Leave Something Behind in SFA Lesion

Wei Liang

Dept. Vascular Surgery, Shanghai Renji Hospital
School of Medicine, Shanghai Jiaotong University

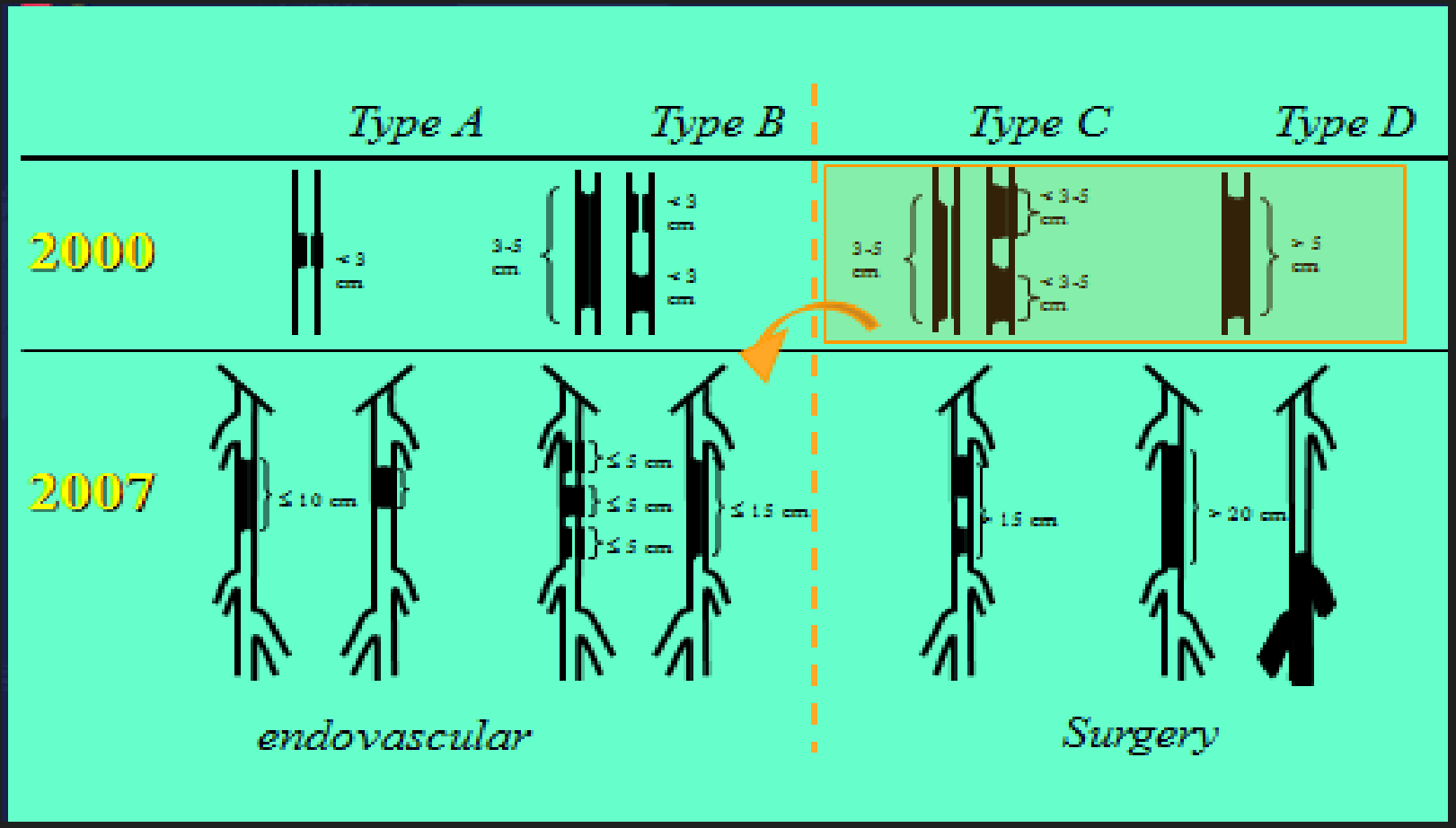
Disclosure of Interest

Speaker name: .....

- I have the following potential conflicts of interest to report:
- Consulting
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)

- **I do not have any potential conflict of interest**

The challenge of SFA-POP treatment



Outcomes of SFA Stents

Clinic Trials	PP @12 M	Lesion Length
Fast	68%	4.4 cm
Resilient	80%	6.2 cm
Durability	72%	9.3 cm
Astron	65%	9.9 cm
Vienna	68%	10.9 cm

