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Simplified method to predict structural properties of cardio-vascular stents based on Design of Experiments (DOE)

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Table of contents

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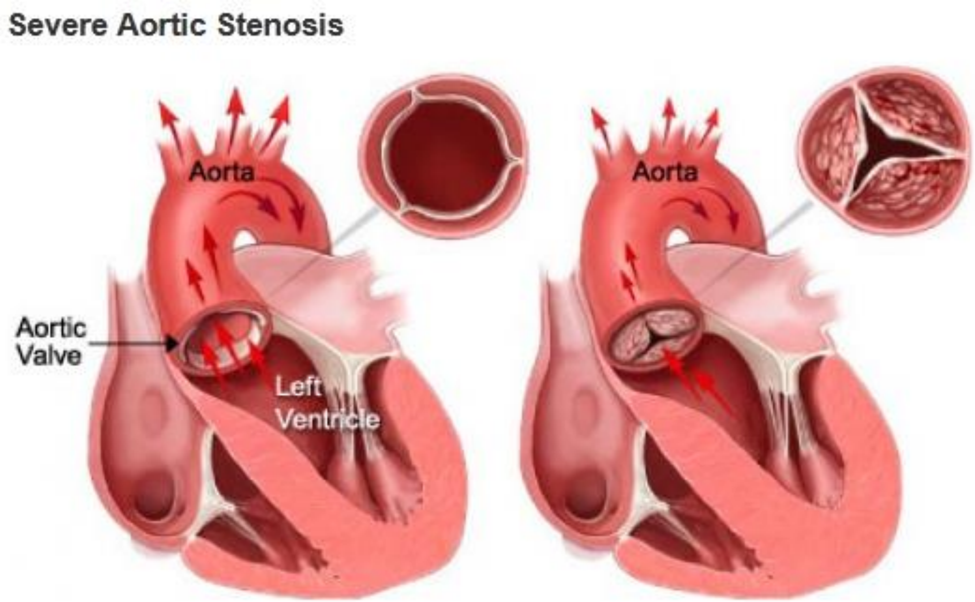
Introduction anatomy and diseases

- Aortic valve with aortic stenosis (calcified leaflets)
- Insufficient valve opening during systole (decreased blood flow)
- Increased muscle activity in the left ventricle



Source: Health Care Utah

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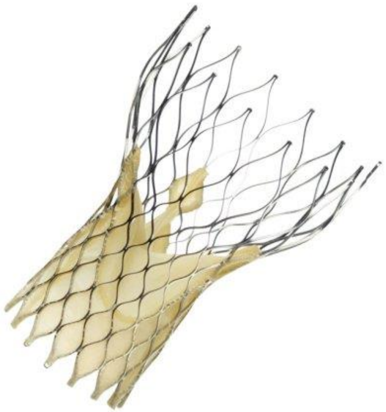
Introduction TAVI (Transcatheter Aortic Valve Implantation)

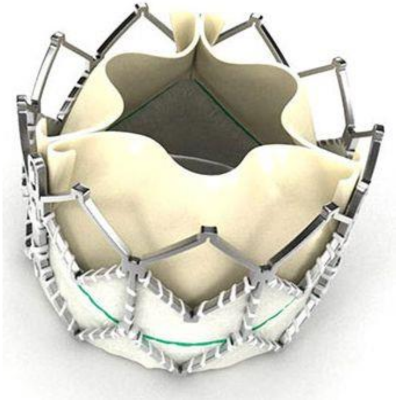
- Patients suffering from aortic stenosis
- Not suitable for conventional open heart surgery
- Minimal invasive approach (commonly transfemoral)
- First-in-man in 2002 (Alain Cribier)

Todays market leaders:

- Self expanding (Medtronic) or balloon expandable (Edwards)



NiTi Frame

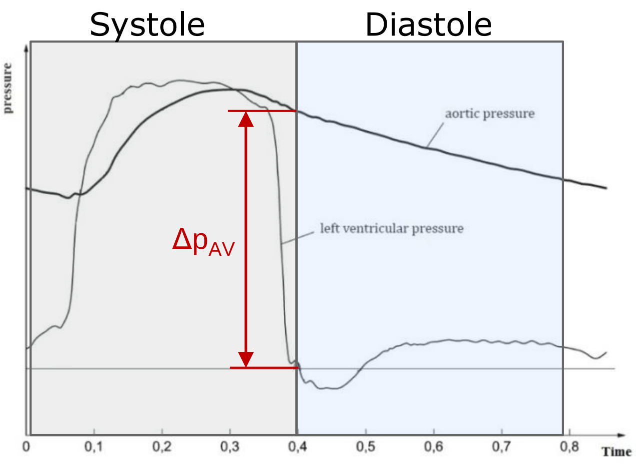


CoCr Frame

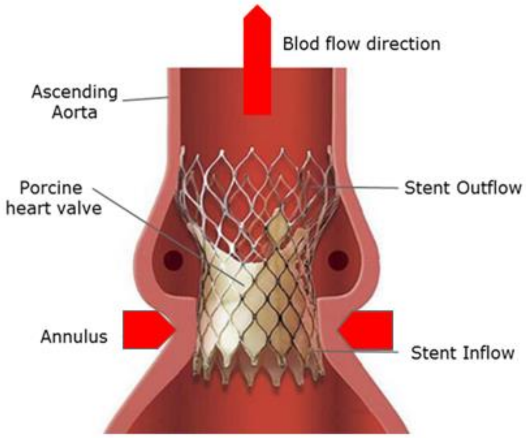
G. Webb, 2012

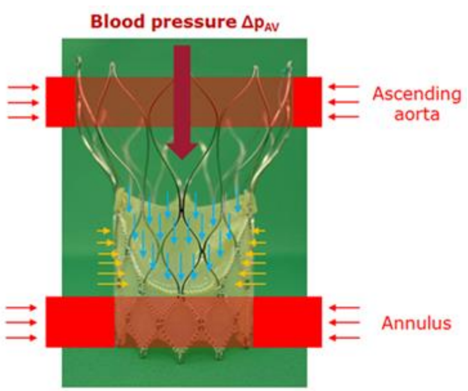
Introduction Biomechanics

- TAVI stents in vivo loads:
  → radial loads
  (pulsatile vessel movement)
  → multi-axial loads
  (resulting from closed valve)



