

A Virtual Product Development Strategy for Minimally Invasive Medical Devices

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Abstract: Virtual design tools are gaining more and more importance in the production process of medical devices. Biomedical devices and their surrounding boundary conditions are usually characterized by complex geometrical shapes, materials and interactions, and current Abaqus capabilities in dealing with highly non-linear problems are highly needed to realistically capture these complexities. As an example, stents can be laser-cut or braided, driven by folded balloons to expand or be self-expanding and they interact with stenosed, tortuous, highly non-linear and anisotropic blood vessels. In order to investigate in detail some of the above mentioned aspects of stenting we have developed a dedicated pre- and postprocessing tool based on the open-source design software pyFormex. The enormous potential of combining this design environment with Abaqus is illustrated in this paper, focusing on balloon- and self-expanding stents, embolic protection filters and patient specific modeling. This paper aims at providing a survey of the latest developments carried out in our research unit in this area and detailed information with respect to the simulations can be found in the cited works.

Keywords: Design Optimization, Balloon-expandable, Self-Expandable, Stent, Embolic Protection Filter and Patient Specific.

1. Introduction

The trend in current cardiovascular surgery is to minimize the impact of the procedure on the patient in order to speed up post-procedural recovery; consequently the application of minimally invasive techniques is growing rapidly. Minimally invasive interventions are characterized by minute incisions, through which the surgeon is able to insert and maneuver minuscule surgical instruments and/or implants to the target site. A good example of a minimally invasive surgical procedure as an alternative for open chest surgery is the use of stents, which are tubular structures deployed in a narrowed section of an artery to enlarge its cross-section and consequently to restore the local blood flow. More than 2 million stent implantations are performed world-wide annually, yet the market still changes rapidly and there is still a need for procedural improvement and innovative stent designs. Moreover other minimal invasive devices such as embolic protection filters, stented valves, etc are rapidly entering clinical practice. To date, these devices are mostly developed using a trial and error approach: a first prototype is manufactured and physical tests are performed to check whether the design criteria are fulfilled. If this is not the case, the design is adapted and a new prototype is manufactured and tested. This approach is time-consuming,

expensive and often not able to fully address the product's performance and (bio)mechanical requirements. Moreover, performing physical tests on these generally small devices is challenging. A promising strategy to design medical devices is virtual product development. This approach enables the development and optimization of novel designs and, consequently, reduces the costs and the time to market. Our research focuses on the development of innovative methods combining Abaqus with the open-source pyFormex design software to facilitate virtual product development of minimally invasive devices. This paper provides a brief overview of the latest developments carried out in our research unit in the following research areas: (i) balloon expandable stents; (ii) self-expanding braided wire stents; (iii) embolic protection filters; and (iv) patient specific modeling.

2. Balloon expandable stents

Balloon expandable stents are currently the most frequently used stents, particularly for coronary arteries. Accurate design analysis of such a class of stents requires accounting for the interaction between the stent and the balloon, the apposition in the target vessel (e.g. bifurcation lesions) and the accurate understanding of the impact of the stent geometry on its mechanics. This section focuses on our developments with respect to the previously discussed issues.

2.1 To fold or not to fold

Restenosis after (drug-eluting) stent implantation is correlated with non-uniform stent strut distribution (Takebayashi, 2004). This observation is related to the protrusion of the vascular wall tissue between the struts of the stent (prolapse) and the local drug concentrations and gradients, resulting from inhomogeneous strut placement (Hwang, 2001). Therefore efforts should target optimization of the uniformity of the stent strut distribution upon stent deployment. We hypothesized that the folding pattern of the delivery balloon contributes to the non-uniform strut distribution.

