

Virtual scaffolding and radial strength testing of stents

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Abstract: Virtual design tools are gaining more and more importance in the development and evaluation of medical devices. Inherently each medical device is subjected to (very) different (patient) specific loading conditions and thus requires dedicated simulation strategies. In addition, specific post-processing of the data obtained from the numerous simulations is needed to evaluate the device behavior. For example, stents can be virtually subjected to radial compression, bending, torsion and are characterized by a number of important design characteristics such as flexibility, radial strength, fatigue resistance, foreshortening, recoil, vessel scaffolding, etc. As a result, to virtually design a stent, each design iteration undergoes the same series of numerical simulations. In other words each (intermediate) stent design has to be pre- and post-processed in exactly the same way, urging the need for automation.

Over the past years the Abaqus solver has proven to be very efficient, accurate and robust to study the above mentioned stent design characteristics, both for balloon and self-expandable stents. This paper presents a novel simulation strategy and post-processing tool to accurately analyze balloon expandable stents in terms of radial strength and scaffolding. The underlying platform for this advanced and interactive pre- and post-processing tool is the open-source pyFormex design software.

Keywords: pyFormex, Design, Automation, Balloon-expandable, Self-Expandable, Stent, Medical Device, Scripting, GUI, pre-processing and post-processing.

1. Introduction

One of the main trends in current cardiovascular surgery is to minimize the impact of the procedure on the patient in order to speed up post-procedural recovery; as a result the application of minimally invasive techniques is growing rapidly. Minimally invasive interventions are characterized by small 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 minimally invasive surgery is the use of cardiovascular stents, which are tubular structures deployed in a narrowed artery section to enlarge its cross-section and consequently to restore the local blood flow. Even though more than 2 million stents are implanted world-wide annually, the market changes rapidly and there is still a clear need for procedural improvement and innovative stent designs. Moreover other minimally invasive devices such as dedicated angioplasty balloons, embolic protection filters, steerable catheters, etc. are rapidly entering into clinical practice. To date, these devices are generally developed using a trial and error approach: a first prototype is

manufactured and physical tests are performed to check whether the design criteria are met. If this is not the case, the design is modified and a new prototype is manufactured and tested. This approach is not only time-consuming, but also expensive and often not able to fully address the product's performance and (bio)mechanical requirements. Moreover, performing physical tests on these very small devices is generally a challenge. A promising strategy for fast medical device design is virtual product development. This approach enables the development and optimization of novel designs and reduces the costs and the time to market. In addition, these virtual tests are also very useful to examine and compare existing devices. Such virtual bench testing may provide additional information to the interventional cardiologists, helping them in their choice of a specific stent for a specific patient.

Our research focuses on the development of innovative tools (combining Abaqus with the open-source pyFormex design software) to facilitate virtual product development and bench testing of minimally invasive devices. This paper describes a novel simulation strategy and post-processing tool to accurately analyze balloon-expandable stents in terms of radial strength and scaffolding. A pyFormex-based, user-friendly graphical user interface (GUI) is being developed to automate its analysis.

2. pyFormex stent analyzer

Stents are generally classified according to their delivery mechanism as either balloon or self-expandable. Balloon expandable stents are normally made from elasto-plastic materials (such as stainless steel, cobalt-chromium, etc.) and driven by a balloon to expand, whereas self-expandable stents are usually manufactured from shape-memory alloys such as Nitinol and released from within a catheter. Two important stent design characteristics, common to all types, are radial strength and vessel scaffolding, which is directly related to the stent strut density. The developed simulation strategy to study these characteristics is described in this section.

2.1 Radial strength testing simulation strategy

The most important task of a stent is to reopen the artery and support (scaffold) the stenosed lesion in a target vessel. To that extent, the stent requires a sufficient radial strength. Experimental evidence has shown that, in addition to the material properties, this radial strength is also strongly design dependent (Rieu et al., 1999). Its assessment, especially in the case of balloon-expandable stents, requires a sophisticated and accurate test set-up and dedicated experimental protocol.