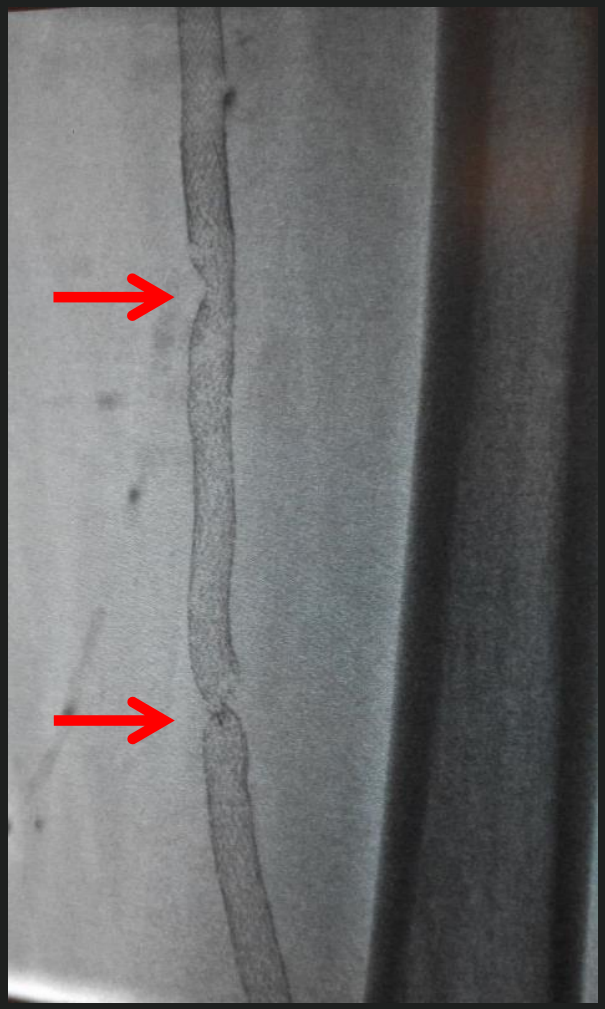
TASC A和B

Outcomes of SFA Stents

139 limbs	PP @12 M	PP @ 24 M
TASC C stent	83%	80%
TASC D stent	54%	28%

J Vasc Surg 2008;48:1166

Failed of SFA Stents

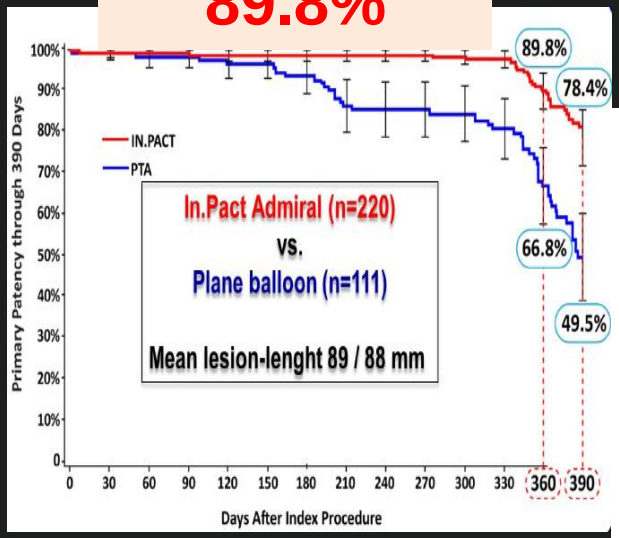


Fracture

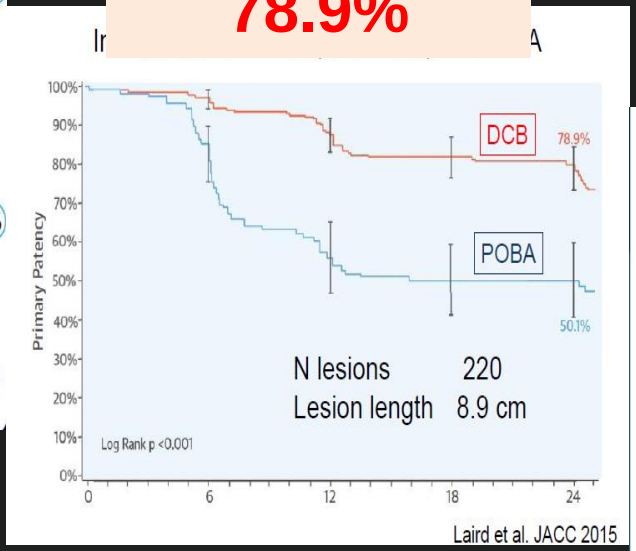
Restenosis

In.Pact SFA Study

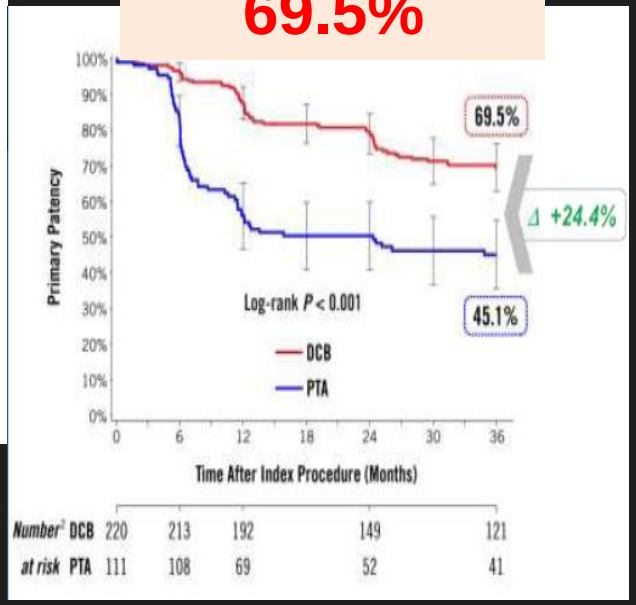
1yr PP 89.8%



2yrs PP 78.9%



3yrs PP 69.5%



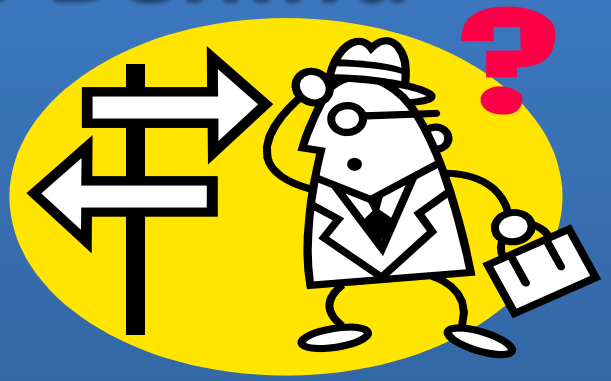
Tepe et al. Circulation 2015

Laird et al. JACC 2015

Krishnan P, VIVA Las Vegas 2015

SFA stents not necessary ?

