Optimization Strategies for the Development of Vascular Stents.

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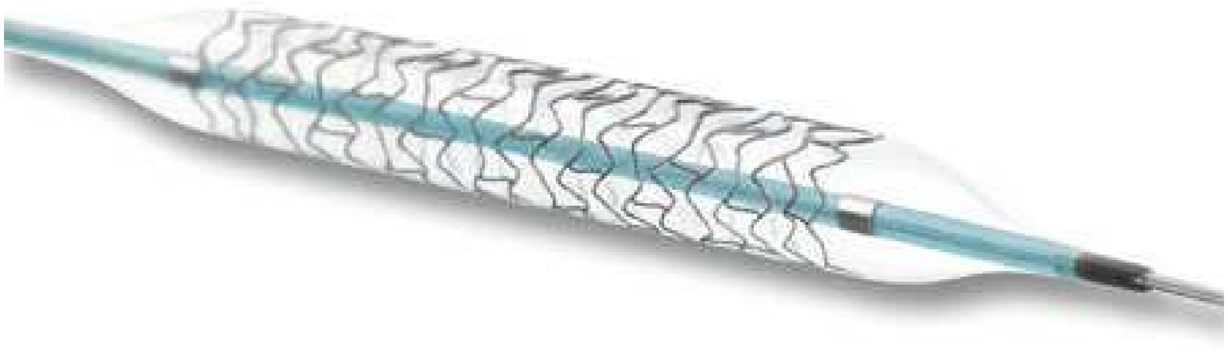
André Schoof



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Agenda

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- Introduction
- Stent Development
- Design Optimization
- Optimization Strategy
- Conclusion & Outlook

Introduction

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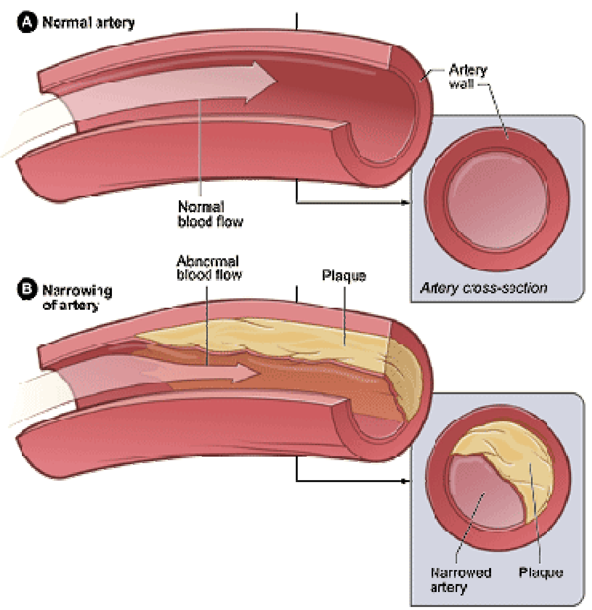
Coronary Angioplasty With Stent Placement

- Atherosclerosis is plaque build-up inside the coronary arteries
- most common type of heart disease
- leading cause of death in EU/US
- lifestyle changes & medicines effective treatment at early stage of the disease

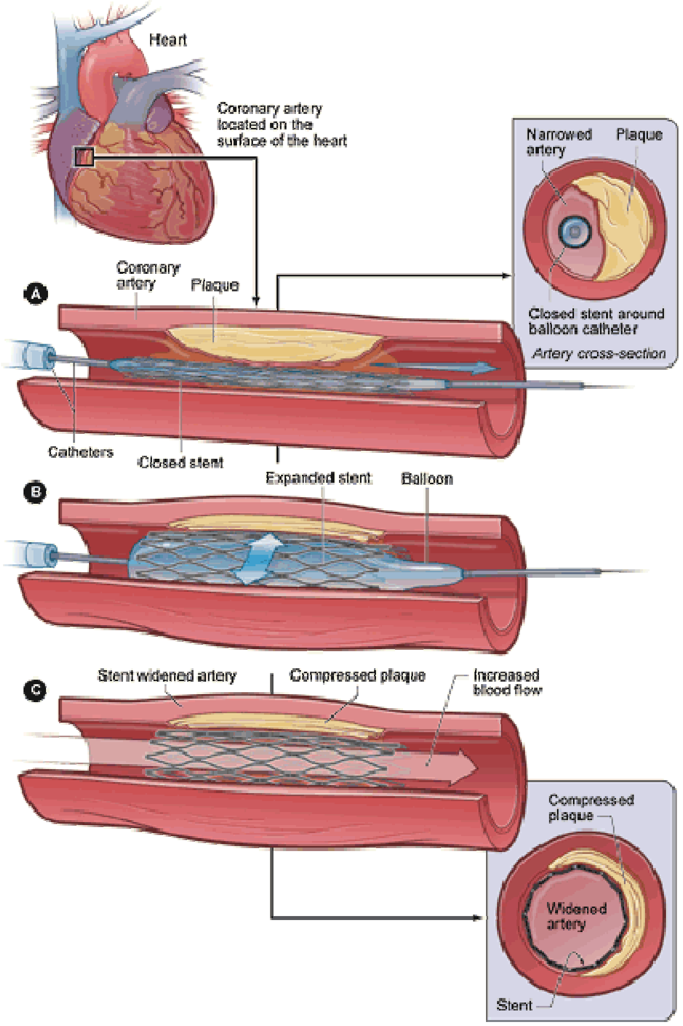


Source: http://www.nhlbi.nih.gov/

Introduction

Coronary Angioplasty With Stent Placement

- one of the most important achievements of the last years in interventional cardiology
- balloon is inflated to compress the plaque
- stent expands and attaches to the artery wall
- stent stabilizes opened vessel until the healing process has finished

