Effects of Balloon Overhang on Stented Arteries

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Background

- The degree of stent endflare has been theorized as a causitive factor in increased levels of neointimal hyperplasia
- Degree of endflare cannot be accurately measured except by *in-vivo* studies due to the presence of the surrounding artery
- The numerical methods described in this presentation provide a method to quantantatively analyze the effects of stent geometries on endflare without expensive *in-vivo* studies

Motivation of Study

- Determine the effect of balloon overhang on the inflation dynamics of the balloon/stent/artery system
- Investigate if the degree of balloon overhang has a direct impact on the magnitude of arterial stresses and vascular injury at the end of stent expansion

Previous Work in Area

- Stent Inflation Studies with no Balloon Dynamics
  - Lally, C., Dolan, Fl, and Prendergast, P.J., Cardiovascular stent design and vessel stresses: a finite element analysis, *J. Biomechanics*, 38, pp. 1574-1581, 2005.
  - F.Auricchio, M.Di Loreto, E.Sacco, Finite element analysis of a stenotic artery revascularization through stent insertion, Computer Methods in Biomechanics and Biomedical Engineering vol. 4, pg. 249-263, 2001
  - Migliavacca F, Petrini L, Colombo M et al. Mechanical behavior of coronary stents investigated through the finite element method. Journal of Biomechanics 2002; 35:803-811.
- Balloon Dynamics with no Artery
  - Mortier P., De Beule M., Carlier S.G., Van Impe R., Verhegghe B., Verdonck P., Numerical study of non-uniform balloon-expandable stent deployment,

Introduction

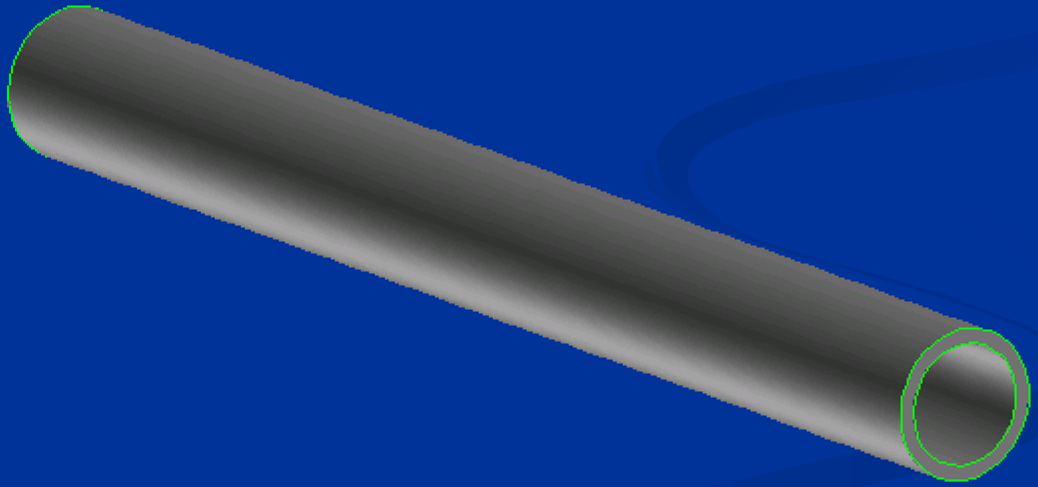
- This model presents a method for simulating the balloon stent expansion, and artery using full-contact nonlinear algorithms.
- Assess the effects of length mismatch on stent expansion characteristics and arterial stresses

