NITINOL STENT OVERSIZING IN PATIENT-SPECIFIC FEMORAL ARTERIES: AN EXPERIMENTAL AND FINITE ELEMENT STUDY

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Introduction

In endovascular stenting, self-expanding Nitinol stents must be over-sized compared to the vessel diameter to ensure adequate levels of lumen gain and apposition to the arterial wall. However, there is a risk of damage into the vessel wall that might trigger undesired clinical outcomes (e.g. restenosis) [1]. While the common practice is to deploy a stent that is 1-mm larger than the lumen diameter, stent sizing is not always driven by objective criteria but relies on the intuition of clinicians and is influenced by the patient-specific anatomy [2]. Given the controversial outcomes of mis-sizing, a combined experimental-computational investigation is conducted to assess the effects of oversizing of a commercial self-expanding Nitinol stent for femoral applications.

Materials and Methods

Experimental: Axial tension and radial compression tests performed at 37°C were carried out on the Zilver Flex (Cook Medical, USA) to determine its mechanical properties. *In vitro* tests of stent deployments in straight silicon vessel were performed and numerically modelled to assess the interaction among the device and the vessel wall to ensure the robustness of the computational model.
Computational: Finite element analysis (FEA) of the deployment of the self-expanding Nitinol stent into a patient-specific vessel was performed with Abaqus/Explicit 6.14 (SIMULIA, Dassault Systèmes). The stent was modelled in different sizes (6.0x60mm, 7.0x70mm and 9.0x60mm) and assigned the VUMAT super-elastic material model, whose parameters were calibrated through the experiments above mentioned. Two patient-specific human superficial femoral arteries (SFAs), namely patient A and B [4], featured with a low-curvature and high-curvature respectively, were modelled. The non-linear behaviour of SFA was described with an isotropic hyperelastic constitutive law [3]. In both scenarios, a FEA of crimping and deployment was performed. A comparison of the impact of stent sizes was provided.

Results

The configuration of the device deployed into the patients A and B is shown in Figure 1 and the summary of key parameters are in Table 1.

Table 1. Key parameters of deployment structural analysis are compared for different stent sizes in both scenarios.

	Patient A			Patient B		
	6x60mm	7x60mm	9x60mm	6x60mm	7x60mm	9x60mm
LG, %	56.5%	63.0%	62.4%	11.3%	24.1%	23.3%
d_{MAL}, mm	0.63	0.22	0.37	3.03	0.94	0.59

The lumen gain (LG) defined as the increase in the lumen area with respect to the initial cross-section was similar regardless of the stent size in patient A. Contrastingly, in patient B, LG showed a two-fold increase between the 6.0x60mm and 7.0x60mm/9.0x60mm devices. For malapposition, the maximum distance (d_{MAL}) between the stent strut and the arterial wall was reported for the 6x60mm size (0.63mm and 3.03mm in A and B); a consistent improvement was found for 7.0mm and 9.0mm sizes in both patients, although, a critical malapposition (≫0.2mm) was still present in B regardless stent diameter. Additionally, the distribution of maximum principal stress (SMax) in the arterial wall showed lower values induced by the 6.0x60mm, while higher but substantially similar values were reported for 7.0x60mm and 9.0x60mm stents.

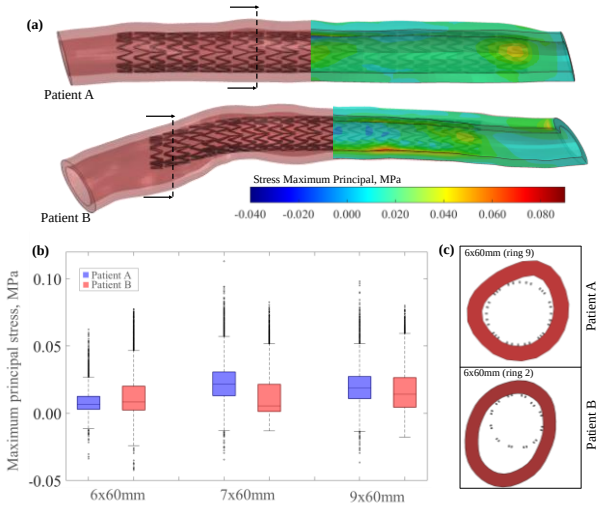

Figure 1. (a) Configuration of stent deployed in patient A and B; (b) boxplot of maximum principal stress values; (c) cut views of the malapposition detachment induced in the most representative rings.

Discussion

In this study, a computational patient-specific analysis to predict the effects of stent oversizing was performed. The relation between the key parameters (luminal gain, mal-apposition detachment, maximum principal stress) with stent diameter showed varying behaviour in both scenarios. For patient A, higher oversizing ratios caused increased arterial stresses, with low additional lumen gain. For patient B, as the oversizing increase, a substantial lumen gain was observed associated with lower malapposition detachment and only modest increases in arterial stress. Results suggest that the choice of oversizing is case-specific; thus, *in silico* tools might provide a clinical support to select the best practice. Next, experimental deployment in 3D-printed patient-specific vessels will be performed to confirm the computational outcomes.

References

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