SCIENCE ▪ PASSION ▪ TECHNOLOGY

TU Graz

NUMERICAL ANALYSIS OF STENT DELIVERY SYSTEMS DURING PRE- AND INTRAOPERATIVE PROCESSES

DYNA MORE

15. DEUTSCHES LS-DYNA FORUM

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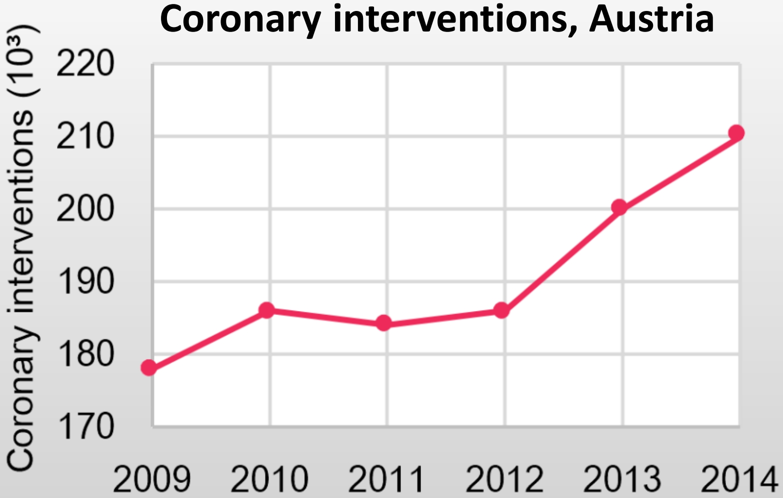
CLINICAL RELEVANCE

Coronary interventions, Austria



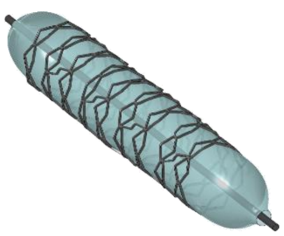
Mühlberger V, Kaltenbach L, Ulmer H. Cardiac catheterization, coronary angiography (CA) and PCI in Austria during the Year 2014. Austrian Journal of Cardiology; (23): 7–12, 2016.

Coronary stent implantation (CSI)

- ❑ Restenosis still 15 – 20% (Bønaa et al. 2016)
- ❑ No improvement in fatality rate by drug eluting stents (DES) (Bønaa *et al.* 2016, Sabate *et al.* 2012, Kaiser *et al.* 2010)
- ❑ Vascular injuries due to high loads as main indicator for intimal/medial thickening.

Stents with lower injury potential via FEA

1. Correlation: **Mechanical response** – **injury severity** – **wall thickening**
   - ❑ Long term *in vitro* experiments
   - ❑ Morphological analysis
   - ❑ Immuno-histological analysis
2. New material damage and growth model
3. FEA of an expanding stent inside an artery.
   - ❑ Three-layer artery model
   - ❑ Stent/balloon catheter model



HYPOTHESIS AND MOTIVATION

Classical approach

STEP 1: Geometry modeling with CAD
STEP 2: Discretization and pre-processing
STEP 3: FEA of stent deployment
- ❑ Explicit solver
- ❑ Simplified balloon models
  - Expanding cylinders
  - Folded cylinders
  - Geometries from micro-CT scans
- ❑ Stent without residual stresses

STEP 4: Post-processing

Improved approach

STEP 1: Geometry modeling with CAD
STEP 2: Discretization and pre-processing

STEP 3: FEA of pre-operative processes
- ❑ **Folded and pleated balloon model**
- ❑ **Crimped stent**

STEP 4: FEA of stent deployment
- ❑ **Implicit solver**

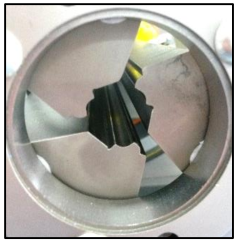
STEP 5: Post-processing

More realistic CSI simulations
- ❑ No dynamic inertia effects (mass scaling)
- ❑ Ideal for quasi-static problems (large time steps)
- ❑ Realistic simulation times

- ❑ Entire and detailed balloon geometry
- ❑ Influence of expansion mechanisms and tapers
- ❑ Stress/strain behavior of the balloon membrane

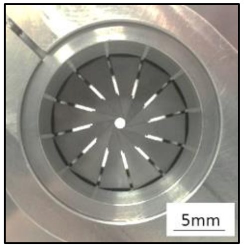
- ❑ Residual stresses / deformations.
- ❑ Deformation depending on crimping blades

Preoperative processes



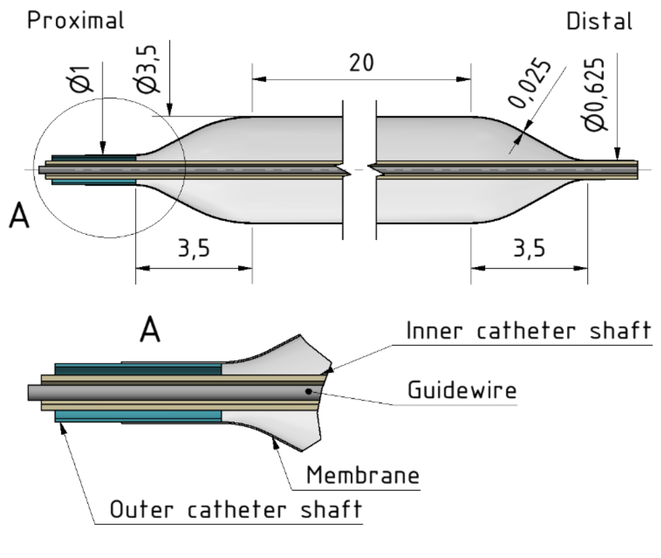
Folding

Pleating



Crimping

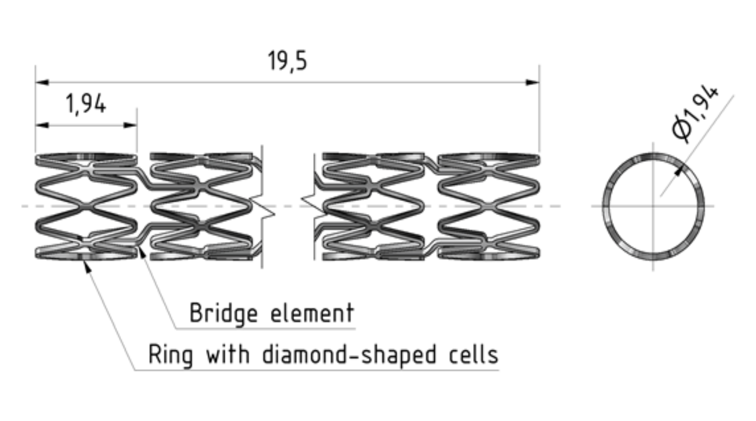
STEP 1: Geometry modeling with CAD



Balloon catheter *Baroonda SDS* (BMT GmbH, Weßlingen)