Geometry Creation

- Three Main Components
  - Artery
  - Stent
  - Balloon
- Full Scale Model

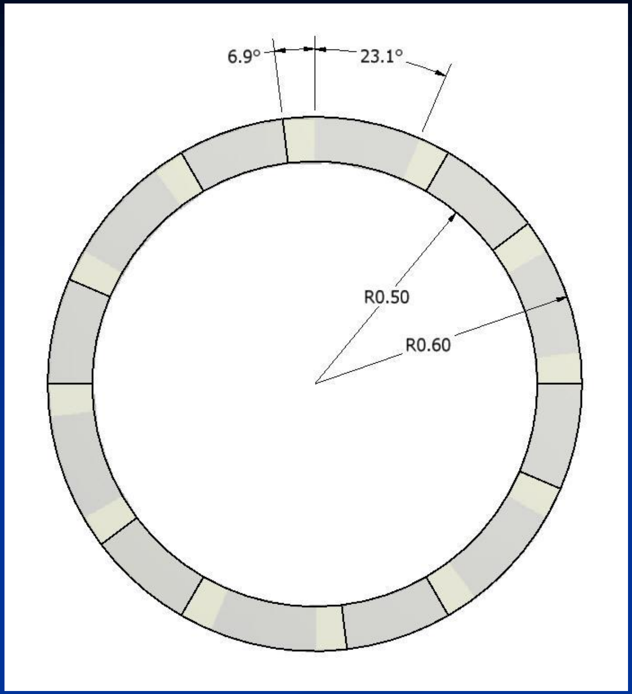
Coronary Artery

- Length: 30 mm
- Inside Diameter: 2.8 mm
- Thickness: 0.3 mm

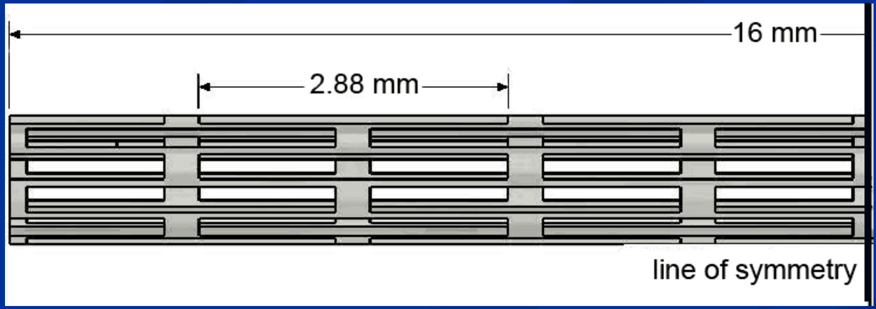


Stent

- Length: 16 mm
- Inside Diameter: 1 mm
- Thickness: 0.1 mm
- 5 slots in longitudinal direction
- 12 slots in circumferential direction



End View of Stent

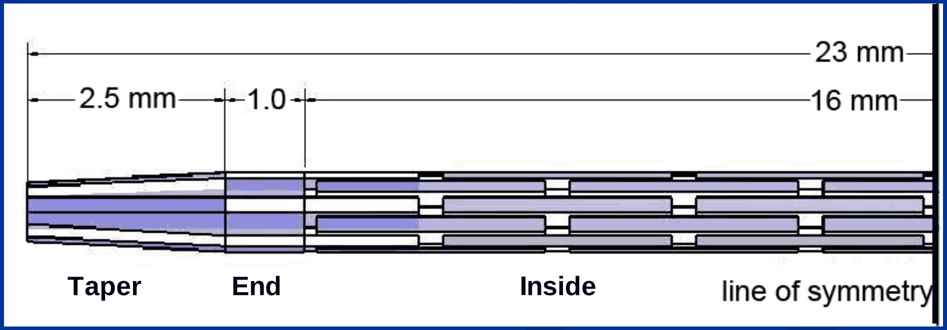


Side View of Stent

Balloon

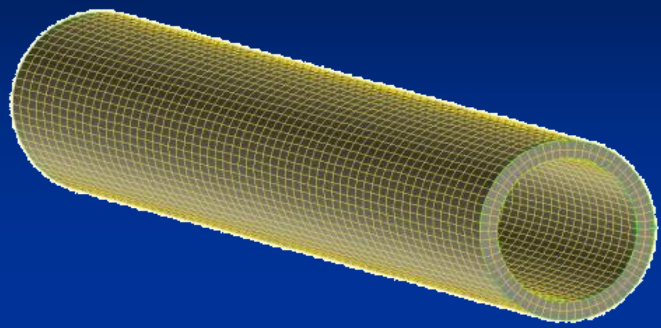
- Length: 23 mm - 22 mm
  - Inside: 16 mm
  - End (Overhang): 2 mm - 1 mm
  - Taper: 5 mm
- Unfolded state
- Assumed to be in contact with the stent

Is our balloon low-compliant, semicompliant, or compliant?

