# The RT3S project: towards safer vascular stenting

A. Chiarini (SCS), C.Silvestro (Medtronic)

# Outline

- Medtronic, Inc.
- Vascular Stenting
- RT3S Project
  - Overview
  - Modelling aspects
  - Response surface
- Results
- Validation
- Conclusions

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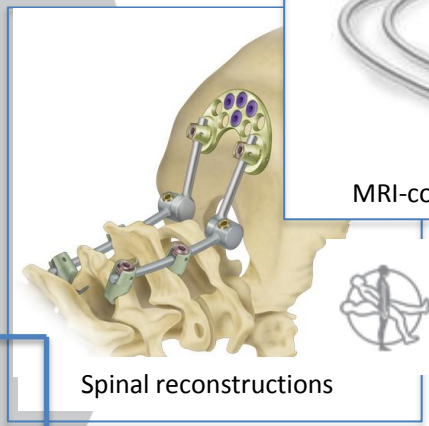
# Medtronic, Inc.

**Medtronic, Inc**. Minnesota (US) based, world's largest medical technology company and a Fortune 500 company

- Business units:
  - CRDM (cardiac rhythm disease management)
  - Diabetes
  - Neuromodulation
  - Spinal
  - **Cardiovascular**
  - Surgical technologies







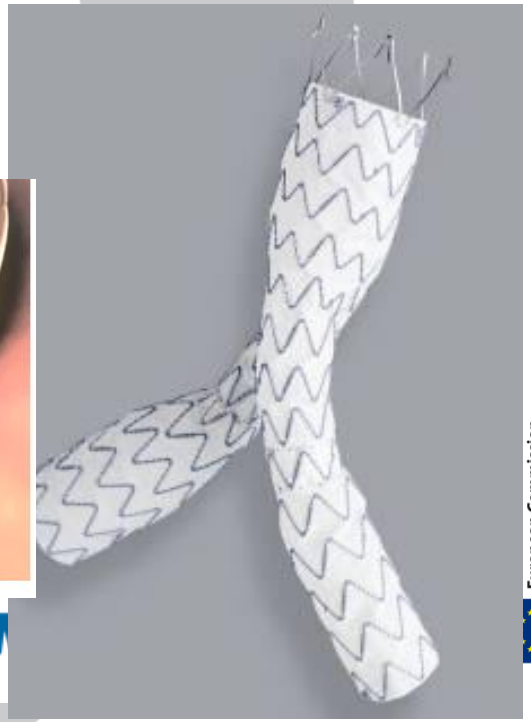
Including **Endovascular Therapies** business unit
Providing minimally invasive solutions for the treatment of cardiovascular disease

# Endovascular Therapies R&D

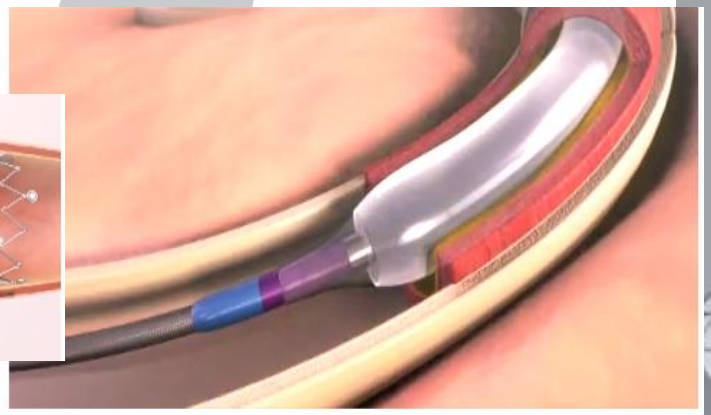
- Based in Santa Rosa (California)
- ~140 engineers and technicians
- Locations in USA, Frauenfeld (CH), Brescia (IT)
- > 50% of group has Master's Degree, Several PhD's
- > 12.5% of revenue invested in R&D

## On the market:

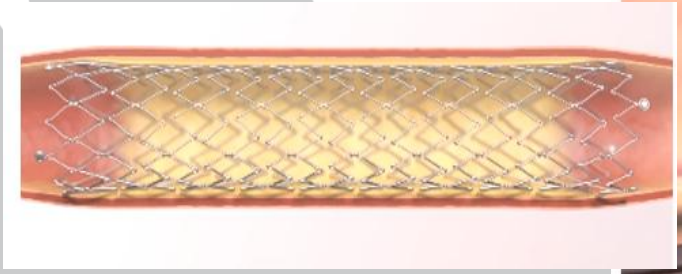
**Aortic and thoracic stent grafts**



**Peripheral angioplasty balloons**



**Stents**



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# Balloon and stent technologies

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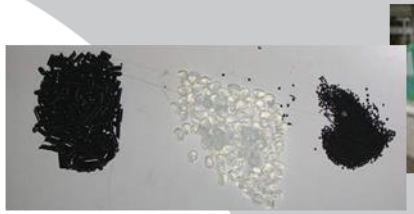
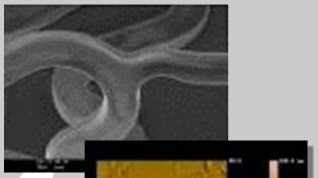
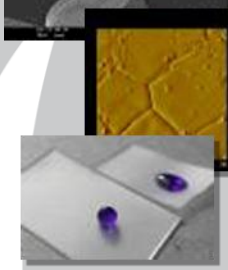
Radio Frequency

Assembling



Compounding





Surface Technology
- Drug Carrier
- Surface Treatment

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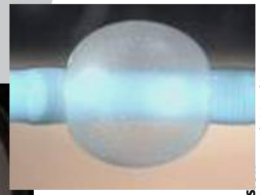
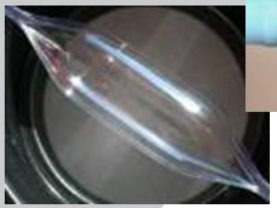
Extrusion/Co-Extrusion
Molding/Over-Molding

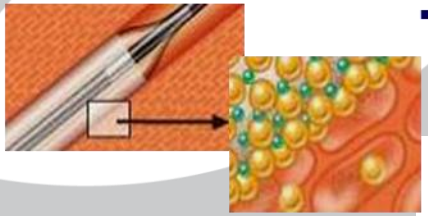
Metal Technology
- Stent Laser Cutting
- Electro-polishing
- Nitinol Thermoforming

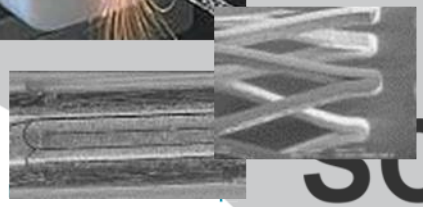


Balloon Technologies
- Dipping
- Blowing
- Molding



DEB, Coating Technology





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# Endovascular Therapies R&D

