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Support for the Calculation of Stent Fatigue Fracture in Peripheral Arteries

N.J.B. McFarlane[1], H. Wei[1], Y. Zhao[1], G.J. Clapworthy[1], D. Testi[2] and A. Chiarini[2]

[1]University of Bedfordshire UK
[2]SCS srl, BioComputing Competence Centre, Bologna, Italy

Abstract

Vascular stenting is a medical intervention in which a wire mesh tube is inserted into an artery or vein to provide internal support. This is a safe and common procedure, but stents are now increasingly being deployed in peripheral locations, such as the femoral artery, as part of a procedure called Peripheral Vascular Angioplasty (PVA). Stents in such locations are subject to cyclic bending, and are therefore at risk of fatigue fracture. This paper describes the work of the RT3S project, which brings together stent modelling, surgical simulation and risk calculation for surgical planning. This will allow the clinical user to interactively assess different stent models and deployment options for breakage risk. In the RT3S system, models of several commercial models of self-expanding stent are available for simulation. The placement of the stent in the vessel and the withdrawal of the catheter sheath to expand the stent are visualised. A simplex control mesh is used to guide the deformation of the stent from its compressed start configuration to its expanded final position. The fracture risk for the given model and its patient-specific final position is precomputed using the response surfaces methodology.

Categories and Subject Descriptors (according to ACM CCS): I.3.m [Computer Graphics]: Miscellaneous—I.6.m [Simulation and Modeling]: Miscellaneous—I.3.m [Computer Applications]: Life and Medical Sciences—Health

1. Introduction

Cardiovascular diseases (CVD) are major causes of disability and death in developed countries; in the EU, they account for 42% of deaths (ca. 2 million) with an associated cost of more than €192 billion/year [Bri08]. Disease of the peripheral arteries gives rise to major morbidity and mortality, with disease in the lower limb arteries being a major cause of morbidity. For these, there is an increasing trend towards the use of minimally invasive forms of treatment including angioplasty and the use of arterial stents. Statistics for England and Wales suggest that endovascular interventions, including angioplasty and stenting, are becoming the preferred form of treatment for many vascular occlusive diseases with a 50% increase in procedures performed over a 5 year period [HSC12].

In vascular stenting, a small wire mesh tube called a stent is permanently placed in an artery or vein to help it remain open. In the commonest procedure – angioplasty and stenting – a balloon-tipped catheter is used to open the artery (angioplasty) followed in many cases by the insertion of a vascular stent (stenting) to prevent the artery re-closing. Self-expandable stents are mounted on a catheter and constrained by an outer sheath; when the sheath is retracted, the stent expands radially outwards onto the wall of the treated segment where it exerts an outward radial force until it reaches its preset diameter.

While the process of vascular stenting is safe, with few complications reported, follow-up of arterial stents shows that stent fracture is a significant problem for stents such as those placed in the superficial femoral artery [SSS*05], where continual flexing of the surrounding tissue can cause metal fatigue and lead to fracture. 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. In such cases, re-stenosis (insertion of another stent) carries significant morbidity and alternatives such as bypass surgery may not be feasible, so there is a risk of severe recurrent symptoms or even limb loss [SD05].

When the fatigue properties of the stent material and patient-specific and surgery-specific factors are known, non-linear finite element models can be used to compute the

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stresses and strains induced by cyclic loading, and from these the probability of a fatigue fracture appearing over time can be deduced. Such information would be invaluable for the clinician to plan patient-specific treatments, but the computational power needed to perform the finite-element calculations is huge, and it is not currently feasible to perform this at a patient-specific level. Recent commercial visualisation software, e.g. Philips Stent Planning [Phi12] and Paieon IC-PRO [Pai12], provide real-time imaging for 3D navigation and geometrical tools for stent interventional planning (device navigation, positioning and post-deployment analysis), but they do not offer any capability for simulating the actual stent deployment nor do they evaluate the risk of fracture.