To test this hypothesis, we studied and compared different expansion modeling strategies for a new generation balloon expandable coronary stent (De Beule, 2008(a,b)). In the early stent design phase, a radial displacement driven cylindrical balloon expansion can provide useful and (relatively) accurate information regarding the stent shape when reaching its nominal diameter. However, to further optimize the stent design in terms of its expansion, we have demonstrated (simulating the deployment of a stent using a trifolged balloon) that it is necessary to account for the balloon unfolding, since this is what drives the free expansion of the stent. Moreover, this methodology shows very good quantitative and qualitative agreement with both manufacturer data and in-house experiments (see Figure 1).

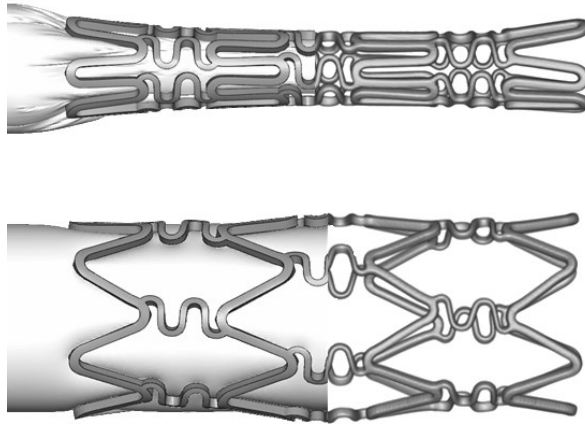


Figure 1. The trifolded balloon expansion methodology (left) shows very good agreement with high resolution microCT images (right).

In a subsequent study, we further examined the impact of balloon length, folding pattern and stent positioning on the stent expansion (Mortier, 2008(a)). Changing the balloon length and/or folding pattern significantly influences the transient stent expansion behavior (see Figure 2). Moreover, the balloon folding pattern is a major factor contributing to non-uniform stent strut distribution. In principle, it should be feasible to assess the most appropriate balloon folding for a specific stent to minimize stent strut non-uniformity attributable to balloon unfolding.

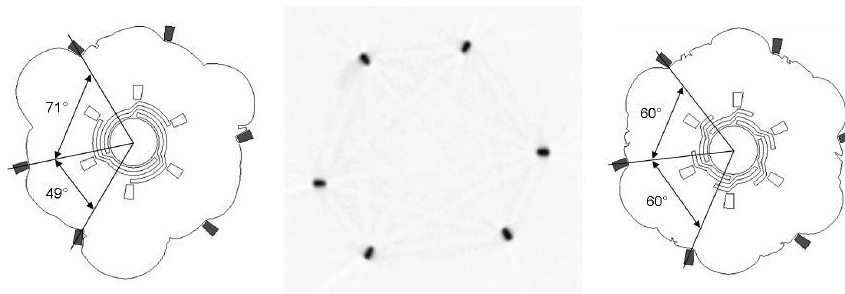


Figure 2. For the trifolded balloon, a non-uniform stent strut distribution was observed (left panel: simulation; center panel: experiment), whereas a six-folded balloon (right panel: simulation) results in a homogeneous strut distribution.

2.2 How to stent a bifurcation

Stenting coronary bifurcation lesions remains a challenge in current clinical practice. In fact, it is associated with a much lower success rate as compared to stenting straight arterial segments (Colombo, 2004). To date, many different techniques have been proposed but all the suggested

methodologies have specific limitations (Louvard, 2004 and Iakovou, 2005). Numerical simulations may help to understand and eliminate the shortcomings of current clinical techniques and devices.

Mortier et al. analyzed one of the currently applied techniques which involves the implantation of a stent in the main branch, followed by subsequent inflation of a folded balloon through the side of the stent (Mortier, 2008(b)). Simulations show that this improves the side branch patency and facilitates access to the side branch for possible later stent implantations. The added value of the proposed numerical model (depicted in Figure 3) is the ability to study many different techniques/stents, without the need for various expensive and time-consuming experiments.

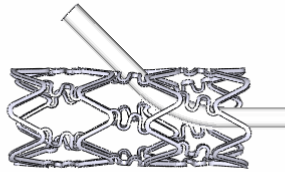


Figure 3. Insertion of the folded balloon following expansion of the stent in the main branch.

