femoropopliteal arteries is a critical issue due to the unique biomechanical environment of this district. Potentially in vitro testing offers a valid method to compare the fatigue behavior in terms of fracture risk of different marketed stents. However, there is still a lack of validated methodologies for bench testing that mimic in a satisfactory manner the complex biomechanical environment present in the SFA. In the present study, the finite element method (FEM) was used to investigate the fatigue behavior of stents when subjected to different in vitro tests. For this purpose, two models of commercial Nitinol stents were developed and different loading conditions were simulated using finite element analyses. In order to reproduce two different test methods recently proposed in the literature, stents were subjected to cyclic axial compression, either alone in the free-expanded configuration or after deployment in a silicone tube. Results were analyzed in terms of amplitudes (ε^1a) and mean values (ε^1m) of the first principal strain through the stent either on a constant-life diagram or in the form of strain field. Results indicated that: i) the two testing conditions lead to quite different fatigue fracture risk and strain fields in the stent, explaining the conflicting findings reported in the literature; ii) different stent designs exhibit a variable ability to withstand in vitro loading; iii) the mechanical interaction with the arterial wall cannot be disregarded as it significantly influences the stent fatigue behavior.

Keywords – Numerical modelling; Nitinol Stent; In vitro testing.

I. INTRODUCTION

Nitinol femoropopliteal stent implantation after balloon angioplasty has proved to be a valuable therapeutic strategy for the treatment of peripheral arterial disease (PAD). Despite its success, the effectiveness of SFA stenting is still undermined by clinical complications related to fatigue failure of these devices. Reported fracture rates for commercially available self-expandable stents differ widely from 1.8% to 18% and are often associated with in-stent restenosis (IRS) [1,2,3]. The unique biomechanical environment of the femoropopliteal arterial district seems to be the main factor for the high incidence of stent fracture [4]. Since the fatigue resistance of femoropopliteal Nitinol stents represents a critical clinical issue, it is important to investigate the mechanical response of these devices when they are subjected to in vivo loading conditions, in order to gain useful information about the potential risk of stent fracture. In vitro testing potentially offers a valid tool to comparatively assess the risk of fatigue failure of different marketed stents, but there is still a lack of validated methodologies for bench testing under the complex biomechanical environment observed in the SFA. To date, only two experimental studies investigated the risk of fracture of Nitinol peripheral stents. Müller-Hülsbeck et al. 2010 [5] tested different stents to cyclic axial compression, bending and torsion in free-expanded configuration. Nikanorov et al. 2008 [6] tested some of the same commercial stents to axial compression and bending after stent deployment in a silicone tube which resembles the presence of the artery. The conflicting findings found by the two groups of authors in terms of fatigue fracture for different commercial stents lead to a major interest in understanding the Nitinol stents in vivo fatigue behavior. In the present study, a computational approach was used to obtain a comparison between the two tests methods considered, referring in particular to two stent geometries resembling the Smart CONTROL (Cordis, Johnson & Johnson, Miami Lakes, FL, USA) and Absolute (Abbott Vascular, Santa Clara, CA, USA) stents.

II. MATERIALS AND METHODS

FEM was used to investigate the fatigue behavior of Nitinol self-expandable stents, mimicking in vitro experimental test loading conditions. The commercial finite element code ANSYS (Ansys Inc., Canonsburg, PA, USA) was used to run the simulations. Based on optical microscopy images,

two different peripheral stent geometries were reconstructed: Smart CONTROL (Cordis) and Absolute (Abbott Vascular). Both stents had an external diameter of 8 mm (typical for SFA treatment) and length equal to 42.7 mm for the Absolute model and 45 mm for the Smart model. The Nitinol material properties required for the ANSYS material model [7] were obtained averaging typical values taken from literature. In the following, the two reconstructed stent models will be indicate as stent A (geometry resembling *Smart* stent) and stent B (geometry resembling *Absolute* stent). The reconstructed peripheral stents are reported in Figure 1.