ISO Norm 5840-3





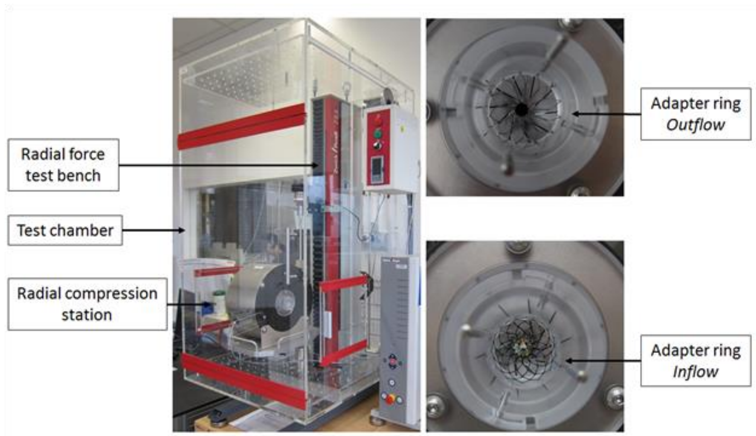
Introduction Radial force

- TAVI stents (Nitinol) require radial force to

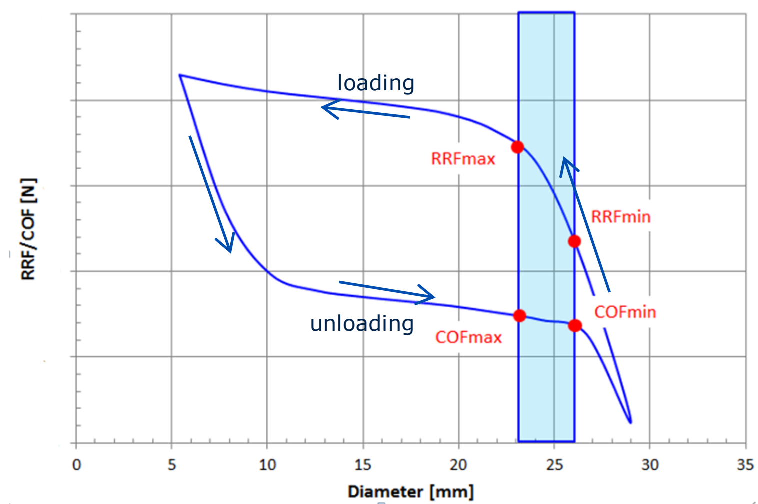
  → allow immediate release from catheter

  → provide anchorage to annulus and prevent migration

  → avoid paravalvular leakage



Experimental radial force setup



Typical radial force curve for a Nitinol stent showing the loading and unloading plateau

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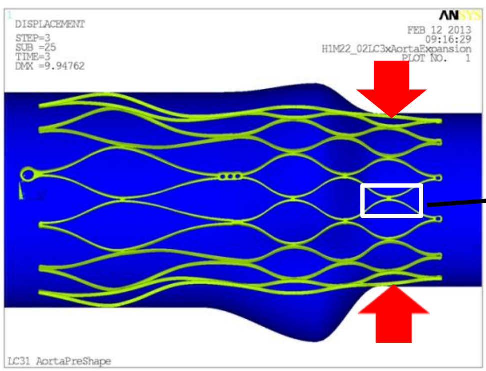
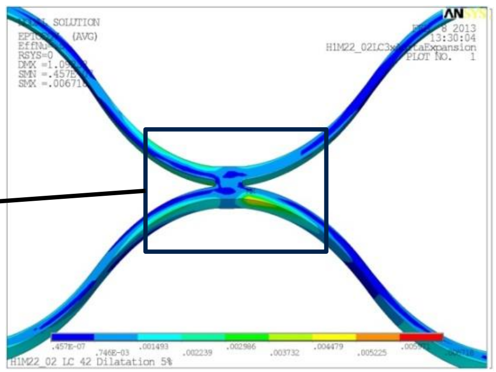
Introduction Fatigue Resistance

- TAVI stents require

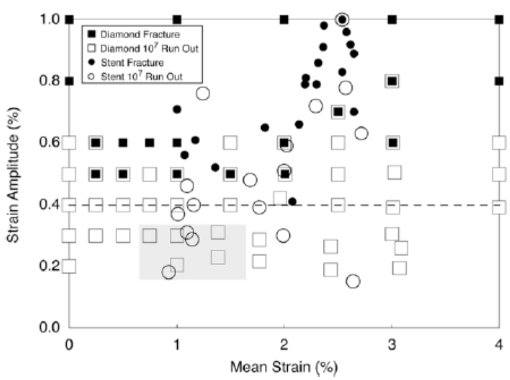
→ fatigue resistance (at least 400 mill. cycles)



Stent in human aorta



Strain amplitude distribution



Fatigue and Durability of Nitinol Stents

A.R. Pelton, V. Schroeder, M.R. Mitchell, Xiao-Yan Gong, M. Barney, and S.W. Robertson,

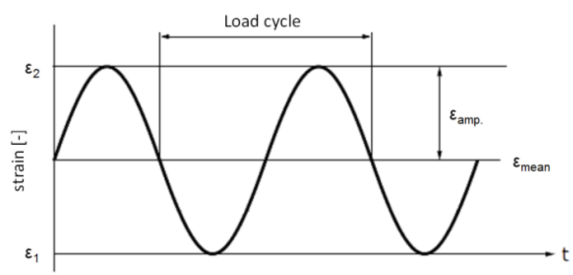
J Mech Behavior Biomed Mater, 1, 153–164 (2008).

