Importance of Stent Design and Technical Aspects of the SFA

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Optimal Stent Design Is a Balancing Act

Engineers Make Trade-offs Between Performance and Clinical Attributes

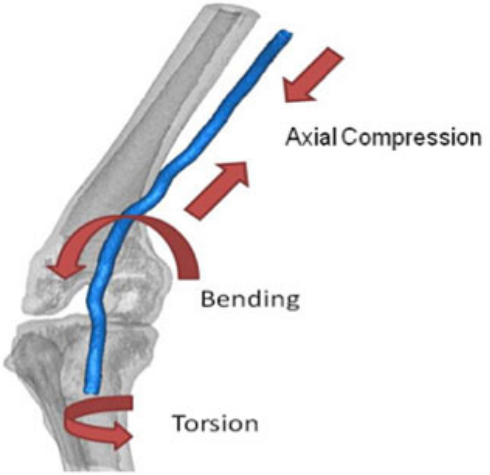
Each clinical application has specific ideal stent characteristics

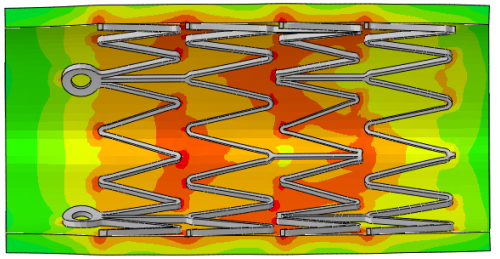
- Deployed stent accuracy
- Radial strength function
- Scaffolding
- Expansion range

- Conformability
- Length compliance
- Broad usage range
- Fatigue resistance
- Profiles
- Metal in the vessel

Stent Design Should Accommodate Natural Anatomic Forces

- Goal: Allow arteries to maintain as much natural behavior and function as possible while addressing atherosclerotic issues
- Dynamic forces of the SFA require a compliant stent to minimize chronic vessel injury and stresses on stent that can lead to fracture
  - Mismatch can lead to stresses and fracture on stent or injury to the vessel
  - Energy should transfer to either stent or vessel
  - Stent should mimic rather than resist the vessel





SFA, superficial femoral artery.
Test(s) performed by and data on file at Abbott Vascular.
Klein AJ, et. al. *Catheter Cardiovasc Interv.* 2009 Nov 1;74(5):787-98.

Stent Design Decisions: Choice of Material

- Options for material: stainless steel, cobalt chromium, nitinol, or other

Illustrations are artist's renditions.
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Self-Expanding vs. Balloon Expandable Stent Loading