Complementary to such experimental methods, we developed a virtual testing procedure which allows to gain valuable insights into the impact of certain design and material variants on the stent scaffolding potential without having to actually manufacture these prototypes and/or materials. It allows to evaluate the following mechanical stent characteristics: elastic dilatation recoil, radial compliance after dilatation and collapse pressure. The developed virtual procedure is validated against experimental data of the PRO-Kinetic-Energy stent which were provided by the manufacturer (Cortronik, Germany).

The virtual radial strength test is developed in accordance with the experimental setup in which the PRO-Kinetic-Energy stent is implanted into a PU-tube. During the stent dilatation the tube experiences a small amount of circumferential stretching. After balloon deflation, the stent recoils and remains inside the tube and the loading pressure is homogeneously applied at the outer surface of this tube. Two rigid pins located at the distal and proximal end of the stent prevent its dislocation during pressure loading and guarantee a defined loading surface. The virtual computer model variant of this setup is depicted in Figure 1. The simulation strategy consists of three steps: (i) crimping of the stent; (ii) expansion of the stent in the PU-tube and (iii) pressure loading on the outer surface of the PU-tube in order to assess the radial strength of the stent. The rigid pins are taken into account by imposing boundary conditions at both tube ends.

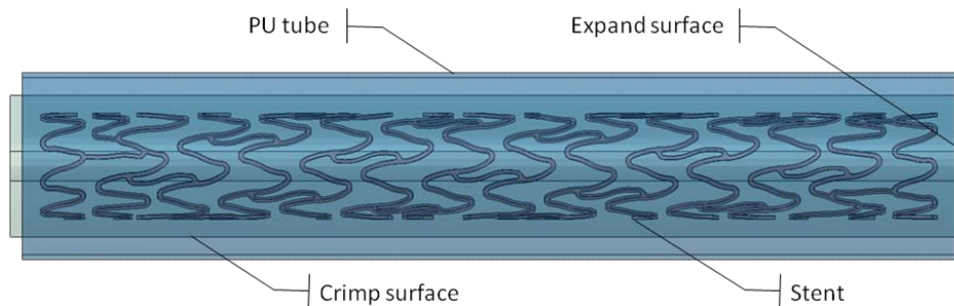


Figure 1. Virtual radial strength test developed by combining Abaqus with pyFormex

The virtual radial strength test is modeled as a quasi-static Abaqus/Explicit procedure accounting for geometric nonlinearity. The general contact scheme ‘All with self’ was used excluding the interaction between the crimp surface and the PU-tube. The isotropic tangential friction behavior was characterized by a friction coefficient of 0.2.

Stent crimping was modeled as a displacement driven process, decreasing the diameter of the crimp surface. The diameter decrease was followed by a gradual increase in diameter to allow the elastic recoil. Subsequently the diameter of the crimp surface was increased and kept constant throughout the rest of the analysis to avoid interference with the stent expansion. Analogous, the diameter of the expand surface is first increased and subsequently decreased to allow elastic recoil. This expansion methodology provides useful and (relatively) accurate information regarding the stent shape when reaching its nominal diameter (De Beule et al., 2008). In order to be able to evaluate the elastic radial recoil of the stent, the diameter of the PU-tube is gradually increased by radially displacing both ends and pressurizing the inner surface of the tube. After full stent expansion this radial displacement and inner pressure are gradually removed. This approach also guarantees a smooth and stable contact between the expanded stent and the PU-tube. Subsequently, a loading pressure is homogeneously applied at the outer surface of the tube. During the complete simulation cycle the longitudinal and circumferential displacement of the PU-tube extremes are prohibited.

The proposed modeling strategy to examine the radial strength provides results in satisfactory agreement with the provided experimental data as the difference between the experimentally determined collapse pressure and the numerically predicted value is less than 2%. The collapsed PRO-Kinetic-Energy stent (computer simulation) is illustrated in Figure 2.