Nothing leave Behind



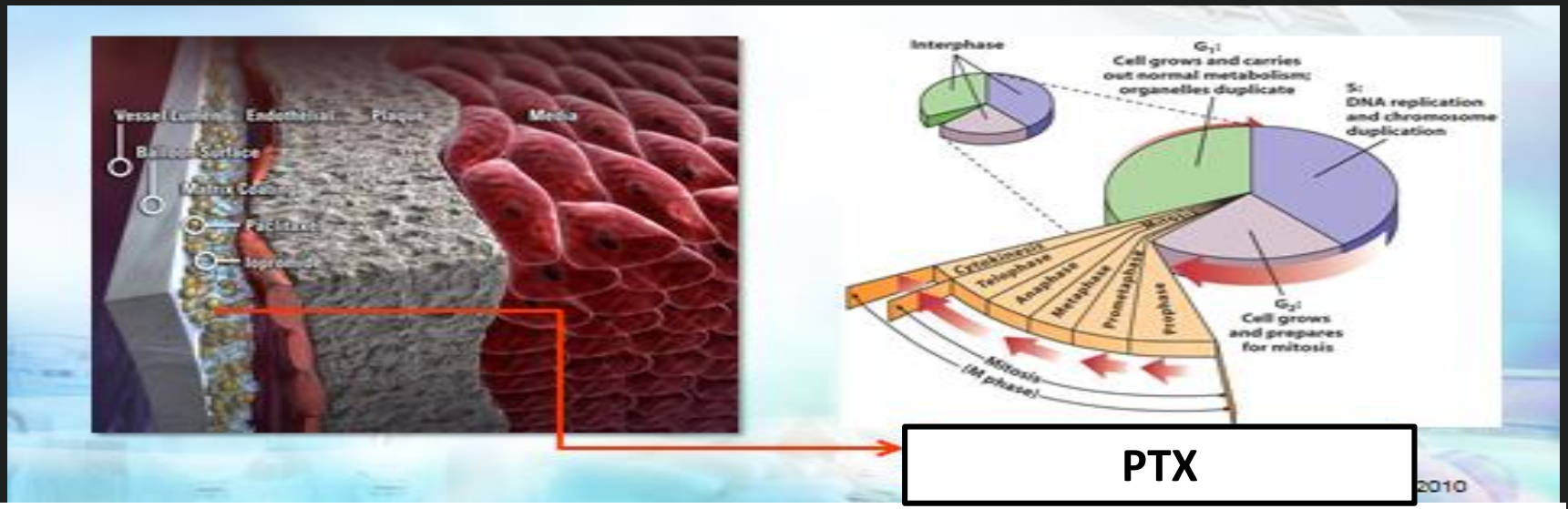
PTA is not perfect

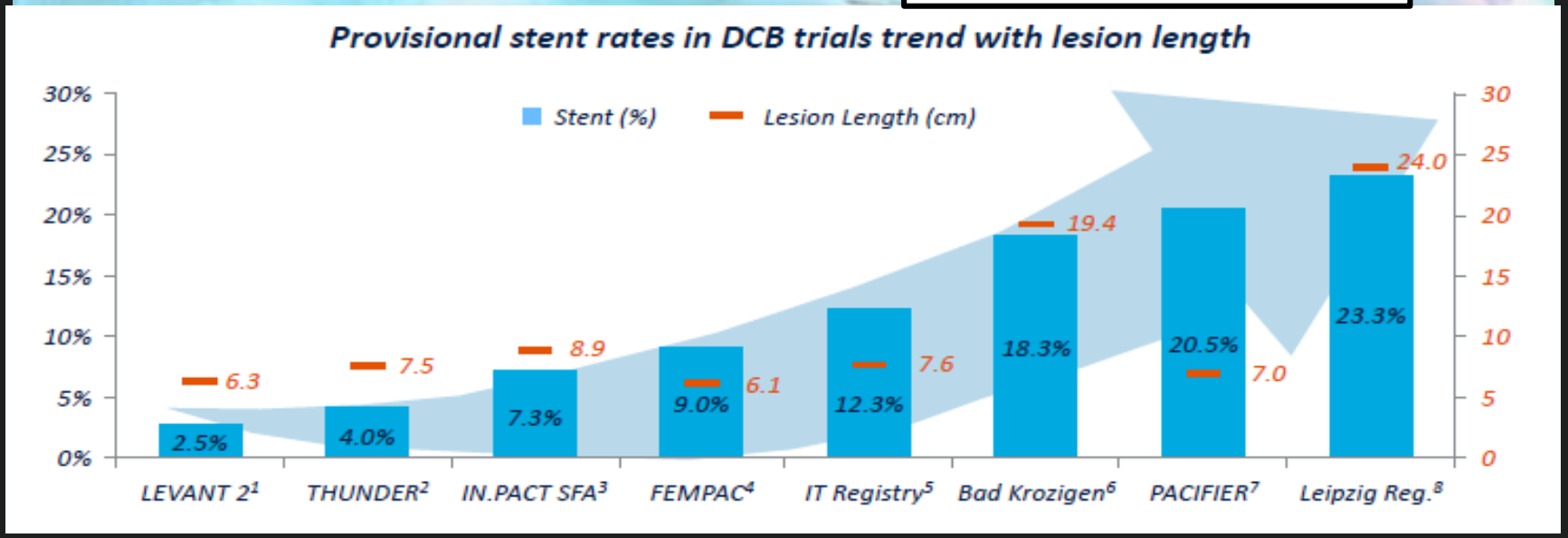
- **PTA study (2002)**
  - 74 patients
  - 43% major dissections
  - 32% residual stenosis >30%
- **ABSOLUTE: Stent vs. PTA (2006)**
  - 104 patients, 1:1 randomization
  - 32% insufficient PTA result led to cross over to stent
- **RESILIENT: Stent vs. PTA (2008)**
  - 206 patients 2:1 randomization 40% PTA cross over to stent due to flow limiting dissections and residual stenosis

Rate of Bail-out Stents>20%

  - 21% and 35% bail out stenting due to flow limiting dissections and residual stenosis