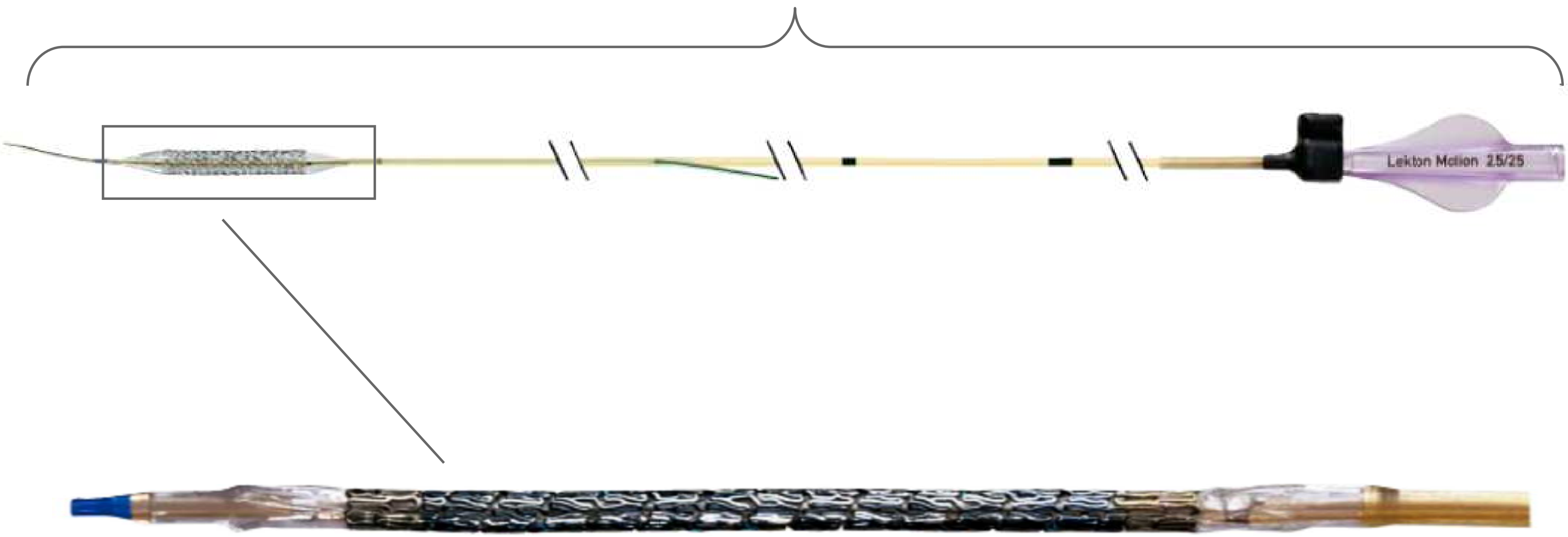


Source: http://www.nhlbi.nih.gov/

Introduction

Stent System Assembly

Stent-Delivery-System

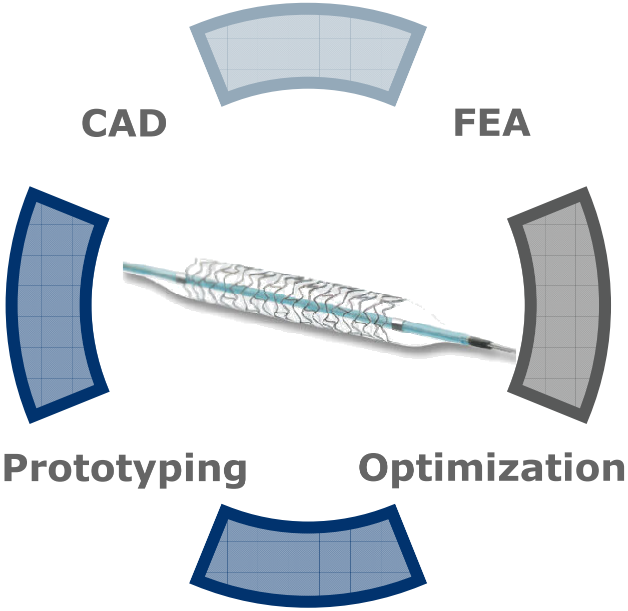


Stent mounted on Delivery System

Stent Development

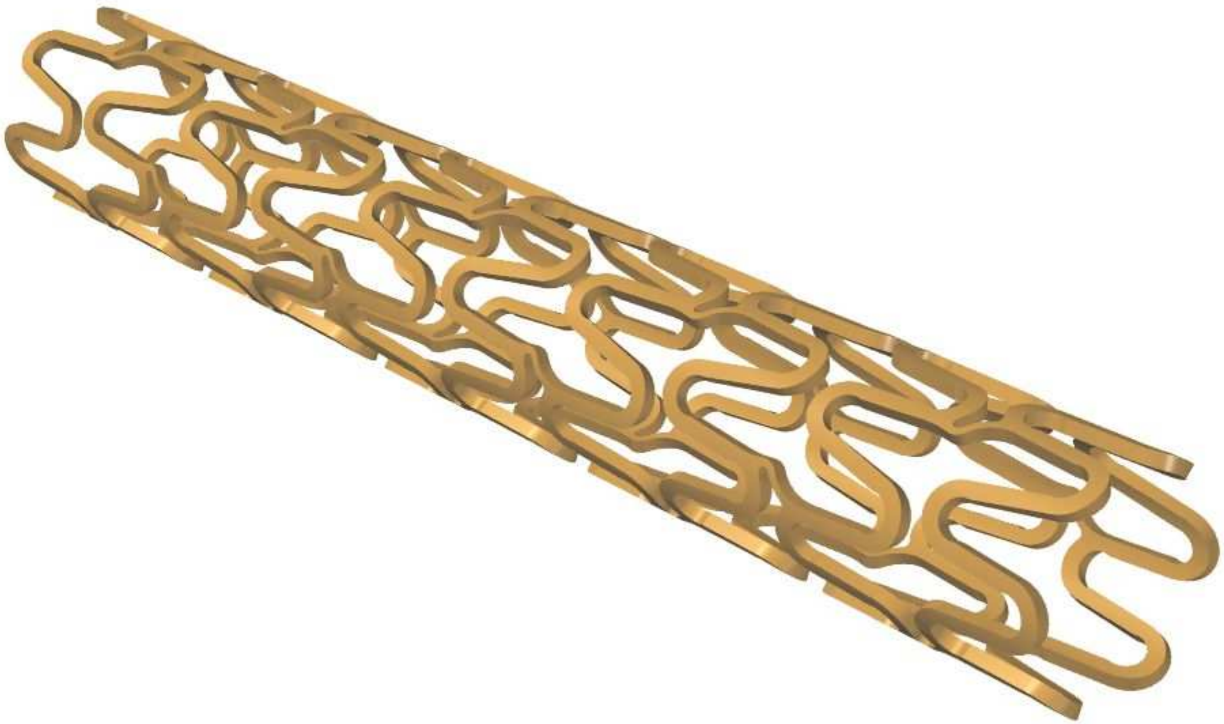
Design Development Circle

- closely integrated CAD + FEA is used from the early development phase on
