AimaSimul: a software tool to plan stent positioning in peripheral arteries and evaluate the associated fatigue fracture risk

D. Testi, N. J. B. McFarlane, H. Wei, Y. Zhao, G. J. Clapworthy, D. M. Ryan, P. Lawford

Abstract— **Vascular stent deployment in peripheral arteries is a medical intervention in which a wire mesh tube is inserted into the artery to provide internal support. However, stents positioned in locations such as the femoral artery are subject to cyclic bending, and are therefore at risk of fatigue fracture. A software tool chain, called AimaSimul, is being implemented to support stent modeling, surgical simulation and risk calculation for surgical planning. In particular, the AimaSimul pre-operative planning tool allows clinicians, starting from patient-specific medical images, to interactively assess different stent models and deployment options for the risk of breakage. This paper describes the main functionalities of AimaSimul and, in particular, the stent deployment and deformation.**

I. Introduction

Peripheral Artery Disease (PAD) in the lower extremities gives rise to major morbidity with a substantial reduction in the quality of life and functional status, and increased mortality and it is associated with significant health care costs [1]. Moreover, as the population ages, the prevalence of PAD is expected to increase [2]. For these reasons, there is an increasing trend towards the use of minimally invasive forms of treatment including angioplasty and arterial stents [3].

In vascular stenting, a small wire mesh tube, called a stent, is inserted into an artery (or vein) at the site of narrowing to support the vessel, thus helping it to remain open for the blood to flow. In the most commonly used procedure, a balloon-tipped catheter is used to open the artery (angioplasty), followed by the insertion of a vascular stent (stenting) to prevent the vessel wall collapse and re-closure of the artery. The majority of stents used in peripheral stenting are self-expanding. Self-expandable stents are mounted on a catheter and constrained by an outer sheath; when the sheath is retracted, the stent re-expands to become opposed to the vessel wall where it exerts an outward radial force until it reaches its preset diameter.

Whilst vascular stenting has a high success rate in the short term, follow-up studies show that stent fracture is a significant problem for stents placed in the superficial femoral artery [4], where continual flexing of the surrounding tissue can cause metal fatigue. Fatigue is a typical failure of metallic materials subjected to cyclic loading, and placement of the stent in close proximity to leg muscles induces cyclic bending loads during daily activities such as walking.

When the fatigue properties of the stent material and surgery-specific factors are known, nonlinear finite element (FE) models can be used to compute the stresses and strains induced by cyclic loading, and from these the probability of a fatigue fracture over time can be evaluated. FE analyses have been extensively used by stent designers to study both the mechanical behavior of stents during their deployment, and the interaction between released stents and the vessel wall in terms of both material and geometry [5-9].

Such information would also be invaluable to clinicians planning patient-specific treatments: a simulation tool able to represent stent-deployment within the given patient's artery and the associated risk of fracture for the stent could help the clinician in the pre-operative choice of stent. As, it has been demonstrated that the position and deployed configuration of the stent play a significant influence on modifying the blood flow, stent positioning must be taken into account [10]. In consequence, the location in the body is fundamental to the selection of the stent to be inserted.

Until now, it has not been feasible to use FEA simulations for routine clinical use with patient-specific geometries because of the complexity of the models (including high constitutive and kinematic non-linearities), and due to the associated high computational costs. The RT3S project, funded by the European Commission, will provide an alternative approach by pre-calculating the likelihood of stent fracture for a large range of vessel geometries on a high-performance computing facility and then using response surfaces [11, 12] to individualize the results for the specific situation being considered.

A software tool is being implemented which allows clinicians to extract the vessel geometry and properties from the subject-specific medical images, to plan the angioplasty and stent deployment and to obtain the risk of fracture for the planned stent using the method outlined above.

The particular focus of this paper is the description of the

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pre-operative planning tool, AimaSimul, and the methods implemented for the stent positioning and deformation. Positioning and deformation together with the stent material and geometry are the most important parameters for the estimation of the stent risk of fracture.

II. AIMASIMUL PRE-OPERATIVE PLANNING SOFTWARE

AimaSimul is a desktop application aimed at the preoperative planning of stent deployment in peripheral arteries. It is implemented based on the C++ open source library, Multimod Application Framework [12], which provides the basic elements on top of which the specialized software is developed.