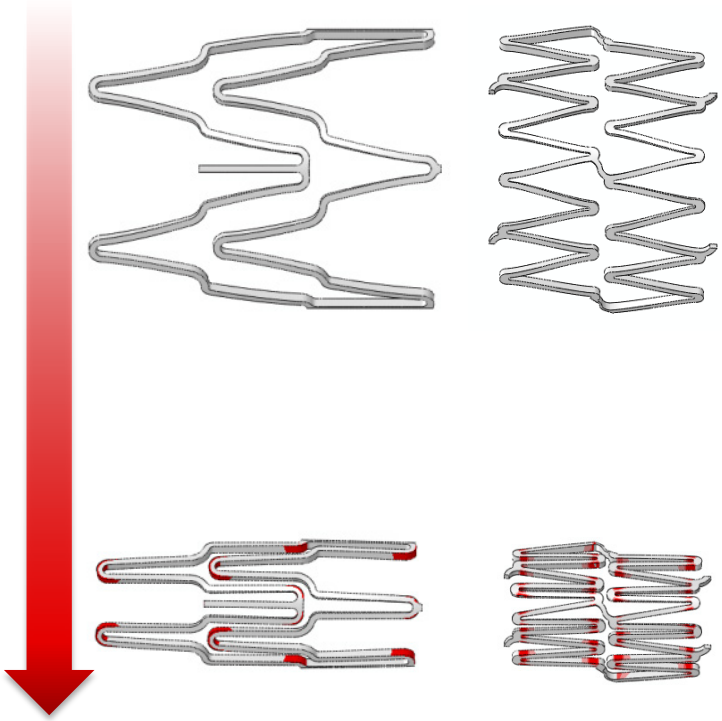
Self Expanding

Absolute

SMART

Decrease Diameter

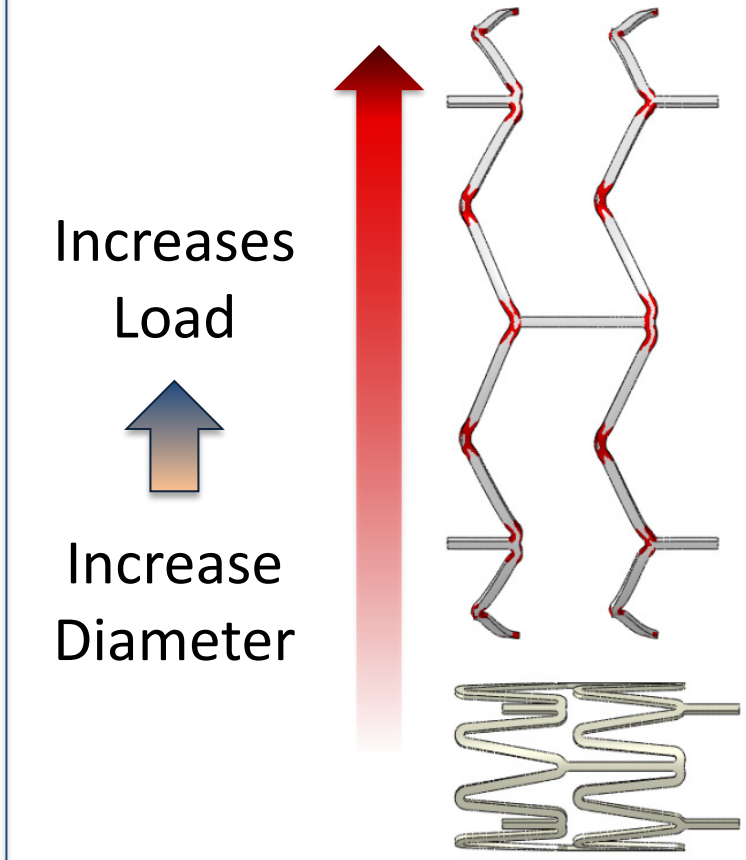
Increases Load



Balloon Expanding

Increases Load

Increase Diameter



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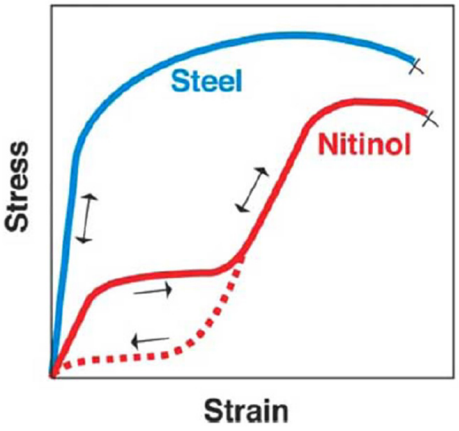
Choice of Material:
Nitinol (SES) versus Cobalt Chromium (BES)



BES, balloon-expandable stent; SES, self-expanding stent.
Test(s) performed by and data on file at Abbott Vascular.
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Self-Expanding Stent Oversizing Leads to Chronic Outward Force

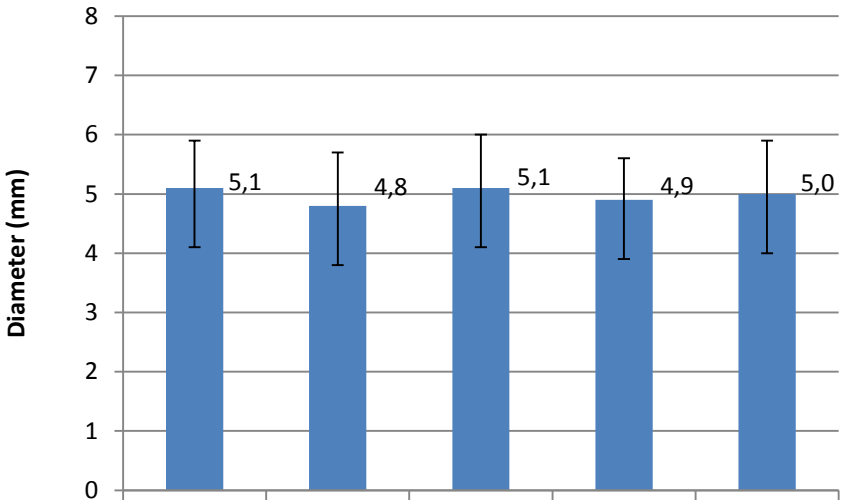
- Self-expanding stents are oversized to the vessel to assure wall apposition
- Oversizing causes the stent to exert COF on the vessel
- Not all SES have the same COF
- Too much COF may lead to chronic stent-vessel irritation

COF, chronic outward force; SES, self-expanding stent.

How Common is SFA Oversizing?

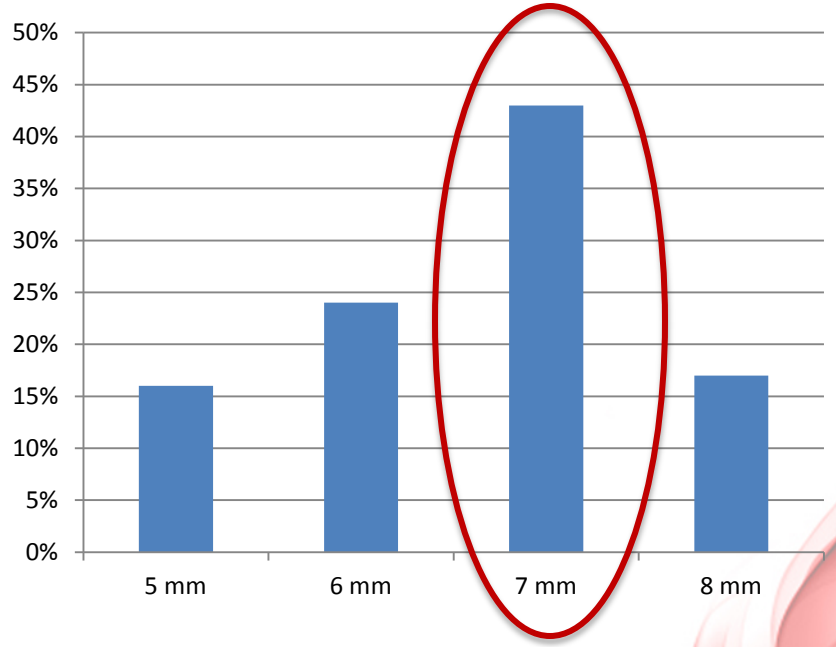
- Average reference vessel diameter of SFA is 5 mm
- Most commonly used stent diameter in SFA is 7 mm