Strain Amplitude

$$\varepsilon_{1-2\,ij} = \left[\frac{\varepsilon_{1\,ij} - \varepsilon_{2\,ij}}{2}\right]$$

Mean Strain

$$\varepsilon_{1+2\,ij} = \left[\frac{\varepsilon_{1\,ij} + \varepsilon_{2\,ij}}{2}\right]$$



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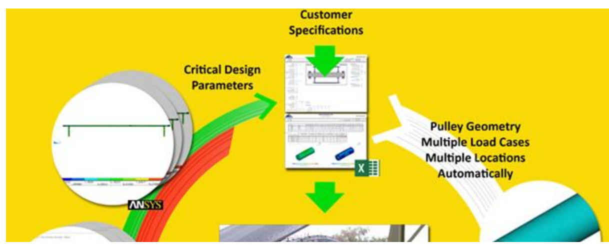
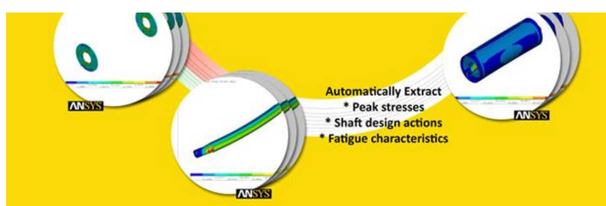
Introduction Classic Design Process

- (1) Idea → CAD design concept
- (2) Parametric CAD model
- (3) Finite Element model with boundary conditions
- (4) Results for product life cycle loads
- (5) Evaluation and next Design Loop



Time and cost intensive



http://www.leapaust.com.au

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Hypothesis

Design of Experiments and statistical modelling are suitable tools to estimate structural properties of stents

and accelerate the initial design phase

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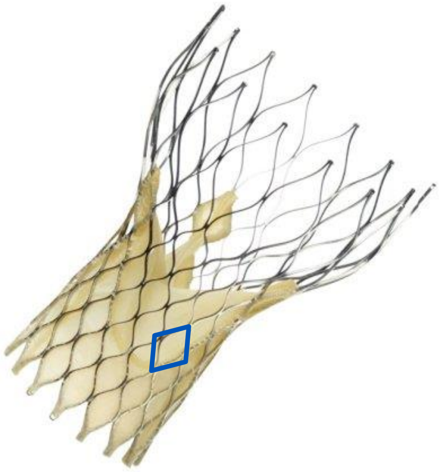
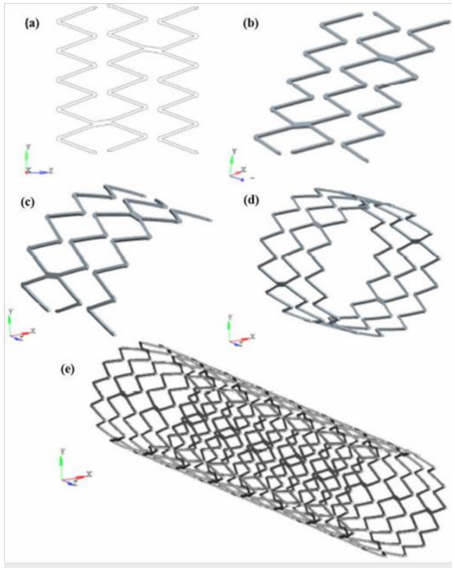
Method

- Most stents show a closed cell design (diamond cells)
- Whole structure can be reduced to a single diamond cell
- Diamond cell consists of at least 2 identical struts
- Main loading modes (radial loads) can be simulated with one cell



CoreValve stent

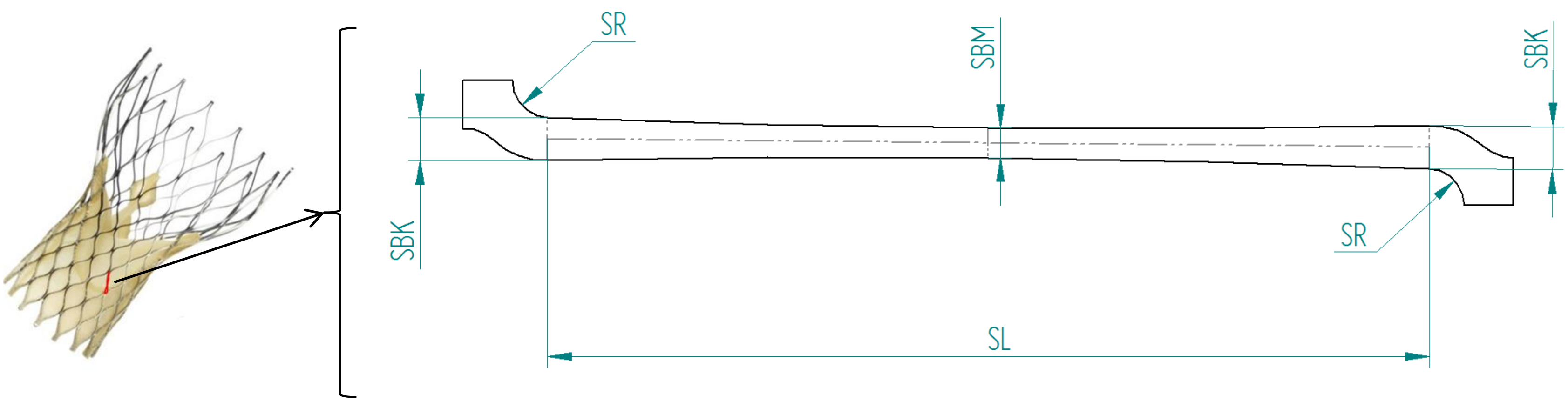


Diamond shaped stent structures (Dordoni et al. 2015)

Method CAD

- Parametric CAD model of single strut with design variables (Solid Edge ST6)

SBK=Strut width at knot; **SBM**=Strut width in the middle; **WS**=Wall thickness; **SR**= Strut radius at the knot; **SL**=Strut length



