Real Time Prediction of the Fatigue Behavior of Peripheral Stents

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***Abstract*—Fatigue resistance of Nitinol peripheral stents implanted into atherosclerotic femoro-popliteal arteries is a critical issue due to the particular biomechanical environment of this district. Hip and knee joint movements associated with patient' daily activities expose the superficial femoral artery, and therefore the implanted stents, to large and cyclic deformations. These loadings may cause fatigue fracture of stents and may lead to re-occlusion of the artery.**

Since this is a clinical relevant issue, the aim of project *RT3S* (Real Time Simulations for Safer vascular Stenting) is to develop a software to help surgeons in the decision making process. The software provides the clinician with the risk of stent fatigue fracture, associated to a particular stent design, vessel morphology and loading conditions, while he/she is planning the operation. In this paper we present the development of a 3D finite element model, based on a set of parameters, including stent type, size and length, degree of stenosis and patient stenosis features; the parametric model aims to pre-compute a huge number of results to store, later, in the software database for the real time prediction of stent fatigue behavior.

I. Introduction

PERIPHERAL artery disease (PAD) consists in the partial or total occlusion of peripheral arteries caused by atherosclerosis. For PAD treatment, surgical intervention is more and more often replaced by an endovascular procedure [1], which consists in the expansion of a balloon (angioplasty) in the stenotic zone to recover the original vessel diameter and a simultaneous (in case of stainless steel) or subsequent (in case of shape memory alloy) expansion of a stent to scaffold the vessel. The peculiar biomechanical environment of lower limbs, characterized by large and cyclic deformations of the arteries [2] due to the hip and knee joint movements, requires a particular attention in the stent manufacturing. Nowadays the majority of self-expanding stents are made by Nitinol [3], a Ni-Ti shape memory alloy (SMA): the SMA pseudo-elastic property allows the stent to recover the original undeformed configuration even after large deformations (6-8%). However, the success of these devices is undermined by long-term fatigue failure: due to walking the stents are subjected to 10^6 cycles/year, which are superimposed to blood pressure cycles (around $40*10^6$ cycles/year). Fatigue fracture, which is related to patient-specific factors (atherosclerotic plaque properties, patient life-style) and implant-specific factors (stent features), often implies the re-occlusion of the artery (in-stent restenosis) and hence the failure of the treatment [4,5]. Considering the large number of peripheral stents on the market, a requirement for the clinician would be a tool able to compare in real time (i.e. during the planning of the endovascular intervention) the fatigue performance of different stents taking into account patient-specific factors. The European project *RT3S* (Real Time Simulations for Safer vascular Stenting) aims to develop such a tool; this work resumes its main biomechanical features.

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II. Fatigue Performance of Peripheral Stents

To satisfy the fatigue requirement, we propose a numerical approach consisting in the following two parts:

1. the development of a finite element (FE) computational model, able to take into account patient-specific and implant specific factors, to compute the stent stresses and strains induced by cyclic leg movements;
2. the development of a procedure for real time fatigue prediction.

In step 1 clinical data are collected and analyzed in order to extract the main geometric parameters characterizing the anatomy of peripheral vessels (e.g. diameter, rate of stenosis, curvature, length, wall and plaque thickness), such as the superficial femoral artery (SFA). These data are used to reconstruct simplified, but representative 3D geometric models of a peripheral leg artery for different scenarios, all of them needing a stenting procedure. The ranges of deformations similar to those acting *in vivo*, are obtained from literature. Such data are used as displacement boundary conditions for the computational stent-SFA models.

To keep into account different stent design, a number of commonly-used peripheral stents are reconstructed on the basis of measurements taken by optical images (Fig.1). Information on stent material and mechanical behavior are obtained from mechanical tests performed on the devices.