The RT3S project ("Real-Time Simulation for Safer Vascular Stenting"), funded by the European Commission, is seeking to 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 [BW51, MMAC09] to individualise the results for the specific situation being considered.

This paper describes the design of the software system supporting the project and the form of the results to be produced; RT3S considers only self-expanding stents. The remainder of the paper is as follows. Section 2 introduces the AimaSimul planning tool which supports the workflow starting with the images captured from the patient which define the vessel geometry to the final stent deployment, while Section 3 elaborates on the advanced features it contains. Section 4 describes the model that supports the calculation of the process of stent expansion during deployment. Section 5 presents results achieved by the project to date and Section 6 discusses the future work required to complete the project.

2. AimaSimul computer-aided planning tool

AimaSimul is a stand-alone software application for the pre-operative planning of stenting in peripheral arteries. It relies on the C++ open source library Multimod Application Framework (MAF) [MAF12], which supplies the basic elements (data structures, data visualization and data manipulation), the procedural "glue" or application logic, and basic graphic user interface elements.

AimaSimul provides the user with a complete workflow for the pre-operative planning of a stenting procedure, which involves the following steps as illustrated in Fig. 1.

(a) *Loading of a stack of DICOM images.* The user can import the patient's CT or MRI images guided by a wizard, which gives a preview of the data at each step; during the import, the user can select a sub-set of the slices or crop the dataset around a region of interest, if desired.

(b) *Visualisation tools.* After importing, the data can be visualised using different modalities, such as standard orthoslice; the software includes 3D volume rendering, which allows the clinician to see the vessels together with the other musculo-skeletal structures by selecting which layer of the body to visualise. Different preset combinations are provided to manage the CT or MRI information or to enhance particular anatomical structures (e.g. muscular system, circulatory system, skeleton).

(c) *Isolating (by segmentation) the vessel.* The user has a choice of three methods for the vessel segmentation:

- *Manual segmentation:* the tool provides a series of painting tools, like brushes;
- *Region growing segmentation:* the operation is based on the Insight Segmentation and Registration Toolkit (ITK) [Kit12a]; it takes as input a seed point lying inside the future volume-of-interest and a range of values characterising the extremities of the volume intensity (lower and upper).
- *Level set segmentation:* this is based on the Vascular Modeling Toolkit (VMTK) [Kit12b]; the user is asked to set a value range, which changes according to data type (MRI or CT), and to select the start and the end point of the future vessel surface.

(d) *Creating a 3D vessel model.* An operation has been developed for creating a so-called Active Vessel, which represents a simplified vessel geometry composed of a centreline and associated circular planes. It has the same centreline as the vessel it is derived from and it retains the information about the sectional area of the perpendicular planes. Each plane is a circle and its radius is the mean radius of the vessel surface section. More details on the use of the active vessel are provided in section 3.1.

(e) *Making quantitative measurements of the lesion.* This classifies the whole vessel according to a predicted diameter value, which is estimated by iterative linear regression. It is performed along the whole centreline in order to reduce numerical error produced by the previous volume and surface processing.

(f) *Lesion recognition.* This classifies the parts of the vessel that have significant reductions of the lumen and provides an estimation of the vessel diameters; it then automatically creates a parametric model of the stenosis.

(g) *Choosing a stent and its position.* An interface allows the user to choose among different stent configurations in terms of length, diameter, supplier; the stent is positioned in the vessel according to the previously identified stenotic regions.

(h) *Simulating the deployment of the stent.* The position and expansion of the stent during deployment is visualised – see Section 4.

(i) *Reporting.* All significant information is collected for the clinician in a report containing critical values of the selected vessels, associated stenotic areas, model reconstruction parameters and stent information.