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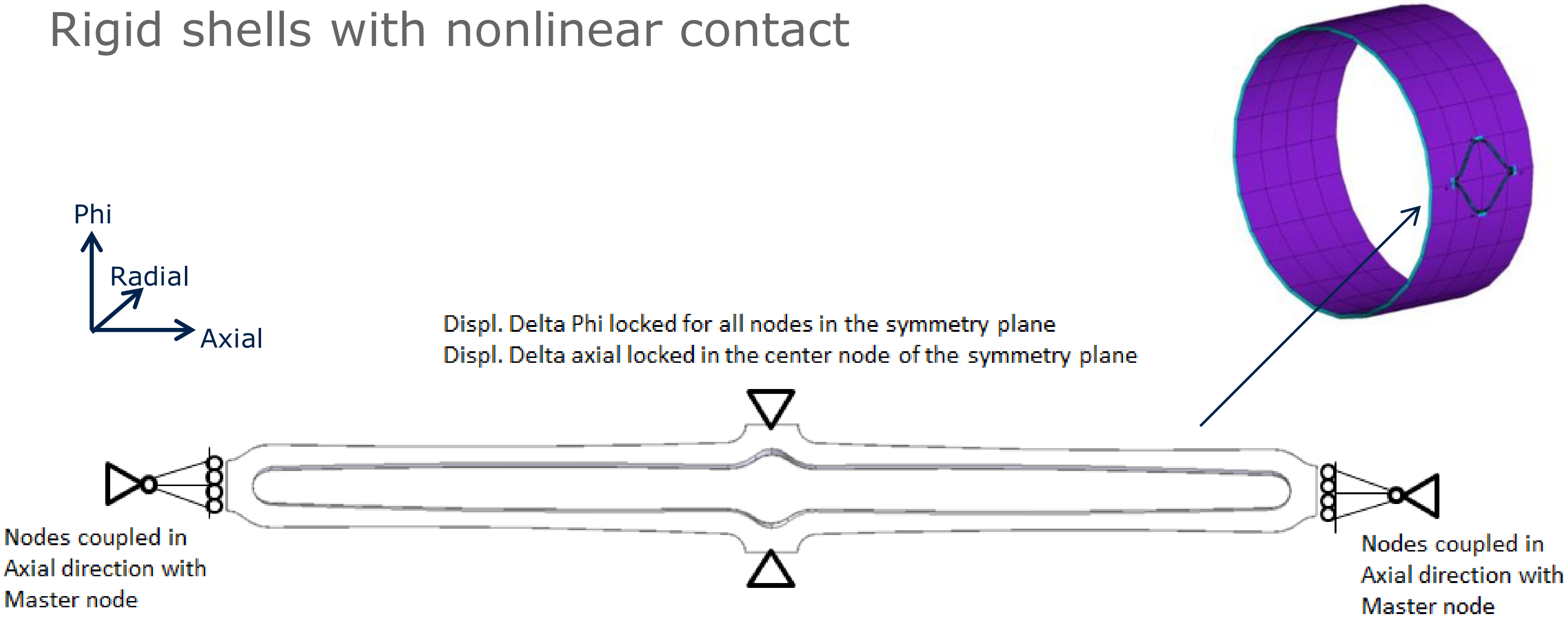
Method FEA Ansys Workbench 14.5

- Parametric FEA model created with Workbench 14.5
- 3D model with solid 185 elements, Nitinol material
- Rigid shells with nonlinear contact

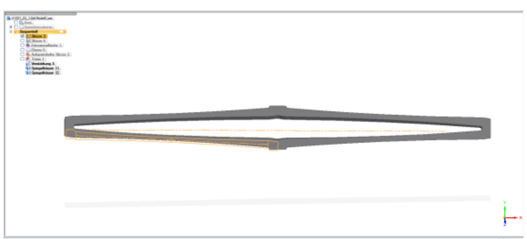


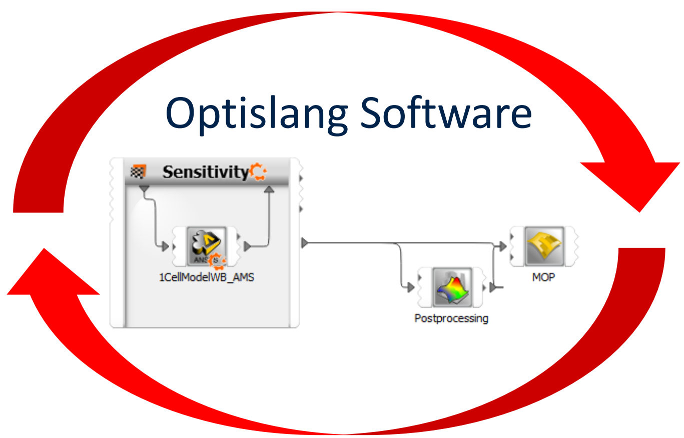
Method Workflow Optislang 4.1.2

- Design of Experiments DOE (Advanced Latin HyperCube) with 75 Design points
- Subsequent MOP (Meta-Model of Optimal Prognosis)

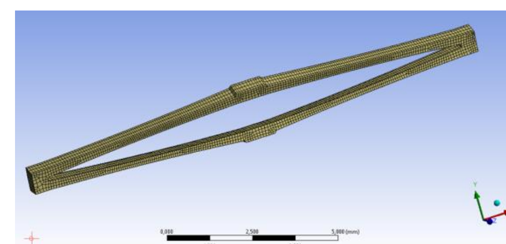
Input Parameters		
Static Structural (B1)		
P20	DS_WS	0,47
P23	DS_SBK	0,3
P24	DS_SR	0,15
P22	DS_SL	5,4
P21	DS_SBM	0,24

CAD Model





FEA Model



Output Parameters	
Static Structural (B1)	
P19	my_fsum4
P18	my_fsum3
P17	my_fsum2
P16	my_fsum1
P15	my_ampl

