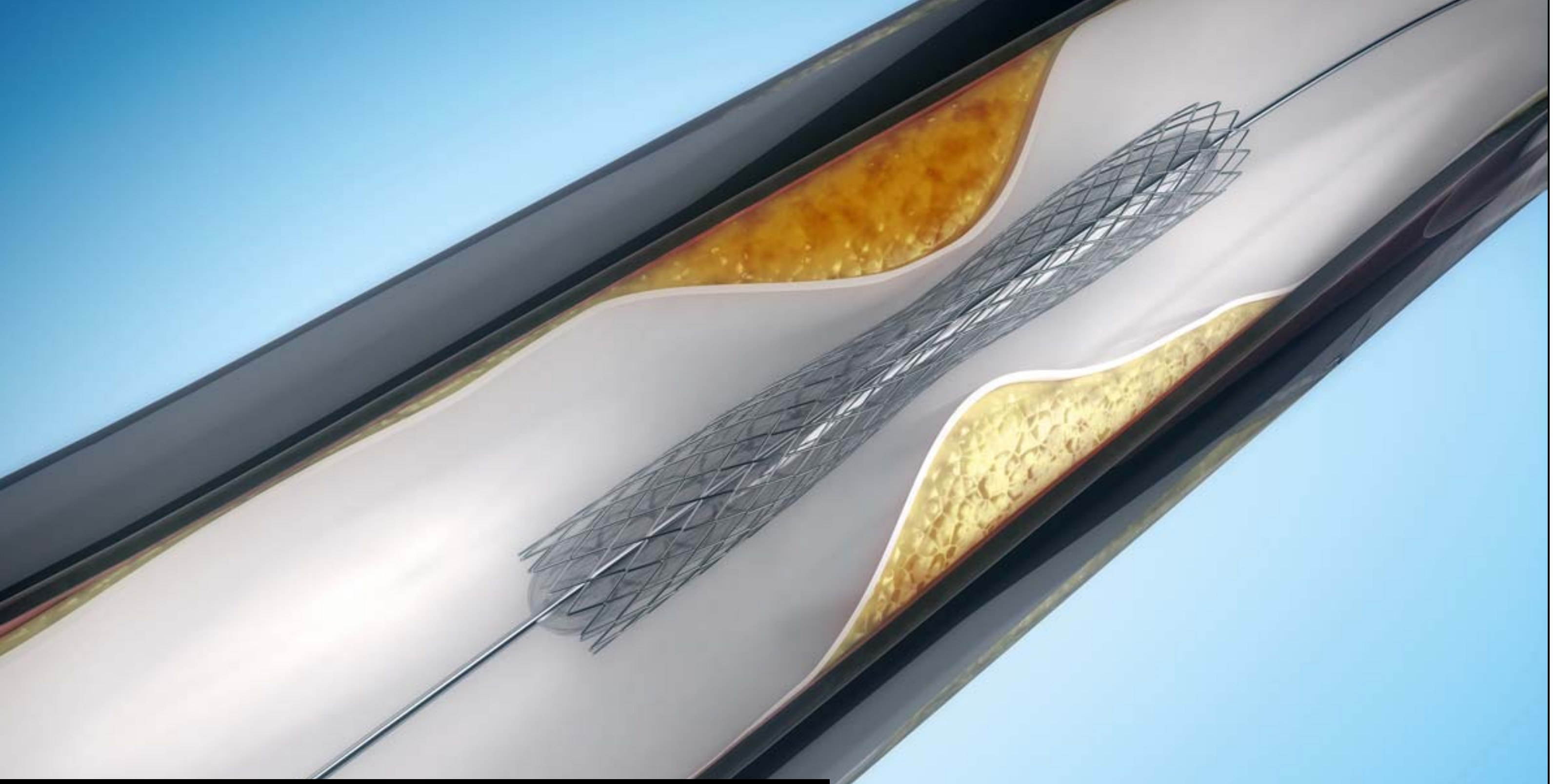

CUSTOMER STORY // BIOMECHANICS & MEDICAL SCIENCE

SIMPLIFIED METHOD TO PREDICT STRUCTURAL PROPERTIES OF CARDIOVASCULAR STENTS

ANSYS Workbench connected with optiSLang enables an analytical approach based on Design of Experiments (DOE) and statistical modelling in order to predict the radial force and strain amplitude of a circular stent structure.