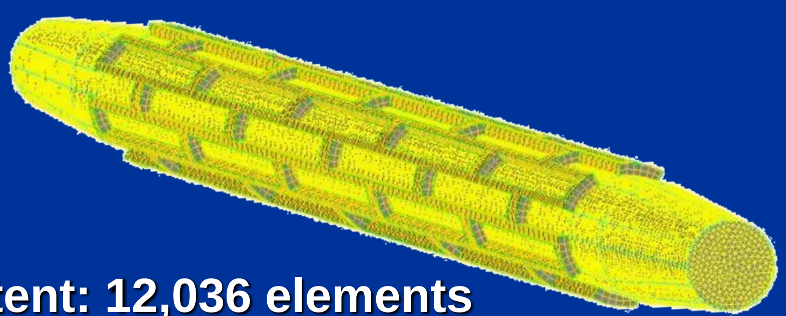


Side View of Balloon (2mm overhang)

Mesh



Artery: 7,680 elements



Stent: 12,036 elements

2mm Balloon: 54,456 elements

1mm Balloon: 51,616 elements

Artery:

Hexahedral Elements

Average element size: 0.5 mm x 0.5 mm x 0.15 mm

Stent:

Hexahedral Elements

Average element size: 0.05 mm x 0.05 mm x 0.05 mm

Balloon:

Triangular Shell Elements

Average element size: 0.025 mm x 0.04 mm

Finite Element Analysis

- Artery
  - Element type: Solid185
  - Characteristics of Element: eight nodes, large deflections and hyperelasticity capabilities (7,680 elements)
  - Constraints: no rotation, axially constrained on ends
- Stent
  - Element type: Solid45
  - Characteristics of Element: eight nodes, large deflections and plasticity capabilities (12,036 elements)
  - Constraints: no rotation, internally applied pressure
- Balloon
  - Element type: Shell43
  - Characteristics of Element: capable of modeling shell structures and have large deflection and plasticity capabilities (54,456 - 51,616 elements)
  - Constraints: no rotation, internally applied pressure

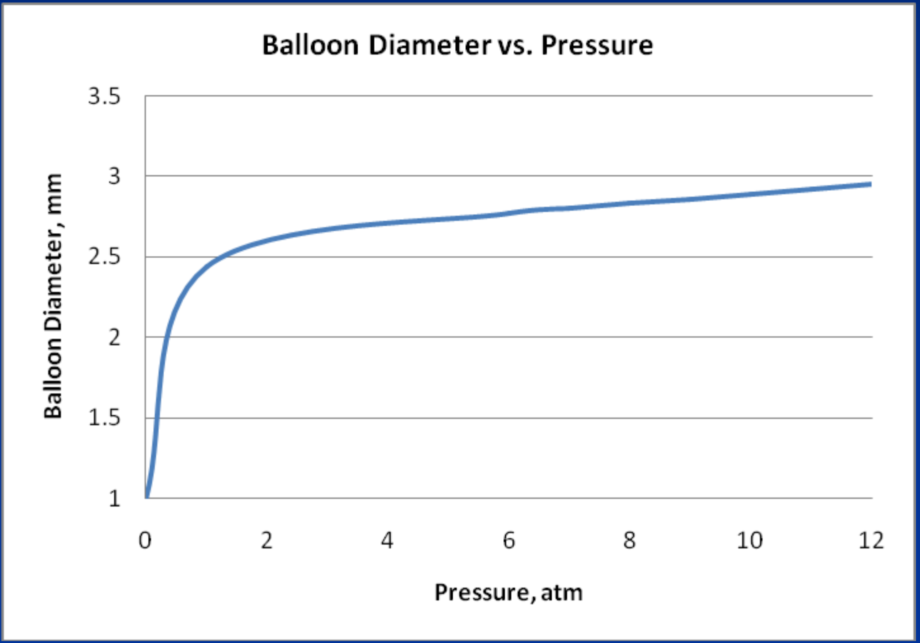
Computational Resources

- Pre-processor: Gambit and Harpoon
- Solver: ANSYS 10.0 and 11.0
- Post-Processor: Ensight
- SHOULD WE INCLUDE SOLVING TIME OR ANYTHING OF THAT NATURE HERE?