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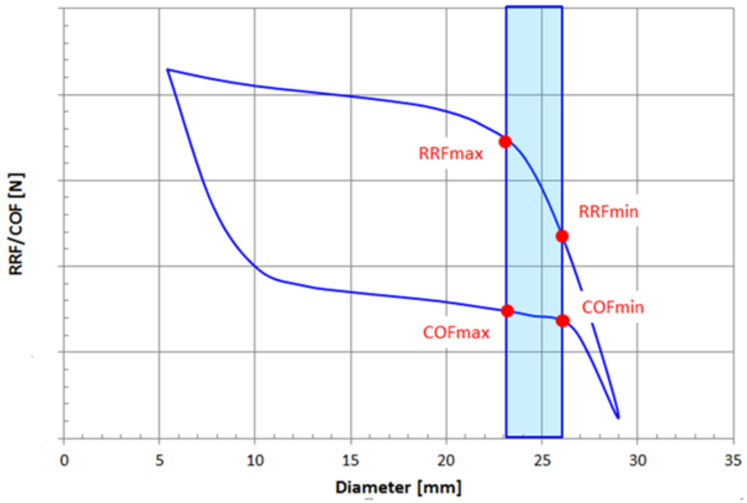
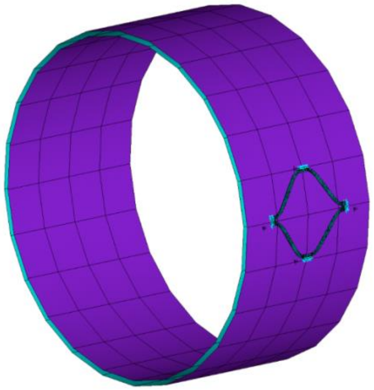
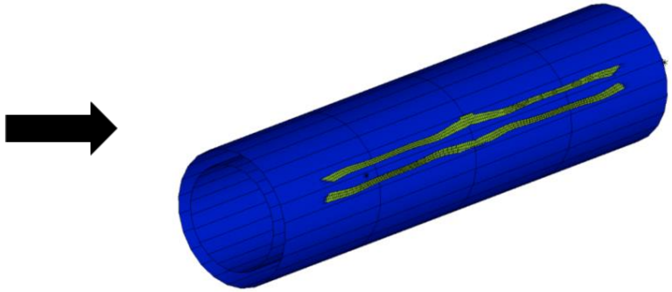
Method Load Cases

- Single cell initially expanded and shape setted (heat treatment)
- loaded and unloaded from 29mm to 5.4mm diameter
- Cyclic loading of a circular annulus (diameter change of 4.5%) simulating one cardiac cycle
- Evaluation of radial force and strain amplitude





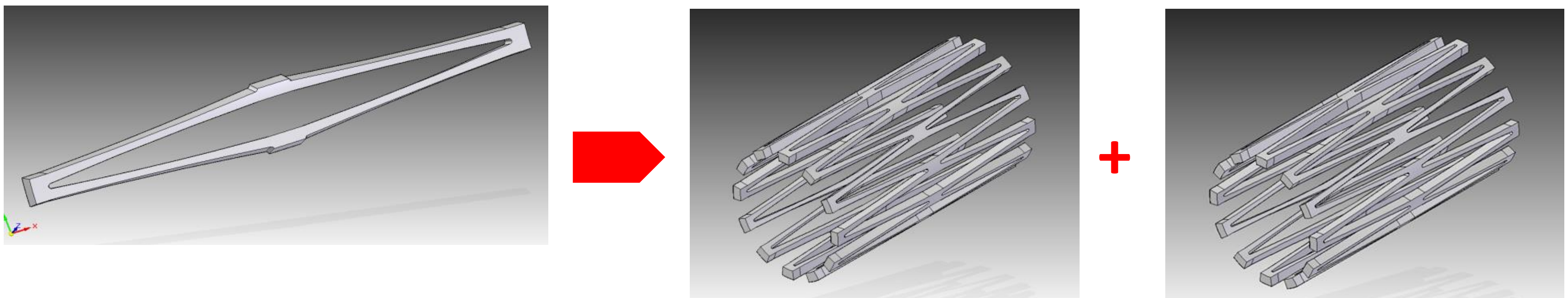
Crimp shells and expanded stent model

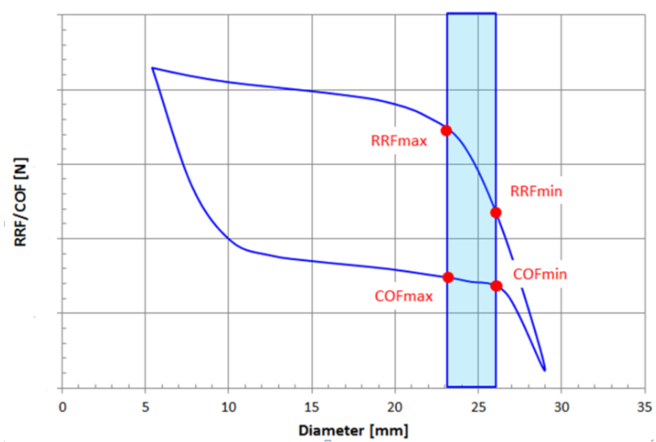


crimped stent model

Method Evaluation Radial Force

- A stent could be regarded as a row of springs allowing to sum up the radial forces of each diamond cell and for all segments





Parameter description:

- Chronic Outward Force (COF) 26mm = fsum1
- Chronic Outward Force (COF) 23mm = fsum2
- Radial Resistive Force (RRF) 23mm = fsum3
- Radial Resistive Force (RRF) 26mm = fsum4
- Max. Strain amplitude = ampl

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Method Statistical Model

$$my\_fsum1 = -18{,}78 + 5{,}423\ DS\_SL + 19{,}2\ DS\_SR - 86{,}99\ DS\_SBK - 21{,}13\ DS\_SBM$$

$$my\_fsum2 = -12{,}65 + 4{,}608\ DS\_SL + 22{,}1\ DS\_SR - 104{,}85\ DS\_SBK - 18{,}71\ DS\_SBM$$

$$my\_fsum3 = -4{,}47 + 1{,}760\ DS\_SL + 8{,}95\ DS\_SR - 45{,}48\ DS\_SBK - 6{,}48\ DS\_SBM$$

$$my\_fsum4 = -4{,}75 + 1{,}773\ DS\_SL + 6{,}79\ DS\_SR - 43{,}24\ DS\_SBK - 5{,}81\ DS\_SBM$$

$$my\_ampl = 0{,}004999 - 0{,}000831\ DS\_SL - 0{,}00109\ DS\_SR + 0{,}005522\ DS\_SBK + 0{,}004700\ DS\_SBM$$