- parametric CAD geometry
- numerical evaluation
- parameter analysis + optimization
- prototyping + experimental evaluation



Design Optimization

From 3D to 2D and back again



Design Optimization

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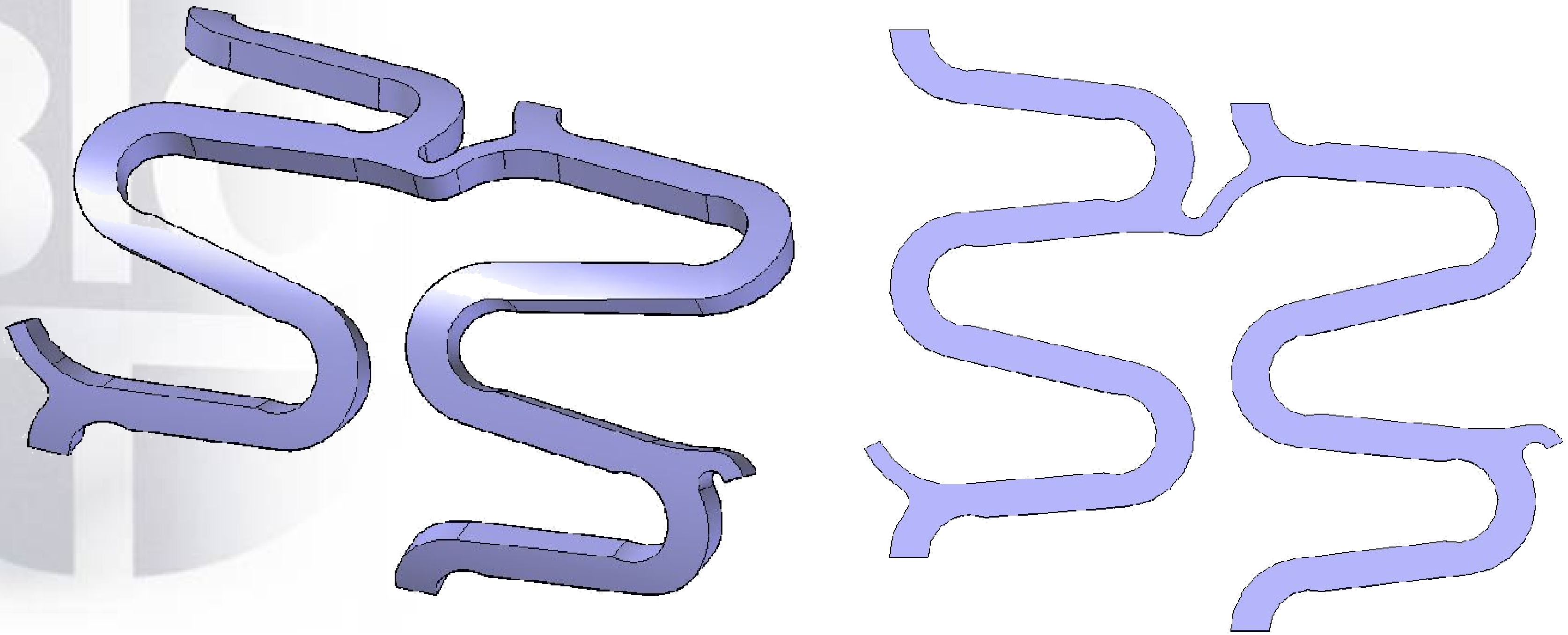
From 3D to 2D and back again