2.3 Automated stent modeling

Numerical simulations have proven to be a valuable tool to investigate the mechanical behavior of stents (De Beule, 2009). However, these computer models require a considerable amount of preprocessing and computational effort and consequently there is a continuous need for automation and accurate simplifications. For this reason, a computational stent design platform, combining parametric geometrical modeling (with pyFormex) with different finite element benchmark tests to study stent flexibility, expansion and radial strength was developed (De Beule, 2008(a)). The parametrically adaptable stent models are discretized with high quality hexahedral meshes using a sweep based meshing approach. This design platform can shorten the design process significantly and allows easy evaluation of the original design and its variations.

In addition Mortier et al. developed a semi-automatic strategy to obtain accurate finite element beam meshes directly from stent samples (Mortier, 2008(c)). The proposed method consists of two steps: (i) creating a triangulated surface representation of the stent geometry from micro CT images and (ii) automatically generating a beam mesh by computing the centerline using pyFormex. This method is time-effective and results in accurate 3D stent models of the original design as depicted in Figure 4. Furthermore, this approach allows also the creation of hexahedral meshes in a semi-automated manner by sweeping the mesh along the computed centerline.

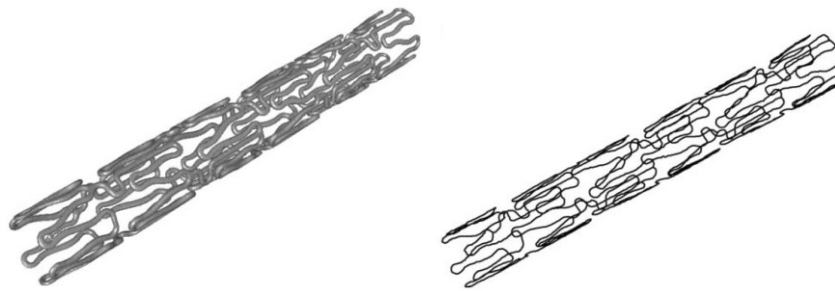


Figure 4. The resulting Finite Element beam mesh (right) is obtained by the centerline determination of the microCT based surface mesh (left).

3. Self expandable braided wire stents

Braided wire stents are a class of self-expandable endoprotheses, made of filaments interwoven in a crisscross pattern to form a tubular mesh configuration. Currently these stents are manufactured in different braiding patterns (single or multi layer) and using various materials (e.g. phynox, nitinol, (biodegradable) polymers). Despite the wide range of applications (Hussain, 2004; Walser, 2004 and Borisch, 2005), some drawbacks still remain in the braided stent design and require further attention, like inaccurate placement due to shortening (Hussain, 2004) or migration after placement related to insufficient radial stiffness (Saad, 2003).

For this reason, a novel pyFormex script-based approach for geometrical and finite element (parametric) modeling of wire stents was developed (De Beule, 2008(a,c)). This approach allows to study braided stents with arbitrary geometry and arbitrary material under complex loading conditions. The proposed parametric modeling strategy allows flexible generation of variations of the original geometry, an essential prerequisite for efficient stent design (see Figure 5). The determining geometrical design variables for braided stents are the stent diameter, the wire diameter, the number of wires and the braiding (or pitch) angle.

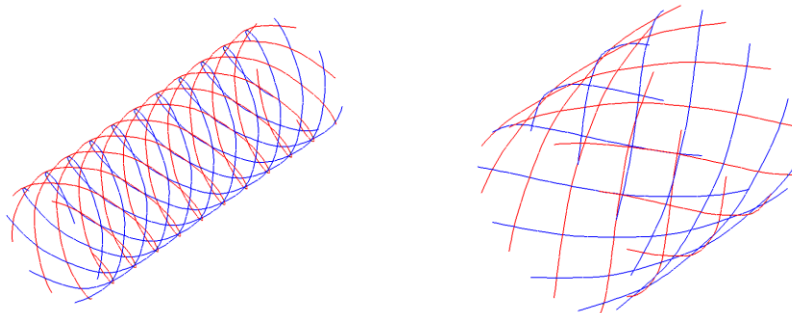


Figure 5. Design variants of the single layer braided wire stent model: 16 mm stent with 6 wires and 25° braiding angle (left) and 32 mm stent with 10 wires and 50° braiding angle.