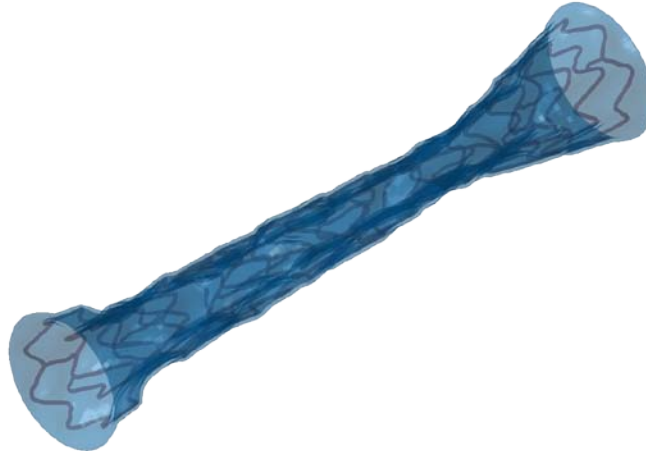


Figure 2. Virtually collapsed PRO-Kinetic-Energy stent

2.2 Strut density analysis

The stent strut density affects a number of parameters, such as drug delivery, tissue scaffolding and balloon-artery contact. Stent designs with a high strut density will lead to a more uniform drug delivery and will minimize the tissue prolapse between the struts. A higher strut density also reduces the contact area between the balloon and the endothelial cells. This is important since Squire (Squire, 2000) has shown that direct balloon-artery contact leads to endothelial denudation.

A novel methodology is proposed to quantify the strut density, as this is an important stent design parameter (Mortier, 2010(b)). As an example, this strut density is analyzed during the expansion of the 3 mm Cypher (Cordis, Johnson & Johnson) and Taxus Liberté stent (Boston Scientific). As described above, a displacement driven simulation strategy was adopted to virtually expand the stent up to 3.5 mm.

The strut density was quantitatively analyzed with pyFormex by calculating automatically the maximum inscribed circle for a deformed, unrolled cell of the virtually expanded stent. The maximum inscribed circle was determined for every output frame and thus the strut density could be monitored as a function of the stent diameter. The main steps to calculate the maximum inscribed circle are listed below:

- A deformed stent cell was selected and unrolled in order to obtain a planar curve.

- A regular grid was generated within the bounding box of the unrolled cell.
- The set of grid points was split into two subsets, the points within the cell and the points outside the cell
- For every point lying within the cell, the minimal distance from that point to the stent cell was calculated. This gives a list with minimal distance values.
- From the list with minimal distance values, the maximum value gives the radius of the maximum inscribed circle.

The grid density was increased until the radius of the maximum inscribed circle converged. The applied procedure to determine the maximum inscribed circle is illustrated in Figure 3. Note that the grid used to generate this figure is clearly not fine enough, since the circle only touches the cell at one location.

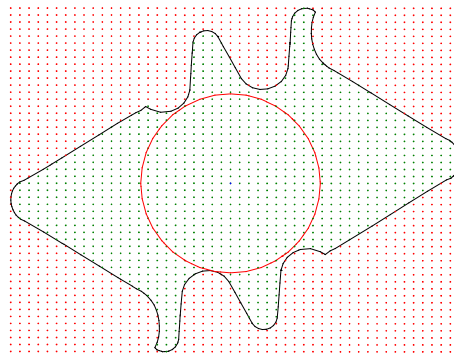


Figure 3. Illustration of an intermediate step during the procedure to determine the maximum inscribed circle for the Cypher stent.

Since stents may be underexpanded or overdilated in clinical practice, it is important to know how the cells deform and how the maximum inscribed circles change when the stent diameter varies. Figure 4 shows the deformed cell of the Taxus Liberté stent at a diameter of 2.5, 3.0 and 3.5 mm. The diameter of the maximum inscribed circle increases significantly as the individual struts tend to move away from each other. A large maximum inscribed circle has also another important clinical consequence when treating bifurcation lesions. Such lesions are often treated by implanting a stent in the main branch, followed by a guide wire and balloon catheter insertion into the side branch. A large maximum inscribed circle logically facilitates this insertion.