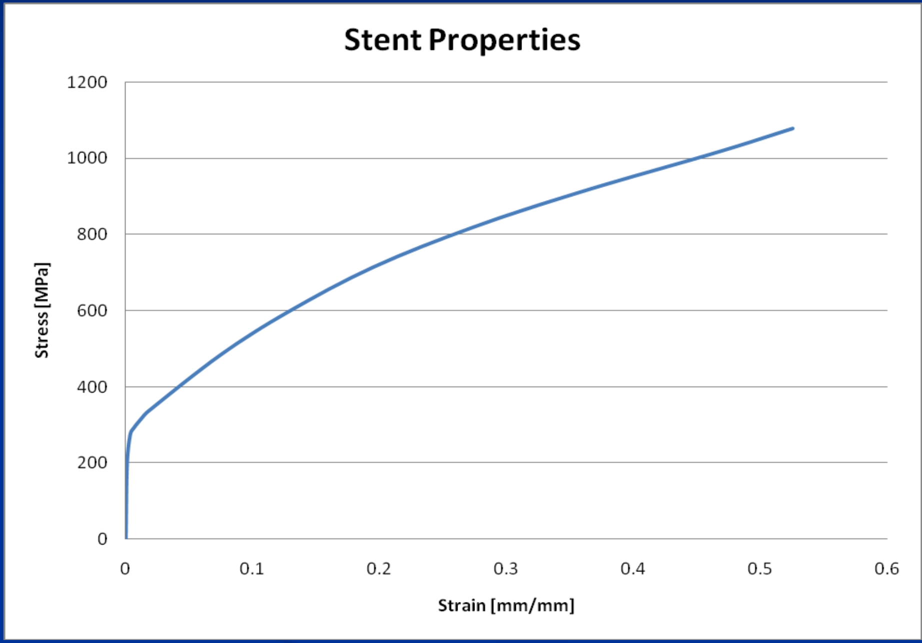
Material Models

- Artery:
  - Five parameter, third-order, Mooney-Rivlin hyperelastic constituitive equation using constants developed by Lally et al.
- Stent:
  - modeled after the slotted tube geometry given by Migliavacca et al.
  - 316LN stainless steel
  - Poisson ratio is 0.3
  - Young Modulus is 200 GPa
- Balloon:
  - Empirically collected data

Material Models contd.