Reference Vessel Diameters from SFA trials



	RESILIENT	DURABILITY II	ZILVER PTX	STROLL	SUPERB[1]
RVD (mm)	5,1	4,8	5,1	4,9	5,0

Stent Diameter Use in SFA, %



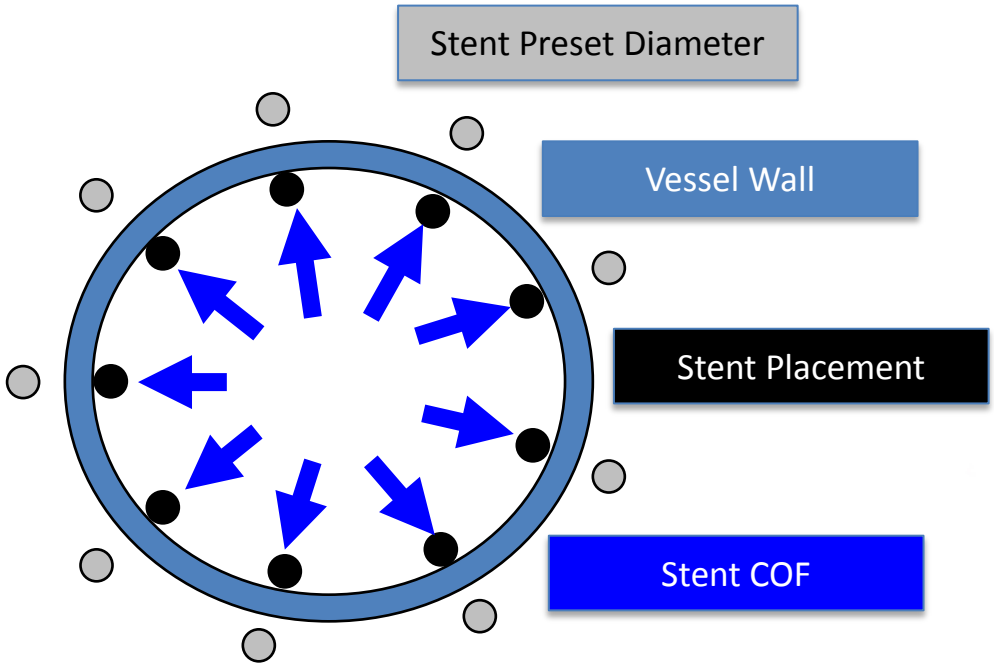
Source: Clinical data from US product Instructions for Use (IFU) except where noted.

1- Garcia L. Superb Trial 12 Month Results. Presented at TCT 2012. Miami, FL.

Data on file at Abbott Vascular.

Chronic Outward Force

- Outward force exerted on vessel by self expanding stents to achieve preset diameter

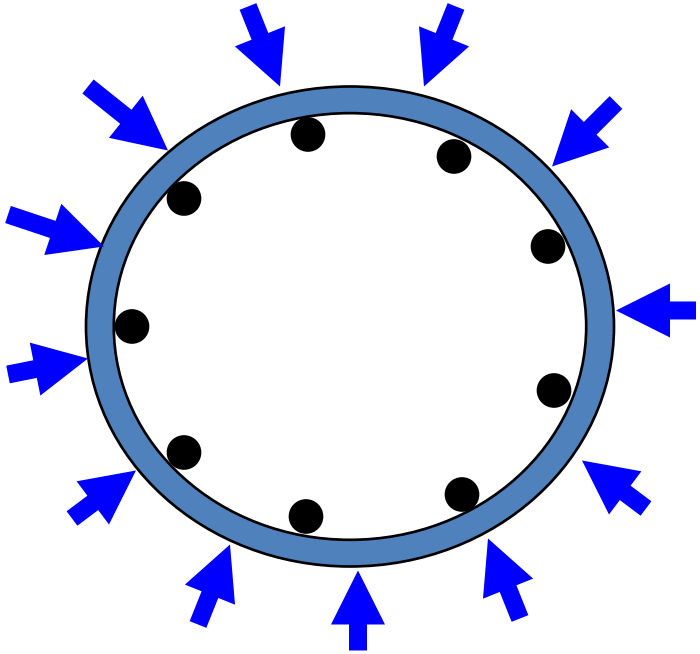


Preclinical animal model.
Zhao HQ et al. *Cardiovasc Intervent Radiol.* 2009;32(4):720-6.

COF, chronic outward force; SES, self-expanding stent.
Illustrations are artist's renditions.

Radial Strength

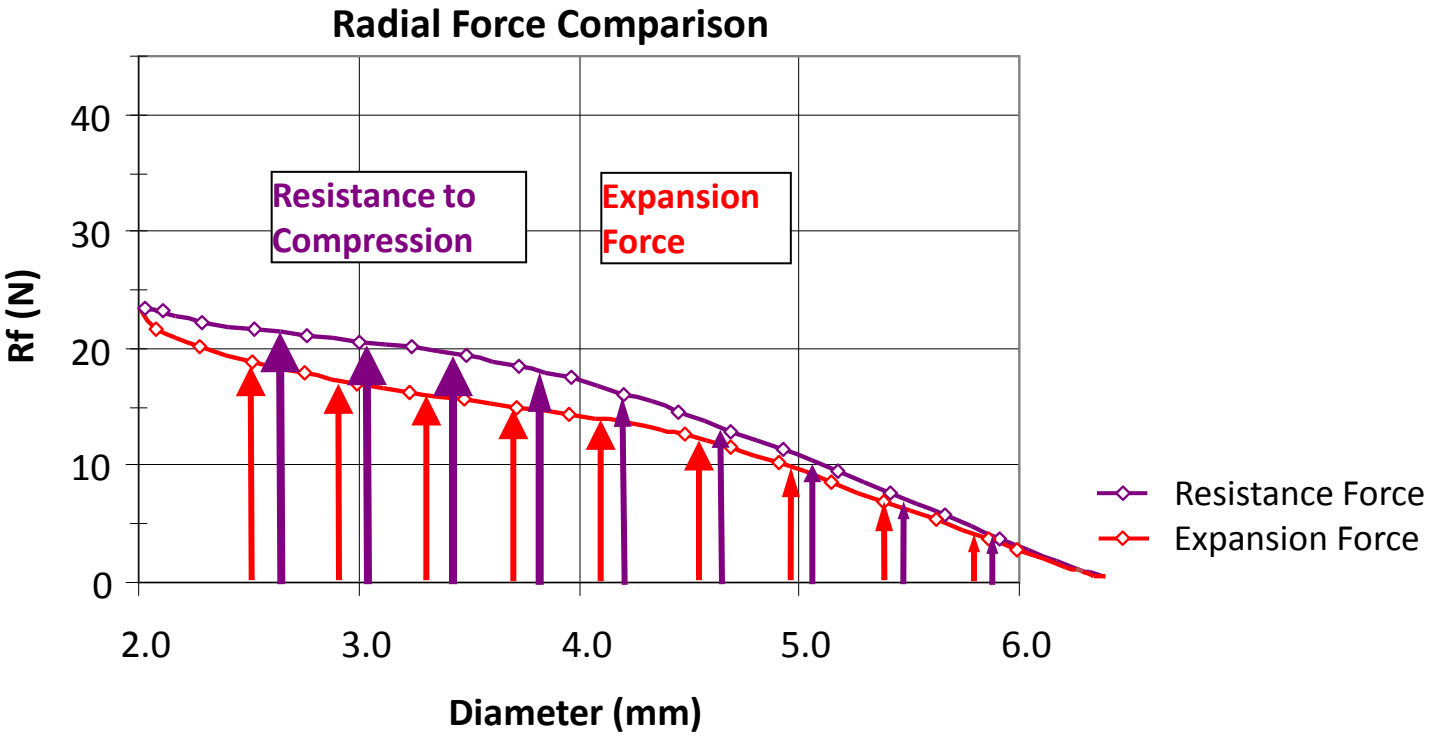
The ability to resist vessel recoil



Illustrations are artist's renditions.