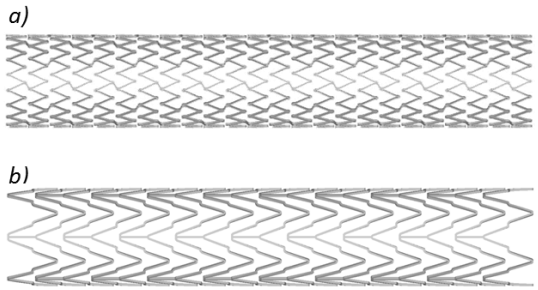

Figure 1. 3D model of the considered stents, which consist of open cell design, peak to peak connections for the stent A (a) and peak to valley connections for the stent B (b).

The two different test methods on peripheral stents were reproduced: cyclic axial compression in the stent free expanded configuration [5] and after stent deployment in a silicon tube [6]. The models used to simulate the two different *in vitro* setups are shown in Figure 2.

For the free-expanded configuration the application of axial compression load was performed through the imposition of displacement boundary conditions on two external stent nodes (master 1 and 2) rigidly connected to the ends of the stent by means of constraint elements.

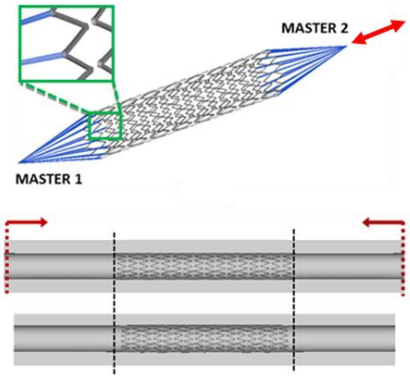

Figure 2. Representation of boundary conditions used to apply axial compression in the free-expanded configuration (upper panel), and after the deployment in a tube (lower panel).

The second considered experimental setups, stent deployment in a silicone tube model resulting in a tube-stent oversizing ratio of 1:1.4, requires the simulation of the stent crimping procedure within the tube. After the crimping, the stent is allowed to freely self-expand and go into contact with the tube inner wall. These two subsequent steps were simulated by means of a rigid cylindrical surface, which is in contact with the stent outer surface, imposing a uniform radial displacement.

Concerning the axial compression load, in order to simulate the methodologies adopted by [6], before the device deployment, the silicone tube was axially stretched; then, after the stent release, it was carried back to its original length and finally stretched again. Due to the friction defined for the stent-tube contact forces, the stent undergoes cycles of axial shortening of the same entity applied to the tube.

To reproduce the loading conditions adopted in [5] and [6], 20% and 5% of axial compression were applied in the free-expanded and after the deployment in the tube, respectively.

III. Results And Discussion

Figure 3 shows the constant-life diagram of stent ε^{I}_{m} and ε^{I}_{a} strains in the two conditions, free-expanded configuration and stent released in a silicon tube, for both the stent models. It can be observed that the devices exerted very different fatigue behaviours depending on the testing conditions simulated. In the free-expanded stent configuration, the calculated data fall in the area closest to the vertical axis. In particular, as there is no oversizing, mean and alternating strain are identical. In this condition stent fracture may occur for low values of ε^{I}_{m} and high values of ε^{I}_{a}. Concerning the configurations in which the stents are released in a silicon tube, as the devices cannot recover their nominal diameter because of the stent-wall interaction related to the oversizing between the stent and the tube, a high mean deformation component is induced in the devices. The calculated data for these configurations are distributed over a wider area in terms of mean strain component. So, stent rupture may occur for a wide range of ε^{I}_{m} depending on the specific fatigue limit curve which is unknown for the material considered in this study.

In Figure 4 the mean and alternating strain distributions through the stent A model are reported. Similar results are obtained for the stent B design.