- Proximal taper attached to outer catheter shaft
- Distal taper attached to inner catheter shaft
- *Grilamid L25* (PA 12) membrane

Density ρ [ton/mm³]	1.010E-09
Elastic modulus E [N/mm²]	1400 (dry) *1100 (cond.)*
Poisson's ratio ν	0.40



Coronary stent *ESPRIT* (concept design)

- 8 Segments, 9 Rings
- 316 LVM stainless steel

Density ρ [ton/mm³]	7.850E-09
Young's modulus E [N/mm²]	2.100E+05
Poisson's ratio ν	0.29

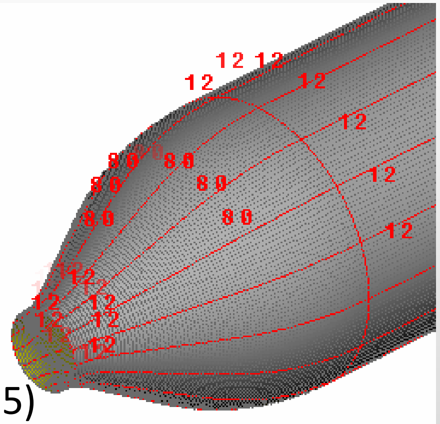
CAD: Computer Aided Design

Performed with **Inventor Professional 2019**, Autodesk, San Rafael, USA

STEP 2: Discretization and pre-processing

Balloon membrane

- Midsurface shell definition
- 97.920 quadrilateral shell elements (CQUAD4)
- Smooth mesh, symmetrical along longitudinal axis
- ELFORM 16, fully integrated shell elements (NIP=5)
- MAT_089, isotropic, plasticity polymer model

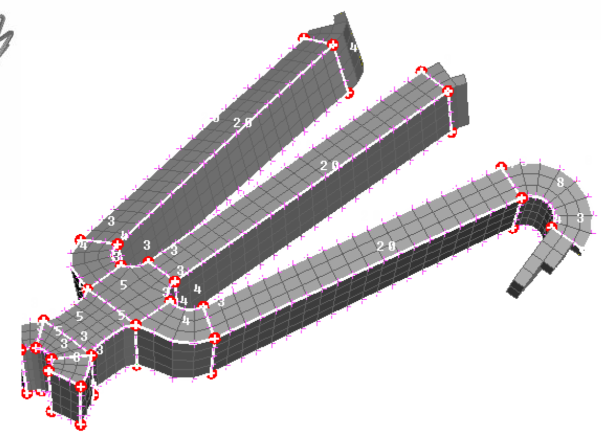


Inner and outer shafts;
folding-/pleating and crimping blades

- Midsurface (shaft) and outer surface (jaws) shell definition
- Quadrilateral shell elements (CQUAD4)
- Rough mesh geometry
- MAT_020, Rigid body definition

Stent

- Solid definition
- 119.680 hexa elements (CHEXA)
- Smooth mesh with focus on connecting and curved segments
- Segment symmetrical arrangement
- Rough element size along straight struts
- ELFORM -1, fully integrated S/R solids
- MAT_024, , elasto-plastic isotropic material



Performed with **ANSA 18.1.0**, Beta CAE Systems, Farmington Hills, USA

IMPLICIT SOLVER smp-d-R10.1 (BRIEF OVERVIEW)

Pros and cons with focus on CSI simulations

+ No dynamic inertia effects (mass scaling)
+ Ideal for quasi-static problems (large time steps)
+ Realistic simulation time

– High demands on elements, materials and contacts
– Case-specific convergence criteria

Convergence criteria (Appendix P)

$$\|\Delta \boldsymbol{x}_k\| < \max\left(\varepsilon_d u_{\max}, \sqrt{\max(\varepsilon_a, 0)}\right)$$

$$\langle \Delta \boldsymbol{x}_k, \boldsymbol{F}_k \rangle < \max(\varepsilon_e e_0, 1000\max(\varepsilon_a, 0))$$
$$e_0 = \langle \Delta \boldsymbol{x}_0, \boldsymbol{F}_0 \rangle$$

$$\|\boldsymbol{F}_k\| < \max(\varepsilon_r f_0, 1000\max(\varepsilon_a, 0))$$
$$f_0 = \|\boldsymbol{F}_0\|$$

k: Iteration step
ε_d, ε_e, ε_r, ε_a: Displ., energy, residual and absolut tol.
$u_{\max}$: Max. attained displacement
$\Delta \boldsymbol{x}_0$: First incremental displacement
$\boldsymbol{F}_0$: Residual vector
f_0: Residual vector norm for implicit step j

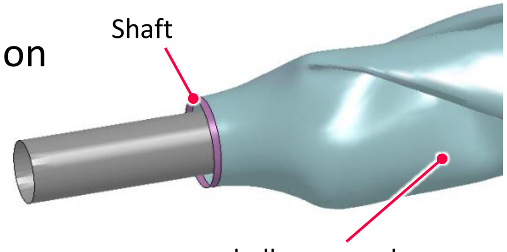
***CONTROL_IMPLICIT_SOLUTION (Default)**

				ε_d	ε_e	ε_r		ε_a
1	NSOLVR	ILIMIT	MAXREF	DCTOL	ECTOL	RCTOL	LSTOL	ABSTOL
	12	11	15	0.001	0.01	1.0E+10	0.9	1.0E-10

RECOMMENDATIONS FOR SIMULATION SETUP

Rigid shafts

- BOUNDARY_SPC for the taper ends led to distortion of the cross section
- CONSTRAINED_EXTRA_NODES_SET to attach tapers to rigid shafts
- Constrained shafts with CON=1 in MAT_RIGID(020)



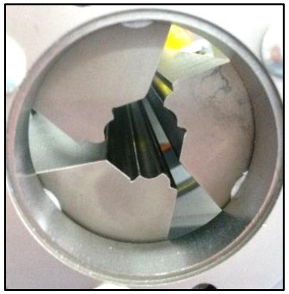
Contact

- Mostly MORTAR contacts (balloon membrane as slave side)
- IGAP=1 (or carefully increased IGAP to stiffen contact)
- For friction set FS=0.2 (stent single surface), FS=0.25 (balloon single surface), FS=0.32 (stent to balloon) and FS=0.2 (jaw to stent)
- Contacts were forced on the initial time step