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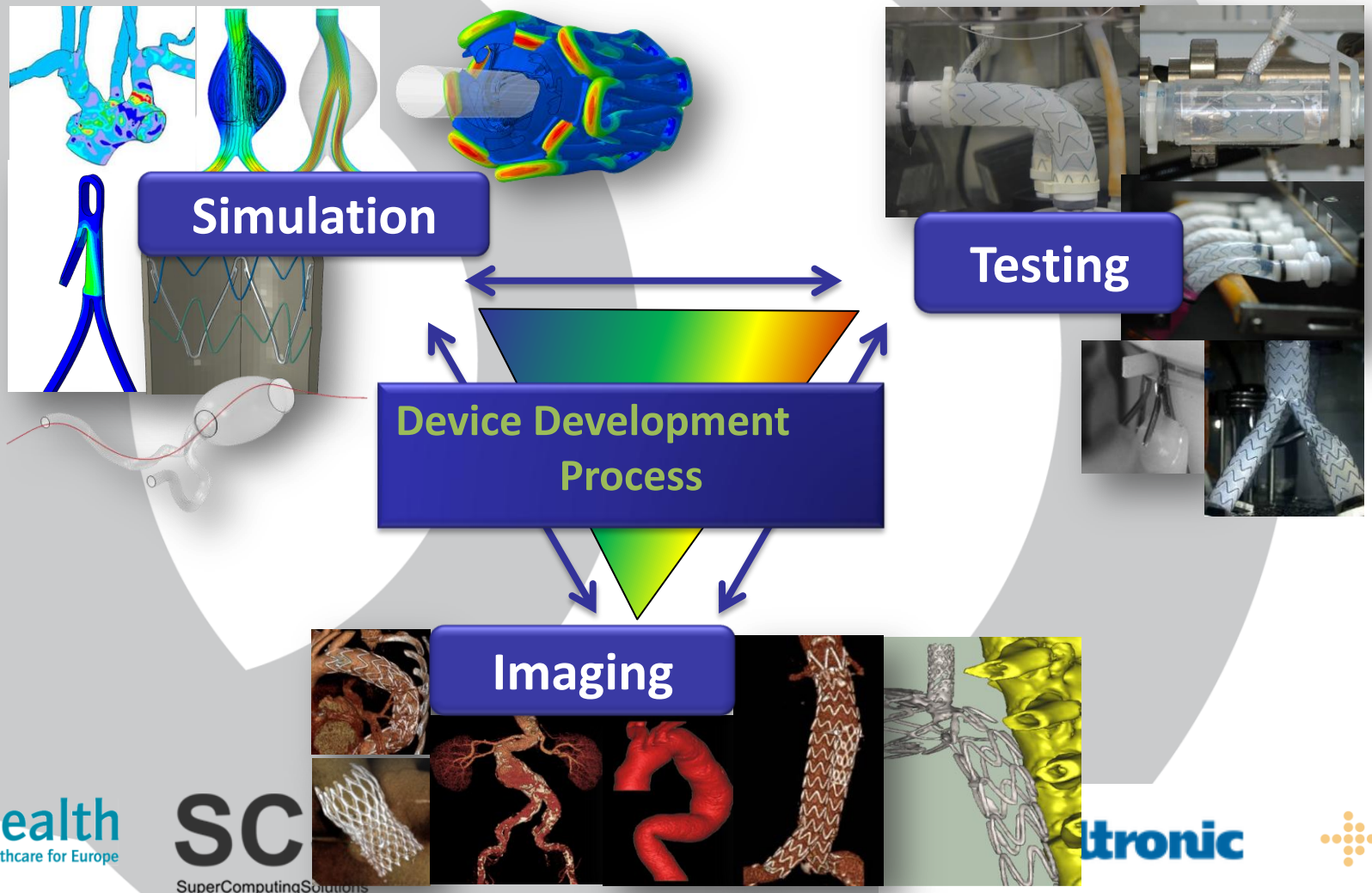
Patient-oriented, strictly regulated Product Development Process

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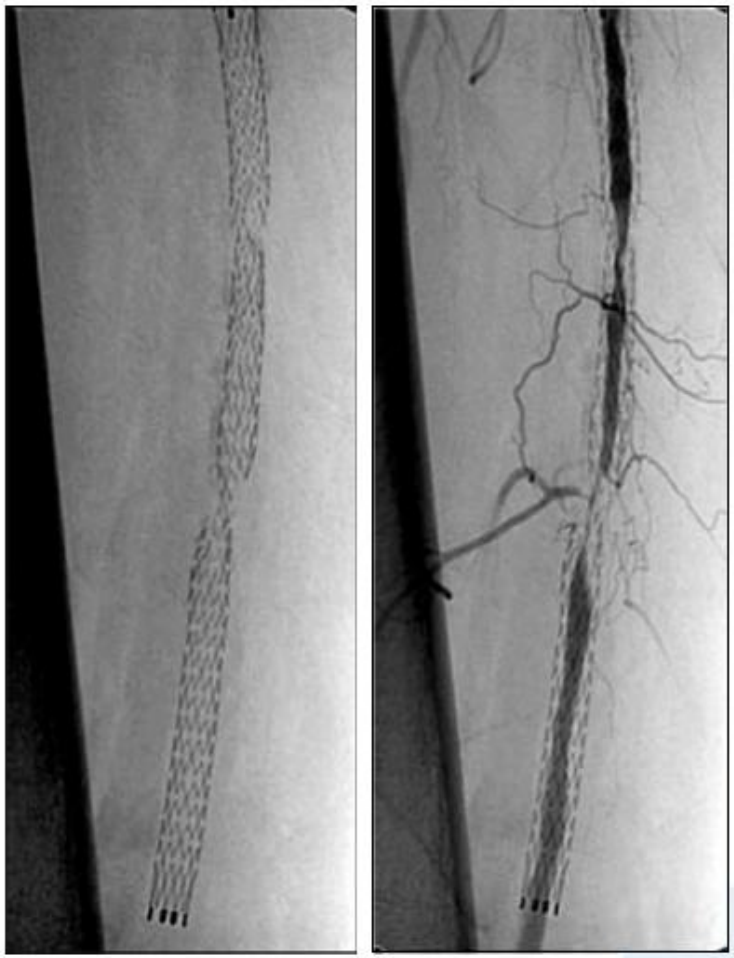
# The problem: stent fatigue fracture in peripheral arteries



- Stent fracture leads to in-stent restenosis.
- By computing the risk of stent fatigue fracture while planning the intervention, a warning can be given when the combination of patient-specific and surgery-specific factors create fracture risks, thus drastically reducing the incidence of this important complication.