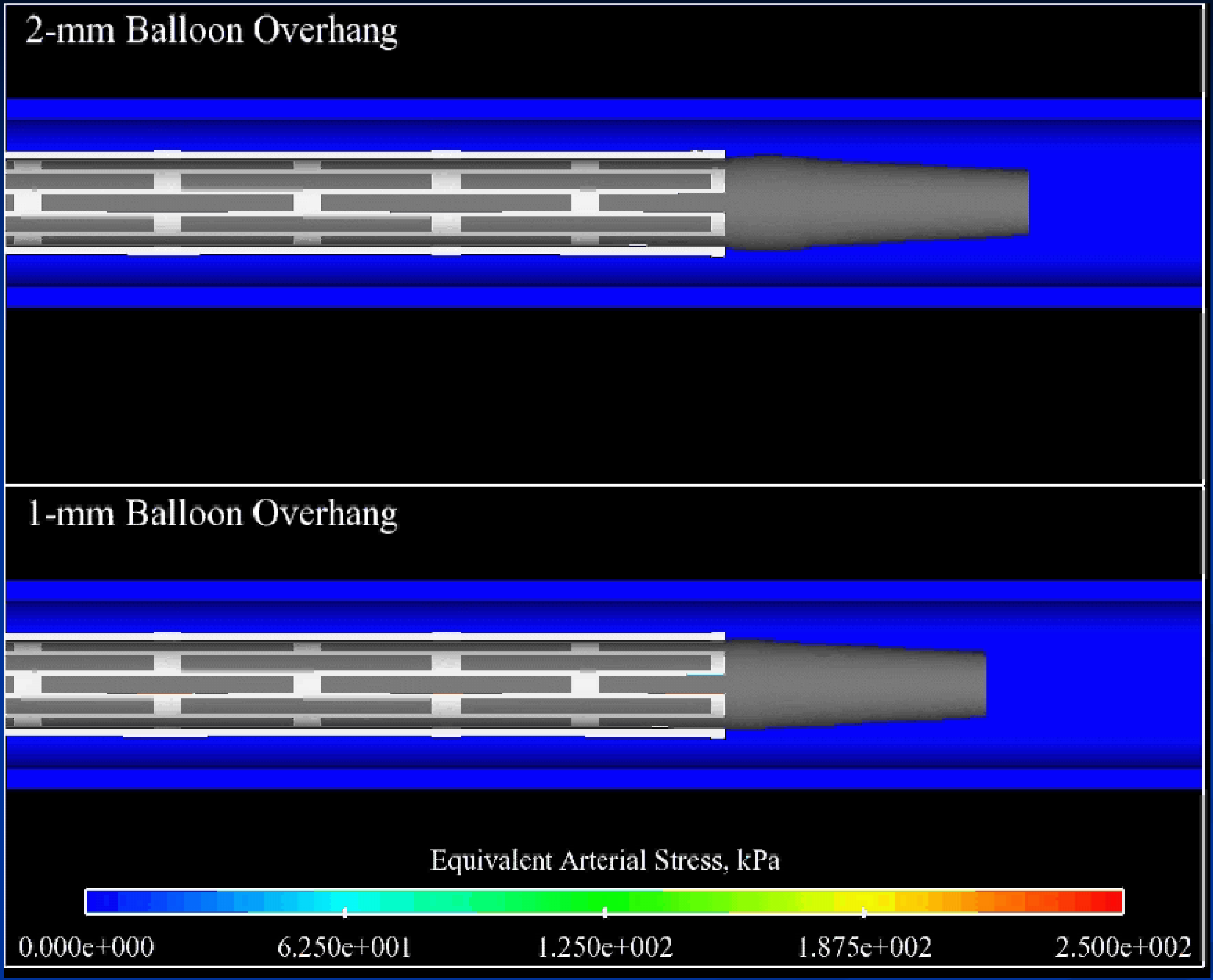
Internally Applied Pressure on Balloon



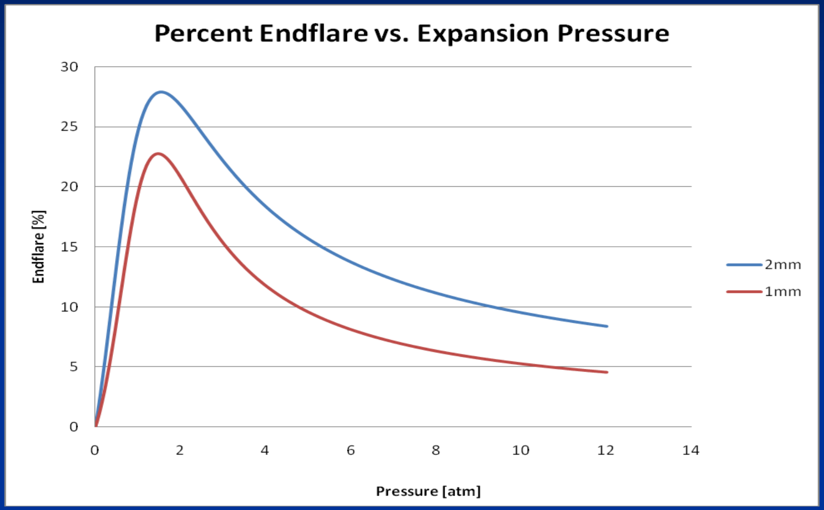
Non-linear Plastic Stent Expansion

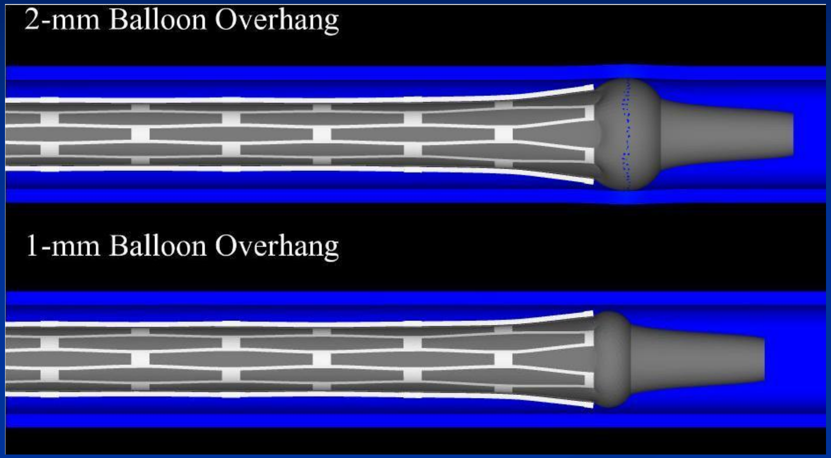
Do you have the balloon stress/strain curve?

This is labeled wrong in the paper as well!


2-mm Balloon Overhang
1-mm Balloon Overhang
Equivalent Arterial Stress, kPa
0.000e+000
6.250e+001
1.250e+002
1.875e+002
2.500e+002