In addition, we also studied the mechanical behavior of the Urolume (Wall)stent (American Medical Systems), serving as a reference benchmark to analyze geometrical variants. This reference simulation showed good agreement with experimental data (De Beule, 2008(a)). Parametrically adapting the original (benchmark) geometry leads to the following design guidelines for stent braiding: (i) increasing the wire diameter and the number of wires increases the stent stiffness (axial and radial), (ii) increasing the braiding angle increases the axial, though decreases the radial stiffness, (iii) the wire diameter is the most significant impact factor for stent stiffness regulation and (iv) the stent foreshortening, independent of the wire diameter and the number of wires, decreases with increasing braiding angle. Subsequently, the interaction of the wire stent with its constraining catheter was further investigated and it was shown that plastic deformation during stent insertion in the catheter should be avoided as it compromises the stent delivery and (mechanical) performance. The experimentally validated numerical modeling tool is able to predict these undesirable plastic deformations and, thus, allows for both material and catheter size evaluation. The elastic material properties do not significantly influence the stent shape exiting the catheter.

Extending parametric modeling, the developed virtual wire stent design tool was subsequently extended with an efficient design optimization algorithm (De Beule, 2008(c)). Consequently, it is feasible to reconcile competing stent characteristics in the quest for the 'perfect' stent by altering the relevant geometrical design variables (e.g. wire diameter, number of wires and pitch angle). To facilitate precise positioning of the Urolume endoprosthesis by reducing the foreshortening with 20%, while maintaining both the radial stiffness and the wire surface ratio, the algorithm automatically proposes to increase the original wire diameter from 0.22 to 0.27 mm and the pitch angle from 30.85 to 37.4 °.

Finally, the virtual design tool was applied to study the mechanical behavior of a complex new generation multilayer 3D structure stent (Henry, 2008) by reverse engineering allowing the creation of parametrically adaptable accurate models directly from the manufacturing software or microCT scanned samples. The mechanical behavior of the multilayer 3D structure stent was examined in terms of central radial stiffness. The numerical model appeared a very good approximation of the experiment as depicted qualitatively in Figure 6 by the corresponding experimental and numerical stent shapes.

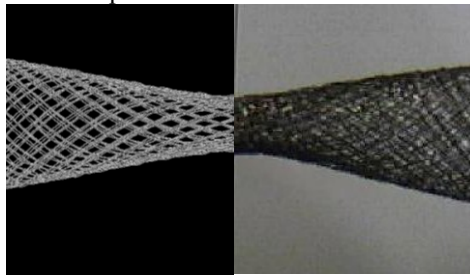


Figure 6. The numerical model (left) is able to predict the shape of the stent when loaded experimentally (right) to determine the central radial stiffness.

4. Embolic protection filters

The widespread acceptance of Carotid Artery Stenting (CAS) to treat a stenosed carotid vasculature and its effectiveness compared with its surgical counterpart, carotid endarterectomy, is still a matter of debate in current clinical practice (Furlan, 2006). A major concern related to CAS is distal embolization potentially leading to severe neurological complications such as stroke. Embolization associated with CAS is primarily due to the plaque debris and thrombi generated during the dilatation of the stenosis and stent positioning. Consequently, embolic protection filters have been developed to capture this released debris and they appear to have a significant favorable impact on the CAS outcomes (Yen, 2005 and Goodney, 2006). Currently, several embolic filter designs are available. However, several drawbacks such as filtering failure, inability to cross tortuous high-grade stenoses, malpositioning and vessel injury still remain and require further design improvement (Kasirajan, 2003).