Design Optimization

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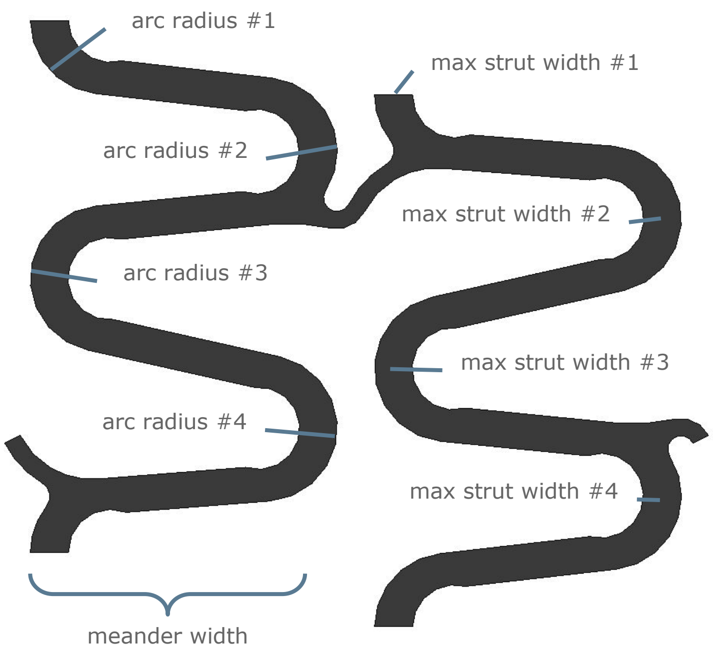
Strategy – CAD

- parametric geometry model with Solid Edge
- independent design features are important for minimum of cross-correlation
- geometry parameters
  - meander width
  - outer crown arc radii
  - inner crown arc radii
  - strut widths
  - strut angle
  - offset values etc.



Design Optimization

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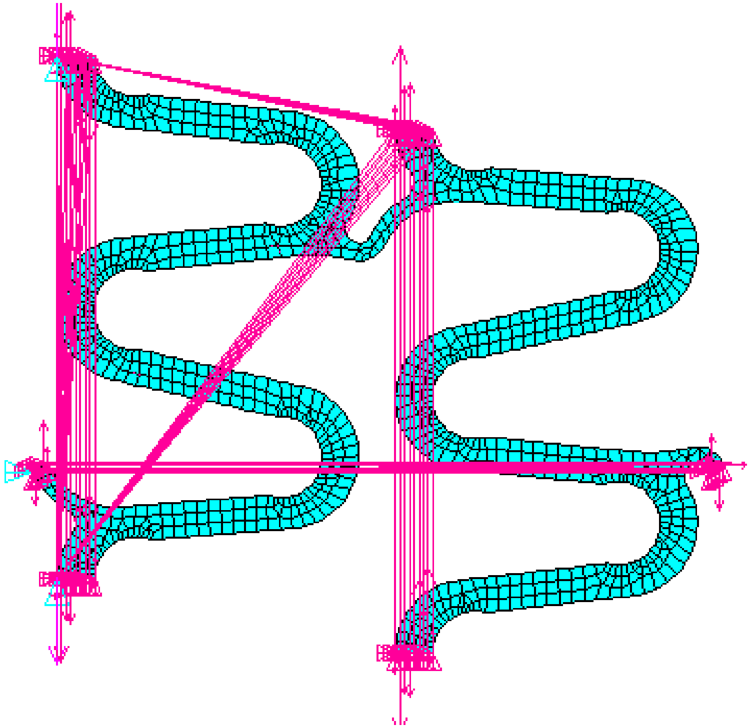
Strategy – FEA

- FE model generation in ANSYS Workbench (WB) bi-directional interface with Solid Edge
- cyclic BC with CEs (APDL scripts)
- non-linear 2D Solution
  - non-linear material model
  - large strain kinematics
  - contact modeling



Design Optimization

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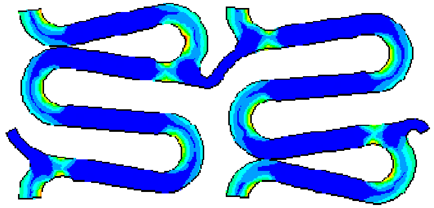
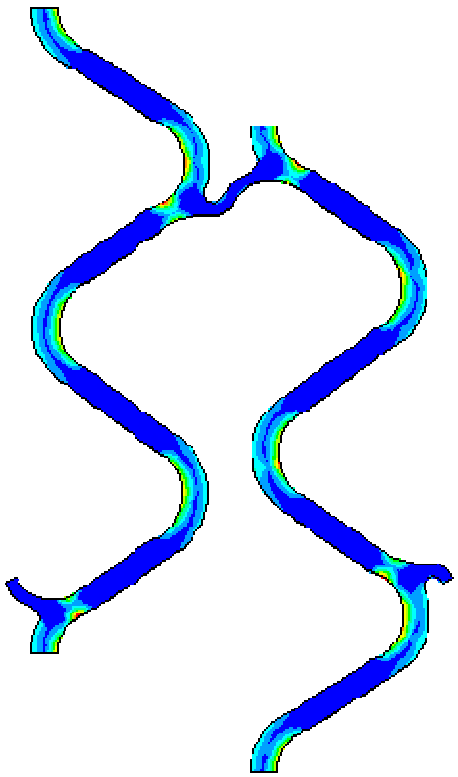
Load Steps

- crimping – radial compression (mounting on balloon)
- dilatation – radial expansion (balloon expansion)
- recoil – radial spring back
- compliance – radial reaction force
- 18 load steps
- run time: ca. 2-4 min.