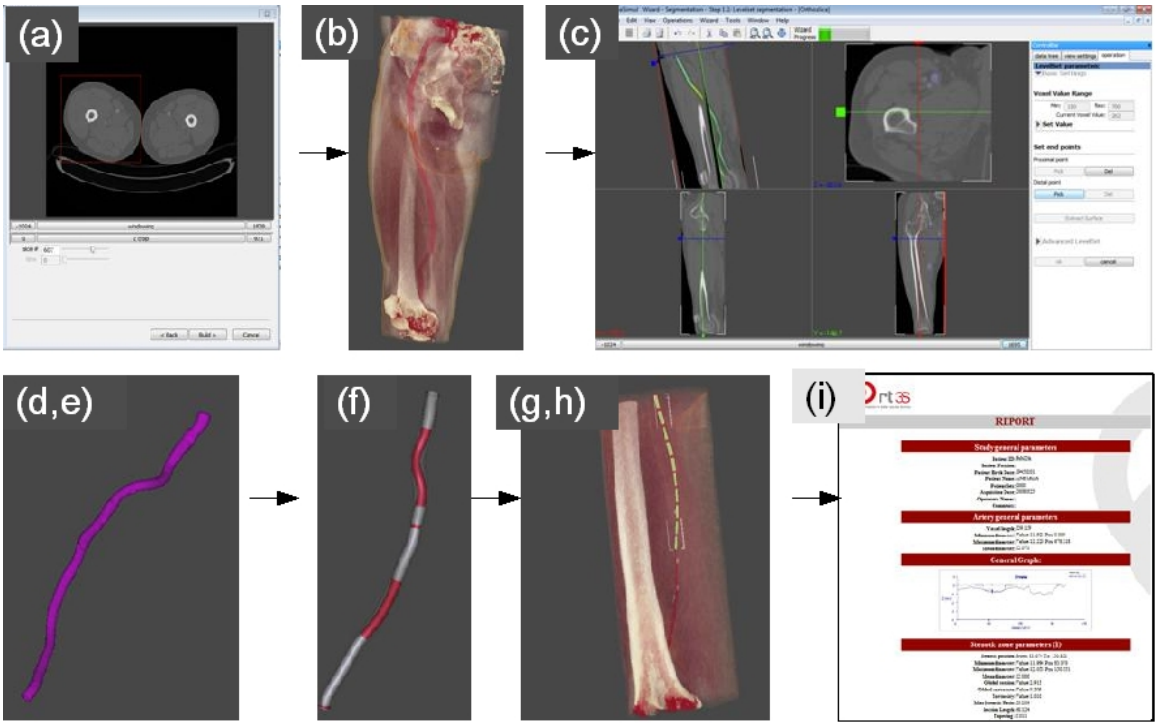

Figure 1: *AimaSimul processing workflow: (a) medical images imported from DICOM files; (b) advanced visualisation method (volume rendering); (c) segmentation (manual, region growing, or level set); (d,e) active vessel creation and centreline extraction; (f) stenosis identification; (g,h) stent selection and deployment; (i) reporting.*

3. AimaSimul advanced features

Among the different operations listed in the previous section, some techniques and tools are considered of particular importance and these are described in more detail below.

3.1. The Active Vessel and automatic stenosis evaluation

To identify the stenosis, a fast algorithm for the automatic vessel reconstruction and the lesion recognition was implemented in AimaSimul. This new approach is sufficiently generic to create a geometrical model of the patient vessel by taking as input a centreline and a set of associated sectional diameters. This output geometry, called the Active Vessel, provides all the parameters necessary for lesion classification and the further treatment planning.

First, a deformable vessel model was created in the form of a semi-parametric object: a tubular surface of connected circular sections; each section is defined by a central point, a radius and a normal. This model is processed by two algorithms: (a) lesion recognition, and (b) centreline deformation.

(a) Lesion recognition is based on iterative linear regression, which estimates the healed radius at each point of the centreline. At first, a regression line is computed, and all points exceeding tolerance thresholds are classified as lesions. Then, a new regression line is computed ignoring previously classified lesions, so that an updated estimation is made by considering the normal tracts of the vessel. In this way, a classification of the lesions and the estimation of the reconstructed vessel diameter profile are obtained. Empirical tests were conducted on the lower leg data sets of three patients to determine the sensitivity of the algorithm and to verify its convergence and stability.

