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Fatigue behaviour of Nitinol peripheral stents: The role of plaque shape studied with computational structural analyses

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ABSTRACT

Fatigue resistance of Nitinol stents implanted into femoro-popliteal arteries is a critical issue for the particular biomechanical environment of this district. Hip and knee joint movements due to the cyclic daily activity expose the superficial femoral artery (SFA), and therefore the implanted stents, to quite large and cyclic deformations influencing stent fatigue resistance. Objective of this work is to provide a tool based on finite element analysis able to evaluate the biomechanical effect of SFA on stent fatigue resistance. Computer simulations of the treatment of stenotic vessel by angioplasty and stenting and of the subsequent *in vivo* loading conditions (axial compression and bending) were carried out. Three different stenotic vessel models were defined, by keeping a constant stenosis rate and changing the plaque sharpness and number of stenoses. The fatigue behaviour was analysed comparing the amplitude and mean value distribution of the first principal strain in the whole stent for the different simulated conditions. Results showed that the maximum mean strain is similar in all the models, while the alternating strain is related to both plaque shape and loading conditions. In conclusion, this study confirms the requisite of replicating *in vivo* loading conditions. It also reveals the importance of taking into account the thickness variation of the vessel in the stenotic zone in the assessment of the stent fatigue resistance.

1. Introduction

Peripheral arterial disease (PAD) is one of the major manifestations of systemic atherosclerosis: it involves the presence of a partial or total occlusion of peripheral arteries due to plaque formation, resulting in a progressive impairment of the distal vasculature. Anatomically, most of these lesions are located in the lower limb arteries downstream from the renal arteries, with more than 50% of all PAD cases involving the superficial femoral artery (SFA) and the popliteal artery (PA) [1].

In the last decades endovascular procedures have become more and more popular with respect to surgical intervention, thanks to their reduced impact on the patient life and their limited cost for the national health systems. In particular, nowadays the placement of self-expandable Nitinol stents, after percutaneous transluminal angioplasty (PTA), is the preferred technique for the treatment of PAD. A number of clinical studies [2–4] reported high rates of technical success of the stenting procedure and higher vessel patency rates in the medium to long-term follow-up than those obtained with PTA alone.

Self-expandable stents exploit the Nitinol pseudo-elastic property. From the procedural point of view, stents are manufactured in an open configuration with a diameter slightly larger than the lumen of the target vessel. The ratio between the external diameter of the stent in the open configuration and the inner diameter of the stenotic vessel is defined as *oversizing*. Stents are radially compressed (crimping) to allow their insertion into a retractable sheath placed on a guide catheter. Finally, at the treatment site, they self-expand while the sheath is gradually withdrawn. After the placement in the stenotic zone, pseudo-elasticity provides the stent with a high conformability to the vessel morphology, a high flexibility and a capability to recover the initial shape during cyclic loads. Despite all these features making Nitinol stents ideal for the application of interest, the effectiveness of SFA stenting is still undermined by clinical complications related to the fatigue failure of these devices. Different studies [5–7] reported various fracture rates of stents implanted in the SFA-PA, ranging between 14 and

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24.5%, often associated with in-stent restenosis and failure of the stenting procedure.

The unique biomechanical environment of this district appears as the main factor for the high incidence of stent fracture. Indeed, hip and knee joint movements associated with patients daily activities expose the artery, and therefore the implanted stent, to repetitive cyclic loadings including axial compression, bending and torsion [8–10] that could lead to long-term failure of the device.

Since the fatigue fracture of Nitinol stents implanted into the femoro-popliteal district represents a critical clinical issue, it is interesting to investigate the mechanical response of these devices, to understand their fatigue behaviour and to gain useful information for the design of stents with higher mechanical reliability.