Design Optimization

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Strategy – FEA

- Script based post-processing in WB
- output parameter definition
  - equivalent plastic strain at arc radii
  - strain distribution in arcs
  - radial compliance
  - self contact forces
  - overall min. strut width

- export of WB to optiSLang project

Design Strategy

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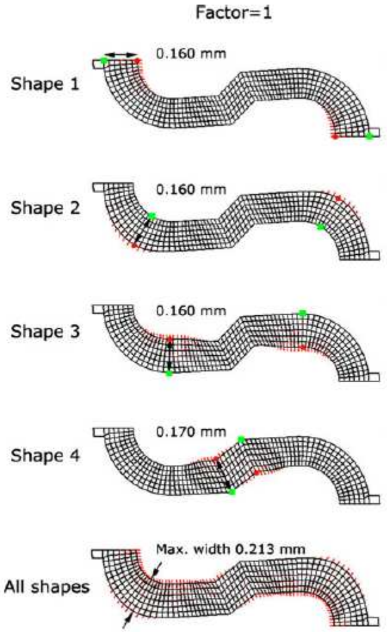
Review

- in the past: optimization as “trial and error approach”
- sensitivity analyses of design parameters using WB Design-Xplorer – limited success
- recently few true optimization studies were published
- using parametric modeling in ANSYS Classics & RSM approach
- or mesh-morphing as modeling tool with ARSM approach
- reduced dimensions in design space

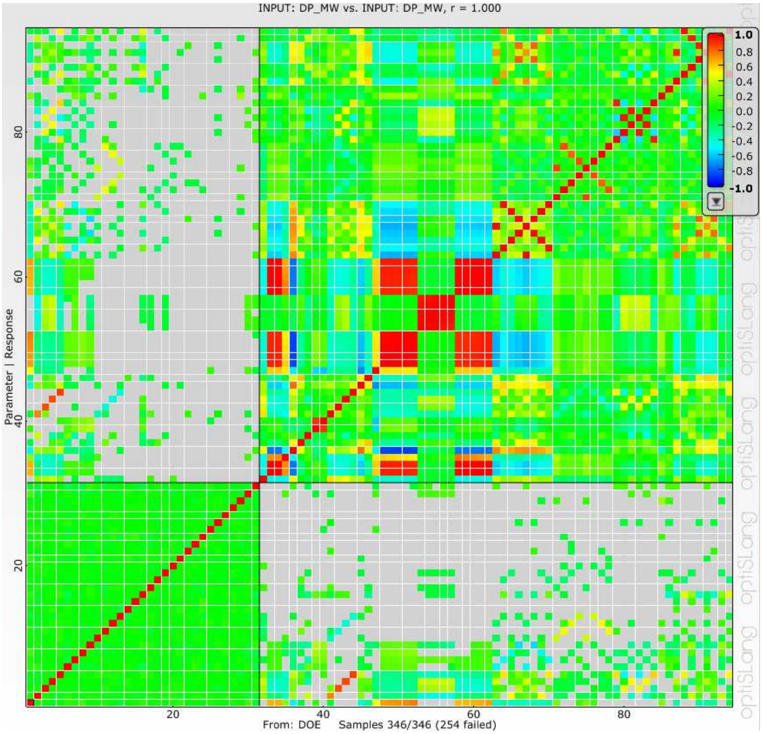


Source: Li, N., Zhang, H., Ouyang, H., 2009, Finite Elements in Analysis and Design
Wu, W. et al., 2010, Annals of Biomedical Engineering

Optimization Strategy

Strategy – optiSLang – DOE

- prior to DOE, input parameters: 31 ; output parameters: 63
- definition of BCs & objective function
- objective function
  compliance +
  compliance range +
  strain distribution (4x) +
  mean contact forces +
  var contact forces
- latin hypercube sampling
- N = 600 (wall clock ≈ 12h)
- parameter range ≈ ± 20%