(b) Centreline deformation is needed as asymmetric vessel lesions may alter the quantitative measurement. However, the algorithm should reduce the lesion effect on the centreline without losing vessel curvature and torsion. AimaSimul implements a self-organised system in which global behaviour emerges from local interaction: local forces are applied to centreline points in lesion areas to correct the centreline position step by step. Four types of forces are applied: elastic (point attraction force between neighbours moves all the points to a common line proportional to distances between them), bending (vessel resistance to bending, correlated with the angle between consecutive points), constriction (it retains the physiological shape of the reconstructed sections) and friction (it avoids the accumulated forces creating unpredictable effects and deforming the vessel shape). All of these forces

act simultaneously at all points in time steps over an empirically predetermined duration. The solution is provided by a Runge Kutta 4 solver, a method that involves evaluating derivatives at multiple points for each time step. At the end of the deformation, the centreline position represents the estimation of the centreline points of the physiological vessel (Fig. 2).

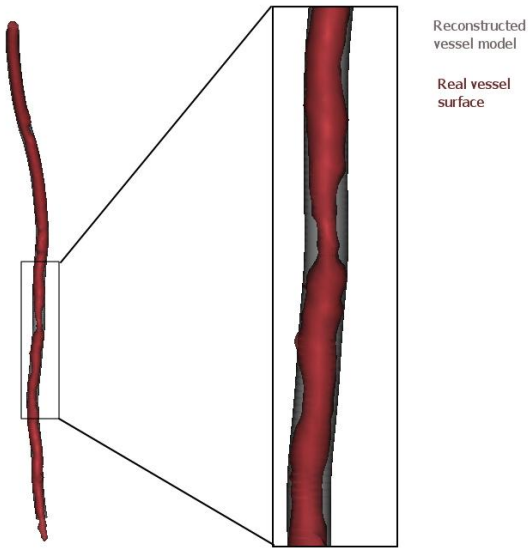

Figure 2: *Active vessel creation and centreline correction to the presence of lesions.*

For the final application, the execution time is important; the operation typically runs in a range of 0.5-3 seconds on a standard PC (Intel i5 with 4GB of RAM). The memory footprint remains constant during execution and is negligible if compared to the clinical data loaded.

In summary, the major strengths of the proposed method are the quasi-real time model deformation, the intuitive parameter adjustment and the minimal user interaction required, all seamlessly integrated into the AimaSimul preoperative planning application.

3.2. Technical background to stent placement and failure calculation

Stent implantation is a common interventional procedure with a high rate of success compared to angioplasty alone. A vascular stent is inserted into an artery at the site of narrowing to act as internal scaffolding or support for the blood vessel, thereby keeping open a passageway for the blood to flow. When crimped, the stents are slim and can be inserted into the artery, using a catheter. Hirabayashi *et al.* [HORC04] demonstrated that the position and the released configuration of the stent play a significant role in modifying the blood flow and must be taken into account, so a simulation tool able to represent stent-deployment within the given patient?s artery can help the clinician in the pre-operative choice of stent. Selection of a stent based on the location in the body is crucial and it needs to be tested for dynamic fatigue and other analysis under different loading conditions to predict its performance. Typical stent fractures are illustrated in Fig. 6(b,c) towards the end of the paper.

Finite element analysis (FEA) is a proven tool used by stent designers. It has been extensively used to study both the mechanical behaviour of stents during their deployment and the interaction between released stents and the vessel wall. The influence of stent material and geometry on its expansion and on the tissue response has been investigated in [MPM*04, WQL*07]. Kleinstreuer *et al.* [KLB*08] simulated the behaviour and fatigue of stents using finite elements; important parameters of the environment were cyclical loading, radial forces and vessel wall compliance. Gijsen *et al.* [GMS*08] and Lally *et al.* [LDP05] developed finite element simulations of stents, paying particular attention to the stress inflicted on the vessel by the stent, a possible risk factor in restenosis. Finite elements can also be used to model deformations of the stent, such as expansion, recoil and 'dog-boning' [LDP05, EMGF07]. However, because of the complexity of these models, including high constitutive and kinematic non-linearities, and due to the high computational costs associated with them, so far FEA simulations are not feasible for general use with patient-specific geometries.