AimaSimul provides clinicians with a complete workflow for the pre-operative planning of a stenting procedure and the evaluation of the associated fatigue fracture risk. The procedure, described below, is illustrated in Fig. 1.

(a) *Importing patient-specific data.* The user can load the patient's CT or MRI images (as a stack of DICOM images) guided by a wizard, which gives a preview of the data at each step; the user is also allowed to select a sub-set of the volume by cropping the dataset around a region of interest.

(b) *Data Visualisation*. Once in the application, the images can be visualized using different modalities; specifically, AimaSimul includes 3D volume rendering, which allows the clinicians to see the vessels together with the other musculo-skeletal structures by selecting the layer of the body to be visualized or one of the available pre-sets to enhance particular anatomical structures (e.g. muscular system, circulatory system, skeleton).

(c) *Vessel geometry extraction*. Three methods are available to extract the vessel shape from the images:

- manual segmentation: the tool provides a series of painting tools, like brushes;
- region growing segmentation: the operation takes as input a point lying inside the future volume of interest (seed) and a range of values representing the extremities of the volume intensity (lower and upper); it relies on ITK [13];
- level-set segmentation: this method is developed based on VMTK [14]; it is based on the identification of a value range, which changes according to data type (MRI or CT), and the selection of the start and end points of the future surface of the vessel.

(d) *Vessel model creation*. We create a so-called Active Vessel, which represents a simplified vessel geometry. It is based on shape information of the vessel but has geometrical properties, which simplify the further simulation steps. This 3D model has the same centerline as the vessel and also retains the information about the cross-sectional area of the perpendicular planes: each plane is a circle and its radius is the mean radius of the vessel surface section.

(e) *Quantification of the lesion*. This step classifies the whole vessel according to a predicted diameter value. The predicted value is estimated by iterative linear regression along the whole centerline to reduce the numerical errors produced by the previous volume and surface processing.

(f) *Recognition of the lesion*. This tool classifies those segments of the vessel that have a significant reduction of the lumen with respect to that predicted and provides an estimation of the "normal" vessel diameter; it then automatically creates a parametric model of the stenosis.

(g) *Choosing and positioning a stent*. A dedicated interface allows the user to choose from a database of different stent configurations in terms of length, diameter, supplier; the stent is then deployed in a position corresponding to one of the previously identified stenotic regions in the vessel.

(h) *Stent deployment*. The position and expansion of the stent during deployment is visualized interactively (see Section III for more details).

(i) *Clinical report generation*. Clinically relevant information is collected in a report. The report contains parameters of the vessel, associated stenotic areas, model reconstruction parameters and stent information.

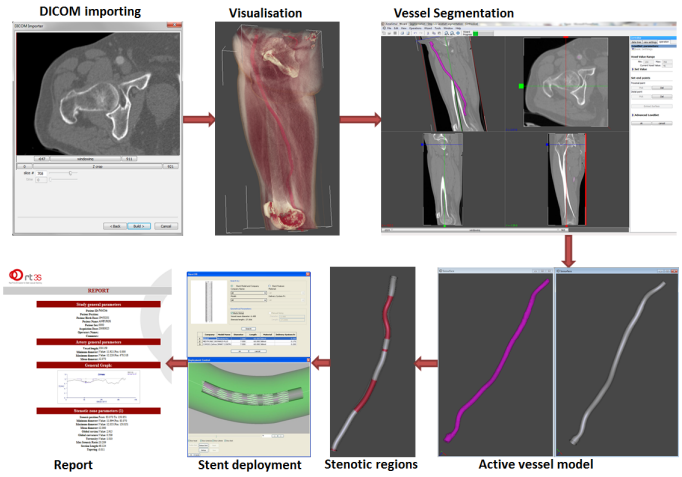

Fig. 1. AimaSimul stenting planning work flow

III. STENT DEPLOYMENT

The aim of the stent deployment is to allow the user to interactively position the stent and to visualize its expansion to the vessel wall. The deformation should execute in quasi real time and provide a reasonable approximation to a full mechanical simulation.

