The Effects of Nitinol Stent Oversizing in Patients Undergoing Femoro-popliteal Artery Revascularization

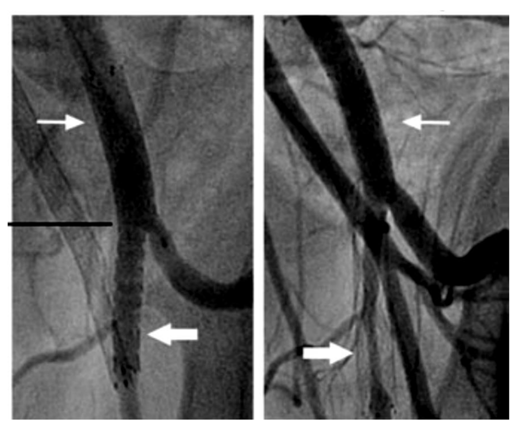
A Finite Element Study

UNIVERSITÄT BERN

Can Gökgöl*, Nicolas Diehm**, Philippe Büchler*

* Institute for Surgical Technology and Biomechanics, Computational Biomechanics, University of Bern, Switzerland
** Clinical and Interventional Angiology, Kantonsspital Aarau, Switzerland

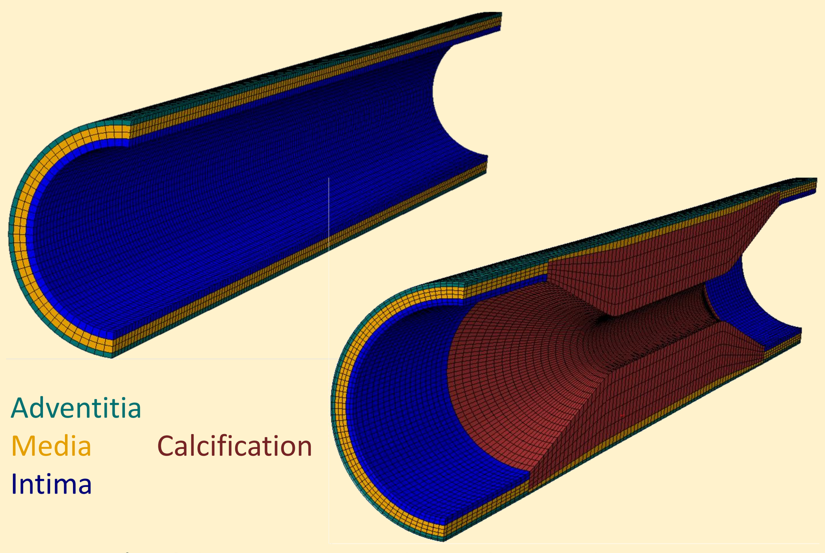
Introduction



Nitinol stent oversizing in peripheral arteries is frequently performed by clinicians to ensure a desirable lumen gain and prevent stent migration. However, the increased radial force exerted onto the artery walls by the stents could lead to significant arterial damage and restenosis. With clinical studies reporting contradictory findings[1,2] on the subject and numerical studies being performed exclusively with balloon-expandable stents and on non-calcified arterial models, the mechanical impact of stent oversizing remains poorly understood. Therefore, the objective of this study was to quantify the effects of gradual stent oversizing in **calcified** and **non-calcified** peripheral arteries.

Arterial Models, Plaque Configuration & Self-Expandable Nitinol Stents

\> A clinically relevant level of Peripheral Arterial Disease
- Diameter of the healthy segment: 5mm
- 70 – 75% stenosis in the diseased section



*Only 1/2 of the arteries are shown for visualization purposes

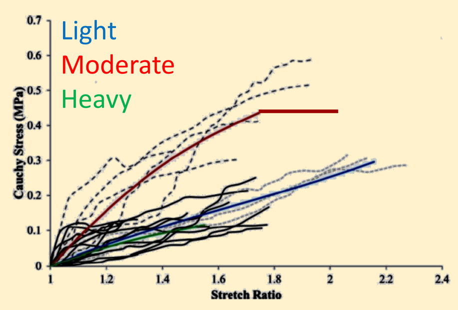
\> Individual tissues represented with an anisotropic, hyperelastic (HGO) model[3]
- Includes 2 families of collagen fibers & fiber dispersions for each layer

$$U = C_{10}(\bar{I}_1 - 3) + \frac{1}{D}\left(\frac{J^2 - 1}{2} - \ln J\right) + \frac{k_1}{2k_2}\sum_{\alpha=1}^{N}\left(\exp(k_2(I_{4(\alpha)} - 1)^2) - 1\right)$$