A different approach allowing the prediction of the stent released shape is based on deformable models. Egger *et al.* [EGF07, EMM*07] developed an active contour model of the aorta with its iliac arms and a corresponding bifurcated (Y-shaped) stent. Collision avoidance between the arms of the model was addressed in [EMM*07]. The advantage of such a deformable model is the ability to simulate the forces between the stent and the vessel wall, and to iteratively fit the stent to the vessel. The surgeon is able to test different stents and other parameters in simulation before operating.

The technique proposed by Appanaboyna *et al.* [AML*08] shows that adaptive unstructured embedded grid approaches are able to release a stent inside a patient specific vessel. By embedding a model of the stent within a real vascular 3D image, Valencia *et al.* [VMO04] achieved the same goal. First, a simple geometrical model, composed of a set of circles or polygons stacked along the vessel centreline, is used to simulate the introduction and deployment of the stent. Second, a simplex-mesh model with an adapted cylindrical constraint is used to represent the stent surface. However, the physical and geometrical characteristics of the stents were not considered, so this method cannot ensure realistic stent configurations.

In contrast, the Fast Virtual Stenting (FVS) methodology, proposed by Larrabide *et al.* [LRF08], 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. The authors extended the method adopted by Montagnat and Delingette [MD05], by introducing a new force that encodes geometric constraints associated with 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.* [FLP*09] carried out an assessment and quantification of the differences between FVS and FEA. It indicated 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.

Apart from FEA and deformable models, measurement using image data is not a new concept. A non-contact method for measuring various stent deformation modes using photogrammetry was developed and demonstrated in [SHA11]. The methodology developed was coupled with FEA for accurate and dynamic characterisation of the mechanical stresses within the stent. Optically measured deformations were used by a dynamically adaptable FEA model as boundary conditions. Zhou *et al.* [ZWG*06] created a preoperative stent planning simulation with a stereoscopic visualization of the CT data, enabling the surgeon to edit measurements and stent parameters interactively in 3D.

3.3. Stent model creation

The stent model used is based on a parameter set defined by other RT3S partners including Invatec, a stent manufacturer. A stent is generally formed of successive crowns consisting of identical struts; the crowns are joined by links, which are often relatively few in number. Apart from the obvious geometric properties, the way in which these links are configured determines the characteristics of the stent. A typical stent and the model representing it are shown in Fig. 3.

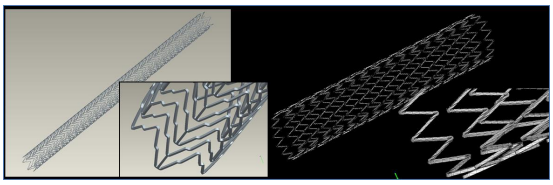

Figure 3: *Left: A real stent; right: the corresponding model.*

To simplify 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 simply connected meshes suited to deformation and are a topological dual of triangulations, making it easy to convert back and forth. They are widely used for shape reconstruction and deformation. Unlike deformable models described by continuous equations involving physics-like elasticity and stiffness parameters, the deformation of simplex mesh is not designed to mimic any physical behaviour, but to model the relative position of a vertex with respect to its neighbours, in terms of simplex angle and the metric parameters.

The simplex angle controls the local mean curvature, i.e, the height of a vertex with respect to the tangent plane. The metric parameters, the barycentric coordinates of its orthogonal projection with respect to the three neighbours, controls the local parameterisation. All vertices of a simplex mesh are considered as physical masses submitted to a Newtonian law of motion. During an iteration, every vertex undergoes a displacement controlled by a regularising term and a data-driven term.

As the stent geometry does not comply with the restriction of three neighbours per vertex, it cannot be represented by standard simplex meshes so, as in [LRF08], the simplex mesh is used as a control mesh, such that when the simplex deforms, so does the stent. A subset of the simplex vertices serves as 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, etc.