Stent Compression & Expansion Forces

Nitinol elastic modulus is non-linear,
path-dependent and temperature-dependent



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Self-Expanding Stents Exert Chronic Outward Force

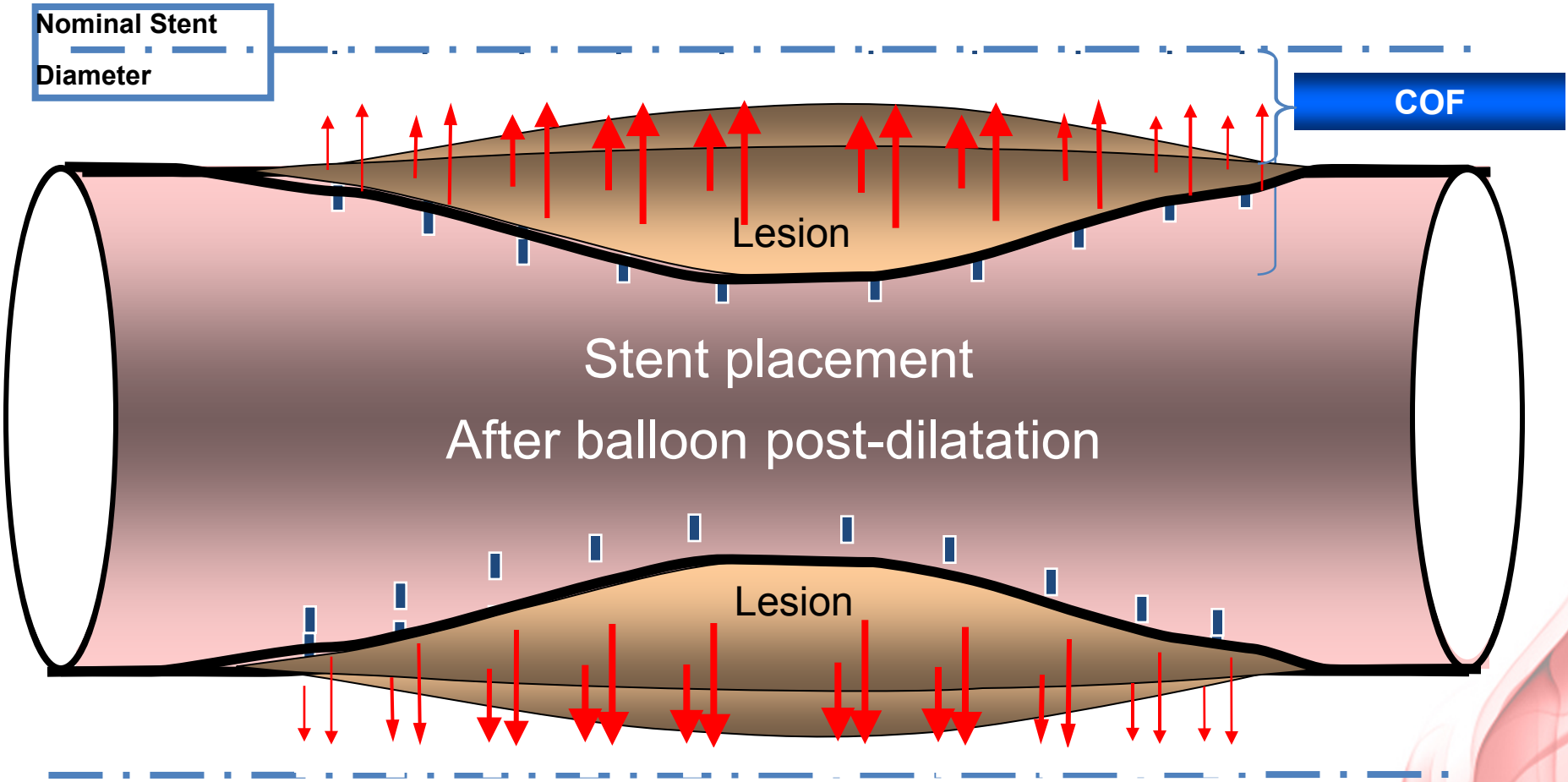
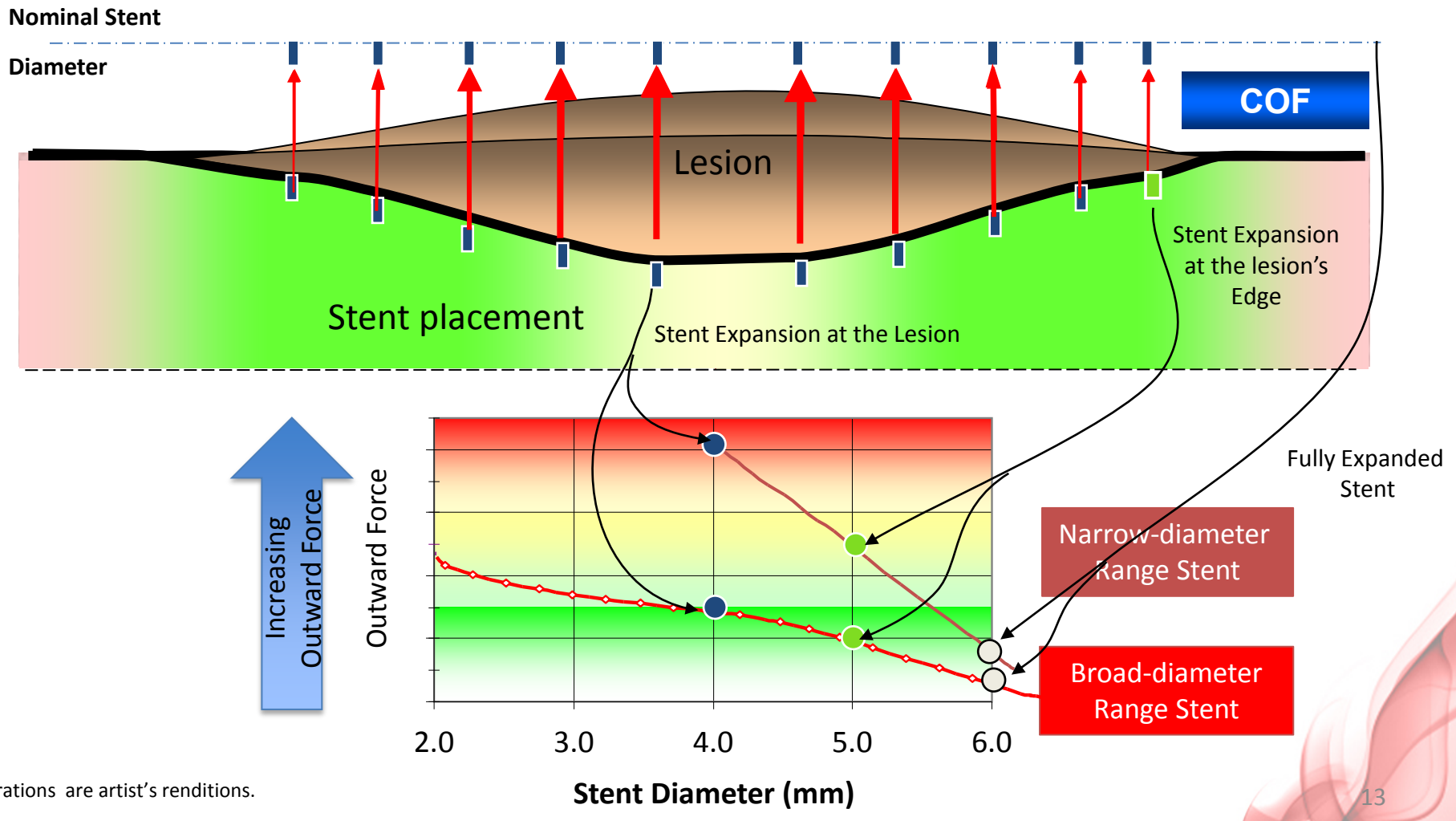