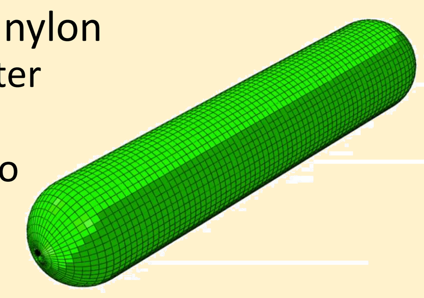
Isotropic hyperelastic matrix — Volumetric change — Fiber orientation

\> Plaque is modeled as isotropic, hyperelastic to represent a moderate calcification[4]

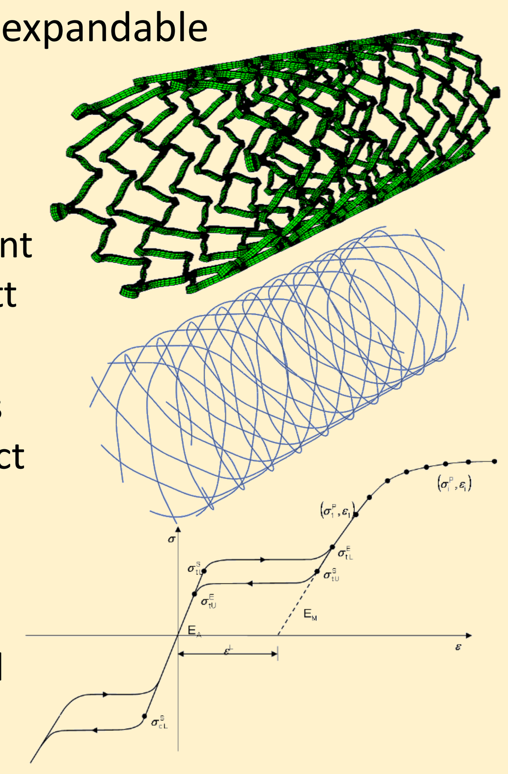
\> A perfect plasticity of failure at 400 kPa



\> Angioplasty balloon is modeled as a semi-compliant nylon
- Nominal diameter of 5 mm
- Depressurized to its folded config.