Results - Endflare

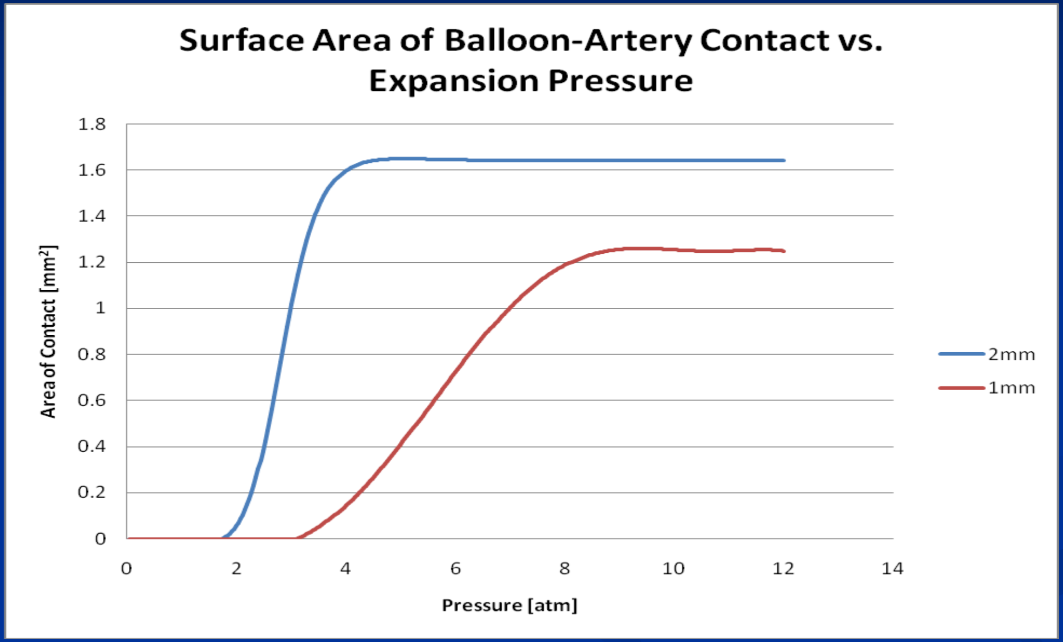




System at Point of Max Endflare

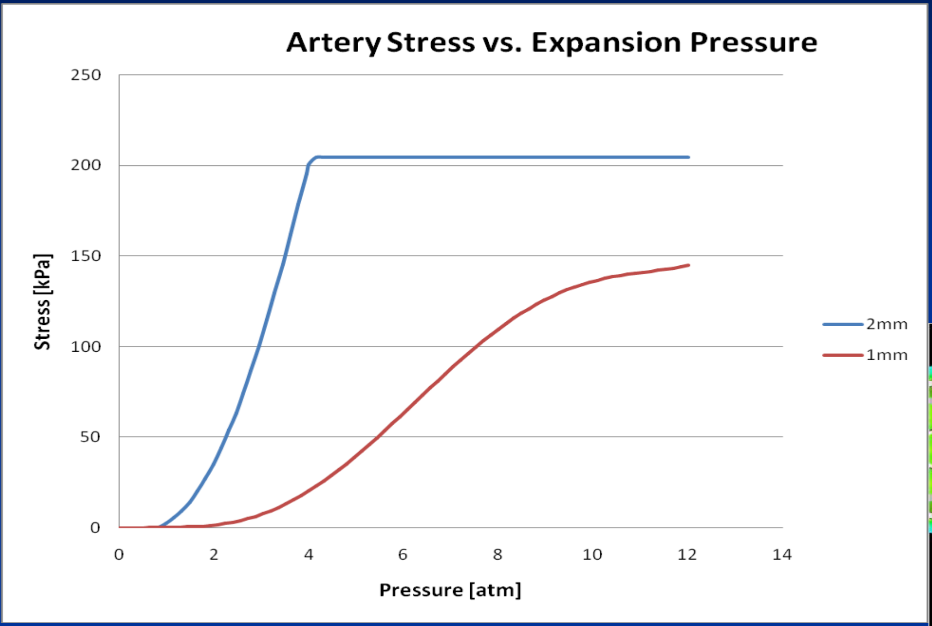
- **End of Expansion:**
  - **increase in max endflare is 2% and increase in maximum arterial stress is 93% at balloon point of contact and 45% at point of contact with far proximal and distal ends of the stent**