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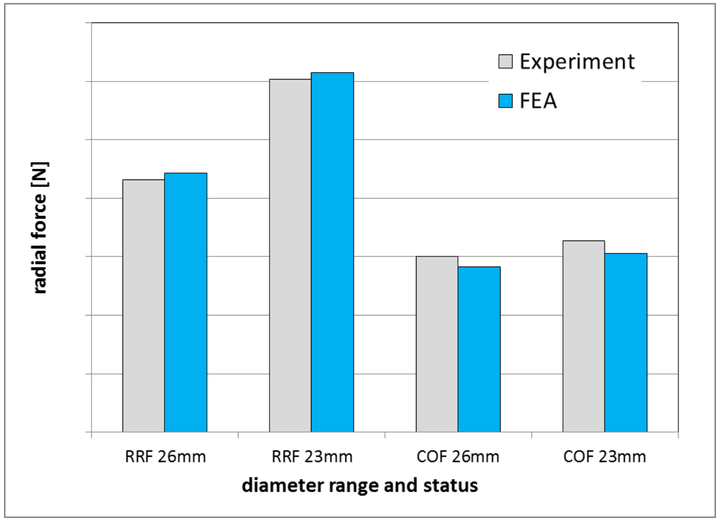
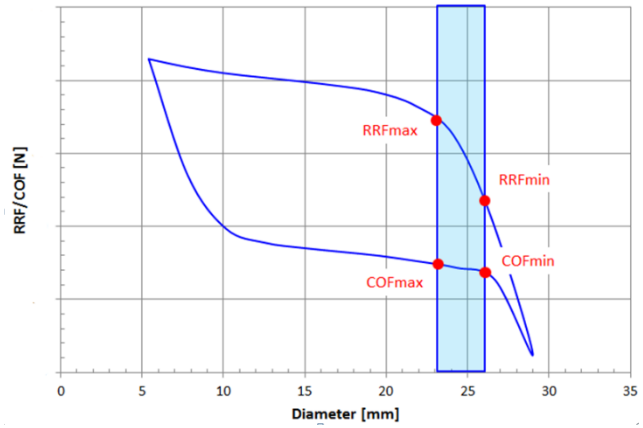
Results Validation

- Comparison of experimental and numerical model





	Exp. vs FEA	Exp. vs Stat
	Delta	Delta
	[%]	[%]
RRF 26mm	-2.88	10.80
RRF 23mm	-1.92	5.84
COF 26mm	5.73	-11.66
COF 23mm	6.36	-9.90
mean (abs)	4.22	9.55

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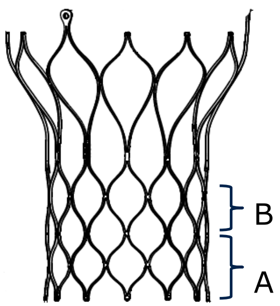
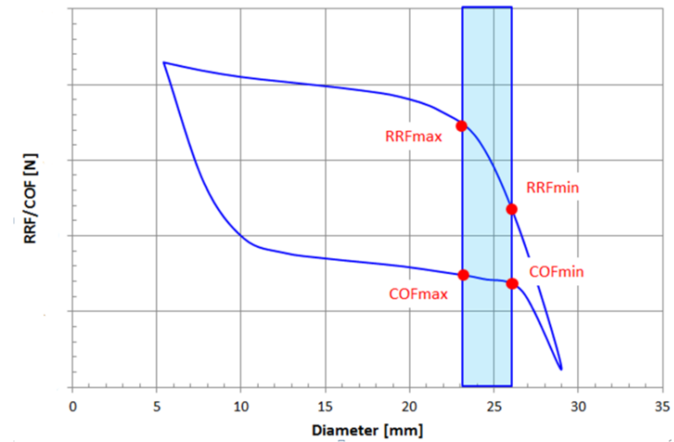
Results Validation+Prediction

- Comparison of experimental and statistical model



	DS_SL	DS_SBK	DS_SBM	DS_SR
Zelle	[mm]	[mm]	[mm]	[mm]
A	6.3	0.3	0.2	0.08
B	7	0.31	0.2	0.08
Zusatz				
Boundaries	max	max	max	max
	8	0.4	0.27	0.06
	min	min	min	min
	4	0.28	0.18	0.12



	Exp. vs FEA	Exp. vs Stat
	Delta	Delta
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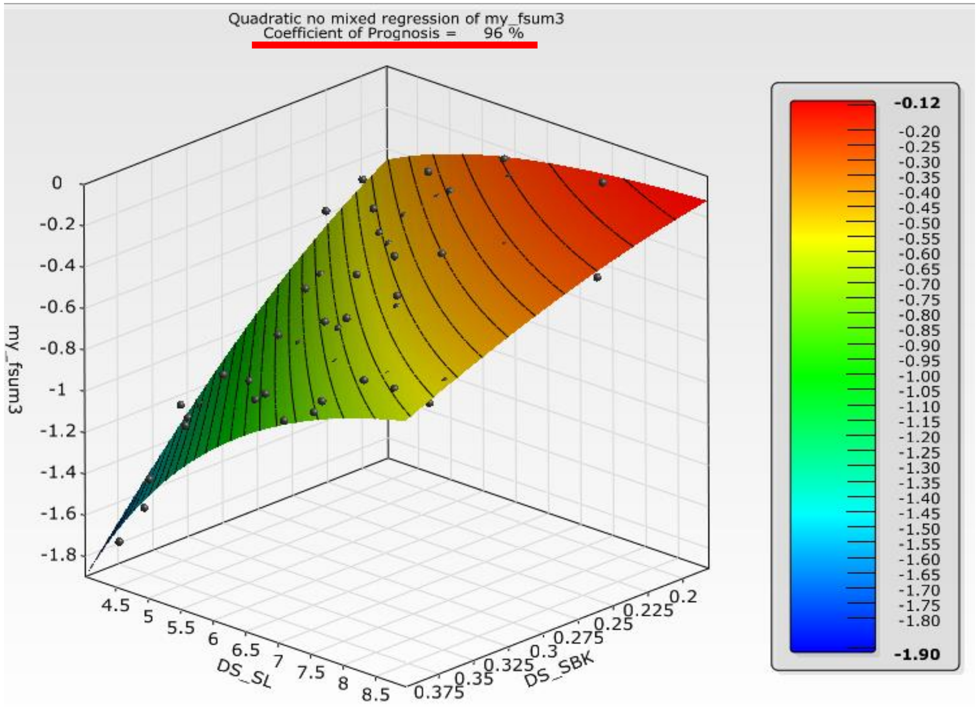
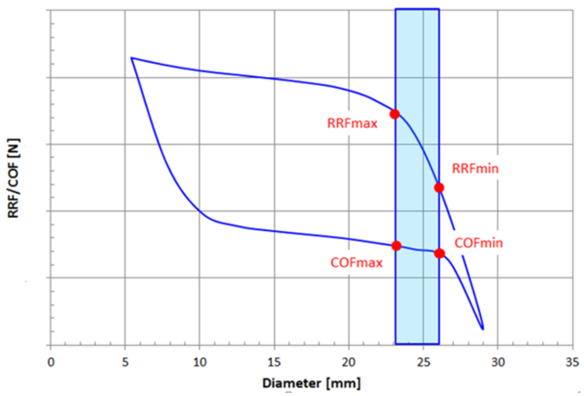
RRF 23mm	-1.92	5.84
COF 26mm	5.73	-11.66
COF 23mm	6.36	-9.90
mean (abs)	4.22	9.55