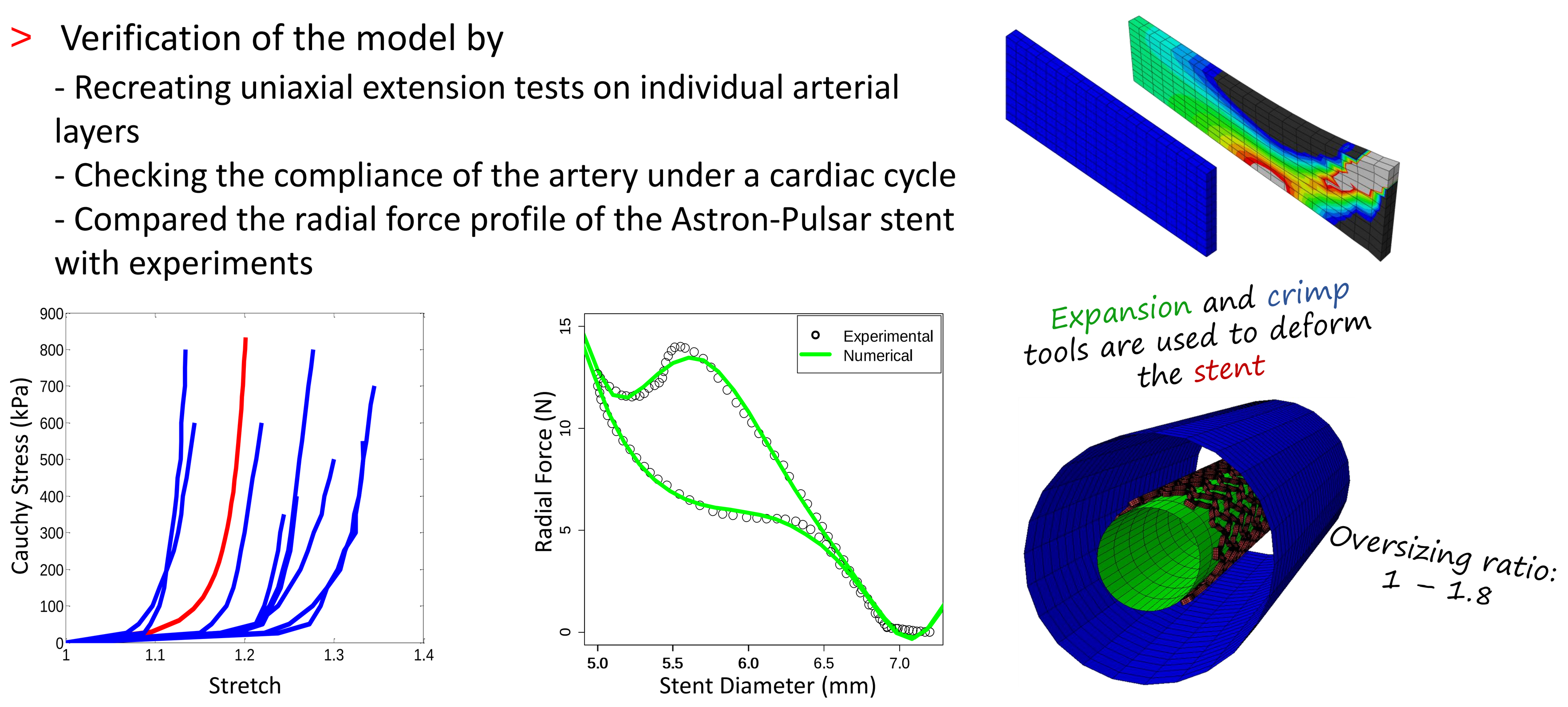


\> Two different, self-expandable stent models
- Astron-Pulsar (Biotronik AG)
- A braided wire-stent Supera stent (Abbott Vascular)
- Two rigid cylinders around the stents act as expansion and crimp tools
- Modeled with the super-elastic Nitinol