Stent has the meaning in DCB study

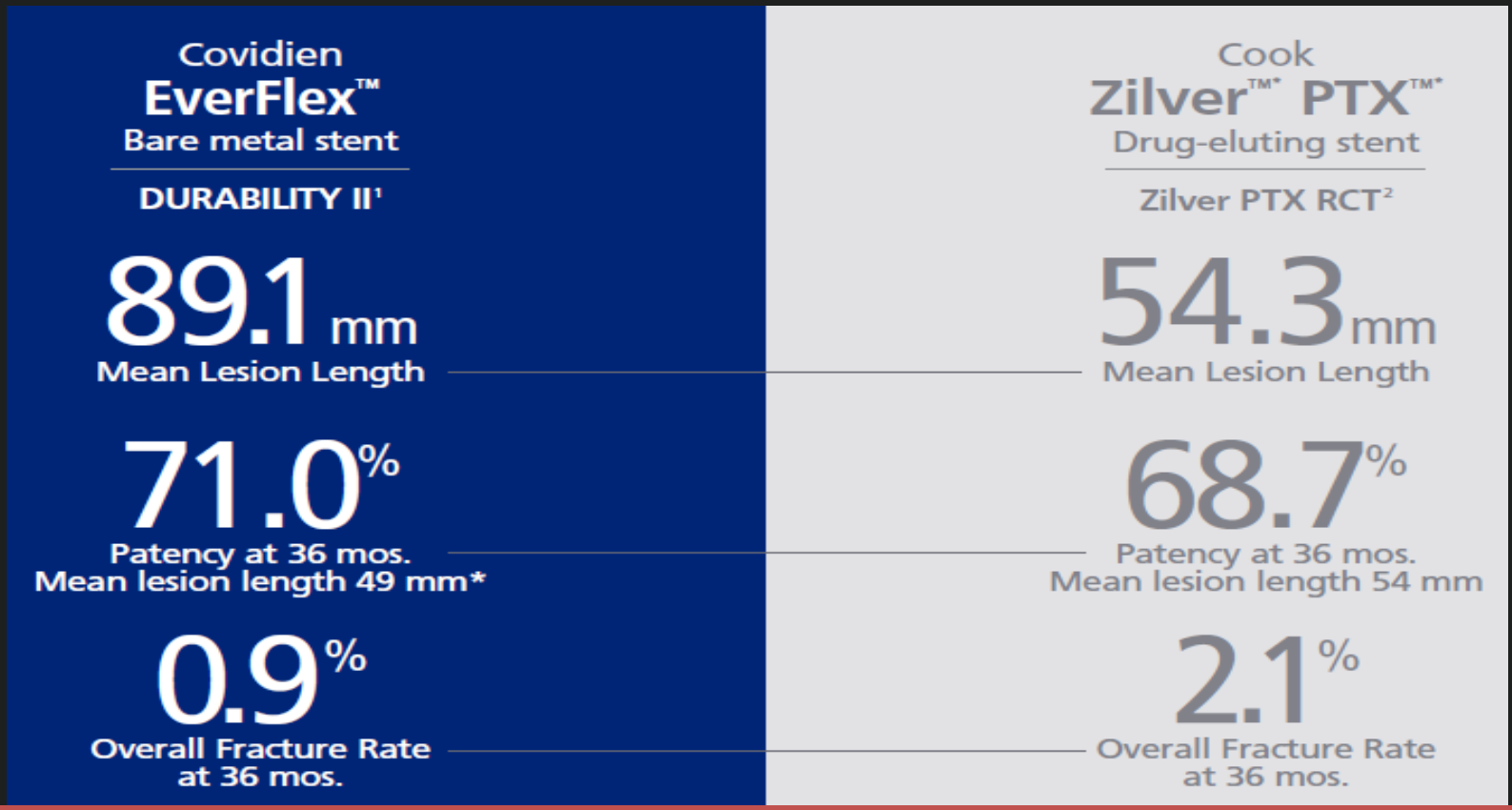




Complex SFA lesion needs stents

Leave sth. Behind

SFA stents are not simple



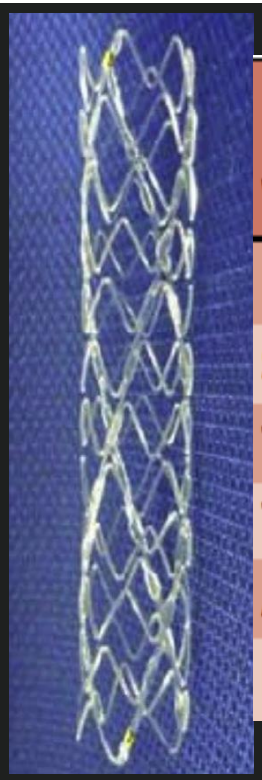
Why DES has no advantage ?

Resorbable stent – Poor Results

Treatment of the femoropopliteal artery with the bioresorbable REMEDY stent

Jan Bontinck, MD,[a] Peter Goverde, MD,[a] Herman Schroë, MD,[b] Jeroen Hendriks, MD, PhD,[c] Lieven Maene, MD,[d] *and* Frank Vermassen, MD, PhD,[e] *Antwerp, Genk, Edegem, Aalst, and Ghent, Belgium*