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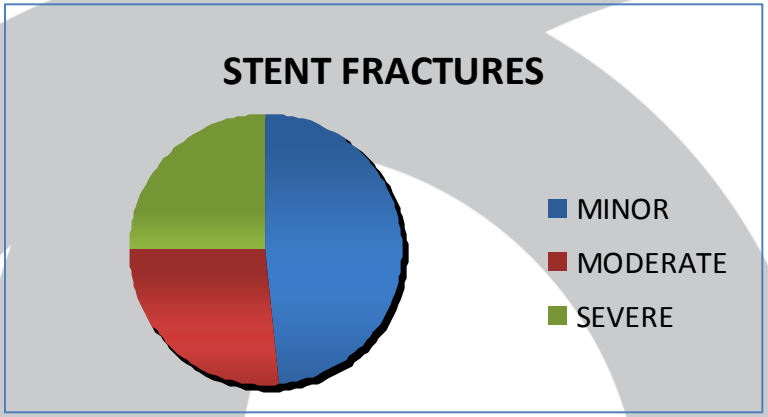
# Clinical trials

- The analyzed trials show a broad range of stent fracture rate
- All the trials underline the importance of fractures investigation in the SFA district

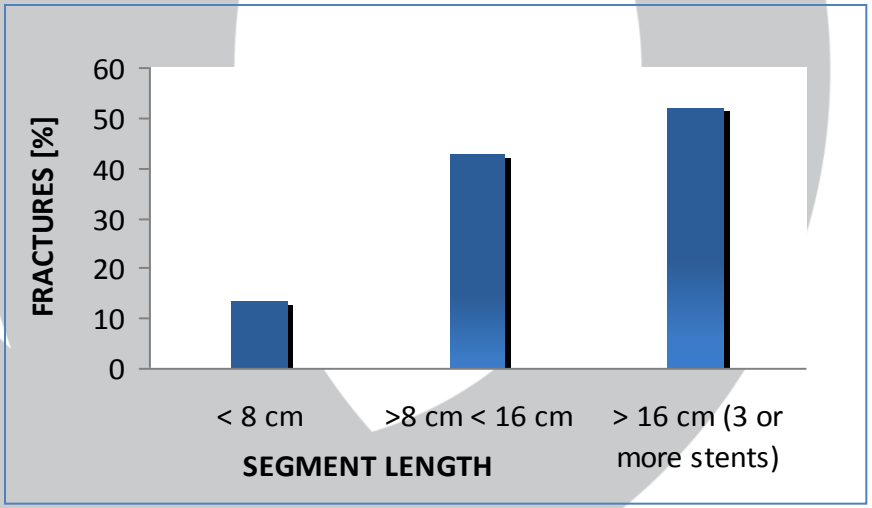
| Trial | Number of implanted stents | FRACTURE RATE | 6-month Restenosis rate (+) | Restenosis rate (12 MONTHS) |
|---|---|---|---|---|
| SIROCCO I | 79 | **27 %** (6 months) | 11.5 % (**) | NA |
| SIROCCO I+II | 177 | **17 %** (6 months)<br>**22 %** (24 months) | 4.6 % | 22% (24 months) |
| VIENNA ABSOLUTE | 106 | **2 %** (6 months) | 25 % | 37 % |
| FAST | 136 | **12 %** (12 months) | NA | 31.7 % |
| FESTO | 261 | **24,5 %** (11 months) | NA | NA |
| Dick et al., 2009 | 54 | NA | 18.2 % | 34.4 % |

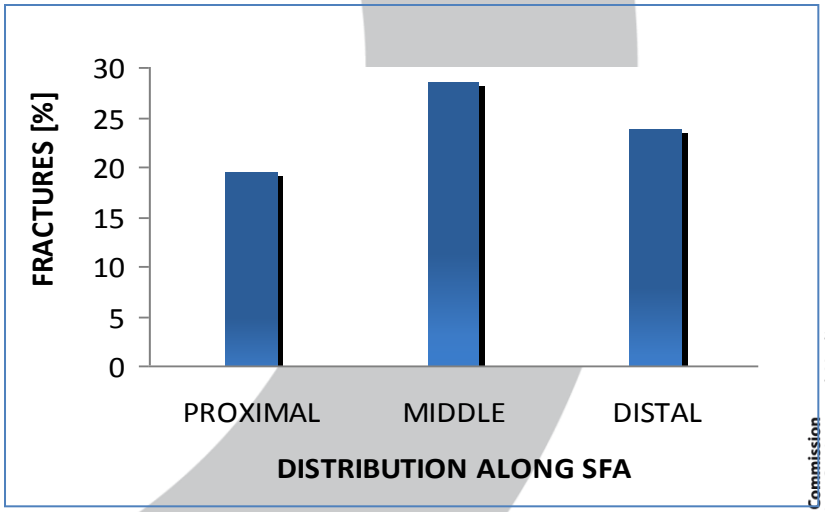
(+) Stenosis of at least 50% of luminal diameter (duplex US) (*) 10.7-month follow up
(**) from angiography

# Geometry Dependence [FESTO]




Stent fractures rate shows clear dependence on stent length

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# The RT3S approach

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**MEDICAL INDUSTRY**

WP9

**Integration**

WP8

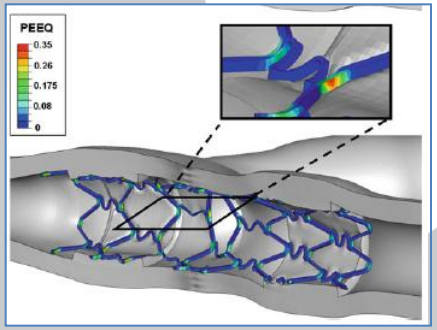
WP7

**Training**

Develop training SW for medical students

**Numerical simulations**

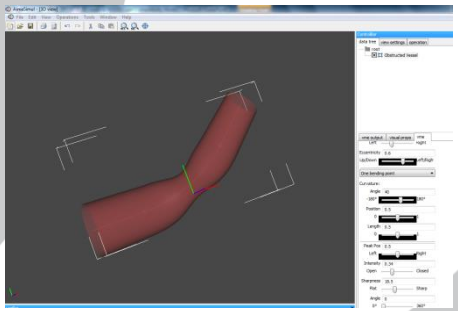
Reproduce *in-vivo* loading conditions of implanted stents




WP2 & WP3

**Software Development**

Integrate device properties with numerical simulations, providing interface



WP4 & WP5

**Clinical**

Test the software tool & provide clinical insight

WP6

**Integration**

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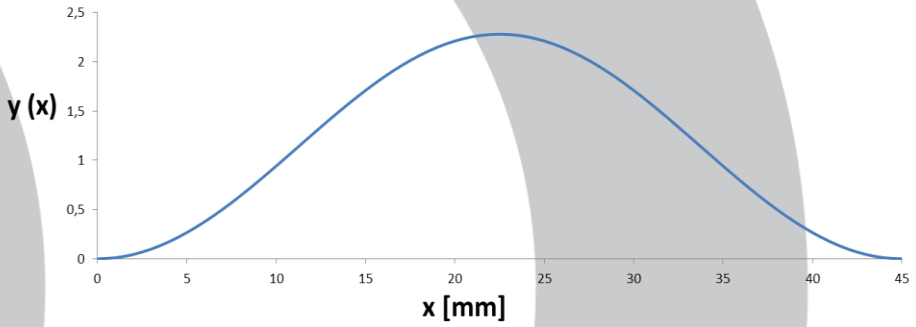
# Modelling: blood vessel and plaque

## Definition of anatomical and stent design parameters for the probabilistic model

- vessel diameter : $D_v$
- residual lumen : $RL = D_P / D_V$
- plaque length : $L_P$
- plaque sharpness : $S$

$$y(x) = \mathbf{D_V} \cdot (1-\mathbf{RL}) \cdot [\ \sin(\pi \cdot x / \mathbf{L_P})\ ]^{S}$$