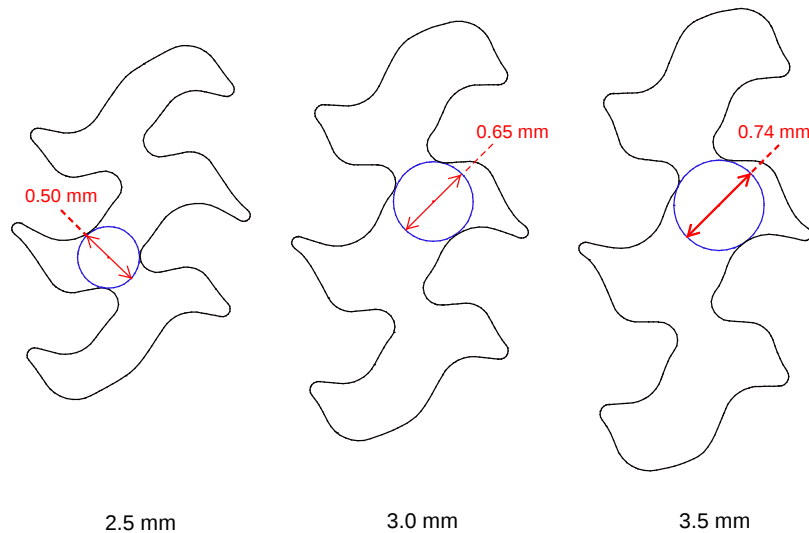


Figure 4. Comparison of the deformed cell of the Taxus Liberté stent at different stent diameters. The corresponding stent diameter is indicated below every cell.

2.3 pyFormex GUI

pyFormex is a tool for generating, manipulating and transforming large geometrical models of 3D structures by sequences of mathematical transformations. Thanks to a powerful (Python based) scripting language, pyFormex is very well suited for the automated design of 3D structures. It also provides a wide range of operations on surface meshes, like STL type triangulated surfaces (e.g. originating from microCT or medical scan images). In this study, pyFormex is used as a pre- and post-processor for Abaqus and the above described simulation strategies and analyses are currently being implemented in a dedicated pyFormex GUI consisting of the following modules: Geometry, Material, Simulation and Post-processing. This GUI allows to create complete Abaqus input files and to read and interpret the result files. This process can be fully coupled, making it an ideal tool for optimization studies, although such a coupling is beyond the scope of this paper (De Beule et al., 2009).

In the following sections, the modules of this custom-built GUI are described:

Geometry

To execute the above mentioned simulation strategies, the following parametrically adaptable geometrical parts are required and created with pyFormex: a cylinder to crimp the stent, a cylinder to expand the stent and a tube to test the radial strength. The GUI allows to specify their respective dimensions and their target element sizes.

With respect to the stent mesh, pyFormex offers several options to include the stent model(s) in the analysis:

- create parametrically-adaptable stent models, discretized with high quality hexahedral meshes, either from scratch or based on STL type triangulated surfaces for example obtained from microCT scanning or CAD
- import stent meshes generated with other packages

All sets necessary for the subsequent analyses and post-processing are created automatically by pyFormex.

Material

This module allows to define the material properties, either by manually inserting the material data or by selecting the material from a database.

Simulation

The simulation module allows the user to select the type of analysis:

- Stent crimping
- Stent expansion
- Radial strength testing

and to fill in the required data fields for the simulation settings of the selected analysis type as depicted in Figure 5.

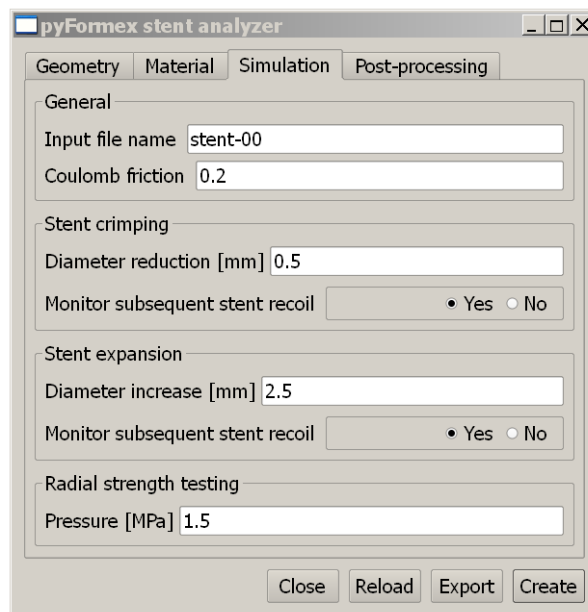


Figure 5. Screenshot of the Simulation module of the pyFormex stent analyzer GUI.
The depicted diameter and pressure values are illustrative only.