The simulation of the stent expansion inside the stenotic artery and the subsequent cyclic loading are carried out

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through the Finite Element Analysis (FEA). The FE stenting simulation consists of eight steps: i) the application of a physiological pre-stretch and of the diastolic pressure (75 mmHg) on the internal surface of the stenotic artery - to take into account the solicitations induced on the artery by the *in vivo* conditions; ii) the crimping of the stent through a rigid surface up to a diameter smaller than the diameter of the stenosis – to take into account the solicitations induced into the stent during crimping; iii) the angioplasty procedure with the expansion of a rigid surface – to take into account the plaque modifications induced by this maneuver performed before stenting; iv) the balloon deflation; v) the stent deployment removing the rigid surface used for the crimping. Starting from this configuration the following cyclic loadings were applied: vi) pressure varying from 75 to 150 mmHg associated with diastolic and systolic arterial blood pressure; vii) axial compression from 0 to 5% and lastly viii) bending from 0 to 28°, associated with movements due to patients daily activities [6].

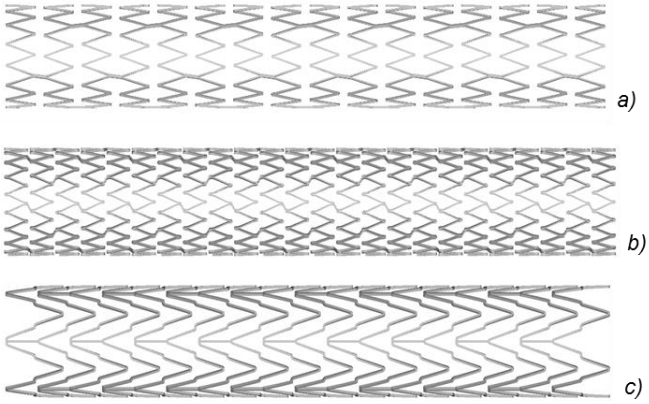

Fig. 1. Peripheral Nitinol stent models for the clinician choice: *a)* Medtronic-Invatec *Maris Plus*, *b)* Bard *Lifestent* and *c)*Abbott *Absolute Pro*.

Stresses and strains induced in the stent by cyclic leg movements (Fig.2) are obtained as results of the FE simulations and used to calculate the stent risk of fracture according to the material fatigue limit.

Unfortunately, this kind of simulations requires an execution time up to one week, i.e. about 100,000 times slower than that necessary for a real-time simulation: they are too demanding in terms of time. Furthermore, they cannot be directly implemented by the clinicians, but by expert engineers or mathematicians.

III. Strategies for Real Time Predictions

There are several strategies for speeding-up predictive models: increasing computational power and efficiency, making the problem simpler, and using pre-computed solutions. In this work we decided either to simplify the model and to pre-compute a large number of possible solutions: exploiting Response Surface (RS) methodology, the patient specific solution, related to the case the clinician is planning, is obtained in few seconds (real-time) by the interpolation of the pre-computed solutions.

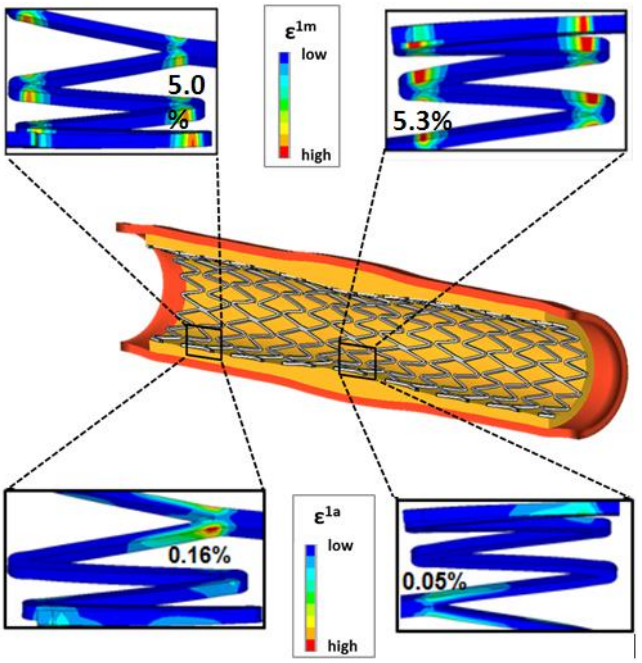

Fig. 2. Accurate biomechanical modeling. Strain distributions (mean value ε_{1m} and amplitude ε_{1a}) induced in a Nitinol stent, after its deployment in a stenotic arterial model, by the cyclic axial compression due to leg movements.