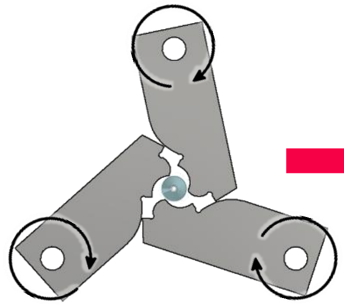
Control

- CONTROL_ACCURACY with IACC=1 and INN=4 for balloon and stent
- CONTROL_IMPLICIT_AUTO for automated and customize DTMAX for capturing fast motions
- For easy problems CONTROL_IMPLICIT_SOLUTION with default values
- For medium problems DCTOL was loosened
- For difficult problems RCTOL=0.01 and ABSTOL=-10 (try and error)

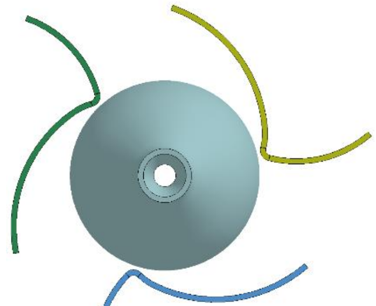
STEP 3: FEA of pre-operative processes - FOLDING



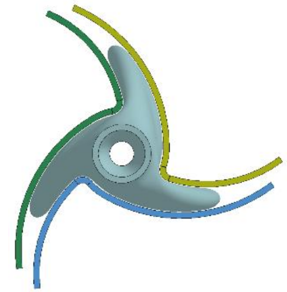
Customized folding device (MSI, Flagstaff, USA)



Folding mechanism with 3 folding blades



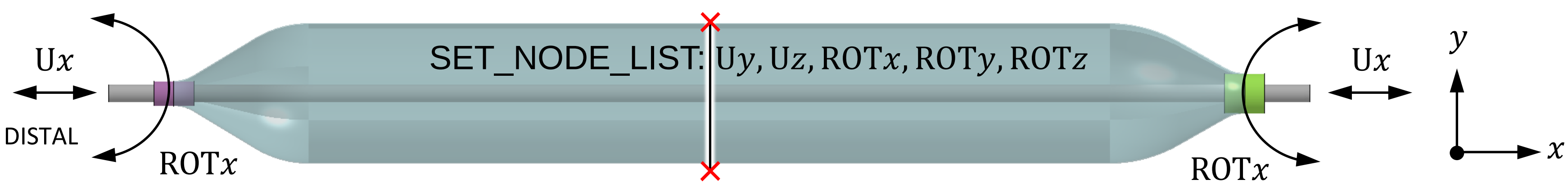
Contact surfaces in starting position



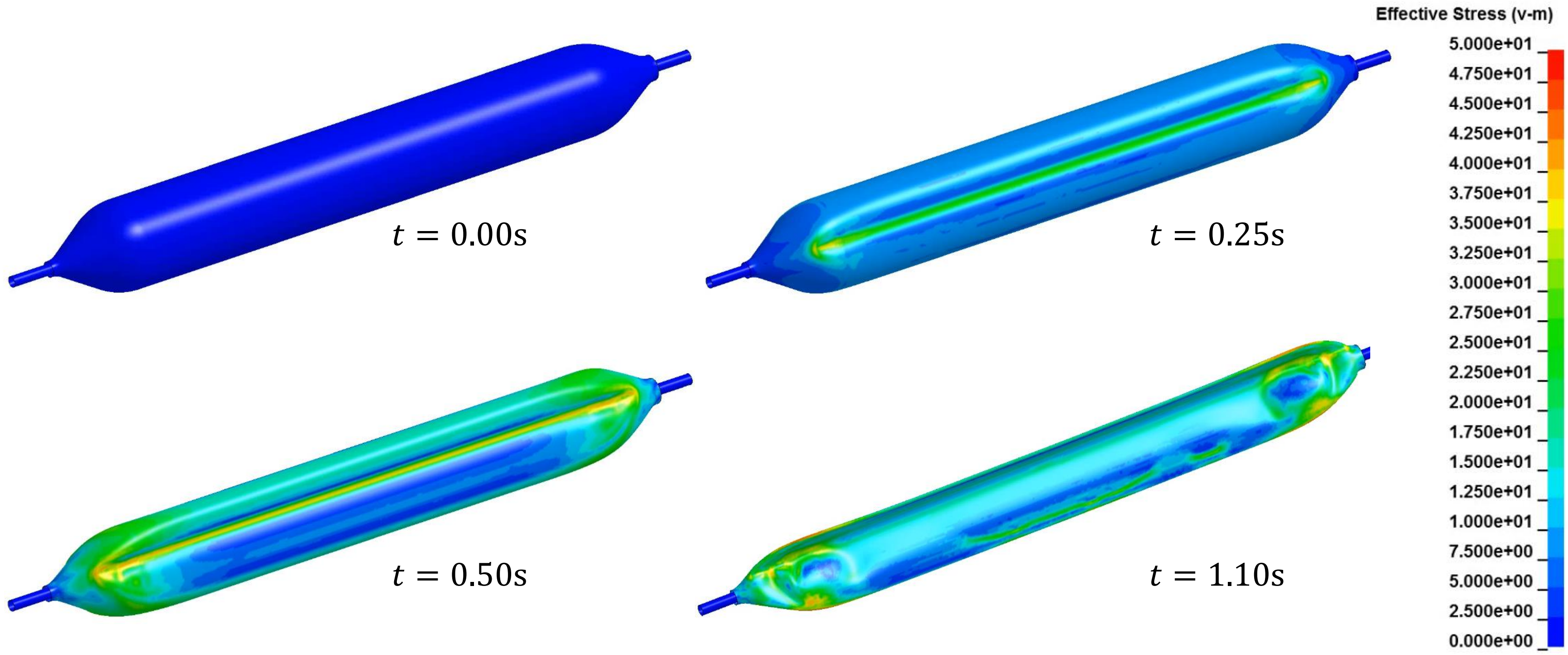
Contact surfaces in end position

Requirements

- ❑ One-to-one blade geometries is crucial for realistic results
- ❑ Contact surfaces rotate around 3 vectors (0 – 0.072rad, PRESCRIBED_MOTION_RIGID)
- ❑ Shafts allow 2 DOFs ($\mathrm{U}x$, $\mathrm{ROT}x$) to prevent membrane buckling (MAT_RIGID, CON1=1)
- ❑ Inner surface of the balloon is pressurized with 0.1 MPa
- ❑ 1x AUTOMATIC_SINCLE_SURFACE_MORTAR (balloon)
- ❑ 4x AUTOMATIC_SURFACE_TO_SURFACE_MORTAR (balloon to tube, 3x blades to balloon, IGAP=1)