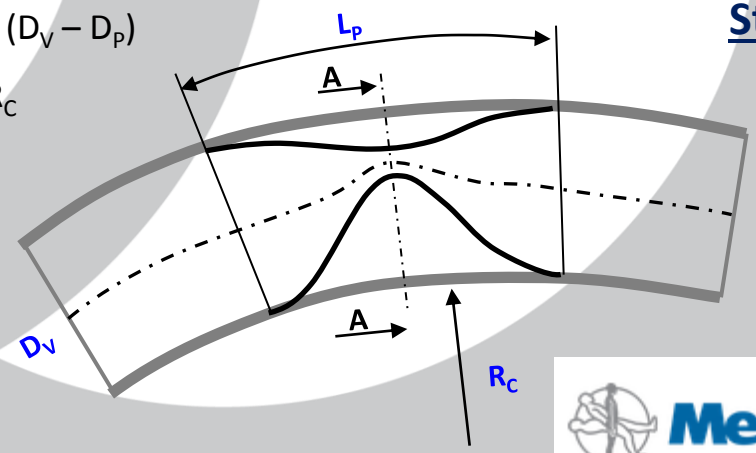
### Plaque profile y(x)



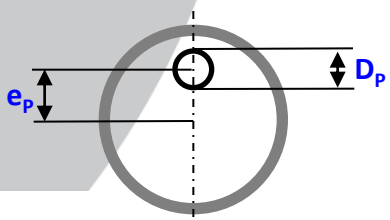

- plaque asymmetry : $As = 2e_P / (D_V - D_P)$
- vessel curvature : $\chi = 1 / R_C$

y(x) can be deformed to match the vessel curvature $\chi$ and to introduce a radial asymmetry As

### Stenotic vessel model




Section A-A

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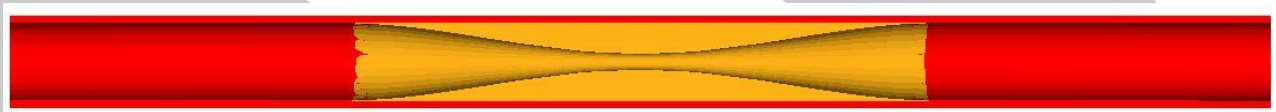
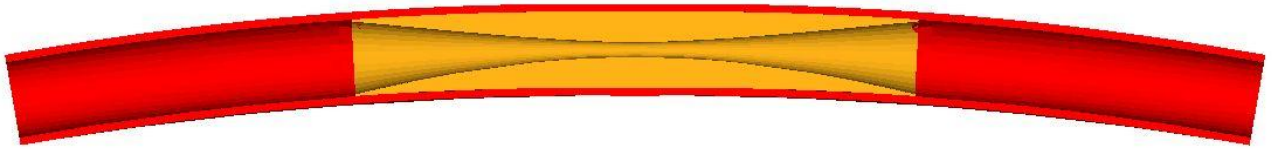
# Modelling: blood vessel and plaque

## Creation of parametric anatomical models



$D_V$ = 5.7 mm $\chi$ = 0 RL = 0.2 $L_P$ = 45 mm As = 0 S = 1.5



$D_V$ = 5.7 mm $\chi$ = 0.008 $mm^{-1}$ RL = 0.2 $L_P$ = 45 mm As = 0

$D_V$ = 5.7 mm $\chi$ = 0 RL = 0.2 $L_P$ = 25 mm As = 0.8

$D_V$ = 5.7 mm $\chi$ = 0 RL = 0.2 $L_P$ = 25 mm As = 0.8

# Modelling: blood vessel and plaque

## Creation of parametric anatomical models

**Range of parameters for probabilistic simulations**

| Model | Parameter | Symbol | Range of values |
|---|---|---|---|
| **Stenotic vessel** | Vessel diameter | $D_V$ | 4-7 mm |
| | Vessel curvature | $\chi$ | 0-0.008 $mm^{-1}$ |
| | Residual lumen | RL | 0.05-0.35 |
| | Plaque length | $L_P$ | 40-190 mm |
| | Plaque asymmetry | As | 0 - 1 |
| | Plaque sharpness | S | 0.1- 1 |

# Modelling: stent

## Definition of anatomical and stent design parameters for the probabilistic model

### Stent models

For the stent models, a parametric description is not used.

Few different geometries are considered for the stent layout, corresponding to different design strategies adopted by different companies. These cell geometries may be considered as representative of the geometries adopted by most stent producers.

A number of diameters and length are modeled for each geometry, taking into account typical dimension of peripheral vessels and plaques.

# Modelling: stent

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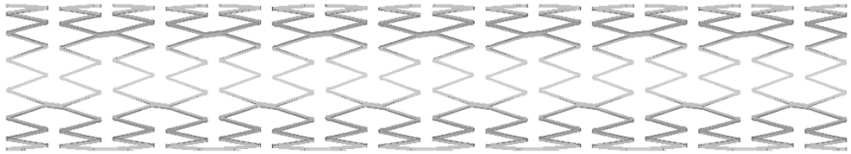
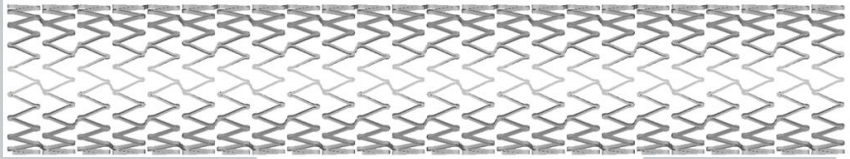
## Creation of stent models → Simulated stents

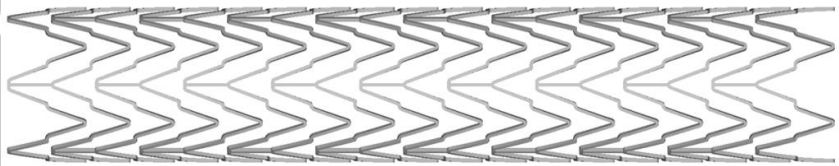
**Maris Plus - Medtronic Invatec**



**S.M.A.R.T. CONTROL – Cordis** (Johnson and Johnson Co)



**Absolute Pro - Abbott Vascular**



| COMPANY | PRODUCT | DIAMETER [mm] | LENGTH [mm] | Number of modeled stents |
|---|---|---|---|---|
| ABBOTT | Absolute Pro | 5 ; 6 ; 7 ; 8 | 60; 80; 120; 150; *170* (100+80); *200* (150+60) | 24 |
| CORDIS (Johnson and Johnson Co) | S.M.A.R.T CONTROL | 6 ; 7 ; 8 | 60; 80; 100; *130* (100+40); *170* (100+80); *190* (100+100) | 18 |
| MEDTRONIC INVATEC | MARIS PLUS | 6 ; 7 ; 8 | 60; 80; 120; 150; *170* (100+80); *200* (150+60) | 18 |

Different sizes (diameter and length) are investigated for each geometry, leading to **60 stents** to be simulated and 60 response surfaces to be constructed