J Vasc Surg 2016;64:1311-9

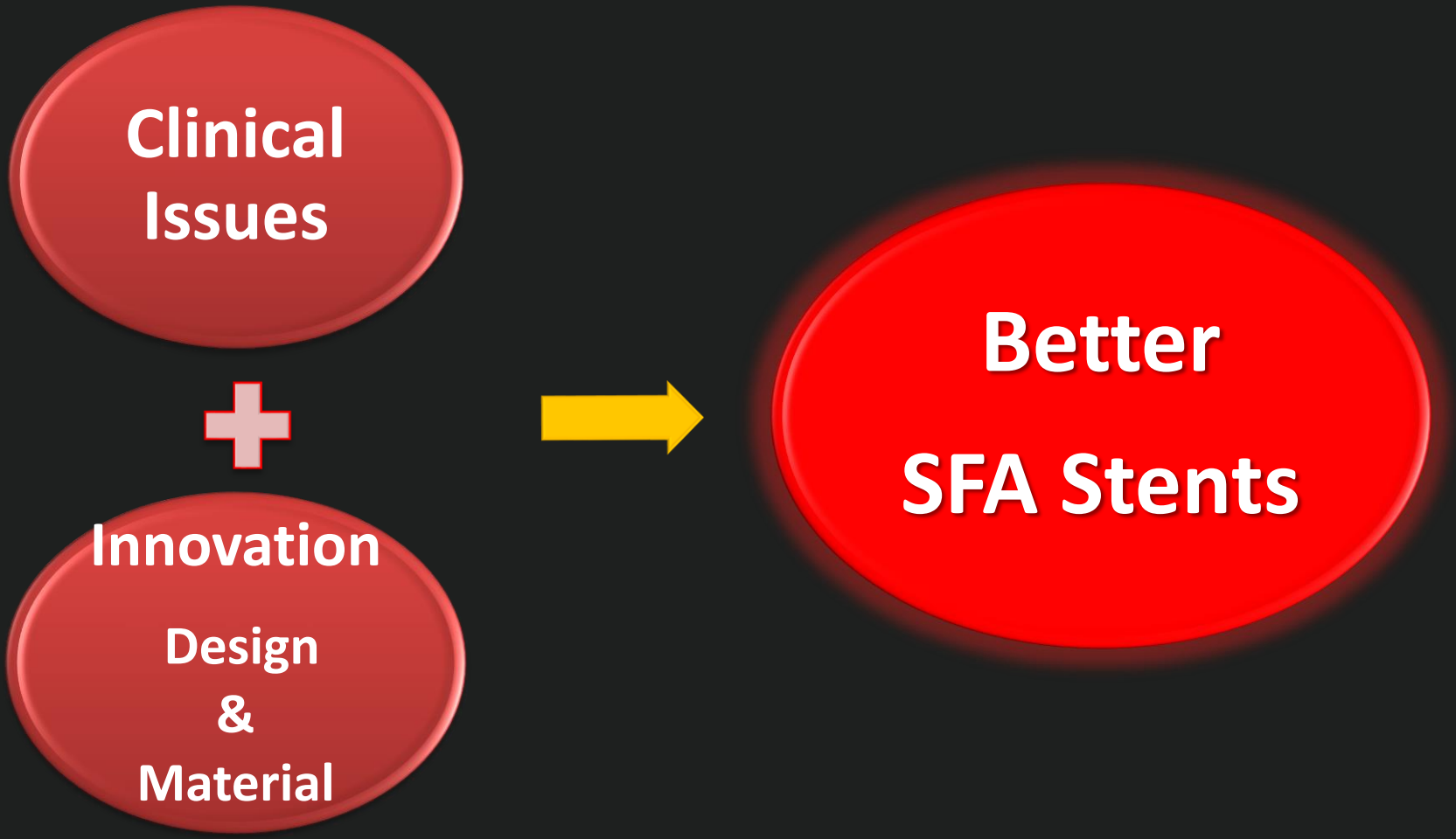


Variable	6 months			12 months		
	No.	Frequency	Percentage	No.	Frequency	Percentage
Primary patency	82	56	68	74	43	58
Secondary patency	81	69	85	71	61	86
TLR	88	17	19	80	26	33
TVR	88	17	19	80	26	33
Amputation	88	1[a]	1	78	3[b]	4
Mortality	88	1[c]	1	76	2[c]	3