Illustration is artist'srendition.

Different Self-Expanding Stents Exert Differing Levels of Chronic Outward Force

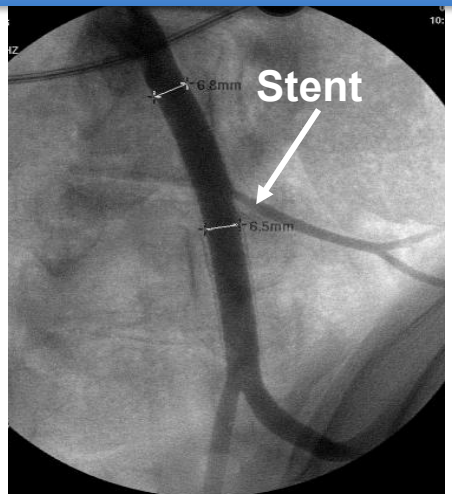
After Post-dilatation… COF reduces as stent diameter grows

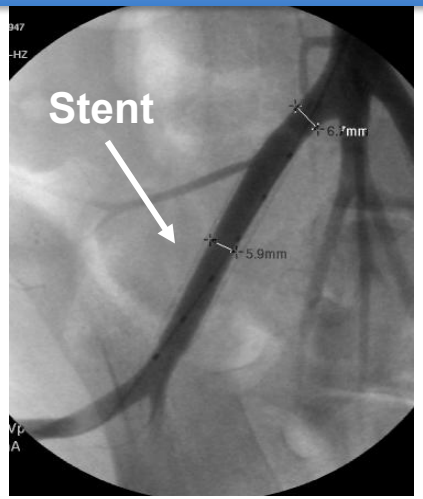


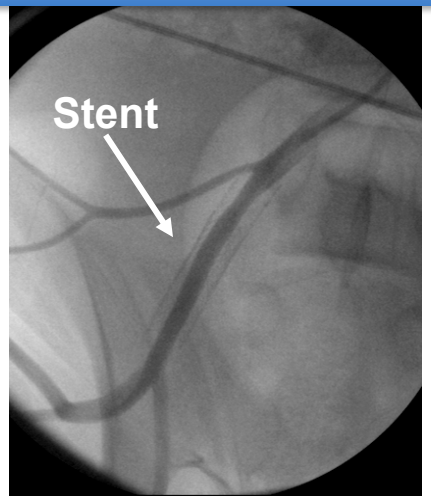
Illustrations are artist's renditions.

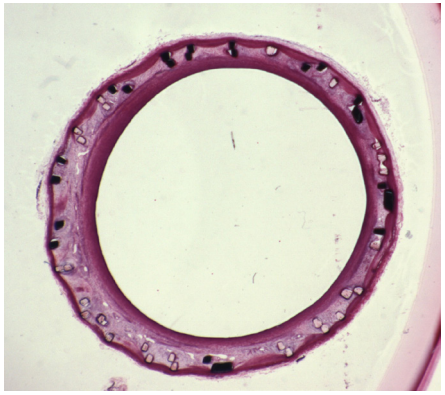
Oversizing Can Lead to Chronic Stent-Vessel Irritation

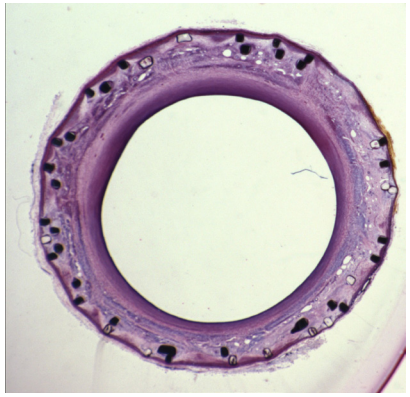
	Optimal Oversizing	Medium Oversizing	High Oversizing
Example: 8 mm stent	7.3 – 6.2 mm	6.2 – 5.0 mm	5.0 – 4.2 mm











Preclinical animal model.