Optimization Strategy

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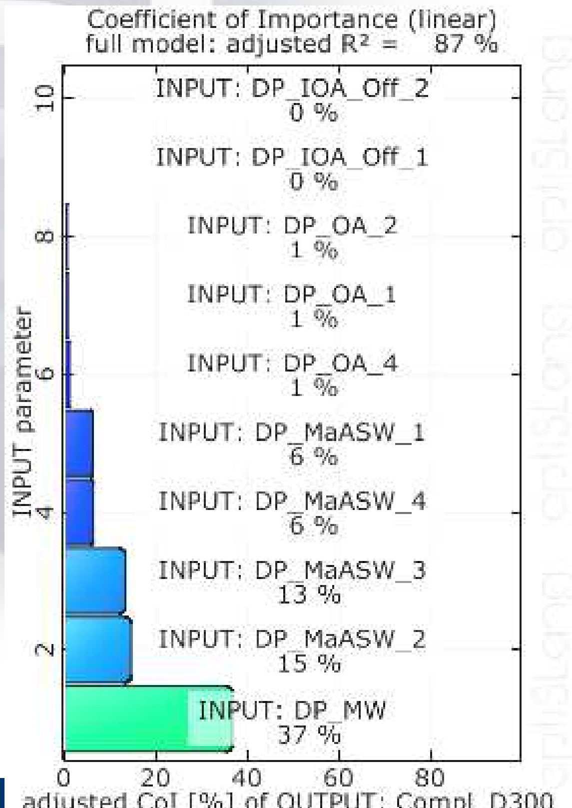
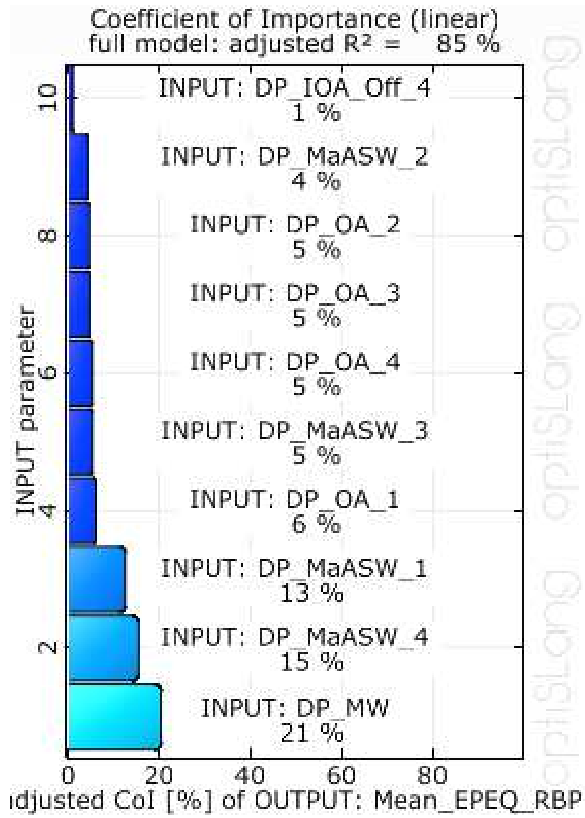
Strategy – optiSLang – DOE