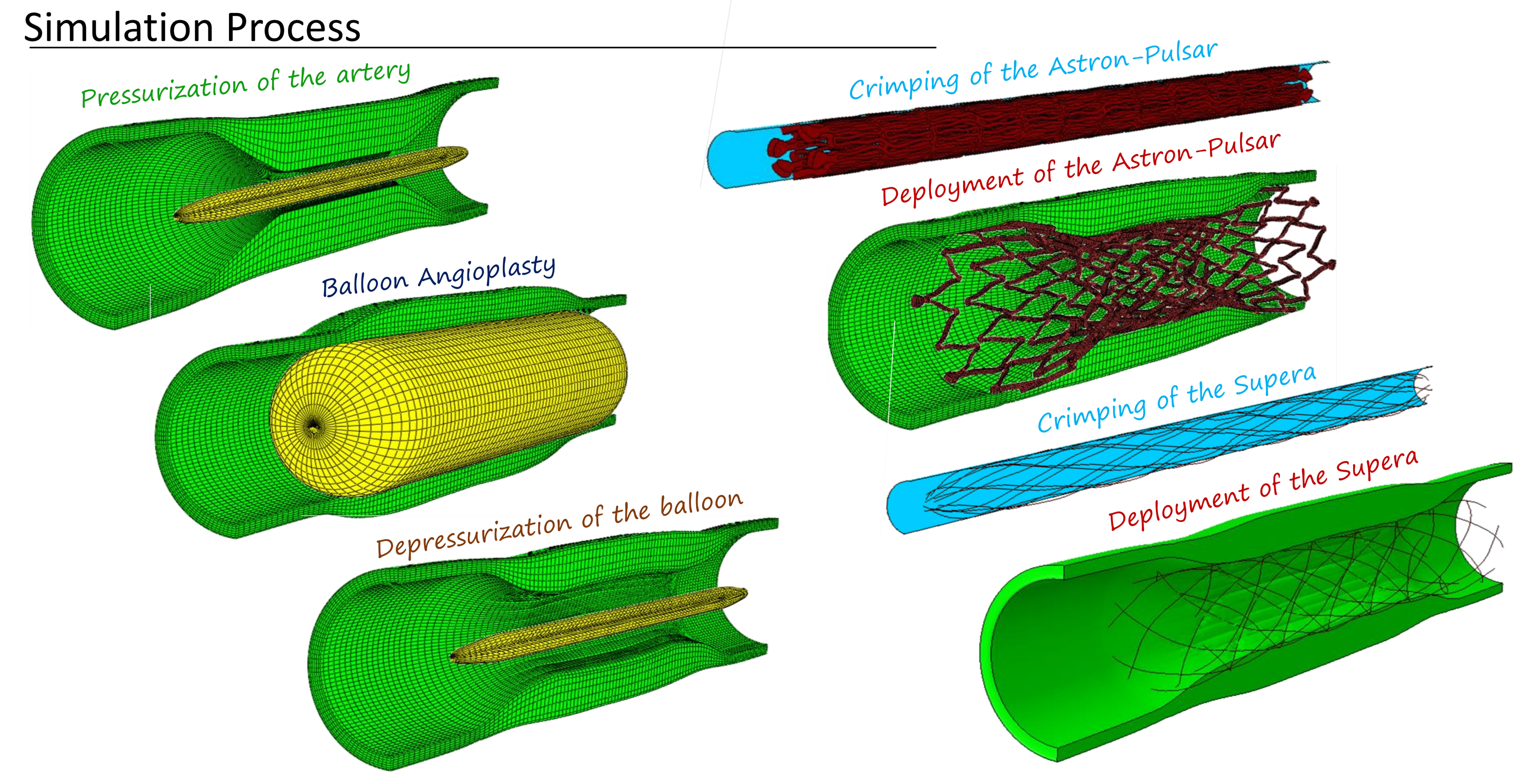


Balloon Angioplasty & Stent Implantation[5]

\> Verification of the model by
- Recreating uniaxial extension tests on individual arterial layers
- Checking the compliance of the artery under a cardiac cycle
- Compared the radial force profile of the Astron-Pulsar stent with experiments