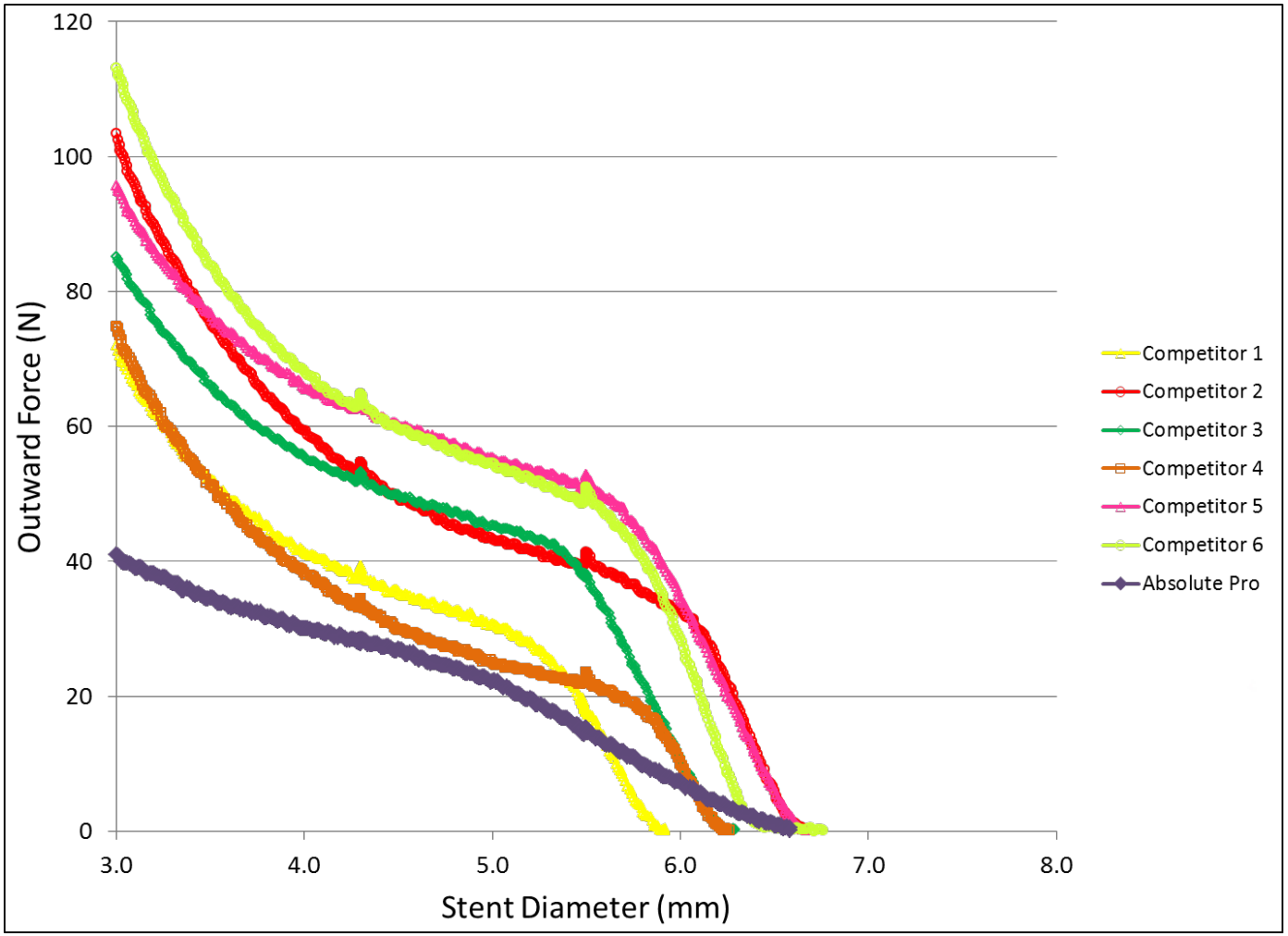
Zhao HQ et. al. *Cardiovasc Intervent Radiol.* 2009 Jul;32(4):720-6.

Not All Self-Expanding Stents Perform the Same

- Complex forces and motion require a stent designed specifically for long-lesions ⇒ Design matters!
- Long lesions require a stent designed to have a wide usage range and low COF