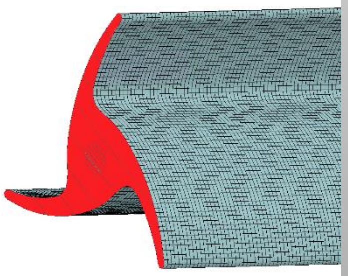


STEP 3: FEA of pre-operative processes - FOLDING

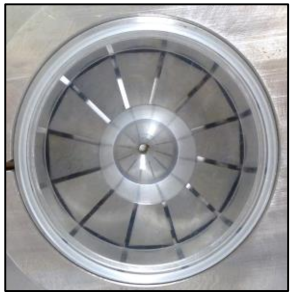


- Simulation time $t = 1.1$s, max. step size $\Delta t = 0{,}02$s
- Membrane pressure (inner surface) $p = -0.1$MPa
- Computational time $t_{com} = 3$h, 38min, i7-6700k CPU, 4.00 GHz, 32 GB

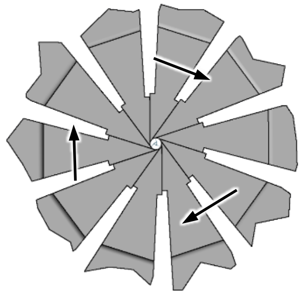
NSOLVR	ILIMIT	MAXREF	DCTOL	ECTOL	RCTOL	LSTOL	ABSTOL
12	5	0	0.0100000	0.0100000	1.000e+10	0.9000000	1.000e-06



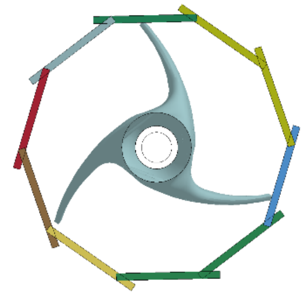
STEP 3: FEA of pre-operative processes - PLEATING



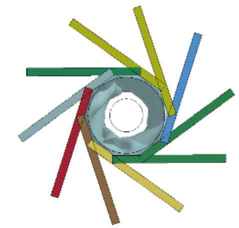
Customized folding device
(MSI, representative photo)