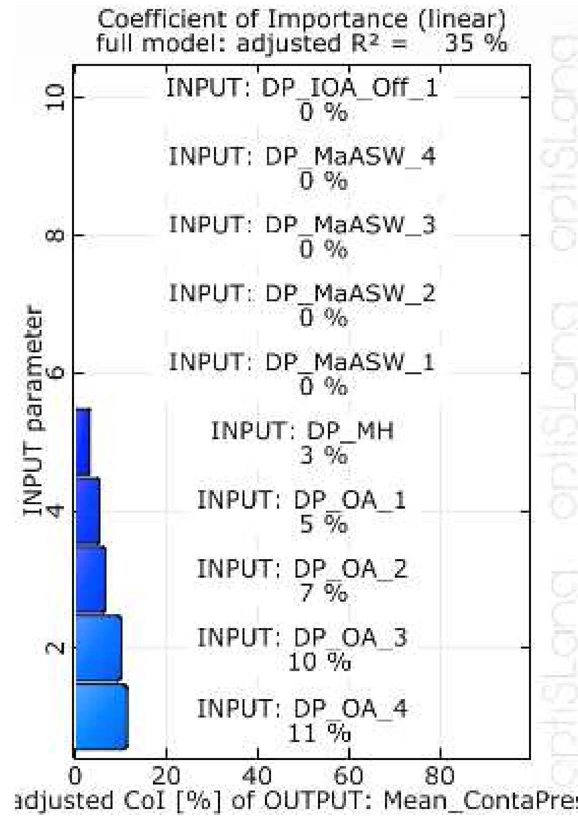
compliance



pl. strain



contact pressure



Optimization Strategy

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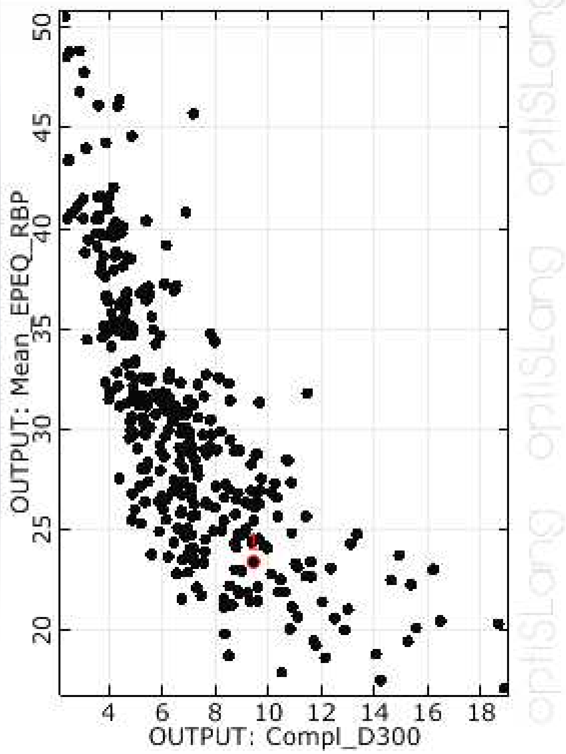
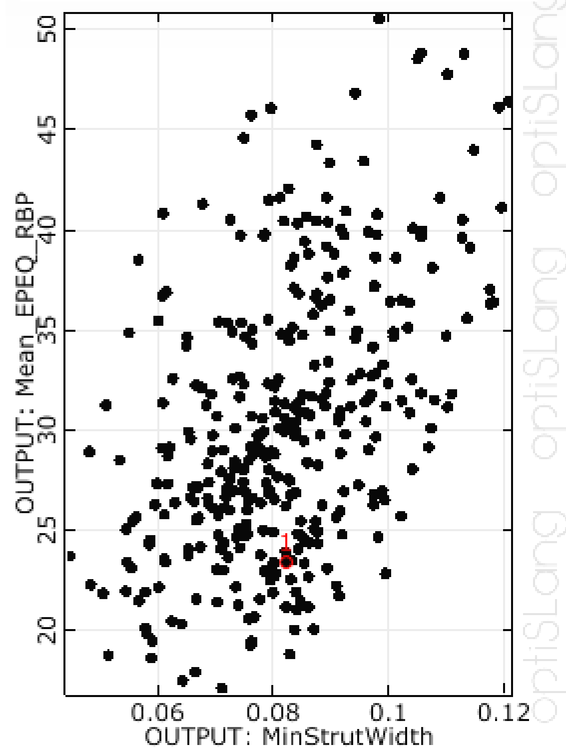
Strategy – optiSLang – DOE

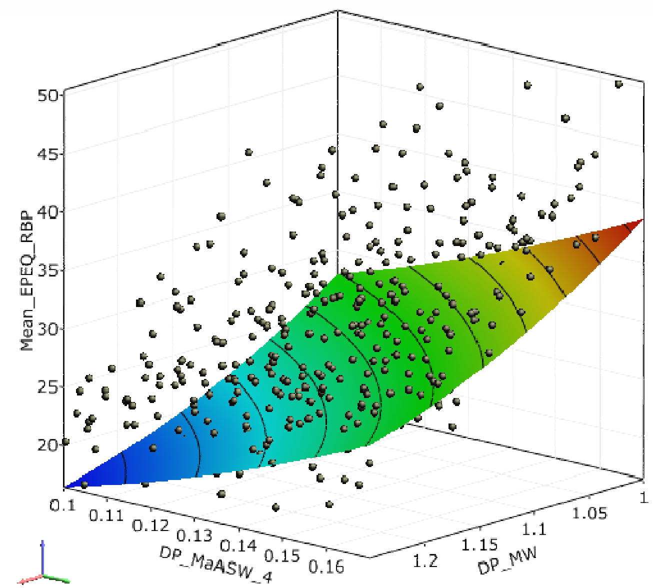
max. plastic strain vs. compliance



max. plastic strain vs. strut width



max. plastic strain vs. strut width & meander width

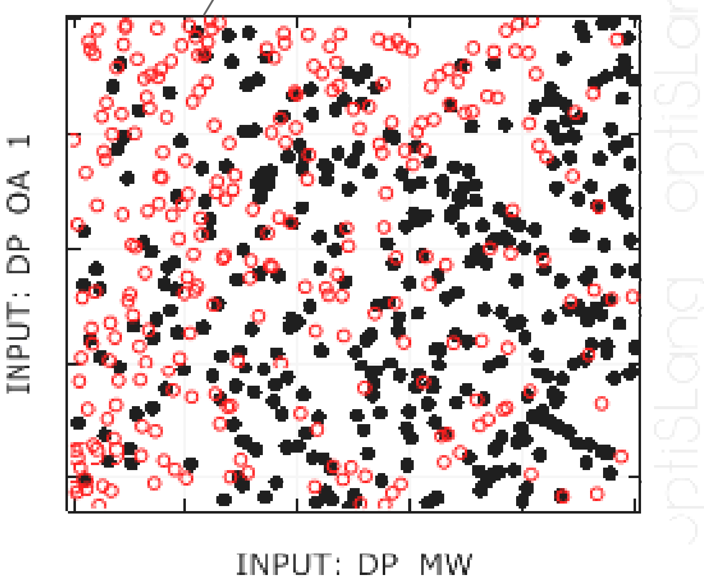


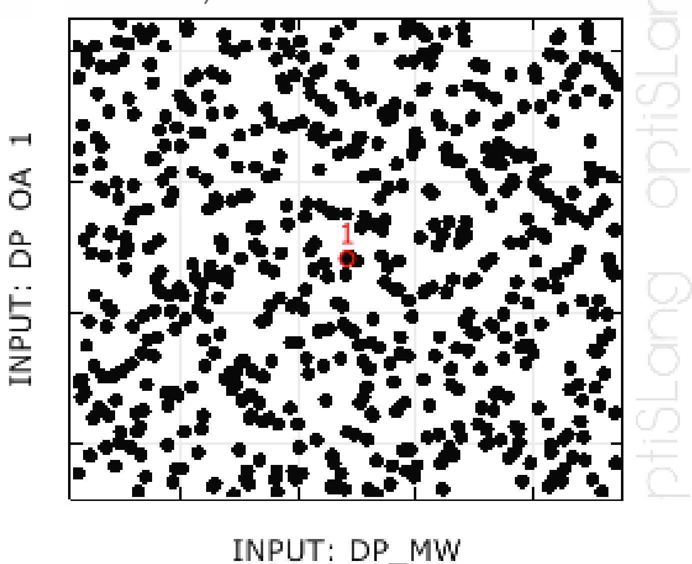
Optimization Strategy

Strategy – optiSLang – DOE

parameter ≈ **±20%**:254 failed

parameter ≈ **±7%**: 0 failed !!!