Conti et al. created a parametric model of an embolic protection filter, based on a high resolution microCT scan of a 4 mm diameter Angioguard filter (Cordis, J&J) using pyFormex (Conti, in press). The most important model parameters are the number of struts, the percentage of filter coverage and the filter length and diameter. Some design variants are depicted in Figure 7. Using pyFormex as a dedicated preprocessor for Abaqus, the filter was discretized with brick and membrane elements for respectively the nitinol struts and filter membrane. Subsequently, simulation of the filter deployment showed good agreement with a targeted, microCT visualized, experiment and this validated model was then used to investigate the wall apposition of the filter.

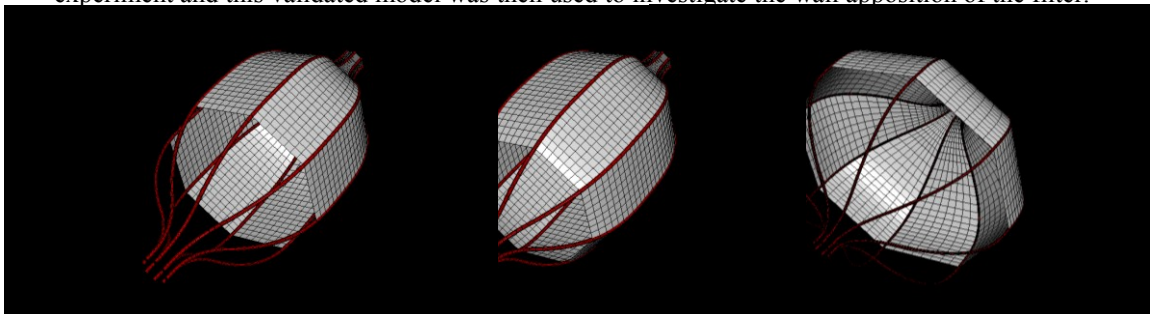


Figure 7. Design variants of the Angioguard model: original 4 mm device with 50% membrane coverage (left), 70% membrane covered 4 mm filter (middle), 8 mm device with 50% membrane coverage (right).

5. Patient specific modeling

To date patient-specific FEA and CFD analyses are limited by the complex pre-processing procedure needed for generating a high quality patient-specific mesh. The classical approach requires several commercial software packages for a number of serial (and often manual) procedures: CT / MRI images undergo reconstruction/segmentation, leading to STL surfaces, and finally a mesh is generated. A novel approach is proposed for 3D angiographic coronary data, which allows generating structured parametric patient-specific mesh using a single open-source

software and importing the mesh file into Abaqus. A patient-specific geometry of the vessel lumen obtained from 3D rotational coronary angiography was chosen as a starting point for the procedure (courtesy of Philips). The 3D reconstruction consists of a stack of circular representations of the vessel cross sections, with center and inclination of each circle known. A specific region of this geometry has been selected (see Figure 8) and analyzed with pyFormex.

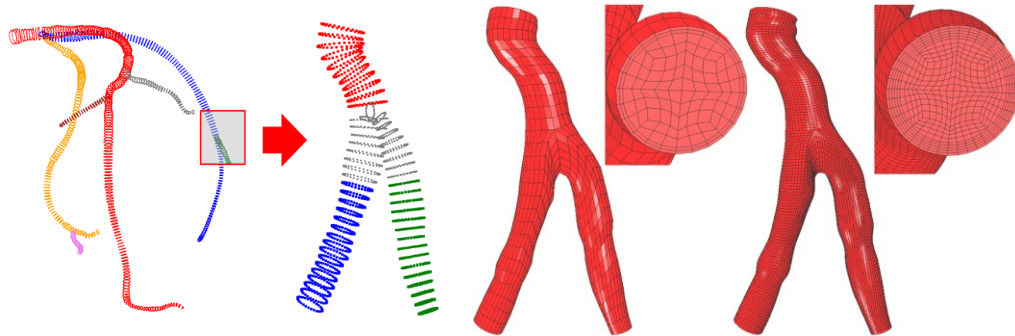


Figure 8. Geometrical data from coronary angiography (left), coarse and fine mesh models (right).