Introduction

Vascular stents are used to treat occluded or calcified vessels or carry heart valve tissue in case of Transcatheter Aortic Valve Replacements (TAVI). The TAVI procedure was successfully introduced during the last decade and provides a safe option for elderly patients who are not suitable for conventional open heart surgery.

For all applications it is necessary in the design phase to predict the radial force and fatigue behavior of such devices. The radial force is a crucial parameter in preventing migration or even a collapse of the device under physiologic loading (pressure difference) or during the delivery (bending, crush). Similarly, the strain amplitude within a stent serves as an essential parameter for estimating the fatigue resistance of Nitinol stents.

In the medical device industry it is common practice to perform multiple design loops (CAD and FEA) to achieve a final design with preferable attributes. This process is time consuming and requires repeated interaction of the developer with multiple software tools. For all iterations a fully processed FEA model has to be calculated and evaluated which consumes time and physical resources. Therefore the present study aims to simplify this process by employing a Design of Experiments and statistical modelling.

Method

A fully parametrized CAD (Solid Edge) model of a single Nitinol strut which can be used in all closed cell stent designs was developed (Fig. 1). This model was imported into Ansys Workbench and connected with the optiSLang interface (Fig. 2). The main design parameters (strut length, radius and strut width) were included in a Design of Experiments (75 designs, Latin Hypercube Method) using the software optiSLang 4.1.2. As output parameters, the radial force and the strain amplitude within the clinically used design range were evaluated. Subsequently, the radial force for a complete circular stent structure was reconstructed based on a single cell. For all design iterations, the cell was shaped (heat treatment), crimped and deployed into a vessel followed by a radial force measurement and a cyclic cardiac pulse (pressure related decrease and increase in diameter). As a result, the radial force for the loading and unloading plateau (characteristic of Nitinol) was evaluated at the two extreme clinical diameters. Based on the 75 design points, a linear regression model was developed for all result parameters (radial force, strain amplitude) including all input variables (Software Minitab 17.0). The derived equations were then used to develop a simplified analytical prediction of the radial force and strain amplitude for a complete circular stent segment.

Fig. 1: Single diamond cell and the reconstruction of a 360° full stent model with 12 single cells