Self-Expanding Stents are Not Designed the Same

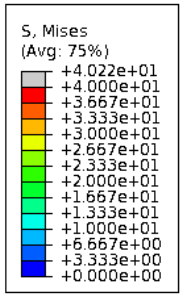
Increasing Outward Force

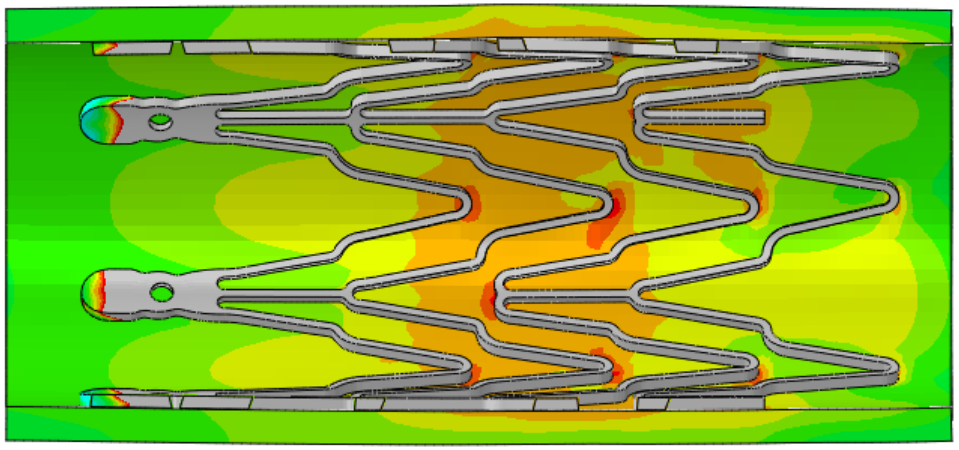


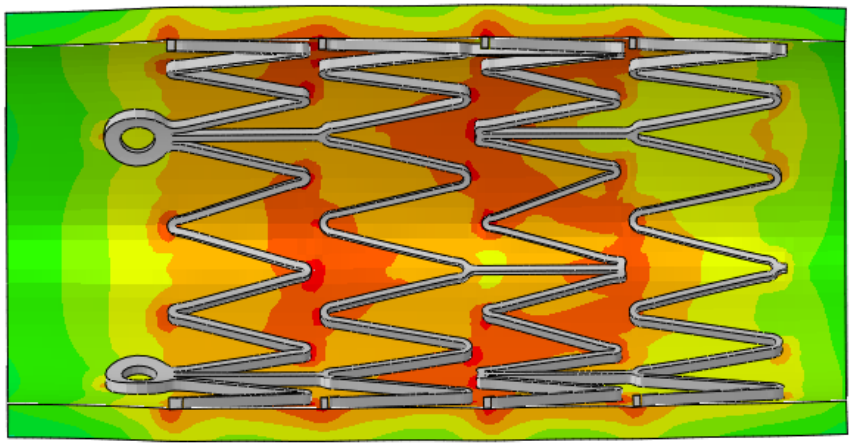
Test(s) performed by and data on file at Abbott Vascular.

Stent Design Affects Stresses on Vessel Wall

- On stent deployment, higher stresses may be induced on the vessel wall with stents that have a higher COF







Lower COF

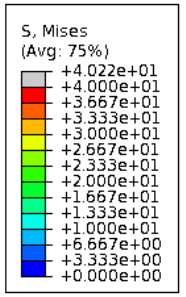
6 mm Absolute stent deployed in 5 mm ID vessel

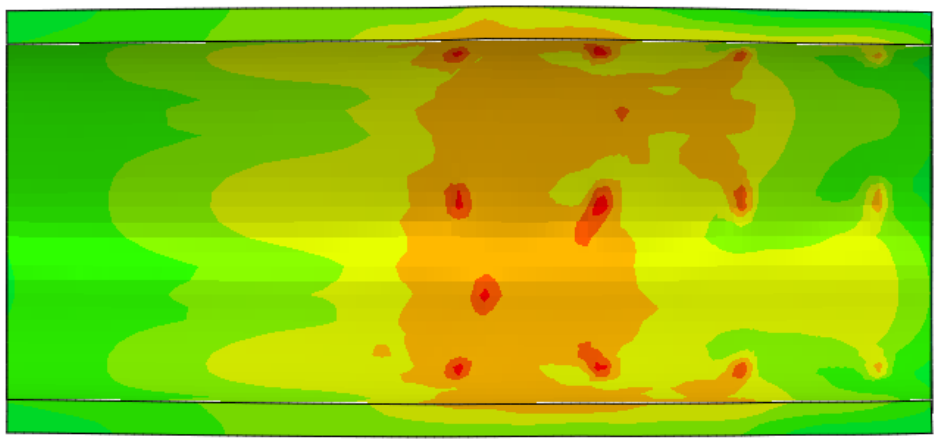
Higher COF

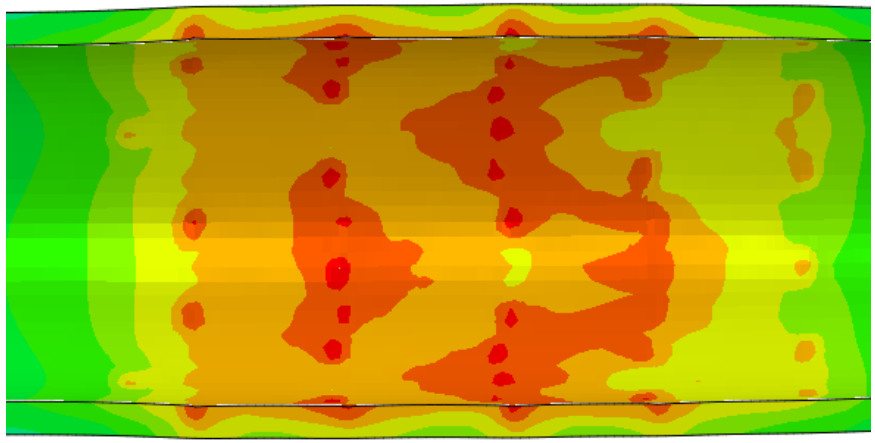
6 mm Zilver PTX stent deployed in 5 mm ID vessel

COF, chronic outward force;
ID, inner diameter.
Test(s) performed by and data on file at Abbott Vascular.