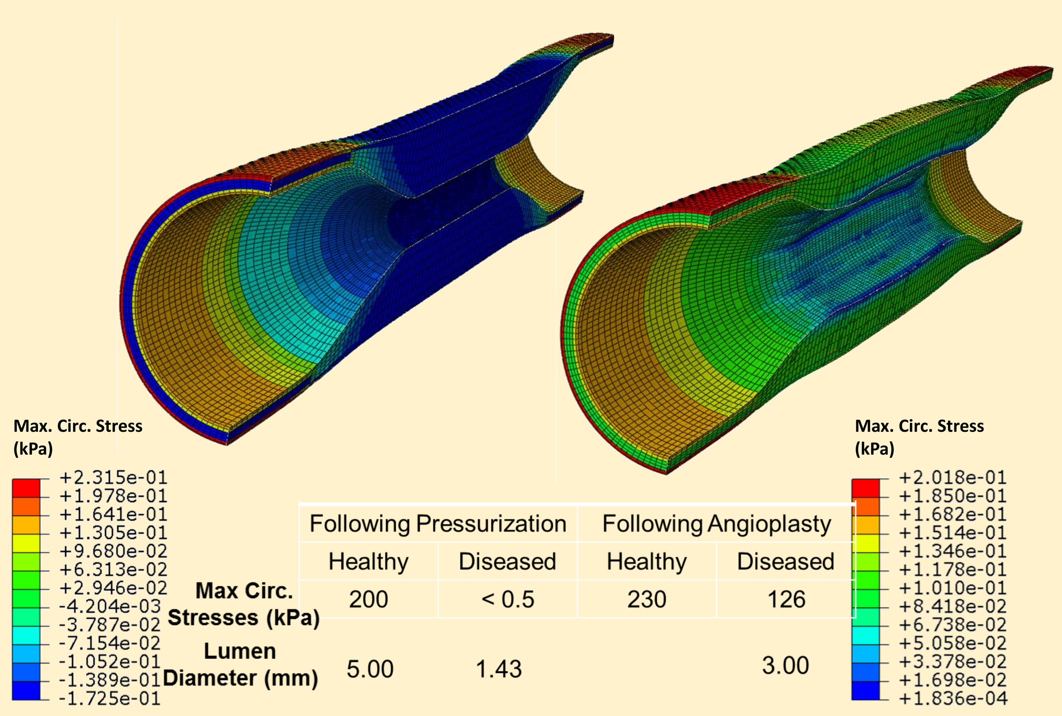


Simulation Process



Results

The Effect of Balloon Angioplasty

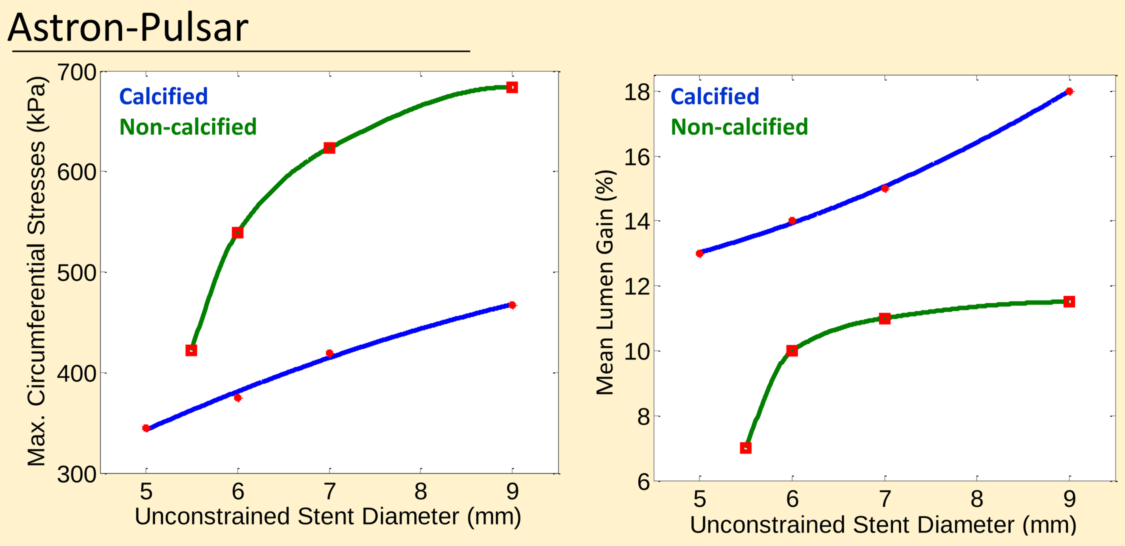


	Following Pressurization		Following Angioplasty	
	Healthy	Diseased	Healthy	Diseased
Max Circ. Stresses (kPa)	200	< 0.5	230	126
Lumen Diameter (mm)	5.00	1.43		3.00