Pleating mechanism,
iris with 10 blades



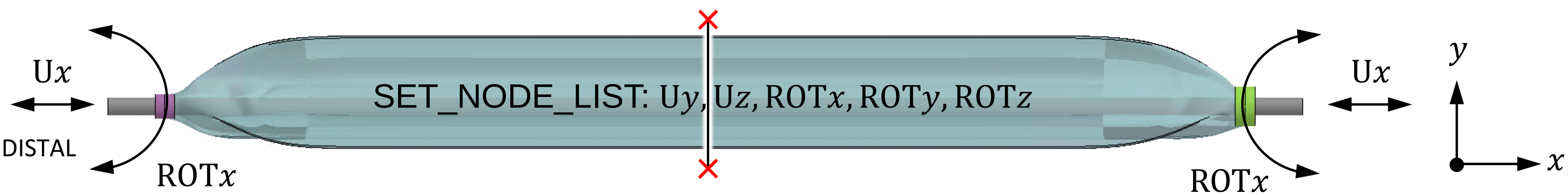
Contact surfaces
in starting position



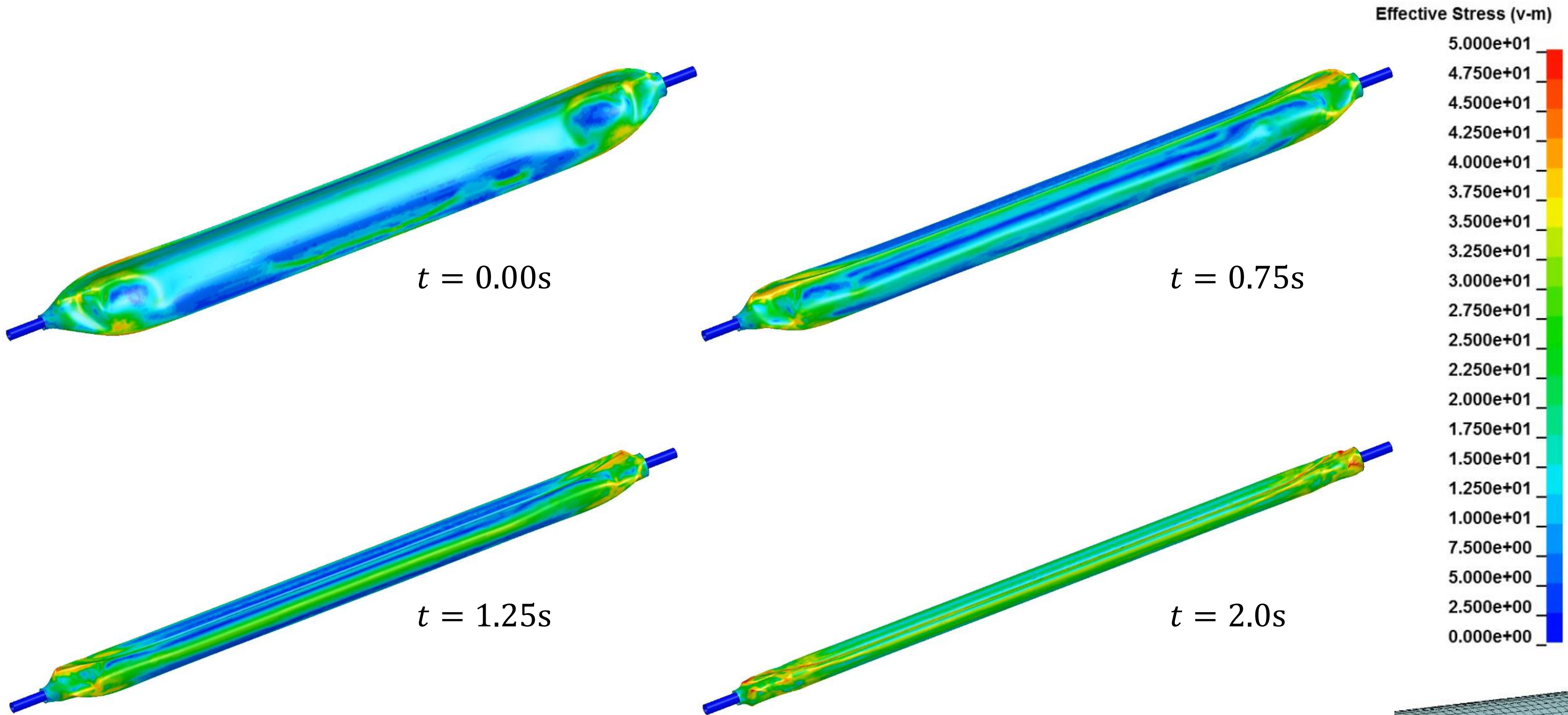
Contact surfaces
in end position

Requirements

- ❑ Contact surfaces rotate around 10 vectors (0 – 0.015 rad, PRESCRIBED_MOTION_RIGID)
- ❑ Shafts allow 2 DOFs ($\mathrm{U}x$, $\mathrm{ROT}x$) to compensate longitudinal elongation
- ❑ 1x AIRBAG_SINGLE_SURFACE (balloon) to allow in-plane bending (MAT_RIGID, CON1=1)
- ❑ 1x AUTO_ONE_WAY_SURFACE_TO_SURFACE (balloon to tube)
- ❑ 10x SURFACE_TO_SURFACE (10x jaws to balloon, SOFT=1, IGAP=1)
- ❑ $d_{\text{start}} = 1{,}77$ mm, $d_{\text{end}} = 0{,}55$ mm

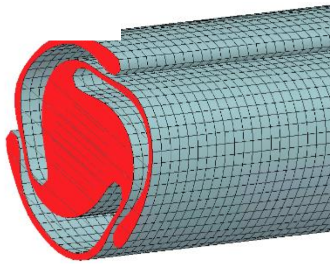


STEP 3: FEA of pre-operative processes - PLEATING

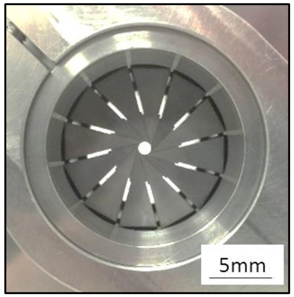


- Simulation time $t = 2.0s.$, max. step size $\Delta t = 0{,}02s$
- Computational time t_{com} =11h, 41min, i7-6700k CPU, 4.00 GHz, 32 GB

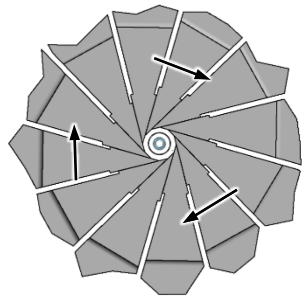
NSOLVR	ILIMIT	MAXREF	DCTOL	ECTOL	RCTOL	LSTOL	ABSTOL
12	5	0	0.0100000	0.0100000	1.000e+10	0.9000000	1.000e-06

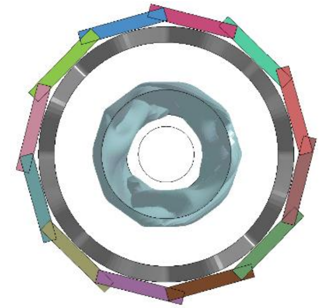


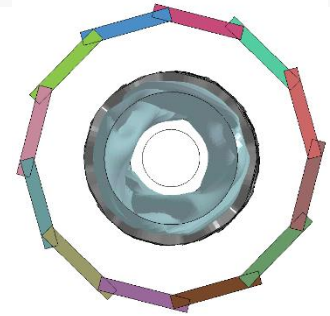
STEP 3: FEA of pre-operative processes - CRIMPING



Prototype, crimper
(OTH Regensburg)