The simplified parametric model consists in a small portion of the stent, deployed in a simple elastic tube. The features of the tube were derived from the 3D stenotic vessel model and consist in post-angioplasty vessel size, wall stiffness and local vessel stretching (Fig. 3). The simplified simulation requires a much smaller computational time (hours) allowing to perform a huge number of simulations to build the RSs for different stents, investigating different vessel parameters.

The whole simulation workflow is implemented into ANSYS Workbench in order to take advantage of its parametric platform which has 2 main features:

- *Parameter manager* to define input parameters (any simulation input data including shape parameters, loads, boundary conditions, etc.) and output parameters (any simulation result) and to manage a fully automated computation update;
- *DesignXplorer* to compute Design Of Experiments (DOE) and RSs between input and output parameters.

RS methodology explores the relationships between input parameters and response variables of a selected number of simulations and hence, using these relationships, it is able to quickly provide approximated values of the output parameters, everywhere in the analyzed design space, without performing a simulation with a complete 3D patient-specific model. Different tools are available in ANSYS to select the "design points", which are the sets of input parameters used to perform the simulations. In this work

Optimal Space Filling DOE is used to get a uniform grid in the Cartesian Product of variation ranges. The RS is obtained by interpolating the design points results (Fig. 4).

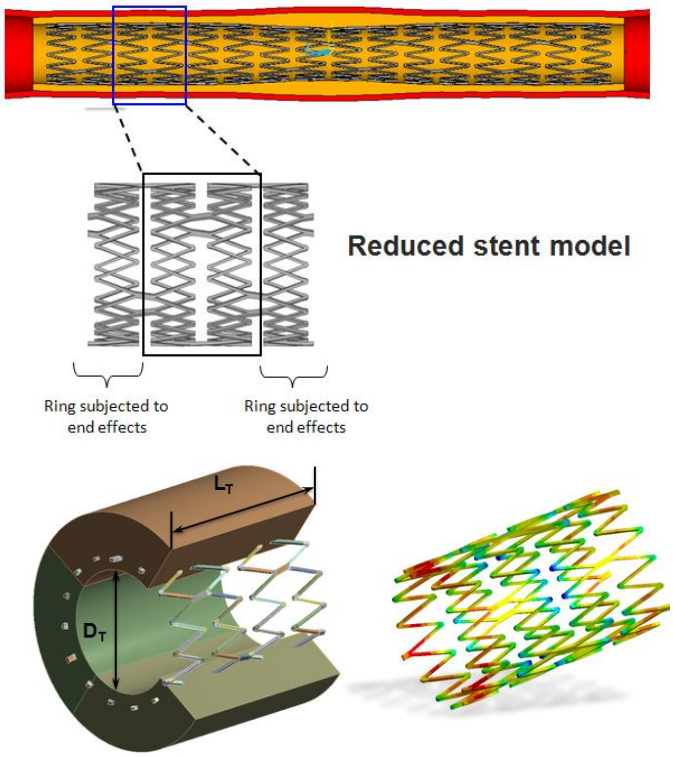

Fig. 3. Simplified parametric model. A reduced stent model (few rings) is considered and deployed in the corresponding stenotic vessel tract. This is described by a simple elastic tube with features derived from the true vessel. Only the central portion of the reduced stent model is taken into account for the fatigue analysis. The additional lateral rings are necessary to avoid end effects and are not representative of the real behavior.