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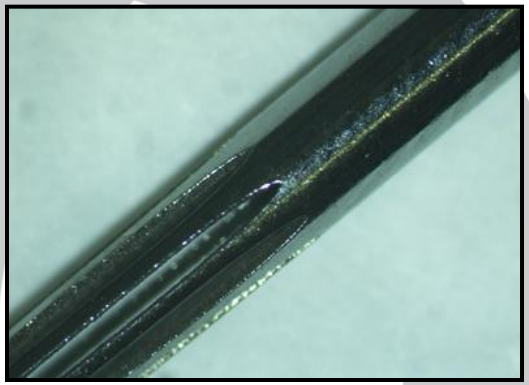
# Modelling: stent

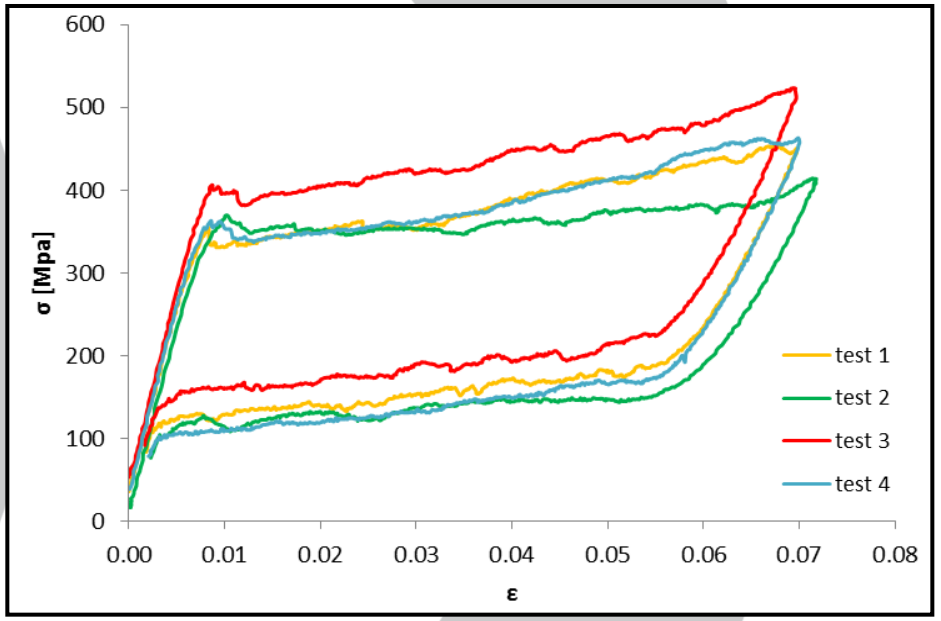
## In vitro characterization of stent materials

→ **Measurements of pseudoelastic properties of Nitinol for peripheral stents**

Samples laser cutted from Nitinol tubes, subjected to the same treatments of a stent



Temperature control system - water at 37° C



# Response Surface Technologies

- Design of Experiments and Interpolation Techniques
  - Optimal Space Filling DOE to get an uniform grid in the Cartesian Product of variation ranges
  - Kriging interpolation
- 3D stent fatigue simulation is very expensive. 5-10 days on 8 cores for one single solve
- 3D stent fatigue simulation is not robust. Convergence issues due to highly distorted elements.
- Mesh Morphing can't be applied due too large variations of shape parameters
- Single solve poor scalability due to large contact zones
- Perfect scalability of multiple solves
- Design Exploration of Solution Fields to get more than an interpolation of scalar values

# Geometry Partition

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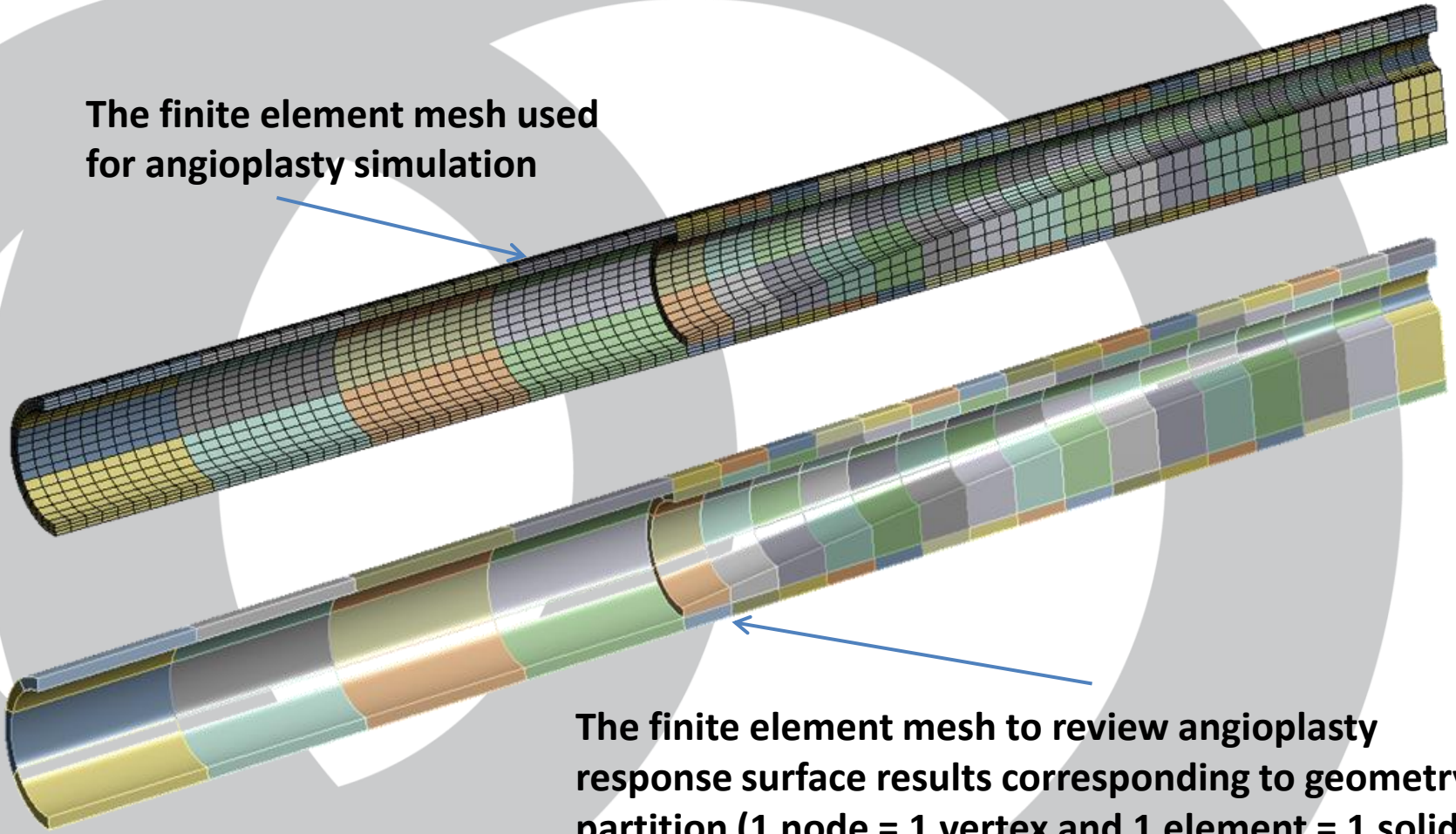
The finite element mesh used for angioplasty simulation