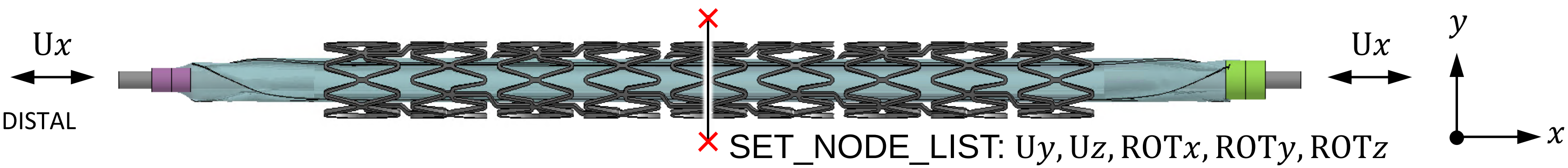

Crimping mechanism,
iris with 12 blades


Contact surfaces
in starting position

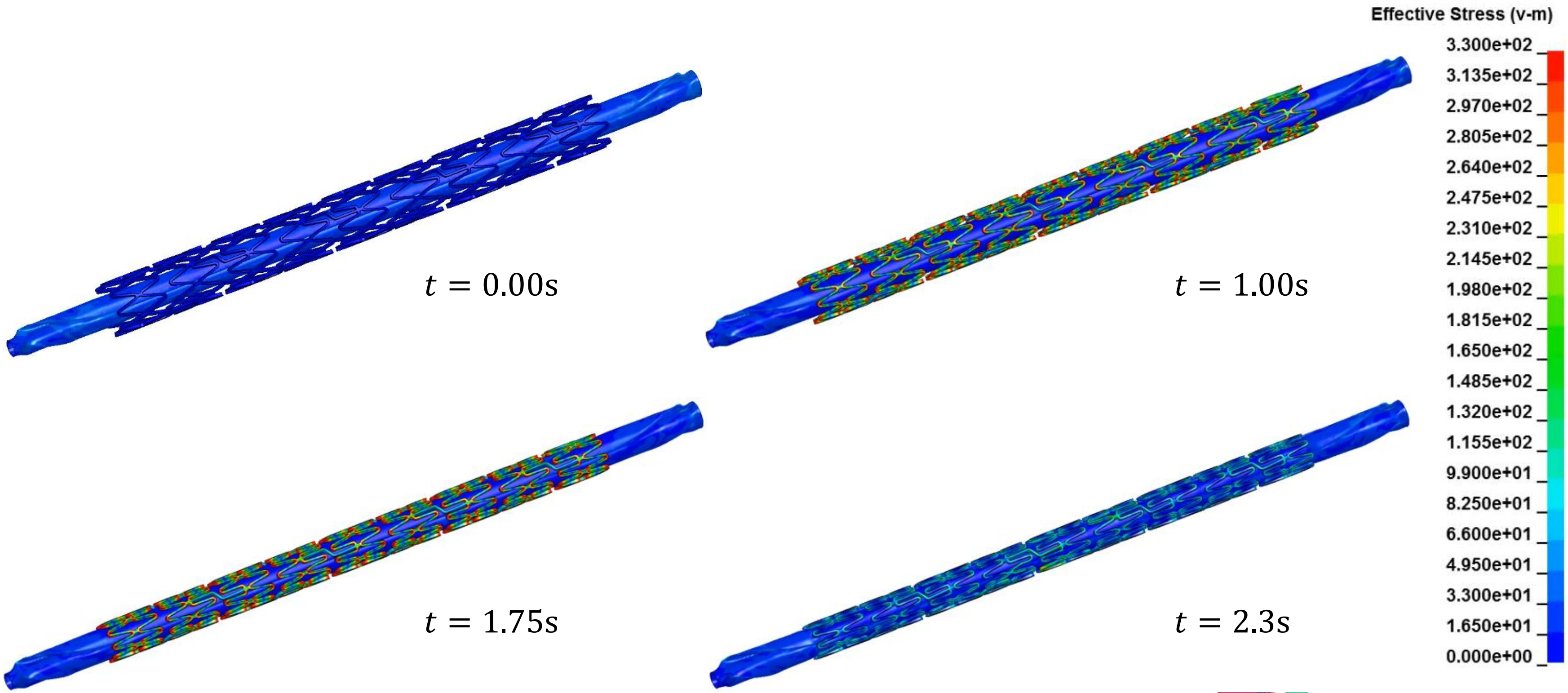

Contact surfaces
in end position

Requirements

- ❑ Contact surfaces rotate around 12 vectors (0 – 0.015 rad, PRESCRIBED_MOTION_RIGID)
- ❑ Both shafts only allow 1 DOF ($\mathrm{U}x$) to compensate longitudinal elongation
- ❑ Very expensive to solve due to initial gap between stent and balloon
- ❑ 2x AUTO_SINGLE_SURFACE_MORTAR (balloon, stent)
- ❑ 14x AUTO_SURFACE_TO_SURFACE_MORTAR (12x blades to balloon, stent to balloon, balloon to tube, IGAP=1)
- ❑ $d_{\mathrm{start}} = 1{,}97$ mm, $d_{\mathrm{end}} = 1{,}10$ mm, $d_{\mathrm{recoil}} = 1{,}26$ mm (experiment: $d_{\mathrm{recoil}} = 1{,}29$mm)

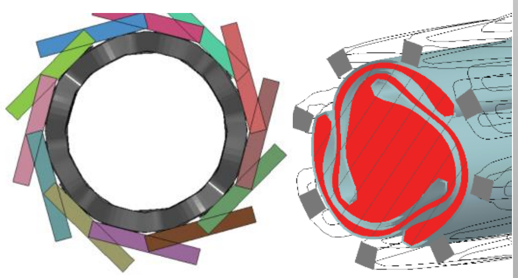


STEP 3: FEA of pre-operative processes - CRIMPING

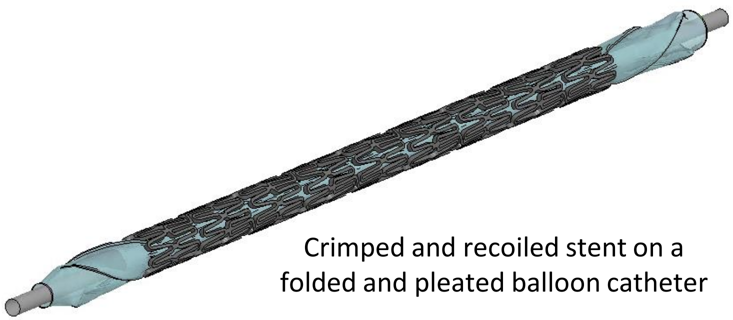


- Simulation time $t = 2.3\text{s}$, recoil at $t = 2.0\text{s}$, max. step size $\Delta t = 0.005\text{s}$
- Computational time t_{com} =10h, 17min, i7-6700k CPU, 4.00 GHz, 32 GB
- Iris geometry and blade number are important for realistic twist

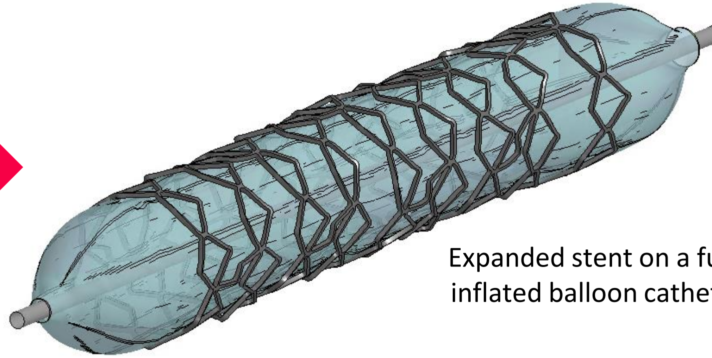
NSOLVR	ILIMIT	MAXREF	DCTOL	ECTOL	RCTOL	LSTOL	ABSTOL
12	11	15	1.000e+07	1.000e+07	0.0100000	0.9000000	-10.0000000



STEP 4: FEA of stent DEPLOYMENT



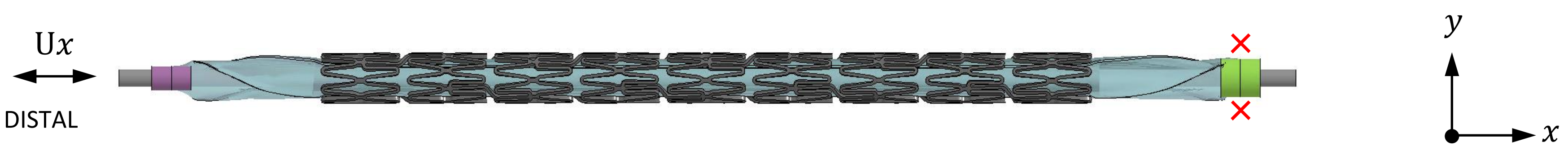
Crimped and recoiled stent on a folded and pleated balloon catheter