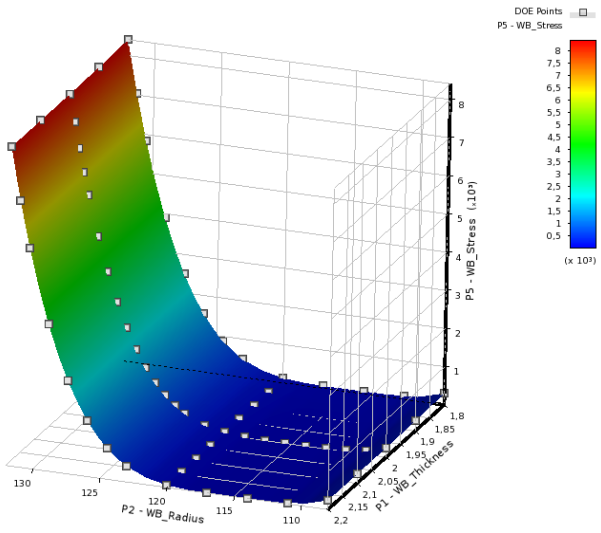

Fig. 4. Example of a response surface (design points are represented as white squares)

RS accuracy depends on several factors: complexity of the variations of the solution, number of points in the original DOE and choice of the RS type. ANSYS *DesignXplorer* includes different RS methods, in particular in this work Kriging interpolation with auto-refinement was used: it is a meta-modeling algorithm that provides an improved response quality and fits higher order variations of the output parameter using an automated local refinement process to determine the areas of the RS that are most in need of further refinement.

Finally a new approach for storing and calculating the RS results is used. This new technology is based on: i) definition of a vector of output parameters (field); ii) computation of this vector for any point of the DOE; iii) compression of the list of vectors using Singular Value Decomposition (SVD), and computation of the modes that approximate the field; iv) parameterization of modes coefficients using standard RS techniques; v) review of parametric vector results in the entire design space using linear combination of the SVD modes.

The accuracy of the whole procedure was verified studying the fatigue behavior for the simplified model (Fig. 3) of a stent resembling the Maris Plus peripheral stent (Medtronic Endovascular Therapies, Roncadelle, BS, Italy) considering the following 4 parameters:

-Inner Diameter of the tube ranging from 4.2 mm to 7 mm

-Young Modulus of the tube ranging from 0.15 MPa to 1.5 MPa

-Initial stretching of the tube (Is) ranging from 3% to 20%

-Cyclic axial stretching ranging from 20%Is to 100%Is.

A 4-parameters DOF of 200 points was launched on the CINECA cluster (Casalecchio di Reno, Bologna). For each run, the following results were stored for the 2 central rings of the stent: i) displacements for each step on each node, ii) first principal strains for the last fatigue cycle (sub-steps 7 and 8 of the simulation) on each element, Def_{LS7} and Def_{LS8}. Of the 200 points DOE, 158 simulations were performed (42 runs aborted due to I/O errors on the cluster) using 8 CPU per run. The average computation time (for 1 run) was 19 hours, with a minimum of 7 hours and a maximum of 70 hours. 107 of the 158 points in the DOE were used as learning points, 51 was used as verification points.

Two Reduced Order Models (ROM) with 7 and 16 modes derived from the 107 learning points were used for computing the mean first principal strain X and alternating first principal strain Y, defined according to the following equations.

$$X = \frac{Def_{LS7} + Def_{LS8}}{2}$$

$$Y = \frac{Def_{LS7} - Def_{LS8}}{2}$$

For each point of the DOE the error criterion was defined as the maximum difference in Y value between the FE simulation results and the points obtained by using ROM (Fig. 5).

IV. Conclusions

The results were satisfactory in terms of accuracy being the maximum error between all the points of the DOE and all the points obtained by using ROM less than 5.2 10^{-4} (Fig. 6). The assessment of the methodology accuracy for different stent design is under development. Verified the feasibility of RS to perform stent fatigue risk analysis, the final step will be the integration of the response surface in a computer-aided surgery planning application, implemented to run in real-time during the surgical planning, so as to provide advice of the risk of stent rupture associated with a set of patient-specific and surgery-specific input parameters in few seconds. This will be of help in planning the operation.