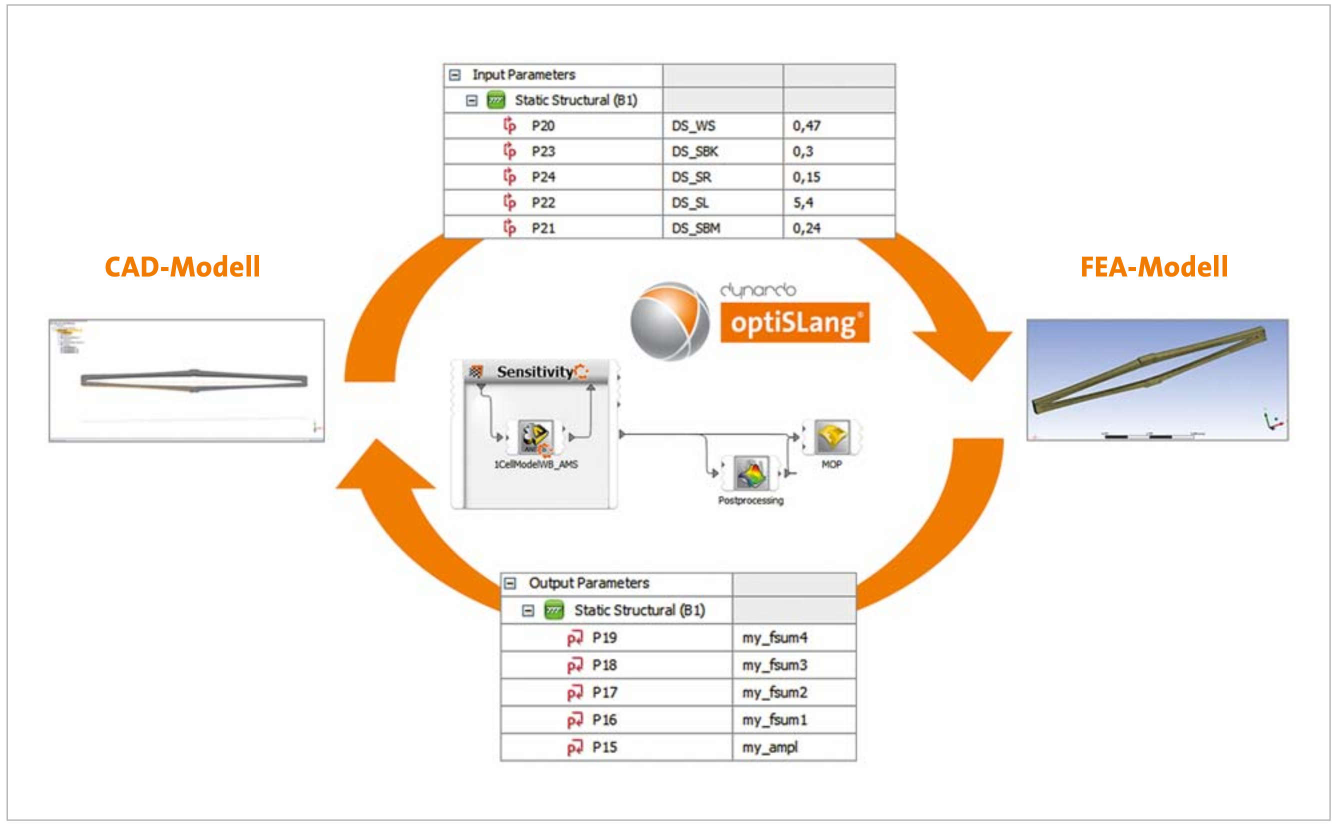

Fig. 2: Workflow including the different software tools

Results and discussion

A good agreement between experimentally measured and numerically simulated radial force was achieved for the exemplified stent design (Fig. 3, see next page). By summarizing the radial force of single cells and using an analytical equation, the radial force of a complete stent segment could be determined and validated by experimental data.

The evaluation points of the Nitinol curve are shown on the right. The table at the bottom shows the comparison of experimental vs numerical (FEA) and experimental vs statistical (analytical) model.

This allows estimating the radial force and strain amplitude of a complete circular stent segment by using a simple regression equation (equation 1 and 2; my_fsum3=radial force; ampl=strain amplitude DS_SL=strut length; DS_SBK=strut width at the radius; SBM=strut width in the middle). In the preliminary design phase during the product development, this procedure holds the potential to save computational time and accelerate the design process.

(1)

```
my_fsum3 = -7,00 + 3,513 DS_SL - 91,05 DS_SBK - 12,90 DS_SBM
```

(2)

```
ampl = 0,004881 - 0,000831 DS_SL + 0,005529 DS_SBK + 0,004696 DS_SBM
```

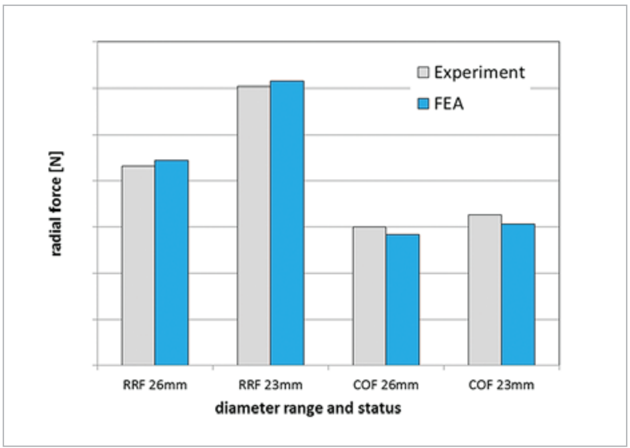

Fig. 3a: Comparison of experimental vs numerical radial force results for an exemplified stent design in a 23mm and 26mm vessel model