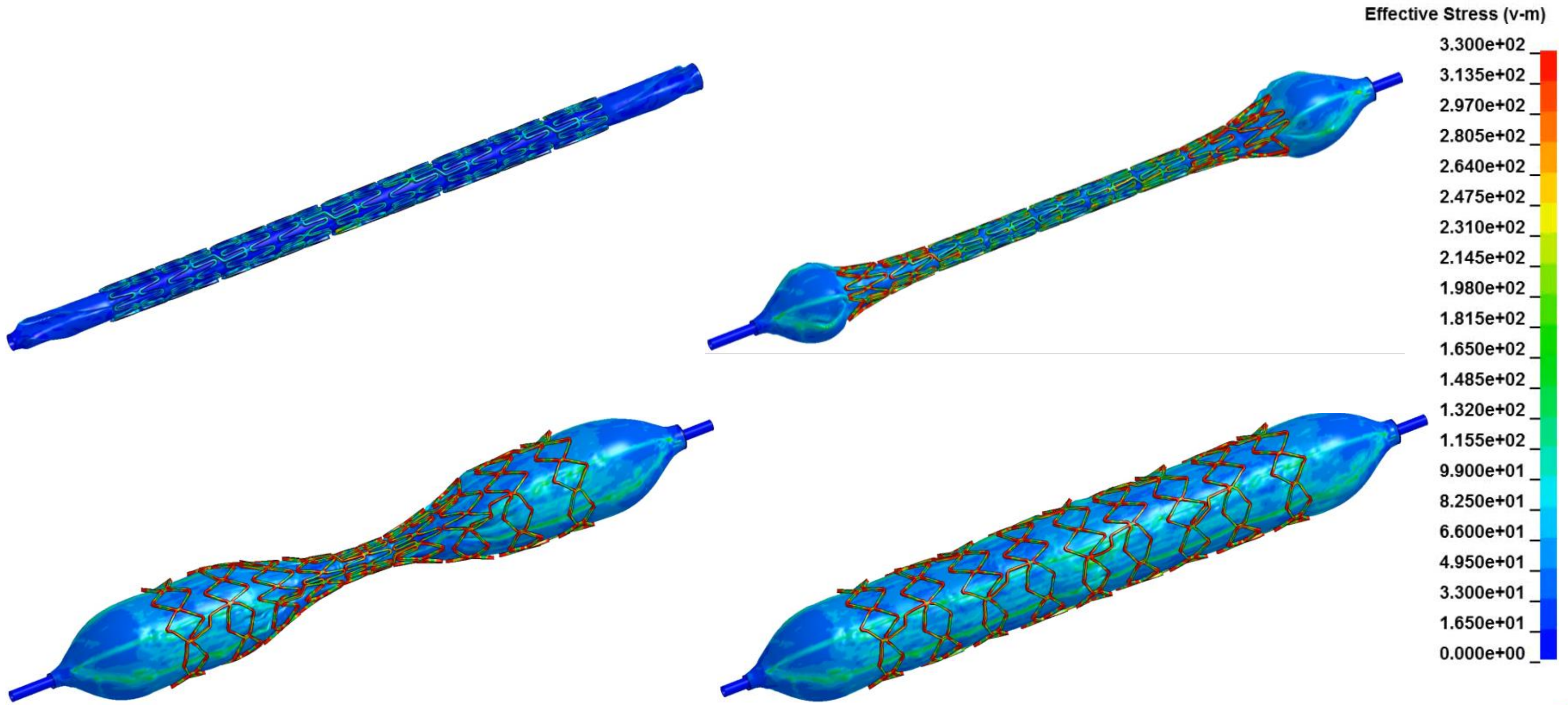
Expanded stent on a fully inflated balloon catheter

Requirements

- ❑ Only distal shaft allows 1 DOF ($\mathrm{U}x$) to demonstrate stent rotation
- ❑ Expensive to solve due to sudden expansion and high deformations
- ❑ 1x AUTO_SINGLE_SURFACE_MORTAR (balloon). No single surface contact for stent
- ❑ 2x AUTO_SURFACE_TO_SURFACE_MORTAR (stent to balloon, balloon to tube, IGAP=1)
- ❑ $d_{\text{start}} = 1{,}26$ mm, $d_{\text{end}} = 3{,}67$ mm (experiment: $d_{\text{end}} = 3{,}65$ mm)

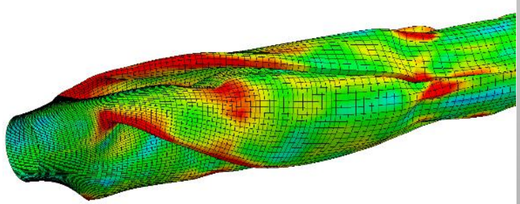


STEP 4: FEA of stent deployment



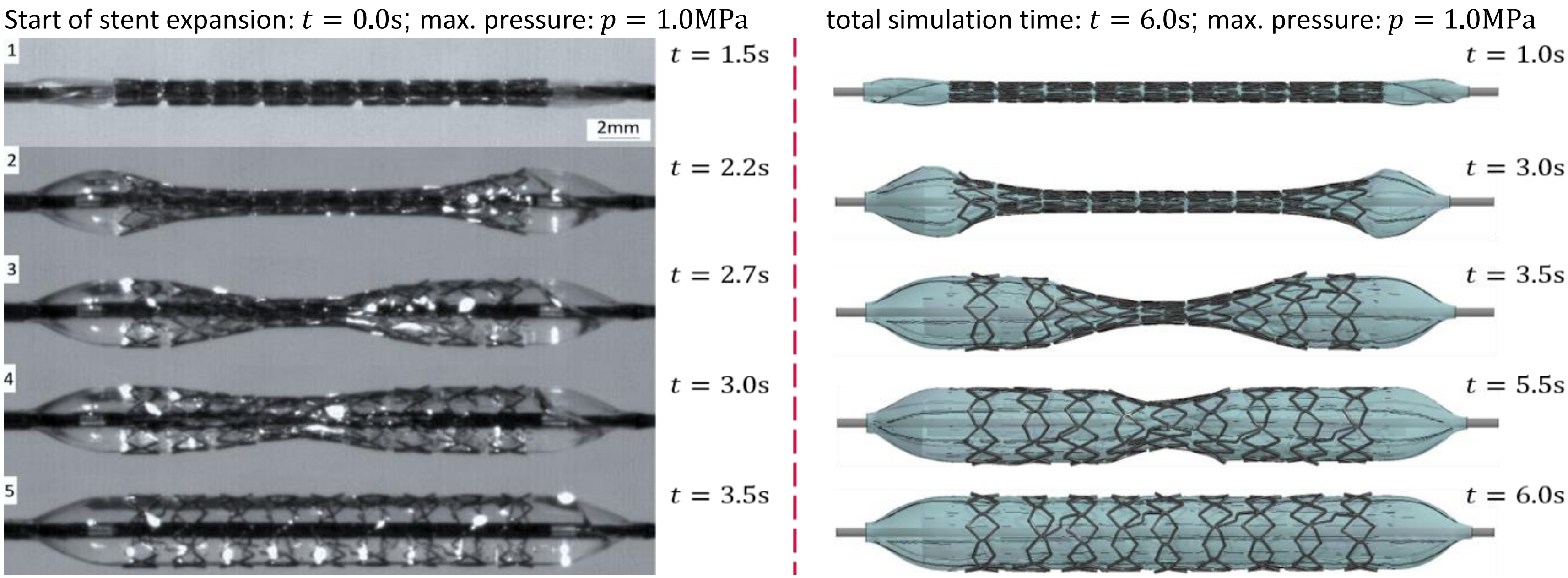
- Simulation time $t = 6s$, max. step size $\Delta t = 0.02s$
- Computational time t_{com} =2h, 37min, i7-6700k CPU, 4.00 GHz, 32 GB