During deployment, the stent starts in a crimped state, that is, it is held in a radially compressed configuration by the external sheath. It is moved along the vessel by the attached catheter and when it is in the optimal position, the sheath is withdrawn and the stent expands to reach the vessel wall (see Fig. 4).

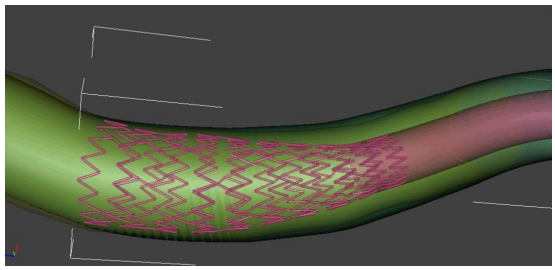

Figure 4: *Stent expansion during sheath withdrawal.*

In practice, the surgeon uses real-time medical imaging to ascertain when the stent is in the correct position for deployment. For the purposes of deployment, it can be assumed for simplicity that the stent lies on the vessel centre-line at the time when deployment is initiated.

In the following section, we shall consider a force-based model to control the manner in which the stent expands.

4. Stent unfolding

The goal here is to define an algorithm that can virtually deploy a stent in a geometry that represents the patient-specific vasculature; the result will be less accurate than that obtained by mechanical modelling but it should be performed

in quasi-real time and provide a satisfactory approximation to the full mechanical simulation. As noted in Section 3, the simulation is based on a constrained simplex deformable model.

We introduce multiple forces and constraints that control how the vertices are displaced at each iteration. The delivery size is the minimum diameter to which a stent can be compressed for delivery via a catheter. It must then expand to fill the vessel subject to the constraints of the vessel wall and the plaque, and the physical structure of the stent.

As in most deformable model schemes, vertices are considered as physical masses subjected to a Newtonian law of motion including the forces listed below, which is solved using finite differences.

4.1. Smoothness force

The smoothness force in simplex mesh deformation has two components. The tangential component tends to distribute the vertices so that the distances between them are uniform – in general, it is preferable to have vertices uniformly spread over the surface. At each vertex, three metric parameters are defined. In addition, we define three reference metric parameters. These two sets of parameters correspond to the barycentric coordinates of two points; the vector between these two points is our tangent force – see Fig. 5. The normal component tries to make the curvature uniform, constraining the mean curvature of the surface through the simplex angle. It is related to the variation of mean curvature in a neighbourhood, so the reference simplex angle is defined as an average of the simplex angles at the neighbouring vertices. More details and the formulae can be found in [Del99].

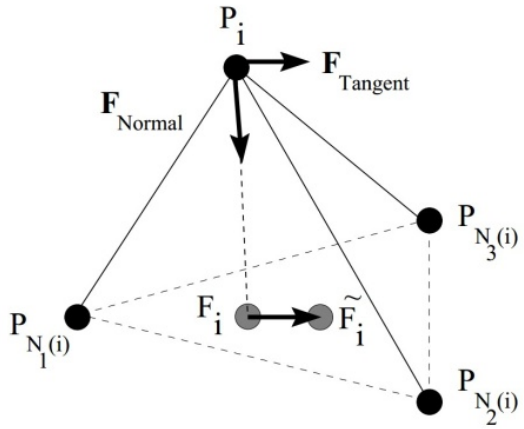

Figure 5: *Definition of tangential internal force and normal internal force.*

4.2. External force

The external force represents the force generated by the stent when it self-expands to a larger diameter; in effect, it ensures attraction of the stent mesh to the vessel wall. It acts in the mesh normal direction and we simply compute it as displacement vectors along the direction normal to the simplex surface. The external force is adjusted by a weight shown in the evolution equation; this weight, β, is set experimentally and is the main parameter controlling the speed of expansion. To avoid a hard contact with the vessel wall, the external force decays as the squared distance to the vessel wall when close to it.