The stent model used is based on a parameter set defined by other RT3S partners including Medtronic Inc., a stent manufacturer. A stent is typically formed of successive zig-zag crowns consisting of identical struts; the crowns are connected by a small number of links. During the positioning phase of the stenting operation, the stent is radially compressed and constrained within a catheter sheath, and is moved into the required position along a guide wire. When it is correctly positioned, the sheath is withdrawn and the stent expands outwards to its deployed position against the vessel wall. A stent model in its catheter sheath is shown in Fig. 2.

The control of the stent deformation follows the Fast

Virtual Stenting (FVS) methodology of Larrabide *et al*. [15], which takes into account the geometric properties of the stents and uses a constrained deformable simplex mesh to successfully fit virtual stents into arbitrarily-shaped vessels.

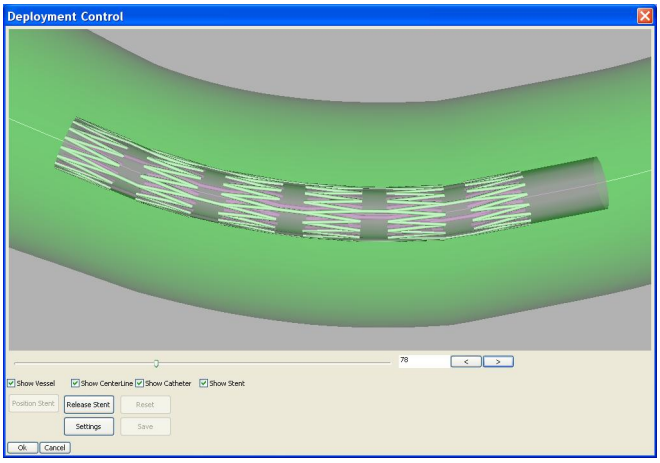

Fig. 2. Stent model and catheter sheath (purple) in blood vessel (green)

This extended the method of Montagnat and Delingette [16] by introducing a new force to encode the geometric constraints of the specific stent design. In an interactive simulation, deformable models have the advantage of speed and simplicity over finite element simulations because they do not attempt to model the detailed physics of the structures. Flore *et al*. [17] carried out an assessment and quantification of the differences between FVS and Finite Element Analysis (FEA), and concluded that, for vessels that are straight or do not have excessive curvature, FSV could provide results close to those obtained from FEA simulations under the same conditions, with a significant reduction in the computational time.

In the FSV method, to simplifying the calculation of the expansion, the stent is embedded in a simplex mesh, vertices of which coincide with vertices of the stent model. Simplex meshes are 3-connected meshes, which are widely used in deformable modeling. They are a topological dual of triangulations, making it easy to convert back and forth.

As the stent geometry does not comply with the restriction of three neighbors per vertex, it cannot be directly represented as a simplex mesh so, as in [18], the simplex mesh is used as a control – when the simplex deforms, so does the stent. A subset of the simplex vertices coincides with the extremities of the struts and links, and the connections include geometric information specific to the stent being released, such as strut layout, strut length, link configuration and link length.

The deformation of the stent is controlled by forces acting on the vertices of the simplex control mesh. These are as follows.

A. *Smoothness force*

The smoothness force in simplex mesh deformation has two components: a tangential component which tends to distribute the vertices so that the distances between them are uniform, and a normal component which tries to make the curvature uniform, constraining the mean curvature of the surface through the simplex angle.

B. *External force*

This is a force attracting each vertex to the nearest point on the vessel. It represents the expansion force which in a real stent would be self-generated. The force is constant except when the vertex is very close to the vessel wall, when it becomes proportional to distance from the wall to allow for a soft impact.

C. *Length-preserving forces*

This is an additional elastic force, which acts between vertices to preserve the lengths of the struts and links in the stent.

D. *Catheter and vessel wall constraints*

No force acts on the vertices that are inside the catheter at a given time step. The neighbors of such vertices must also be constrained, in order to stop the connecting struts expanding through the catheter. Similarly, when vertices reach the vessel wall, they are assumed to "stick" in place, and no further force acts upon them. The expansion stops at a small nominal strut thickness inside the vessel wall, which avoids the visual problem of the thick struts protruding through the vessel wall.