Results – Contact Area

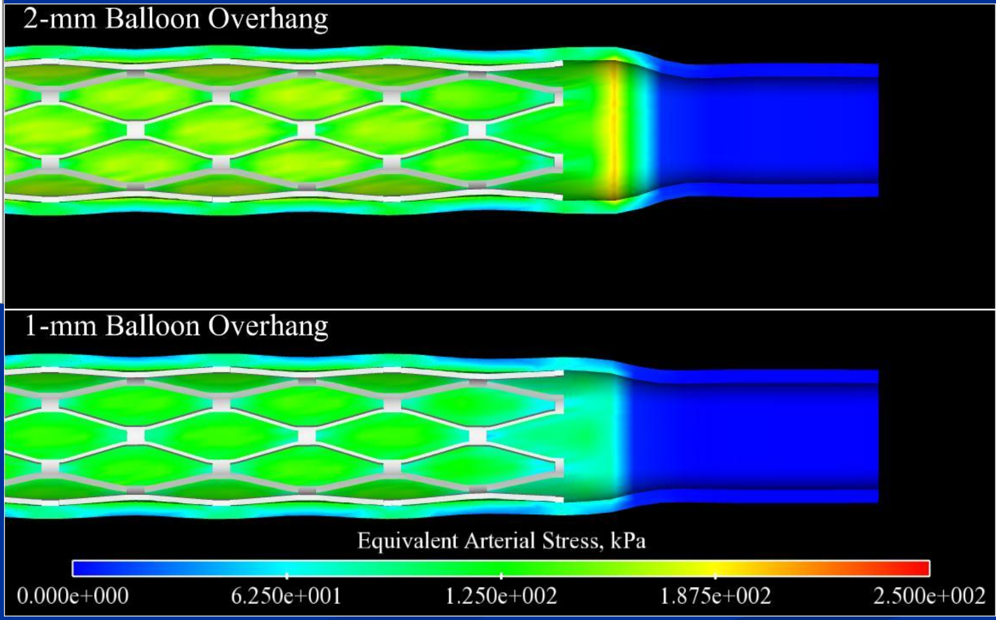


- **Larger balloon sizes cause higher balloon-artery contact areas which may cause greater neointimal hyperplasia through increased surface-contact stresses**