4.3. Length preserving forces

This force maintains the length of the struts and links of the stent – that is, the distance between two vertices connected by a strut or link should be preserved. For vertices not in the subset of the stent structure, this force is set to zero. For vertices attached to a link, there are two components – from the struts in the crown and from the link.

Every strut extremity will be connected to two struts in the same crown, so will have two neighbours, P_{i1} and P_{i2}. The length preserving force is the mean of the two respective forces that try to drag the point to a position in which the strut length is equal to its reference length d_{strut}.

The stent-specific properties are used as soft constraints, as a balance between the length force and the smoothness and external forces is required. From our experiments, this force works well in keeping the mean strut and link length error small.

4.4. Vessel wall constraint

We assume that potential expansions or morphological modifications of the vessels induced by the stent are negligible, so the expansion needs to halt when the stent touches the vessel wall. To achieve this, we calculate and update the distance between the vessel wall and every vertex on the simplex mesh. If the vessel is represented by a sufficiently dense point cloud or 3D mesh, a kd tree can be employed for rapid closest-point searching. Kd trees [dBCvKO08] are an extension of binary search trees to k-dimensional data. They facilitate very fast searching and nearest-neighbour queries. When the distance, d, from the vessel wall is below the threshold, ε, the external force is reduced proportionally to d^2.

4.5. Sheath constraint

When the stent reaches its deployment location, the sheath is drawn away, gradually exposing the stent crown by crown. As a crown emerges from the sheath, it begins to expand. Thus, for different crowns, there are time delays for expansion from one end of the stent to the other.

To simulate this, the retraction speed of the sheath is synchronised with the starting time for the expansion of each crown, that is, none of the forces mentioned comes into play for a crown while it remains covered by the sheath.

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

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

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 and γ are weighting parameters.

5. Outcomes

A system is being developed in which patient-specific and implant-specific factors are incorporated in order to provide clinical users with an improved prediction of the likelihood of failure of stents implanted and thus reduce the necessity for restenosis, particularly in femoral arteries. The level of computation involved in resolving this problem is immense, so that with existing technology it is not feasible to attempt such prediction within normal clinical timescales. Hence, no system similar to AimaSimul currently exists.

Early results are encouraging. AimaSimul has shown itself to be robust and efficient in operation, and testing with users, using synthetic data where the final data is not yet available, has demonstrated its effectiveness and that it is light in terms of demands for input from the user, while still providing all the facilities requested in the specification phase.

In relation to stent expansion, expert opinion on the form of deployment produced has been positive and investigations of the efficacy of the length-preserving constraint have shown that it is very effective in practice. The slight elasticity it provides enables the initial geometric changes to take place without causing disruption to the expansion process, and the strut and links quickly settle in a stable manner to their fixed values.

6. Future work

The fracture risk of a given stent model and its deployment position is precomputed using the response surfaces methodology [BW51,MMAC09]. This computation demands many months of supercomputer time, the full set of data from which the calculation of the likelihood of stent failure is not yet available. Nevertheless, various possibilities have been investigated for their ultimate presentation to the clinical user group.

The response surfaces will provide the likelihood of failure only by region, that is, somewhere in an individual crown or in a set of links at a specific cross-section. Users have requested visual illustration of the risk by colour in 4-level scheme. For this, colouring the stent only presents problems for stents in which links are short (see Fig. 6(a), while colouring the surroundings of the stent has been found to cause confusion in areas where crowns and links overlap. It is likely that a combination of colouring on the stent supplemented by external tokens linked to the stent components will be used; this will be fully user tested when the response surface results are available and reported in a future publication.

Full testing of the complete system by clinical users will take place before the end of the project.

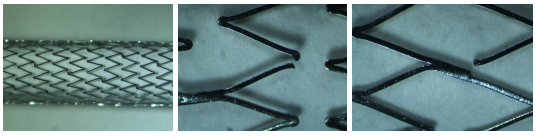

Figure 6: *(a) Stent with short links; (b,c) illustration of stent failures.*

7. Acknowledgement

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