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NITINOL PERIPHERAL STENTS: A COMPUTATIONAL FRAMEWORK TO INVESTIGATE THE STENT DESIGN FROM LASERCUTTING TO DEPLOYMENT

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INTRODUCTION

Cardiovascular disease (CVD), which is often related to atherosclerosis, is the most common cause of death in European countries [1].

At present, the deployment of an intravascular stent has become a common and widely used treatment for coronary heart disease and the trend is to apply such a technique also to peripheral occluded vessels such as carotid artery or superficial femoral artery (SFA).

However, stenting these vessels, which are located in highly deformable regions of the body, remains a problem without an optimal treatment.

Particularly, the state of the art of SFA stenting implies the implant of nitinol self-expanding stents. Although this class of stents addresses the biomechanical requirements (i.e. flexibility, kink resistance, etc.), it has been observed that many of these stents implanted in the SFA are fractured [2,3]. Many stent designs were designed only to survive under a standard pulsatile fatigue environment, however, especially in the highly deformable peripheral arteries, the in-vivo stress-state is multi-axial and complex [4] and the vessel anatomy is tortuous and non-homogeneous. Several SFA stent designs are currently available on a dedicated, fast-growing market exhibiting a variable ability to withstand chronic deformation depending on stent design and the type of deformation applied [5]. Computer models have shown to be a very useful tool in the investigation and optimization of stent design [6- 7] and to provide novel insights on fatigue/fracture mechanics [8].

This study proposes a software framework, coupling pyFormex [9] and Abaqus [10], allowing to numerically analyze a stent design from the lasercutting stage to its deployment in a curved vessel.

MATERIALS AND METHODS

The proposed computational framework takes into account two main steps in order to simulate the whole work flow (represented in Fig. 1) characterizing the stent design forming and its implant: 1) creation of 3D parametric finite element (FE) model of a laser-cut stent and expansion of the laser cut stent before heat treatment; 2) crimping/bending of the expanded stent mimicking the stent insertion by the delivery system and gradual deployment of the stent within the curved vessel.

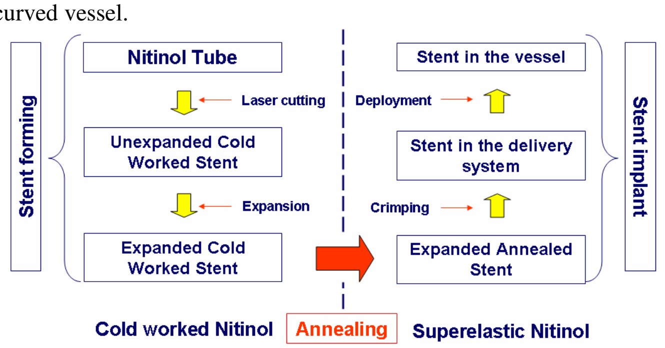

Figure 1. Workflow of stent design forming and implant

Within the computational framework, pyFormex is used to create directly the input files for the FE solver (ABAQUS).

In the first step, the stent model is created in pyFormex, which allows for an easy definition of a parametric mesh accounting for several stent features (i.e. stent radius, stent length, number of rings, number of bridges, strut thickness, etc.). The stent mesh is combined with a cylinder mimicking the rigid expander leading from laser-cut to

expanded stent configuration before the heat treatment. At this stage Nitinol is considered as an elasto-plastic material [11].
Subsequently to perform step 2, the obtained expanded mesh is imported and combined with the catheter and vessel mesh. For this step, Nitinol super-elastic behavior is taken into account [12]. Moreover vessel tissue is modeled as an isotropic hyperelastic material.

RESULTS AND DISCUSSION

For demonstration purposes, the present study shows the application of the computational platform to a stent design with an outer diameter of 1.46 mm (in laser-cut configuration), 12 V struts, 6 rings and 6 bridges connecting the rings (see Fig. 2a). The stent mesh consists of 50544 C3D8R elements and the expander mesh of 800 SFM3D4R elements.
The simulation performed in step 1 provides the expanded stent configuration as shown in Fig. 2b.

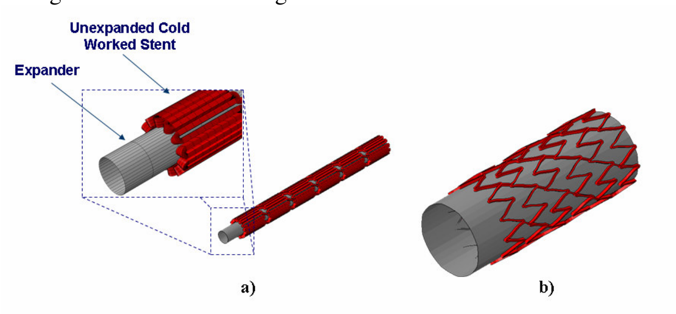

Figure 2. Laser-cut stent and expander: a) closed configuration; b) open configuration.

Using pyFormex, the free expanded stent mesh is subsequently combined with (i) a rigid cylinder mesh mimicking the delivery system and (ii) the vessel (see Fig. 3a).
In a first stage, the device structure is crimped and bent accomplishing the curved configuration of the vessel. It has an inner diameter of 4 mm and is meshed with 4320 C3D8R elements (see Fig. 3b); in this first part of the simulation the contact between the stent-delivery system and the vessel is deactivated.

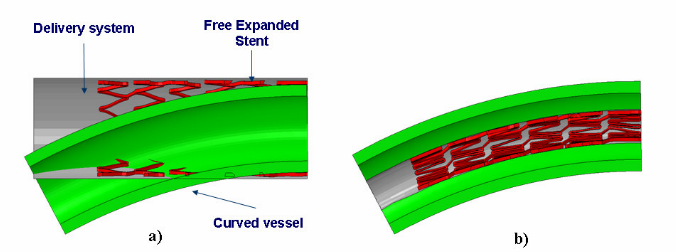

Figure 3. Stent and delivery system: a) undeformed configuration; b) crimped/bent configuration.

In a second stage, the contact between the stent-delivery system and the vessel is activated while the contact between the delivery system is gradually deactivated in order to realistically simulate the stent expansion during its deployment (see Fig. 4a) and the subsequent complete stent apposition to the vessel wall (see Fig. 4b).

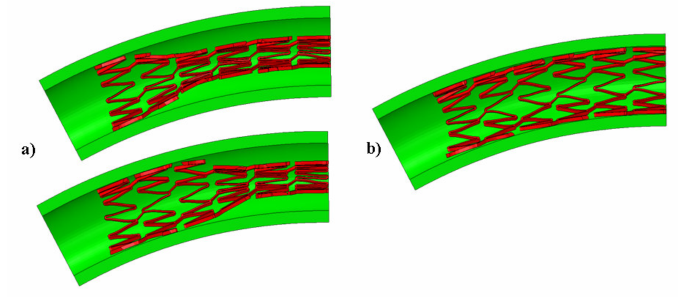

Figure 4. Stent expansion in a curved vessel: a) partially deployed stent; b) fully deployed stent.

CONCLUSIONS

Computer modeling can play an important role in the design of medical devices and in the investigation of their mechanics. In the present study, a computational framework to numerically investigate the forming and implant of Nitinol laser-cut stents is presented. This study can represent a solid base for further parametric studies. Further investigation can include the combination of the developed computational framework with a patient-specific vessel model.

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