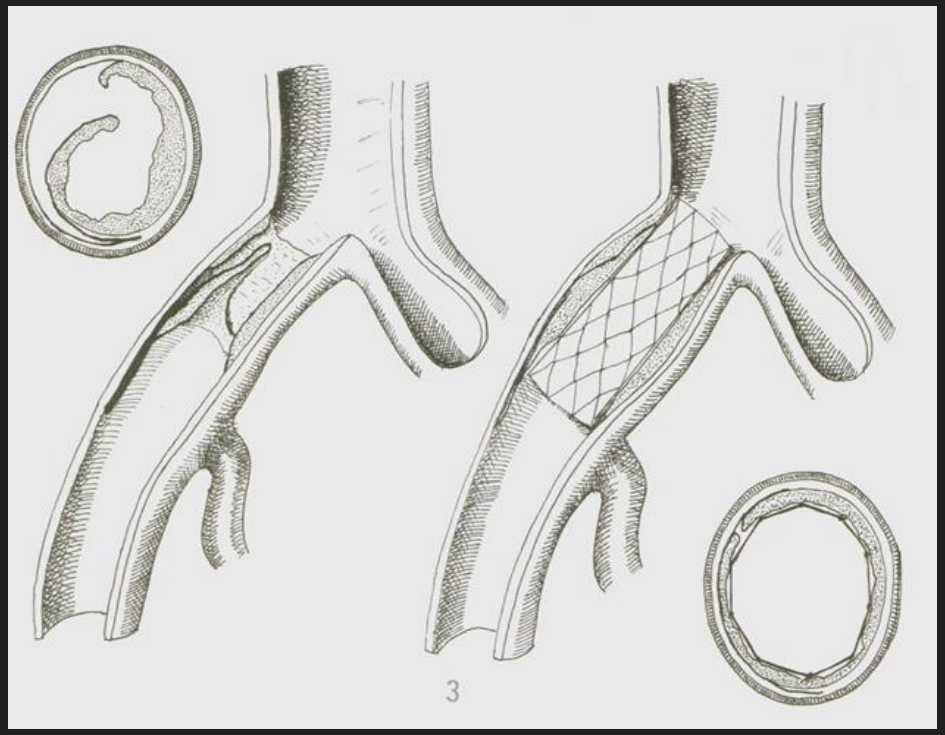
We need better SFA stents

Leave right things Behind

What is Perfect SFA stent