The finite element mesh to review angioplasty response surface results corresponding to geometry partition (1 node = 1 vertex and 1 element = 1 solid)

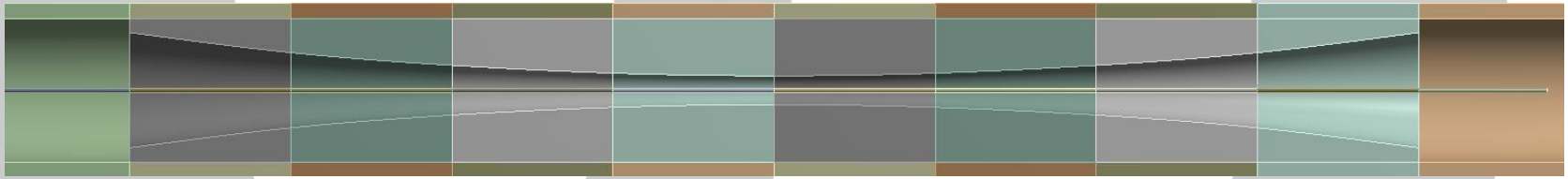
# Angioplasty Output Parameters

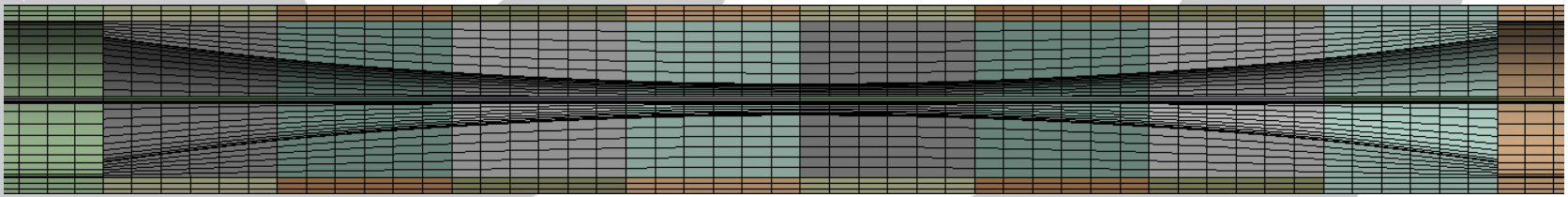
- Residual Stenosis
  - Scalar value computed after release of the balloon
  - Field of displacements results on vertices corresponding to each simulation step
- Axial reaction Force
  - Scalar value computed at the axial stretching step
- External Pressure
  - Scalar value computed at the angioplasty step
- Maximum first principal stress and maximum Von Mises stress
  - Scalar values computed at the angioplasty step
  - Field of stresses on solids

# Parametric model

| | | | |
|---|---|---|---|
| 26 | P28 | Commands (APDL) ARG3 | -0.75 |
| 27 | P5 | plaque_length | 50 |
| 28 | P16 | residual_lumen | 0.8 |
| 29 | P17 | asymmetry | 0 |
| 30 | P18 | sharpness | 0.8 |
| 31 | P19 | tb | 0.56 |

**Geometry with Asymmetry = 0**





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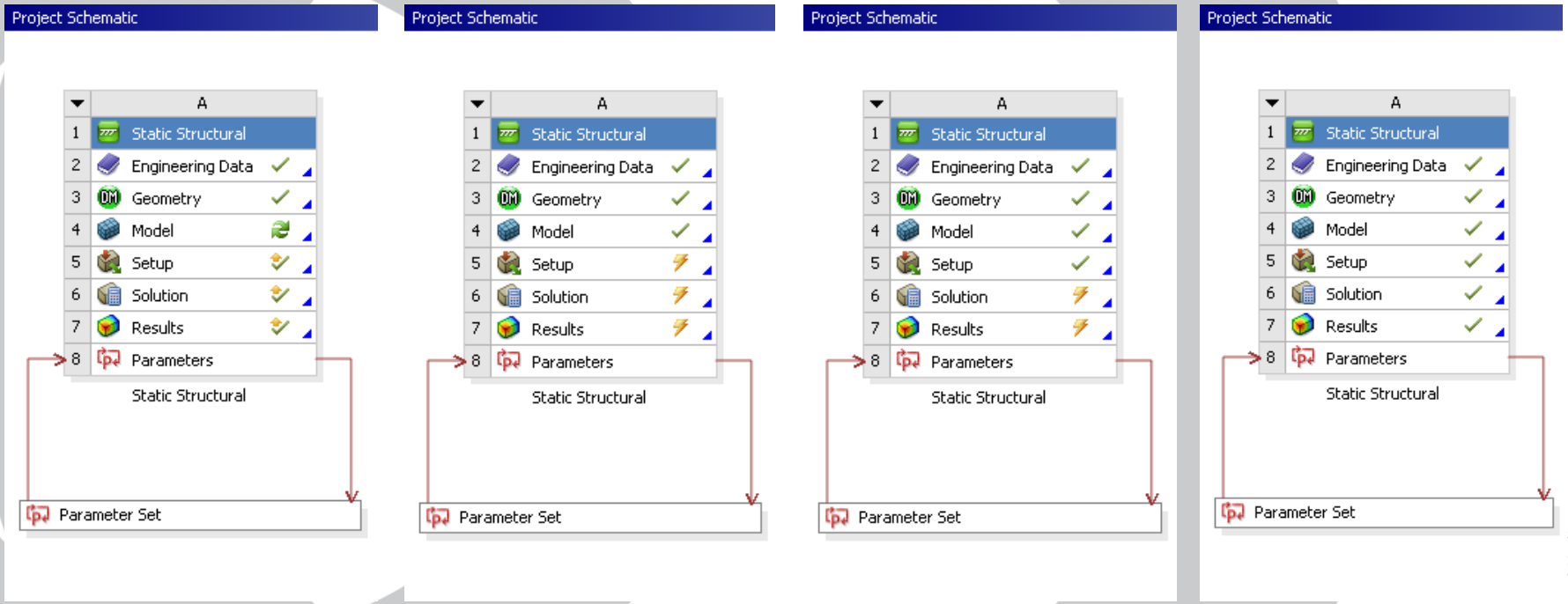
# One-click update