Nowadays, numerical studies on the performance of femoro-popliteal Nitinol stents – mostly based on finite element analyses (FEA) – are already available in the literature [11–15]. However, those considering the stent fatigue failure disregard the presence of an atherosclerotic plaque [11–13], even if PAD is often characterized by long and diffuse lesions, with frequent, distributed occlusions [1,16,17]. On the contrary, studies considering the plaque presence do not consider cyclic loading conditions [14,15]. From the experimental side, there are two recent papers devoted to the study of fatigue in peripheral Nitinol stents. Müller-Hülsbeck et al. [18] compared the performance of different marketed devices, but they did not apply physiological cyclic loading conditions; those authors only tested stents in their fully-expanded configuration, neglecting the stent–vessel interaction. Nikanorov et al. [19] carried out axial compression and bending tests on stents after their deployment in a silicone tube; they were able to reproduce the presence of the femoral artery (without plaque) and the applied loads were consistent with *in vivo* ranges of deformation of the literature [8,20]. In the paper by Meoli et al. [13], where FEA were used to investigate the fatigue testing conditions adopted in the two *in vitro* studies cited above, the authors showed that stent-to-tube oversizing ratio plays an important role in determining the fatigue response of Nitinol stents. However, the vessel was simulated as a tube with uniform thickness. What currently remains unclear is the influence of the plaque shape on the reaction of the stent to the cyclic loading. To clarify this point, the present paper proposes a procedure based on FEA to study the stent fatigue behaviour through the development of different stenotic vessel models subjected to cyclic axial compression and bending after angioplasty and stenting. For each condition, mean and alternate strains are calculated and compared using the Constant Life Diagram. The definition of the most dangerous condition would require the comparison of the results with the Nitinol fatigue strain limit curve for a number of cycles $N = 10^7$ corresponding to 10 years of gait [18]. The limit curve should be experimentally built by performing fatigue tests on the real stent material, because the results of these tests are dependent on the specific material properties and thermo-mechanical treatments (laser cut and surface processing). However, researchers usually refer to the curve proposed by Pelton et al. [21] adding a number of simplifications. In some cases [11,12] the alternating strain is considered constant (0.4%) independently from the mean strain value; in other cases [22] the alternating strain is assumed constant (0.4%) only among 0% and 1.5% of mean strain, while it increases with almost constant slope of 0,133 between 1.5% and 4% of mean strain (Fig. 1). In this paper considerations on Nitinol fatigue strain limit curves and device fatigue life are also reported and discussed.

2. Methods

Finite element analyses were used to simulate the deployment of a self-expandable Nitinol stent in a peripheral artery and the subsequent *in vivo* loading conditions. The commercial finite element code ANSYS Mechanical APDL 14.0 (Ansys Inc., Canonsburg, PA, USA) was used to run the simulations.

A 3D stent model resembling the geometry of a commercial peripheral stent from Invatec (now Medtronic Endovascular Therapies, Roncadelle, BS, Italy) was built with the aid of the software Pro/ENGINEER Wildfire 4.0 (Parametric Technology Corporation), starting from images acquired by a stereo microscope Nikon SMZ800 (Nikon Corporation, Tokyo, Japan). The stent in the open configuration has an external diameter of 8 mm, a length of 45.8 mm and a strut thickness of 0.17 mm. The device is made by Nitinol, whose pseudo-elastic behaviour was described through the Shape Memory Alloy (SMA) material model already implemented in the ANSYS code. The non-linear mechanical input properties for the SMA material model were derived from uniaxial tension tests performed on Nitinol samples. The samples were cut by laser from the same tubes used to produce the stents under study and subjected to the same treatments, according to the methodology presented in Petrini et al. [23]. The value of the parameters used by the ANSYS constitutive model to take into account the tension-compression asymmetry observed in Nitinol [24–26], was set equal

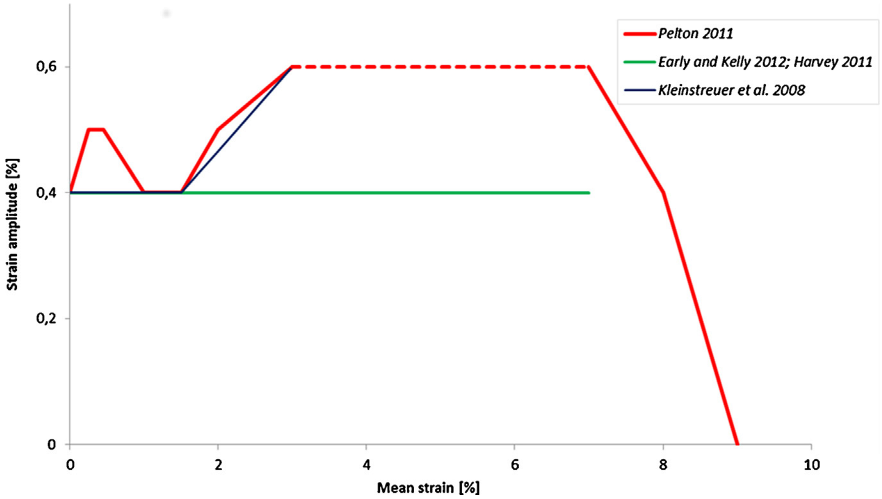

Fig. 1. Nitinol fatigue strain limit curves at $N = 10^7$ cycles found in literature. The red line is the limit proposed by Pelton [21], based on experimental fatigue tests on Nitinol specimens; the green and blue lines are simplification of the previous one, showed by Early and Kelly [11], Harvey [12], and Kleinstreuer [22]. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of the article.)

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