Optimization Strategy

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Strategy – optiSLang – ARSM

- initial parameter are selected based on COI (DOE)
- 1st loop:
  - design parameters:
    - meander width
    - max. arc strut width (4x)
    - arc radii (4x)
    - radius offset (4)
  - ± 20% parameter range
  - GA/NLPQLP
  - 20 iterations
  - up 10h wall clock time per ARSM loop (300-600 simulations)

Optimization Strategy

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Strategy – optiSLang – ARSM

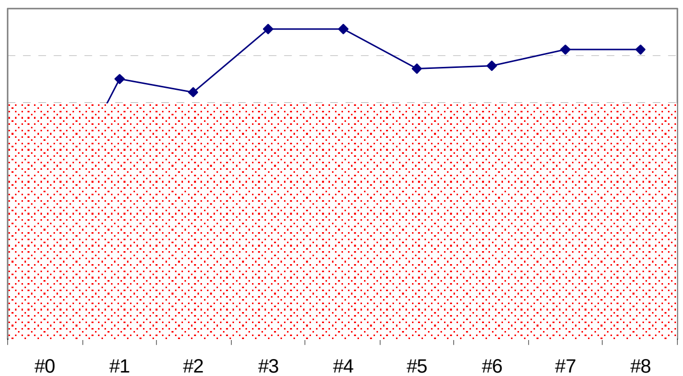
- following loops (up to 8 loops):
  - start design = best design from previous loop
  - design parameters = combination of few initial and new parameters
  - less important variable will be replaced by new ones
  - parameter range will be reduced stepwise down to ± 3%
  - 20-30 iterations

Optimization Strategy

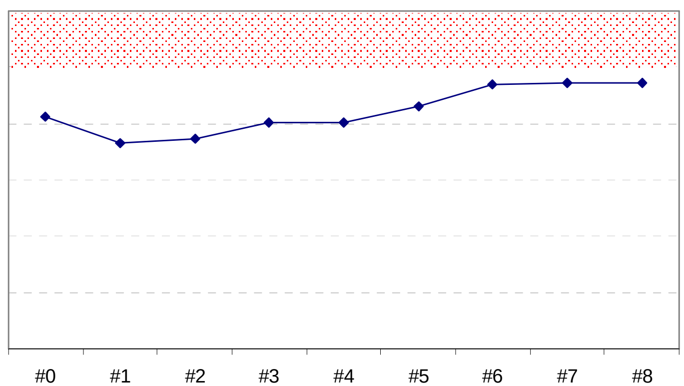
Strategy – optiSLang – Results

Boundary Conditions

Minimum Strut Width

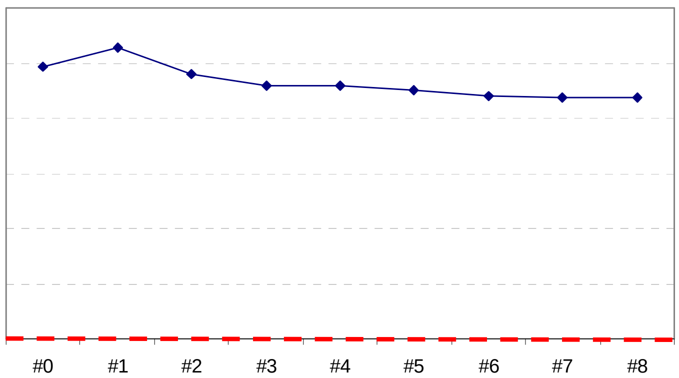


Plastic Strain

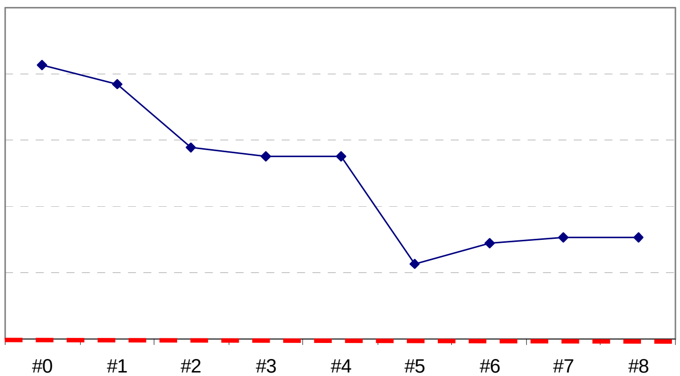


Objective Terms

Radial Compliance



Inhomogeneous strain distribution



Conclusion & Outlook

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optiSLang

- 1 year intense usage & experience of optiSLang at Cortronik Stent Development
- proofed to be very successful and highly effective
- confidence with new tools & algorithms
- new challenges in terms of model generation (stability) & formulation of objective function

- extended usage planned – robustness analyses
  - include geometrical variance (production tolerance)
  - include scatter of material properties (elongation fracture)


Vielen Dank