**Geometry update**

**Model update: Mesh**

**Setup update: boundary conditions (loads,...) and Analysis Settings**

**Job run is finished**

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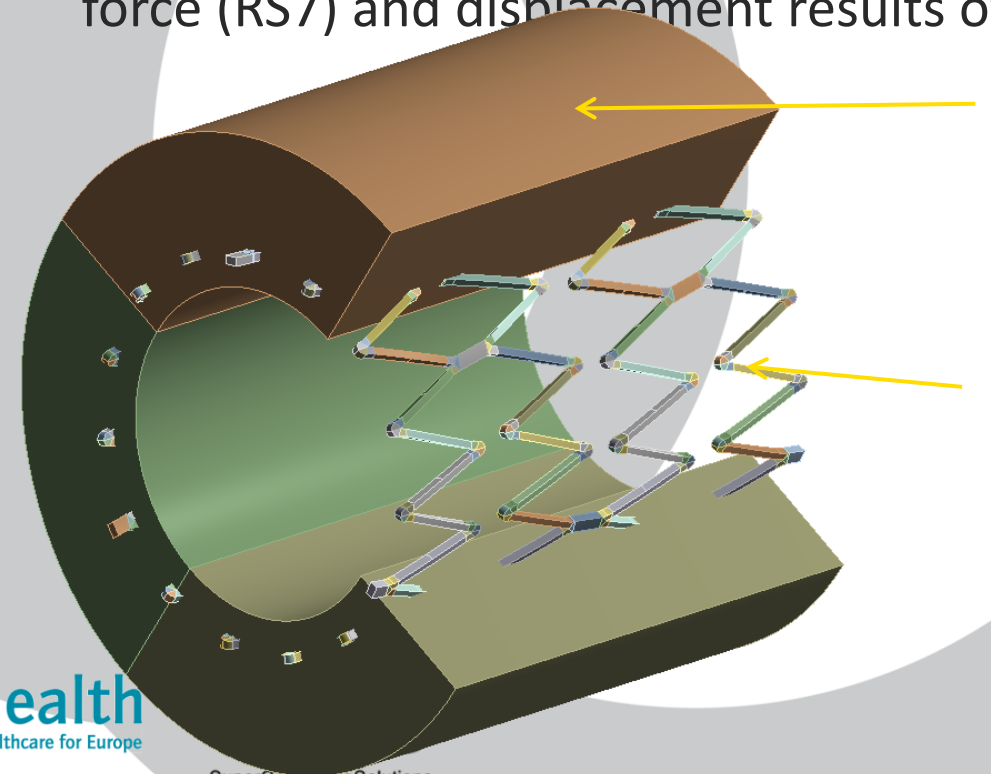
# Angioplasty Response Surface

- Around 450 Angioplasty solves launched in parallel on the CINECA PLX Cluster
- 2 sets of design points
  - Learning set to build the response surface
  - Validation set to compare interpolated results and reference results
- Parameterization of solution fields based on
  - Singular Value Decomposition of the list of vectors
  - Approximation of modes coefficients using Kriging interpolation
  - Scalar output parameters computed from solution fields
- Variation of the number of learning points
- Variation of the number of modes
- Validation using scalar output parameters accuracy

# From Angioplasty to Fatigue

- The Fatigue models use 2 input parameters which are computed from Angioplasty results:

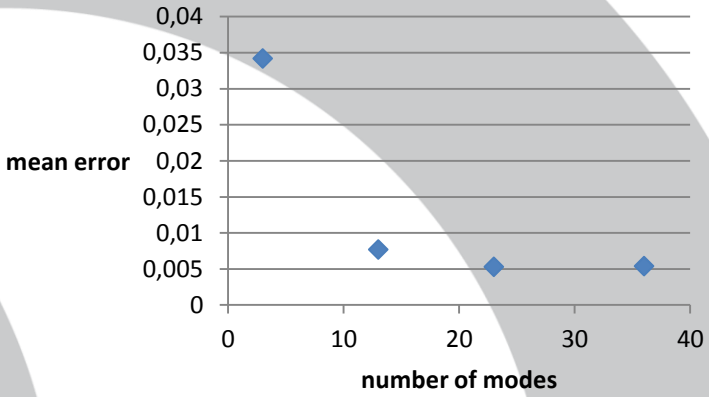
1. Inner Diameter of the tube using RS1 and RS4 on the nodes corresponding to the central section
2. Young's Modulus of the tube computed from the axial reaction force (RS7) and displacement results of RS4

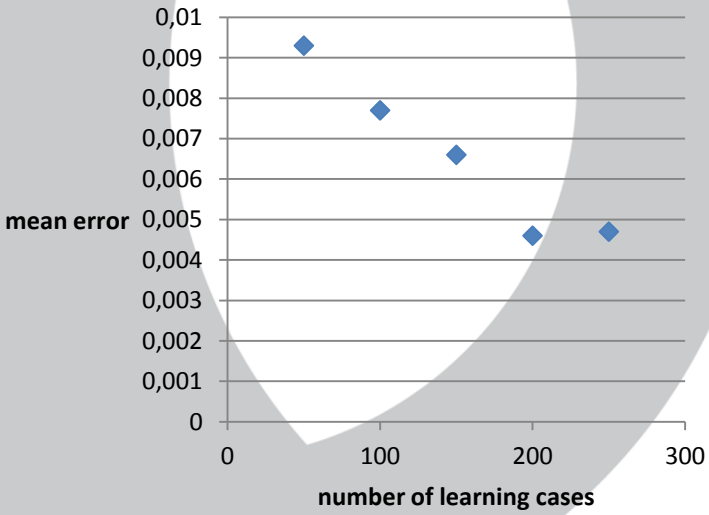


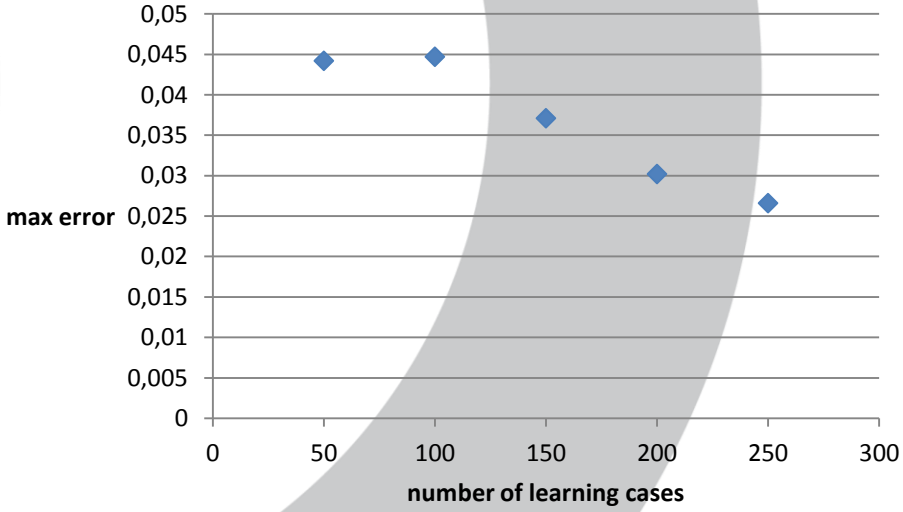
# Response Surface Validation

Results on Residual Stenosis

Variation from 0.13 to 0.83
Mean Value = 0.42




Validation using the full set of points (around 450)