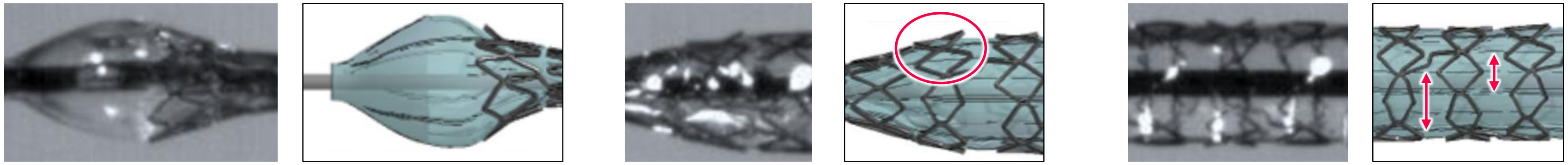
NSOLVR	ILIMIT	MAXREF	DCTOL	ECTOL	RCTOL	LSTOL	ABSTOL
12	11	15	1.000e+07	1.000e+07	0.0100000	0.9000000	-10.0000000



Residual stresses of the distal taper ($t = 0.0$s), fringe range 0 – 50 MPa

VALIDATION





Dogboning

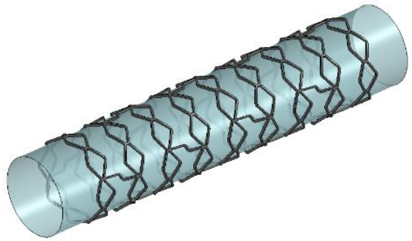
Segment bending

Asymmetrical expansion

- ❑ Very satisfying agreement of geometries and expansion mechanisms
- ❑ Details, such as dogboning, segment bending and asymmetrical segment expansion
- ❑ A realistic pressure/time behavior is difficult to replicate due to air pockets, sudden volume expansion and viscous fluid flow (contrast medium solution)

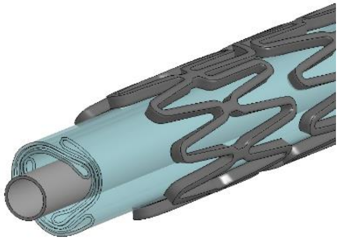
COMPARISON WITH CLASSIC APPROACHES

Expanding cylinder



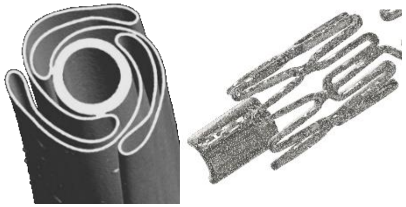
- ↗ Timesaving.
- → Stress/strain behavior
- ↘ Stress/strain distribution
- ↘ Residual stresses / deformations
- ↘ Inflation mechanism
- ↘ Taper geometry
- ↘ Asymmetrical stent expansion
- ↘ Asymmetrical segment expansion

Folded cylinder



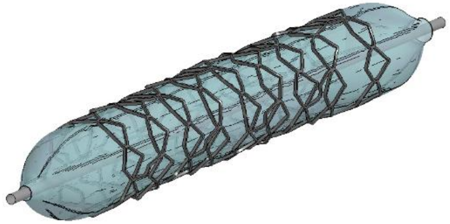
- ↗ Asymmetrical segment expansion
- → Stress/strain behavior of central stent segments
- → Central inflation mechanism
- ↘ Residual stresses / deformations
- ↘ Taper geometry
- ↘ Dimensions of cross section needed
- ↘ Asymmetrical stent expansion

Geometry taken from micro-CT scans



- ↗ Stress/strain behavior
- ↗ Asymmetrical segment expansion
- ↗ Inflation mechanism
- ↗ Taper geometry
- ↘ Residual stresses / deformations
- ↘ Time consuming
- ↘ Difficult scanning / pre-processing
- ↘ Asymmetrical stent expansion

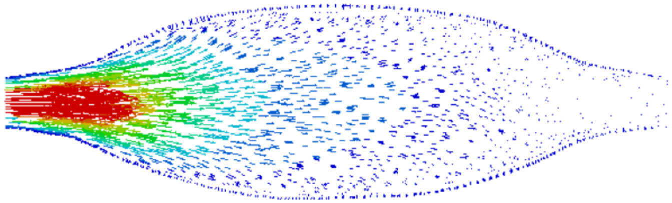
Folded and pleated balloon with crimped stent



- ↗ Residual stresses / deformations
- ↗ Stress/strain behavior
- ↗ Asymmetrical segment expansion
- ↗ Inflation mechanism
- ↗ Taper geometry
- ↘ Clear information about pre-operative processes needed
- ↘ Asymmetrical stent expansion

FUTURE ASPECTS – WORK IN PROGRESS

Expansion caused by volume flow



- ❑ Realistic pressure/time behavior
- ❑ Asymmetrical stent expansion.
- ❑ LS-DEM (Discrete Element Method)
- ❑ LS-ICFD (Incompressible Computational Fluid Dynamics).

Anisotropic and thermomechanical material model for balloon membrane

- ❑ Heated folding / pleating blades.
- ❑ Injection blow molding causes an anisotropic material behavior.

More precise material damage and growth model for coronary arteries

- ❑ *In vitro* simulation of CSI.
- ❑ Correlation of mechanical response, structural damage mechanism and cell proliferation.
- ❑ Multi-scale material damage and growth modeling.
- ❑ FEA of stent deployment in long-term with a three-layer artery model.

Isotropic-kinematic hardening model

→ *Oberhofer G. et al: Numerical Analysis of the Balloon Dilatation Process Using the Explicit Finite Element Method for the Optimization of a Stent Geometry, LS-Dyna Forum 2006*

ACKNOWLEDGMENT / FURTHER READING

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Further reading

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