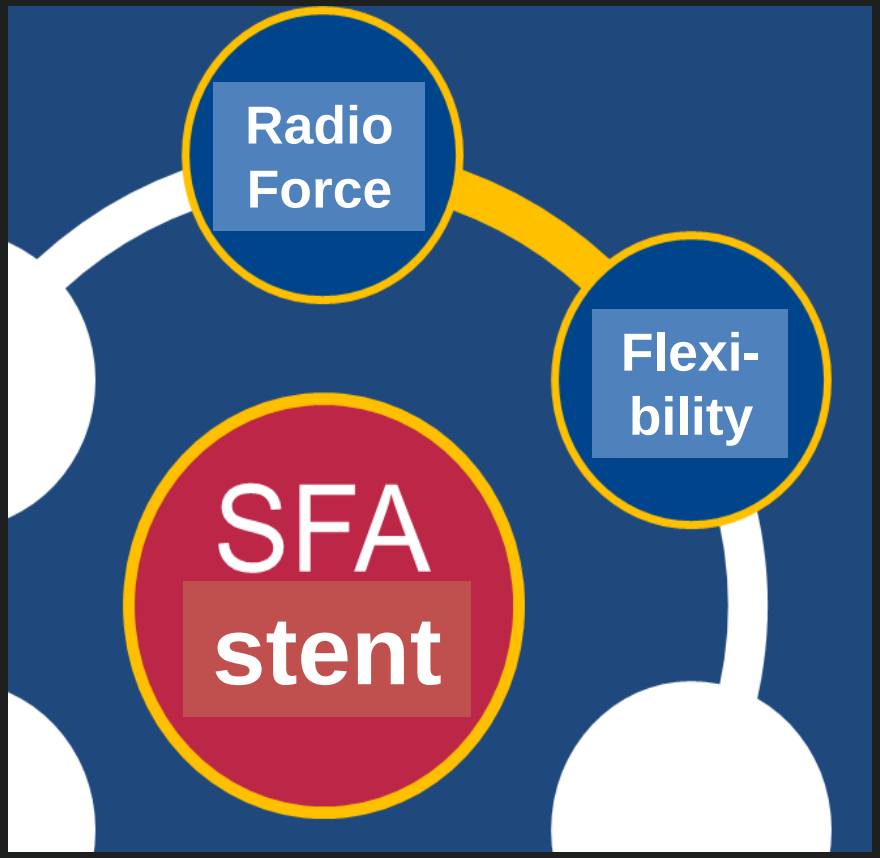


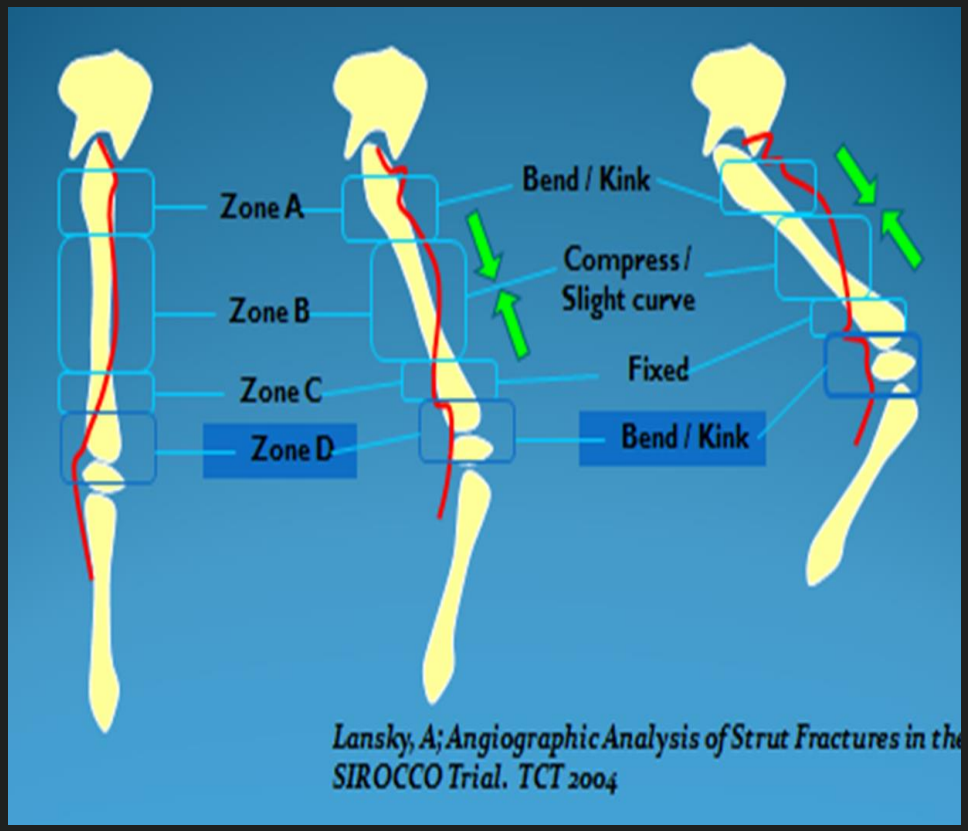
SFA Stent - *1.High Radio Force*