Post-processing

pyFormex allows to directly post-process, summarize and export the results in graphical and/or tabular format. The radial strength test is post-processed by plotting an averaged tube diameter in function of the exerted pressure on the tube, whereas the strut density can be analyzed by plotting the maximum inscribed circle diameter in function of the stent diameter.

Given the fact that the source behind this GUI design environment is completely script based, it is straightforward to use this tool for parametric studies, making it very useful for bench testing of existing stents and designing new ones.

3. Discussion

pyFormex is a completely open and free (GNU GPL licensed) framework based on high quality cross platform technologies (Python, Numerical Python, OpenGL, Qt4). Its simple data models and high level scripting language allow easy and quick development (even by those not trained as a programmer) of both dedicated algorithms and user interfaces for specialized tasks in creating and transforming 3D geometry. Because scripting is the native mode of pyFormex, complex, recurrent and related tasks can be automated in a wimp, with a minimum of user interaction required.

Through the possible integration of nearly any other related software, it can be expanded endlessly with new features. Its interfacing functions with Abaqus (allowing e.g. the export of finite element models in Abaqus input file format) make it into a natural and consistent environment for advanced pre-and post-processing purposes.

While pyFormex is still under development (see website), it has already attained a high level of usefulness. Apart from using it as a pre- and postprocessor in the above mentioned stent simulation environment, here are some other projects that have found pyFormex valuable in speeding up the creation of their 3D models:

- The automatic generation of folded balloon models which have proven to be necessary to accurately study the symmetry of the stent deployment, the stent foreshortening and the interaction of stents with (patient specific) vessel models (De Beule et al., 2008(b), Mortier et al., 2008(b), Mortier et al., 2009).
- The investigation of self-expandable stents and embolic protection filters and their interaction with (patient specific) blood vessel models (Conti et al., 2009).
- The generation of high-quality structured hexahedral patient-specific blood vessel models, paving the way for large population virtual bench testing of medical devices and procedures (De Santis et al., 2010).

The techniques used in these projects could easily be integrated in the stent simulation platform.

4. Conclusions

We have developed a novel simulation strategy and post-processing tool to accurately analyze balloon expandable stents in terms of radial strength and scaffolding. Furthermore, we have created a custom built, user-friendly graphical user interface (GUI) to automate the dedicated pre- and post-processing for this evaluation. This dedicated pre- and post processor is based on the open-source pyFormex design platform, with export capabilities to Abaqus. The Abaqus solver has proven to be very efficient, accurate and robust to study the above mentioned stent design characteristics.

Since the pyFormex design environment is completely script based, it is straightforward to use this tool for parametric studies, making it very useful for bench testing of existing stents and designing new ones. Possible extensions to the developed framework are the generation of folded balloon models, the integration of simulation strategies for self-expandable devices and virtual patient specific analyses of medical devices and procedures.

Future developments in stent modeling will most likely include further integration of innovative stent designs and materials in realistic patient specific stenosis models. Such integrated models may even further raise its share in the stent design phase and eventually enter the clinical practice to optimize the revascularization procedure for a specific patient (e.g. as a pre-surgical planning tool). However, it is necessary to underline that this involves two substantial challenges. At first, there is a need for standardization and automation to go from patient specific imaging to high quality (hexahedral) meshes. Second, there is an inevitable spatial and population variability of mechanical properties of diseased arterial tissue. The only way to properly make progression and avoid the missing-link with reality is to provide as much experimental evidence as possible.

5. Acknowledgements

The authors greatly acknowledge Prof. F. Auricchio (Università degli Studi di Pavia) for the collaboration in the field of nitinol devices and Dr. N. Götzén (Cortronik) and Dr. F. Bakczewitz (Cortronik) for the experimental data to validate the radial strength simulation strategy.

6. Conflict of interest

There is a conflict of interest regarding the radial strength testing part in this paper, as this part is based on investigations carried out as a consultancy project for Cortronik GmbH.

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