From consideration of the above forces and constraints, we are able to express the deformation equation in a finite difference form, as:

$$P_i^{t+1} = P_i^t + (1-\gamma)(P_i^t - P_i^{t-1}) + w_i^t(\alpha f_{smooth}(P_i^t) + \beta f_{ext}(P_i^t) + f_{length}(P_i^t))$$

This equation defines the local displacement of each surface vertex. P_i is a point of the simplex mesh; t is the iteration number; f_{smooth}, f_{ext}, f_{length} represent the smoothness force, external force and length force, respectively, w_i^t is a weight related to the distance from the vessel, and α, β, γ are weighting parameters.

The deployment of the stent is shown in Fig. 3.

IV. User Evaluation

The AimaSimul application was, and continues to be, tested at various development phases by both medical engineers and clinicians (in Sheffield, UK). The potential usefulness of the application was clear at the outset.

Ongoing development and user feedback have crafted the Beta 1 AimaSimul release. This version demonstrated both ease of use and genuine application. The provision of the workflow wizard enables the user (including new/novice users) to be guided through the process of assessing the arterial stenosis using image segmentation and model extraction tools. The user then executes vessel angioplasty, and selects a particular stent from the library for deployment in the stenotic part of this vessel. The fracture risk is calculated, and all relevant patient data, stenosis parameters,

the stent deployed and relevant image/vessel snapshots along with clinical notes are compiled into a report, which is saved for later reference. Patient artery assessment using AimaSimul is quite fast at approximately ten minutes per case. The software runs smoothly on a standard 64bit Windows laptop. Further exhaustive clinical evaluation will be effected on the imminent final software release. The test data for this release will be recently acquired MR patient datasets. Each dataset is for a patient who received a stent in either the left or right superficial femoral artery (SFA).

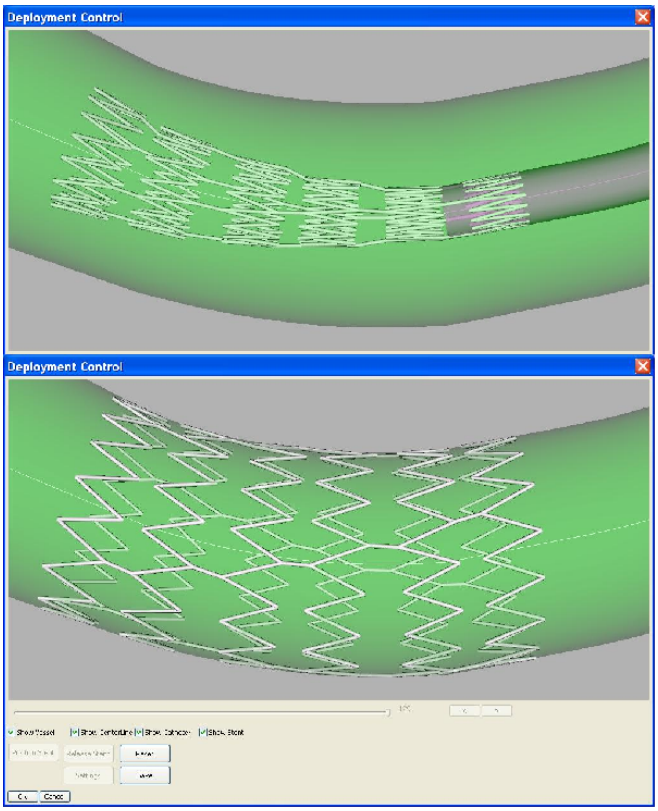

Fig. 3 Stent deployment showing (top) catheter withdrawal and (bottom) final expanded position.

V. Discussion

The AimaSimul application described allows the integration of patient-specific and implant-specific factors in order to provide clinicians with an improved prediction of the failure risk of implanted stents and thus reduce the necessity for restenosis, particularly in femoral arteries.

The software enables patient-specific data to be processed with ease and a stent to be chosen and deployed. Interactive feedback is provided to clinical users by means of integrated pre-calculated response surfaces. To the authors' knowledge no software solutions similar to AimaSimul currently exists.

Results from clinical evaluation are encouraging. The semi-automated nature of the application, low number of user inputs, processing speed and non-specialized computer hardware should facilitate its possible future introduction into clinical practice. The next stage of the evaluation will be a consideration of how AimaSimul might be most effectively integrated into current clinical workflows.

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