Stress Induced in Vessel Due to the Stent's Chronic Outward Force





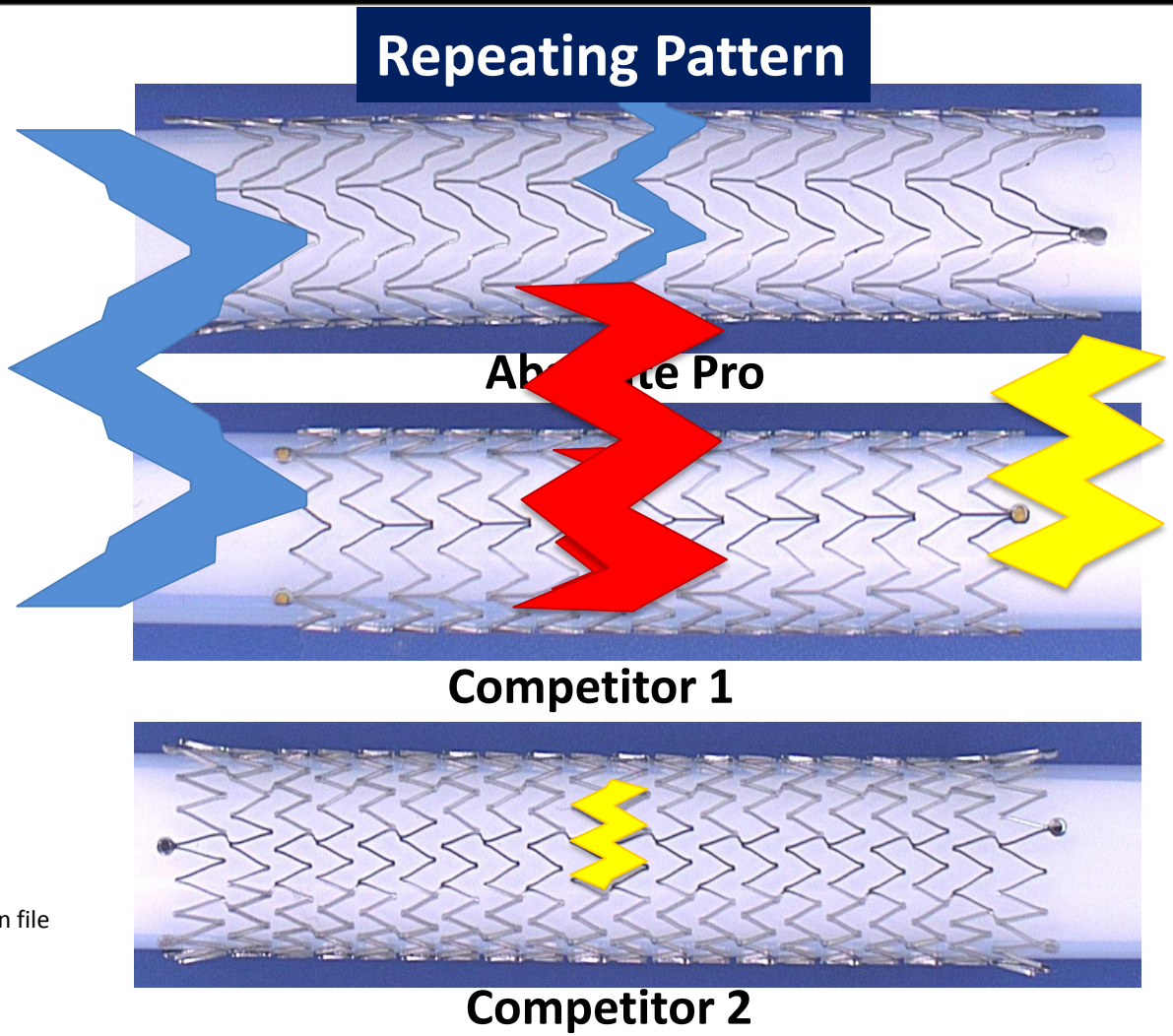


6 mm Absolute Stent Deployed in 5 mm ID Vessel

6 mm Zilver PTX Stent Deployed in 5 mm ID Vessel

Test performed by and data on file at Abbott Vascular.

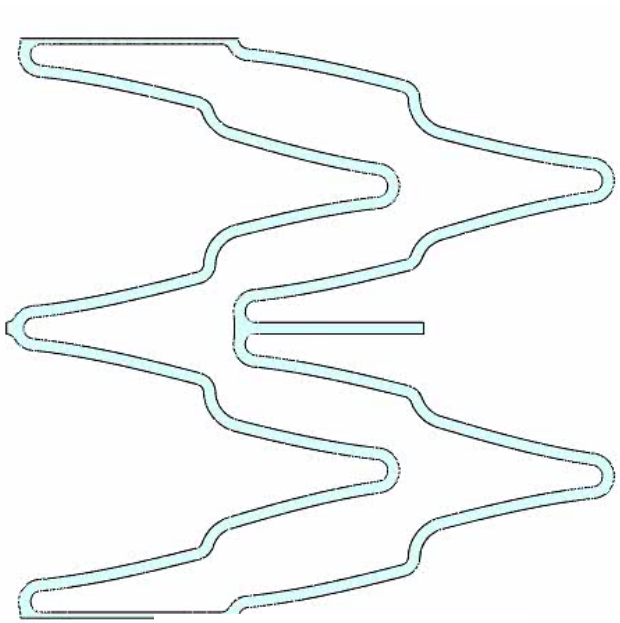
Stent Design Comparison – Why Design Matters
Optimal Scaffolding



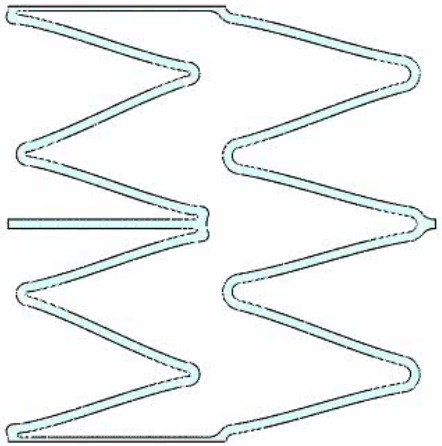
Photographs taken by and on file at Abbott Vascular

Stent Design Comparison
In-Stent Stresses with Leg Motion, and Blood Pressure

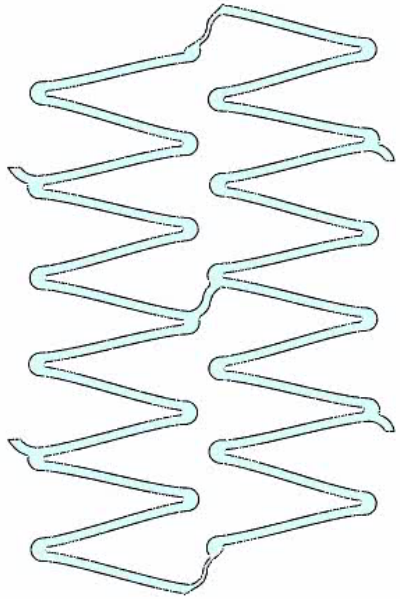
6 mm stent deployed in a 5 mm artery,
then compressed to 3 mm



Absolute Pro



Zilver PTX



S.M.A.R.T. Control

Test(s) performed by and data on file at Abbott Vascular.

SFA: Key Design Objectives for a Self-Expanding Stent

- Minimize restenosis risk with reduced chronic outward force
- Provide optimum scaffolding to promote healing and maintain patency without fracturing
- Absolute Pro: Maximize usage range for each size
  - "Easy to Choose"
  - "Easy to Use"

COF, chronic outward force; SFA, superficial femoral artery.

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