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# Validation

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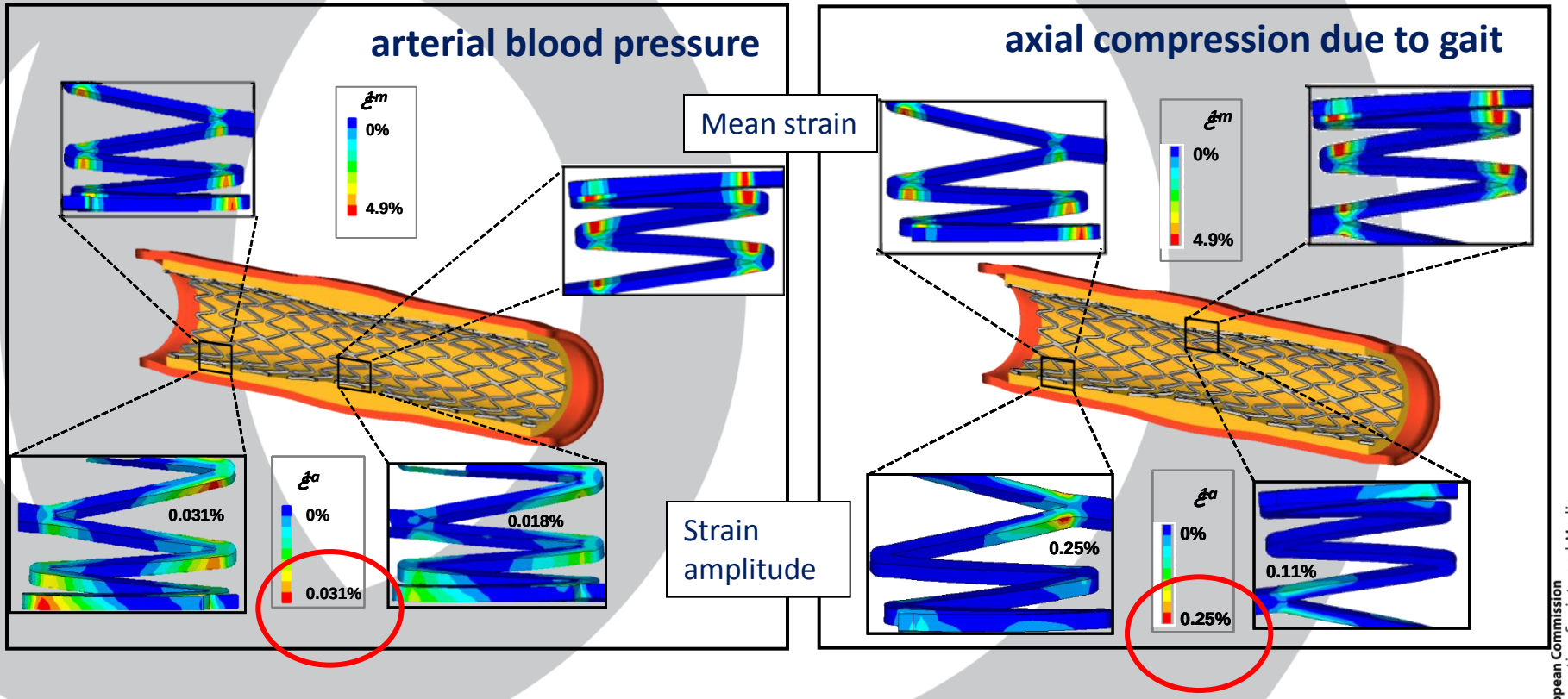
## 3D deterministic stent simulations for the fatigue-life predictions

→ First simulations of fatigue loading on the stent

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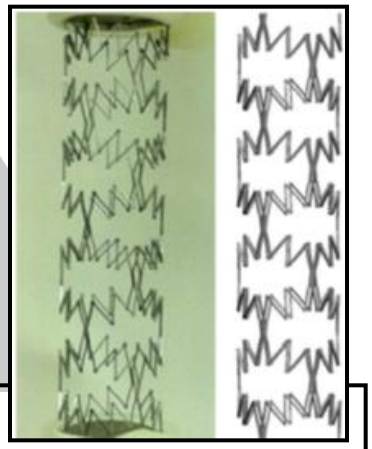
# Validation

## 3D deterministic stent simulations for the fatigue-life predictions

→ **First validation of the stent models through *in vitro* test (static)**

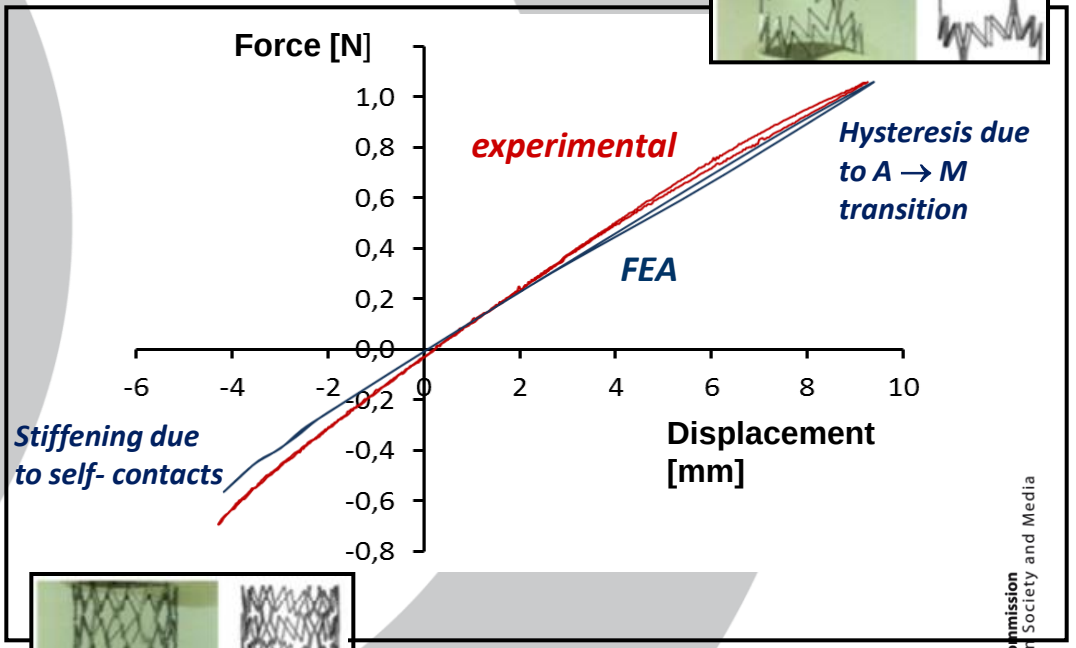


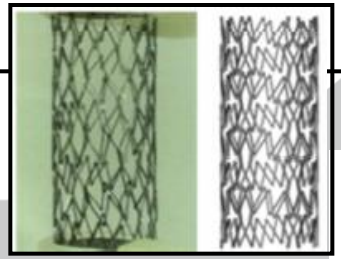
Tensile test (stretching at 40%)
Compression test (shortening at 20%)

a)

**Experimental Setup**

**Prediction of stent axial stiffness**



**Comparison of stent axial stiffness and deformed configurations**

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# Conclusions

- We presented a CAE workflow aimed at predicting failure risk for a stent when deployed in a pathological patient.
- The presented workflow involves time-consuming simulations and it heavily exploits response surface technologies and HPC resources to get data for generating a failure risk prediction.

# Acknowledgements

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