Results radial force

Response surface for the radial force fsum3 = COF23mm

SBK=Strut width at knot; **SBM**=Strut width in the middle; **WS**=Wall thickness; **SR**= Strut radius at the knot; **SL**=Strut length





- Highly accurate nonlinear model CoP = 96%

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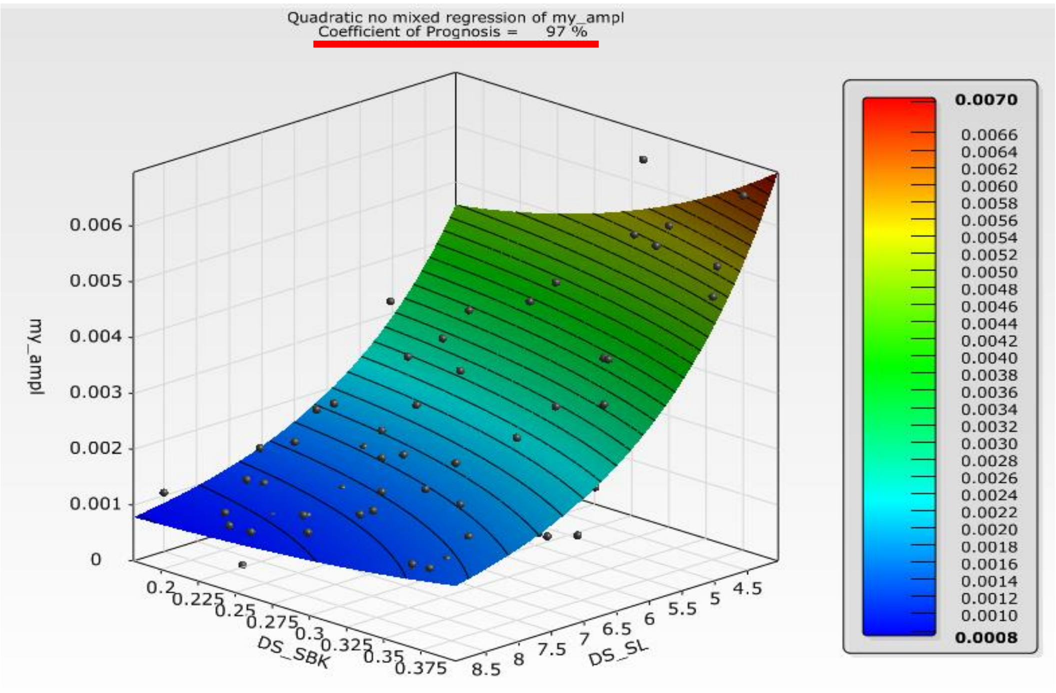
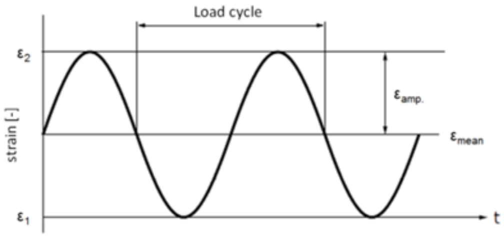
Results strain amplitude

Response surface for the max. strain amplitude

SBK=Strut width at knot; **SBM**=Strut width in the middle; **WS**=Wall thickness; **SR**= Strut radius at the knot; **SL**=Strut length





- Highly accurate nonlinear model CoP = 97%

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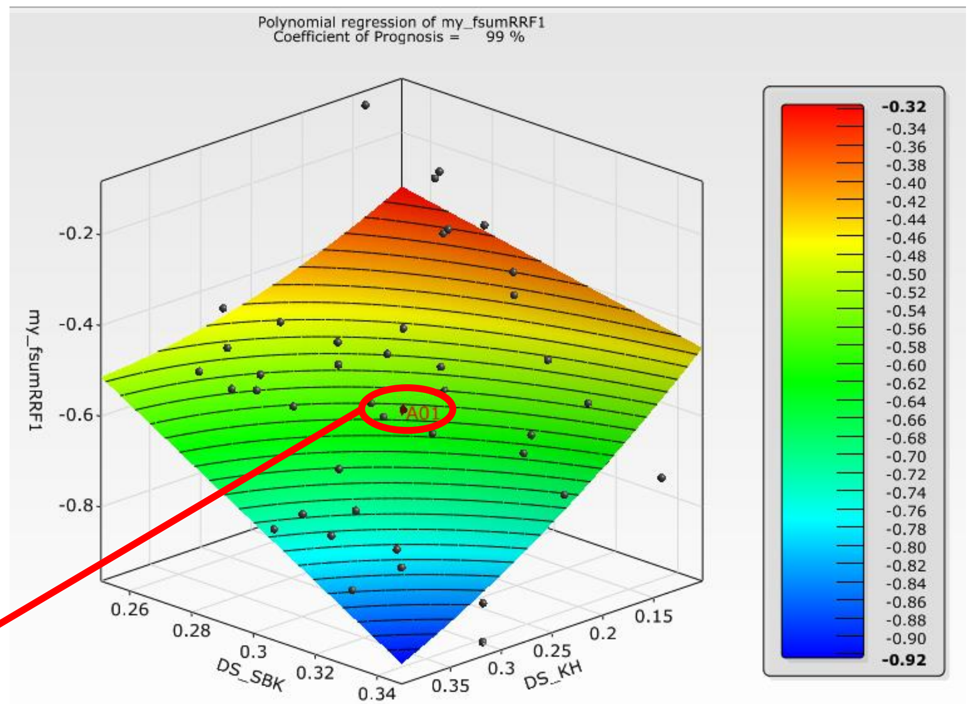
Results MOP example