Because of the coarseness of the data points, a cubic interpolation was needed in order to complete the geometry. The bifurcation was partitioned in four regions: the three vessels and the region near the bifurcation center (Figure 8). Bezier curves and natural splines were used to approximate the boundary of the vessel lumen. Following Holzapfel et al., the wall was reconstructed from the lumen, with a local thickness equal to 60 % of the lumen radius (Holzapfel, 2005). Using iso-parametric transformations, the vessel wall was meshed with a structured hexahedral mesh as depicted in Figure 9. This mesh can be easily combined with state-of-the-art anisotropic constitutive models taking realistic experimental data into account.

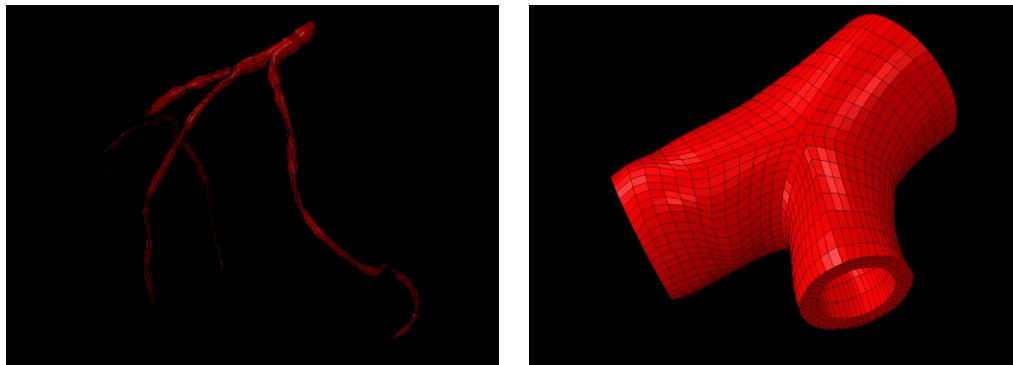


Figure 9. Reconstruction of the wall sections from the lumen and parametric hexahedral mesh generation.

The pyFormex tools provide a highly-controlled mesh generation thanks to the parametric design capabilities. The first advantage of this approach is that it generates hexahedral meshes whereas

most of commercial software packages provide tetrahedral meshes that are not optimal for FEA. The second advantage is the semi-automatic mesh generation overcoming disadvantages related to operator-dependence and time-consumption. The third advantage is the mesh definition in a structured and parametric way allowing fast mesh modifications by only altering some parameters using the same scripts. The fourth advantage is related to the wall and the lumen mesh which have common faces and so they can be easily integrated for FSI simulation using the new capabilities of Abaqus.

6. Conclusions

We have created a validated virtual design space to investigate the mechanics and optimize the performance of stents and other biomedical devices using the finite element method. This efficient design tool, combining pyFormex and Abaqus, is applicable to both balloon and self-expandable stents in a variety of materials (stainless steel, cobalt-chromium, nitinol, etc.) and configurations (laser-cut, braided).

Future developments in stent modeling will most likely include further integration of innovative (braided and tubular) stent designs and materials in realistic patient specific stenosis models. Such integrated models may even further raise their share in the stent design phase and eventually enter the clinical practice to optimize the coronary revascularization procedure for a specific patient (e.g. as a pre-surgical planning tool). However, it is necessary to underline that a substantial challenge is the spatial and population variability of mechanical properties of healthy and diseased arterial tissue. The only way to properly make progression and avoid the missing-link with reality and provoking an (understandable) skepticism with respect to numerical models and to the conclusions drawn from them, is to provide as much experimental evidence as possible.

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