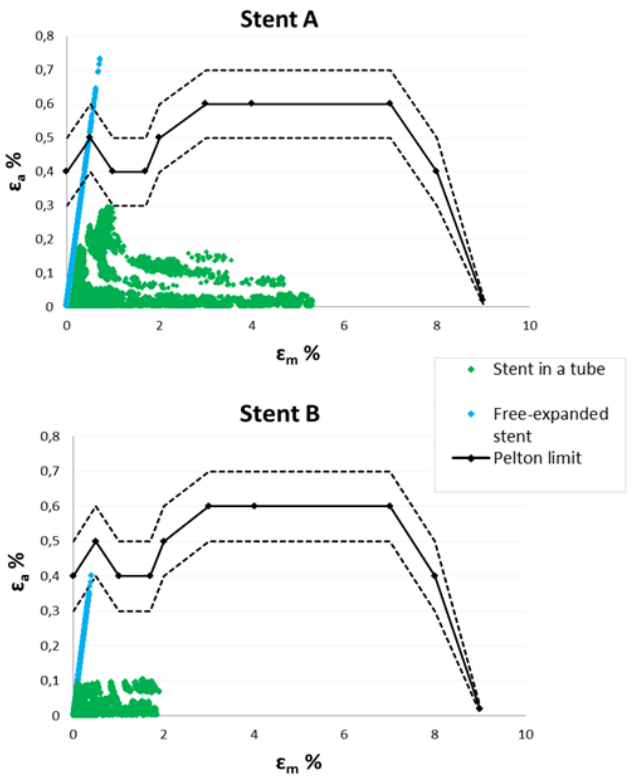

Figure 3. Constant-life diagram for the different loading conditions investigated in the two configurations, free-expanded stent (blue) and stent released in a tube (green), compared with Pelton fatigue limit [8] for the stent A (upper panel) and for the stent B (lower panel).

The two testing conditions proposed in the literature produce quite different strain fields in the stent. The mechanical interaction with the arterial wall plays an important role: neglecting the stent-tube oversizing, as proposed in [5], represents a large simplification which can lead to incorrect predictions of stent failure. Moreover, in all testing conditions the stent B design showed better fatigue resistance.

IV. Conclusions

In this work the use of FEM allowed us to identify important factors that influence stent fatigue fracture. This may be useful in defining fatigue testing conditions to be adopted in the in vitro scenarios to better mimic *in vivo* loading conditions to which peripheral stents are subjected to and thus be able to make reliable predictions on their fatigue behavior.

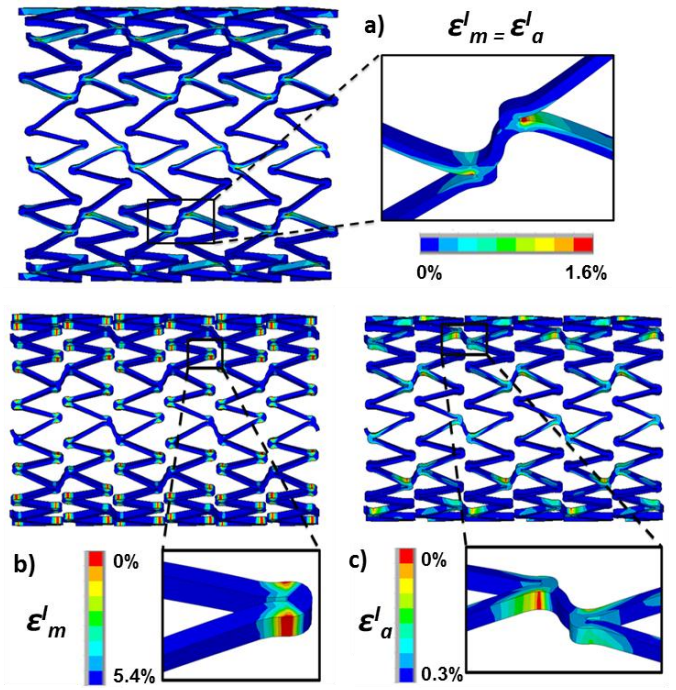

Figure 4. Alternating and mean principal strain distribution map through the stent A design for the two configurations, free-expanded stent (a) and stent released in a tube (b,c).

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