Design Overview | Parameters | Responses | Constraints | Objective Functions | Approximation

#	Details		Parameters					Responses						
	Nr.	Status Info	DS_KH	DS_SBK	DS_SR	DS_KB	DS_KR	my_fsumRRF1	my_fsumRRF2	my_fsumcrimp	my_fsumCOF2	my_fsumCOF1	my_volume	my_maxepto
1	A01		0,25	0,2993333333	0,2013333333	0,3013333333	0,275	-0,5886394231	-1,015367304	-2,242090623	-0,5292931803	-0,4771529479	2368,332009	0,06486804427

- MOP surface allows prediction of design points on the response surface
- Approach is less errorous than linear regression models

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Discussion

- Design of experiments (DOE) is a powerful tool to create statistical meaningful (well distributed) results data sets
- Linear regression provides a fair model for a priori prediction
- A simple Excel based prediction tool was developed allowing a priori prediction of structural properties in less than 1 minute

- MOP approach delivers highly nonlinear and accurate response surfaces
- MOP might be a preferable tool to predict **accurate** design outcomes

Conclusion

- Initial design phase can be accelerated by simplified statistical prediction models which deliver a fair estimation of mechanical stent behavior

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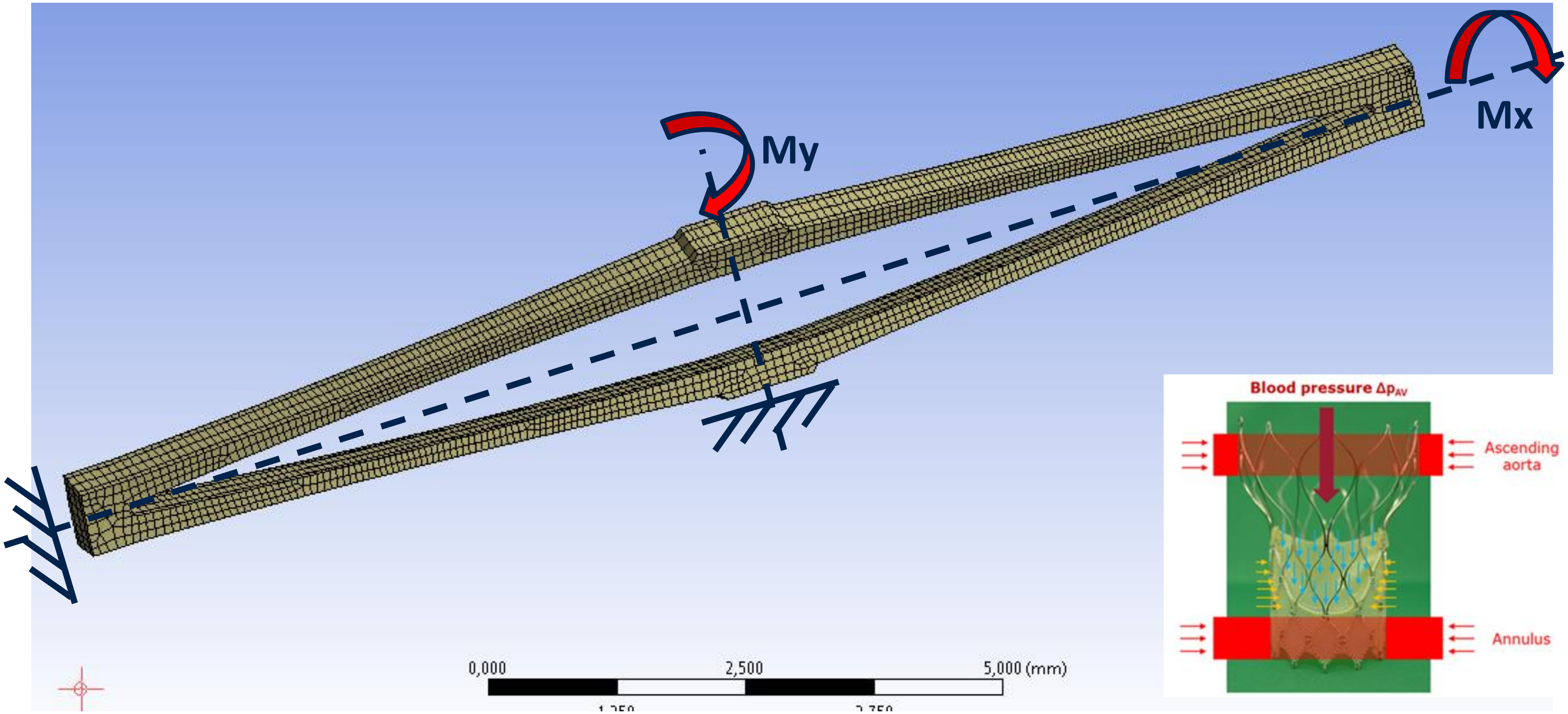
Future perspectives



- Multi-Axial loads can be applied to single diamond cell like they appear in hart valve stents
- This allows tuning designs to different loading modes (radial, axial, bending, torsion)

Statistical modelling

Knowing only a small part of the picture might lead to wrong conclusions:

Old Greece?

Statistical modelling

No, definitely Goethe in Italy

Thank You for the attention

Team Rostock Warnemünde:

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Paul Goebel	Measuring Technology
Stephan Rothstock	Simulation and Validation
Andreas Hof	Managment Research
Karsten Koop	Managment