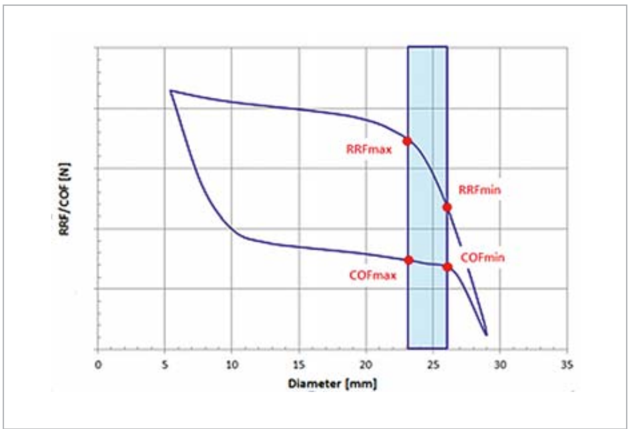

Fig. 3b: Evaluation points of the Nitinol curve

	Experiment vs. FEA Delta [%]	Experiment vs. Statistics Delta [%]
RRF 26 mm	- 2.88	10.80
RRF 23 mm	- 1.92	5.84
COF 26 mm	5.73	- 11.66
COF 23 mm	6.36	- 9.90
Mean (absolute)	4.22	9.55

Fig. 3c: Comparison of experimental vs numerical (FEA) and experimental vs statistical (analytical) model

To improve the prediction of the linear regression model, the Metamodel of Optimal Prognosis (MOP) could be used which also allows the prediction of nonlinear response surfaces. The strut length has the largest influence on the radial force and strain amplitude and thus is one of the design driving variables (Fig. 4). The strut width near the radius is influencing the radial force while the strut width in middle has no clear effect on radial force but might be used to tune the crush resistance (torsional stiffness) of the stent.

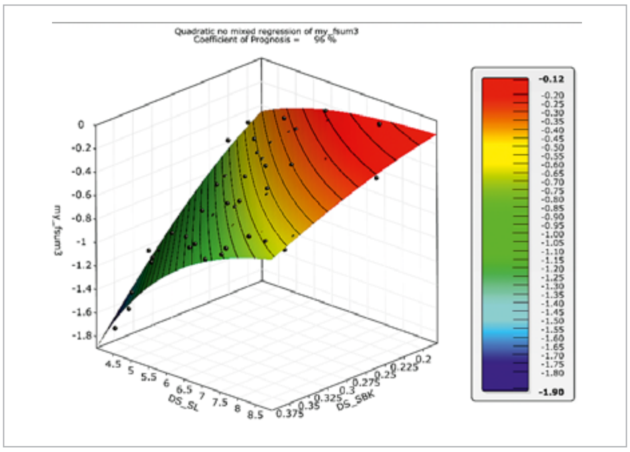

Fig. 4a: Radial force as function of strut length (SL) and strut thickness (SBK)

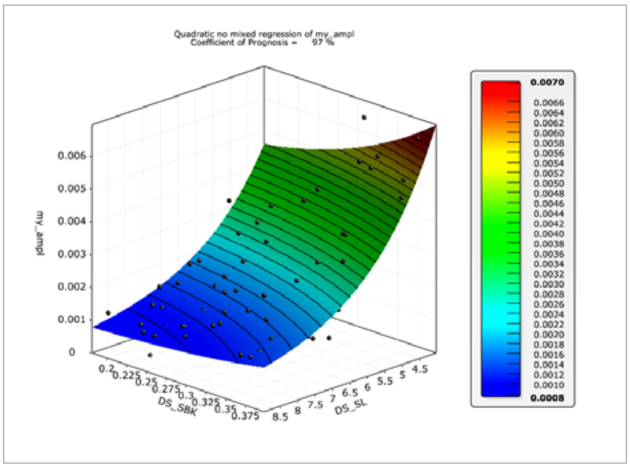

Fig. 4b: Strain amplitude as function of strut length (SL) and strut thickness (SBK)

The Design of Experiments and statistical modeling have the potential to support the initial design phase of cardiovascular devices in order to reduce time and costs for extensive FEA studies which are performed instead.

Authors//
Stephan Rothstock, Andre Hein, Karsten Koop
(Cortronik GmbH/Vascular Intervention)

Source//
www.dynardo.de/en/library