Results – Arterial Stress

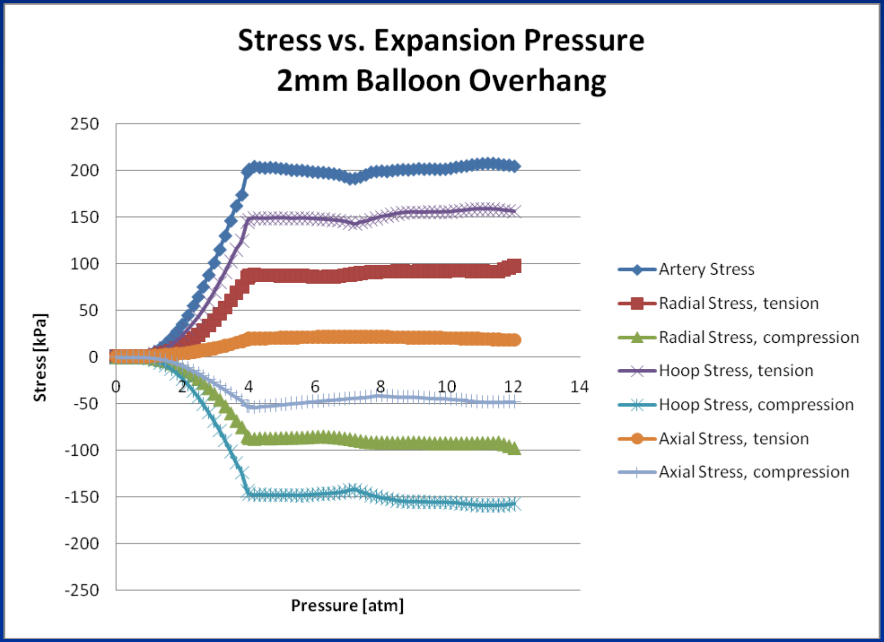


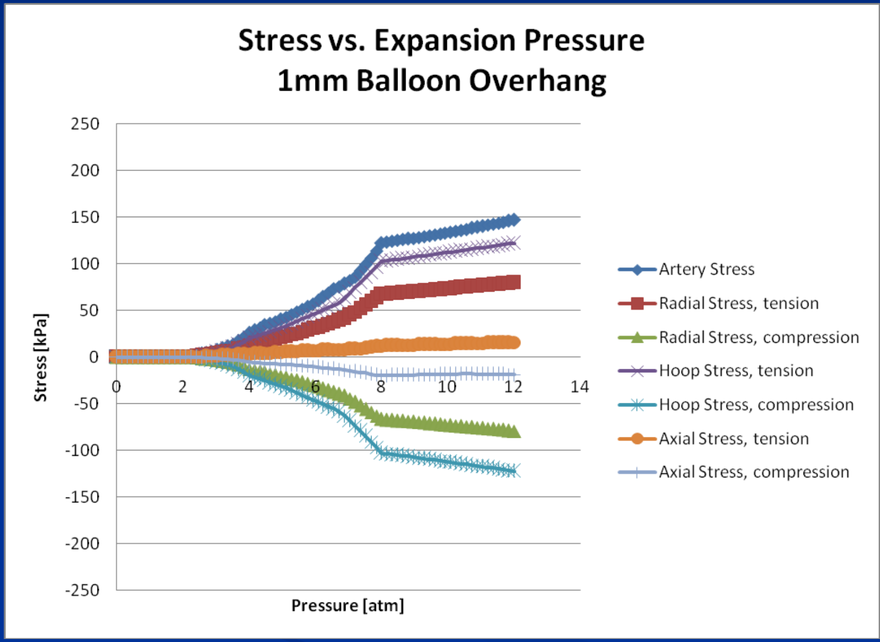
von Mises Stresses on the Artery



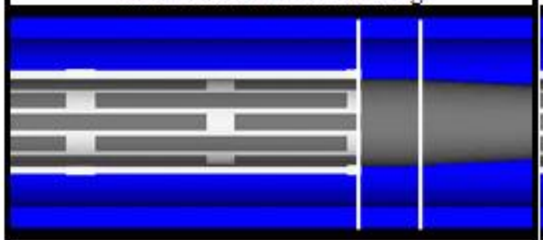
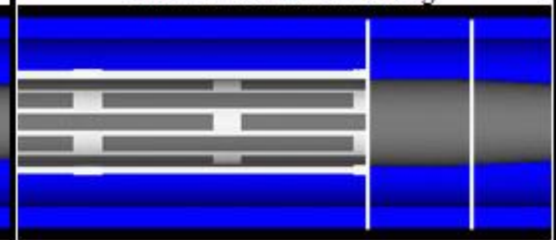
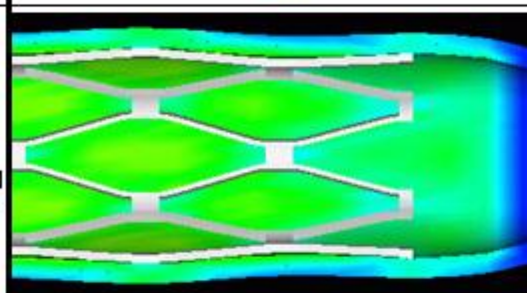
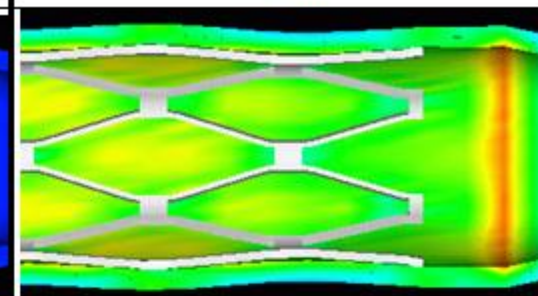
Stress on Artery at End of Expansion

Directional Stresses





Summary of Results

	1mm total balloon overhang	2mm total balloon overhang
Before expansion: artery blue stent light gray balloon dark gray Non-tapered balloon overhang highlighted		
Max endflare	25% @ 1 atm	29% @ 1 atm
Final endflare	2% @ 12 atm	4% @ 12 atm
Final max arterial stress	146.9 kPa	203.9 kPa
Final max arterial stress at balloon contact	103 kPa	199 kPa
Final max arterial stress at the endflare	96 kPa	139 kPa
Equivalent arterial stress (kPa) after full stent expansion. Balloon not shown. 0 125 225		

Modeling Conclusions

- Maximum arterial stress at balloon contact is approximately proportional to the degree of balloon overhang
- A 100% increase in balloon overhang results in a 4% increase in max endflare and a 39% change in peak arterial stress
- At the end of expansion, which is of most clinical importance, the increase in max endflare is 2% and the increase in max arterial stress is 93% at the balloon and 45% at the endflare

Clinical Significance

I really do not know what to do with these slides!!!!

- This method permits determination of regions of endothelial cell (EC) denudation during stent implantation, which is clinically significant because:
  - 1) Regions of EC denudation profoundly impact drug absorbtion/loading profiles of anti-proliferative agents in drug-eluting stents (DES)
  - 2) Anti-proliferative drugs are hypothesized to inhibit EC regrowth causing increased rates of long-term thrombosis, so predictive capability of regions of EC denudation during implantation provides the tool to reduce thrombosis rates of DES

Clinical Significance

- Acute superficial and deep vascular injury has been found to be a strong predictor of chronic restenosis. This method provides a predictive tool to evaluate the degree of acute vascular injury of new stent geometries prior to animal studies.

Questions and Remarks