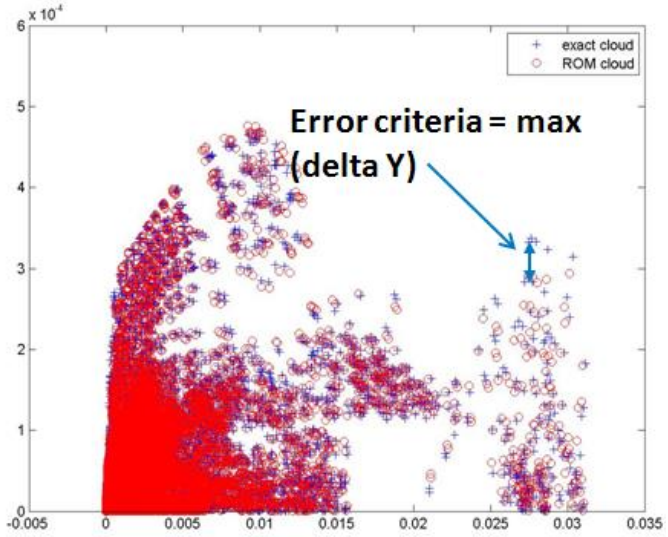

Fig. 5. Distribution of errors in terms of alternating first principal strain between the exact and ROM results for one of the points of DOE.

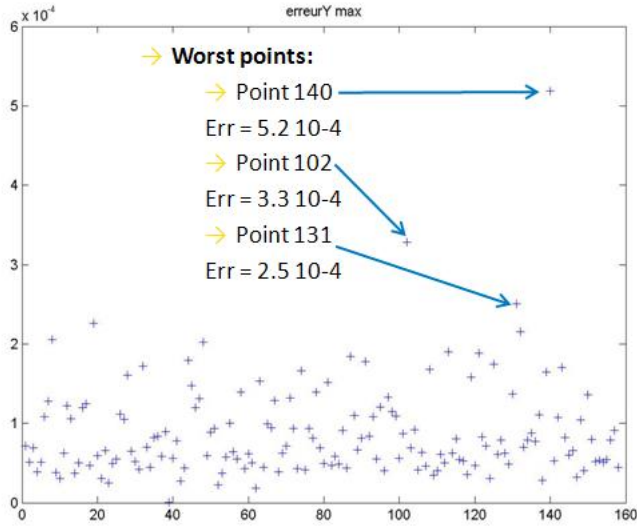

Fig. 6. Maximum errors in terms of alternating first principal strain between the exact and ROM results for all the points of DOE.

References

[1] T. Zeller, "Current state of endovascular treatment of femoro-popliteal artery disease", *Vascul Med*, Vol. 12, pp. 223-234, 2007.

[2] C.P. Cheng, N.M. Wilson, R.L. Hallett, R.J. Herfkens, C.A. Taylor, "In Vivo MR Angiographic Quantification of Axial and Twisting Deformations of the Superficial Femoral Artery Resulting from Maximum Hip and Knee Flexion", *J Vasc Interv Radiol*, Vol. 17, pp. 979–987, 2006.

[3] Y. Nakagawa, J. Yajima, Y. Oikawa, K. Ogasawara, H. Kirigaya, K. Nagashima, R. Funada, S. Matsuno, T. Inaba, M. Nakamura, H. Sawada, T. Aizawa, "Clinical outcomes after percutaneous peripheral intervention for chronic total occlusion of superficial femoral arteries: comparison between self-expandable nitinol stent and stainless steel stent", *J Cardiol*, Vol. 53, 417-421, 2009.

[4] D. Scheinert, S. Scheinert, J. Sax, C. Piorkowski, S. Bräunlich, M. Ulrich, G. Biamino, A. Schmidt, "Prevalence and clinical impact of stent fracture after femoro-popliteal stenting", *J Am Coll Cardiol*, Vol. 45, pp. 312-315, 2005.

[5] J.M. Gibbs, C.S. Peña, J.F. Benenati, "Treating the diseased superficial femoral artery", *Tech Vasc Interv Radiol*, Vol. 13, pp. 37-42, 2010.

[6] A. Nikanorov, H.B. Smouse, K. Osman, M. Bialas, S. Shrivastava, L.B. Schwartz, "Fracture of self-expanding nitinol stents stressed in vitro under simulated intravascular conditions", *J Vasc Surg*, Vol. 48, pp. 435-440, 2008.