Angioplasty only partially successful

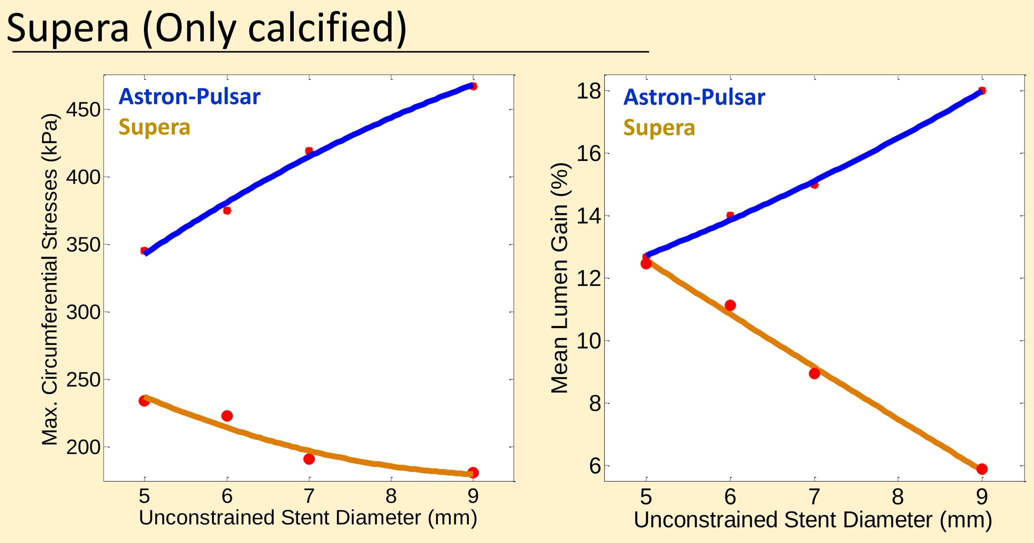
Nitinol Stent Oversizing

Astron-Pulsar



	Non-calcified		Calcified	
	5.5 to 6mm	5.5 to 9 mm	5 to 6 mm	5 to 9 mm
Stress Increase (%)	30	62	9	36
Lumen Gain (%)	3	4	1	5

Supera (Only calcified)



	Astron-Pulsar				Supera			
Unconstr. Stent Dia. (mm)	5	6	7	9	5	6	7	9
Max Circ. Str. (kPa)	345	375	419	467	234	223	191	181
Mean Lumen (mm)	3.38	3.42	3.45	3.54	3.37	3.33	3.27	3.18

Discussion & Conclusion

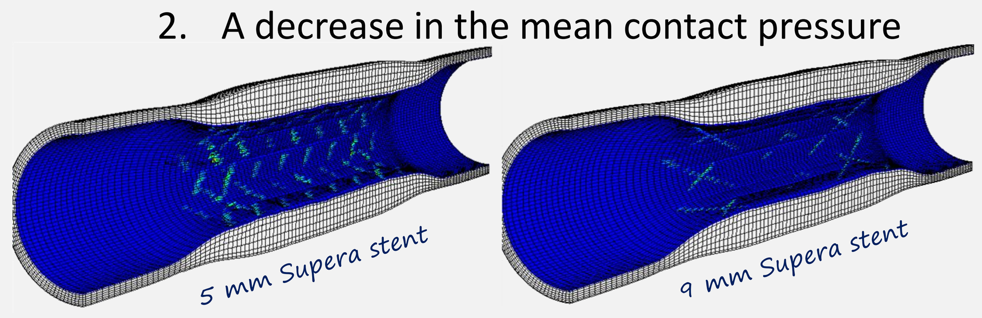
\> Nitinol stent oversizing in *non-calcified* arteries induce an important increase in arterial stresses.

\> *Calcified* arteries are more tolerant towards stent oversizing.
- Depends on the success of the angioplasty.
- The plaque, if partially cracked, acts as a protective layer between the stent and the non-fibrotic layers.

\> Regardless of the presence of a calcified tissue, oversizing provides limited lumen gain.

\> The effects of oversizing in calcified arteries are highly dependent on the stent design.
- In contrast to the Astron-Pulsar, the preliminary simulations with the Supera stent showed **decreasing** lumen gain and arterial wall stresses with increased oversizing.

- For the Supera stent, increased oversizing leads to
  1. A more sparse contact pressure distribution along the length of the calcified segment
  2. A decrease in the mean contact pressure



\> Nitinol stent oversizing is not a risk-free procedure.

\> To avoid creating conditions for restenosis, Nitinol stents should be allowed to contribute to a late lumen gain.

Limitations

\> Both the material parameters and the deployment procedure defined for the Supera stent has been adapted from the Astron-Pulsar.

\> The failure of the plaque is only defined by a perfect plasticity.
- Other techniques, such as stress softening, should also be considered (either on their own or in combination with other methods).

\> Once deployed, the stents were not post-dilated.

References

[1] Saguner et al. 2012. *Cardiovasc. Intervent. Radiol.*
[2] Piamsomboon et al. 1998. *Cath. Cardiovasc. Diagnosis*
[3] Gasser et al. 2006. *J. R. Soc. Interface.*
[4] Cunnane et al. 2014. *Acta Biomaterialia*
[5] Gokgol et al. 2015. *Annals of Biomed. Eng.*