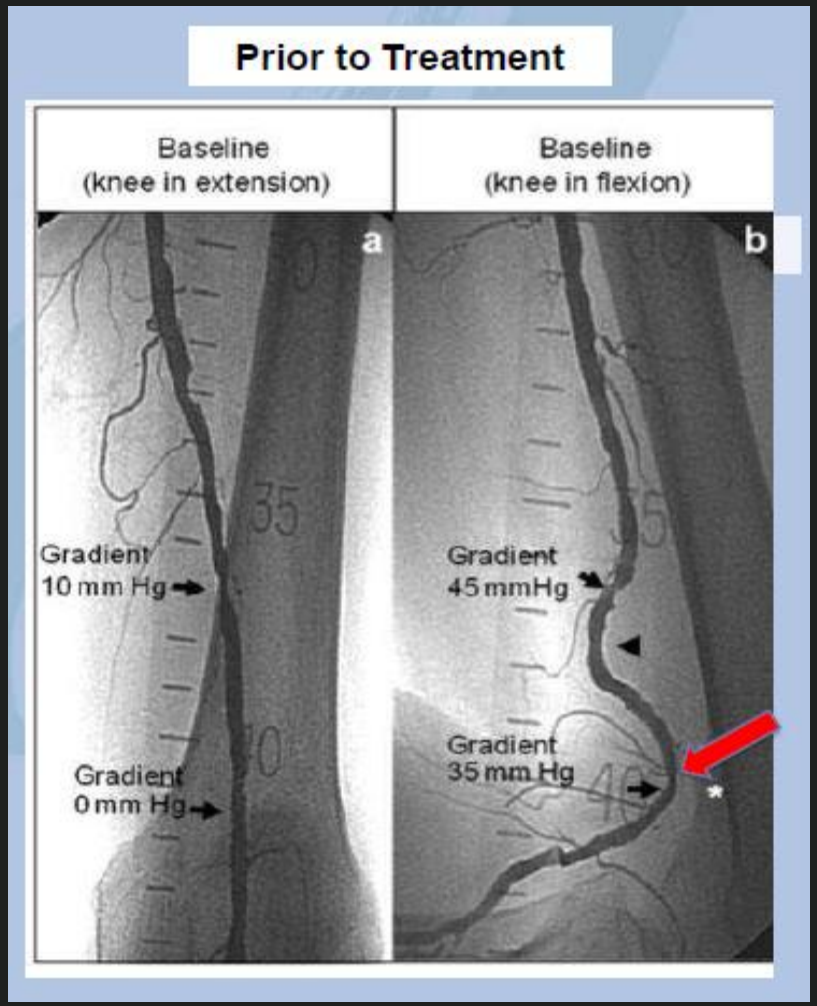
To maintain the lumen open

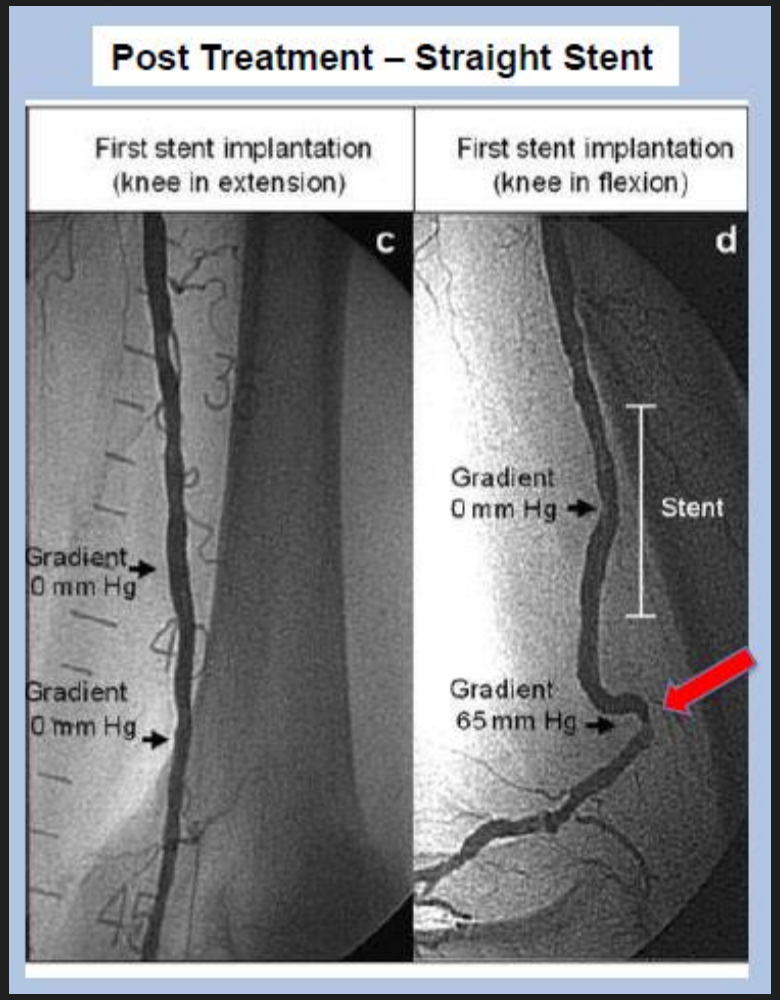
SFA Stent - *2. Flexibility*





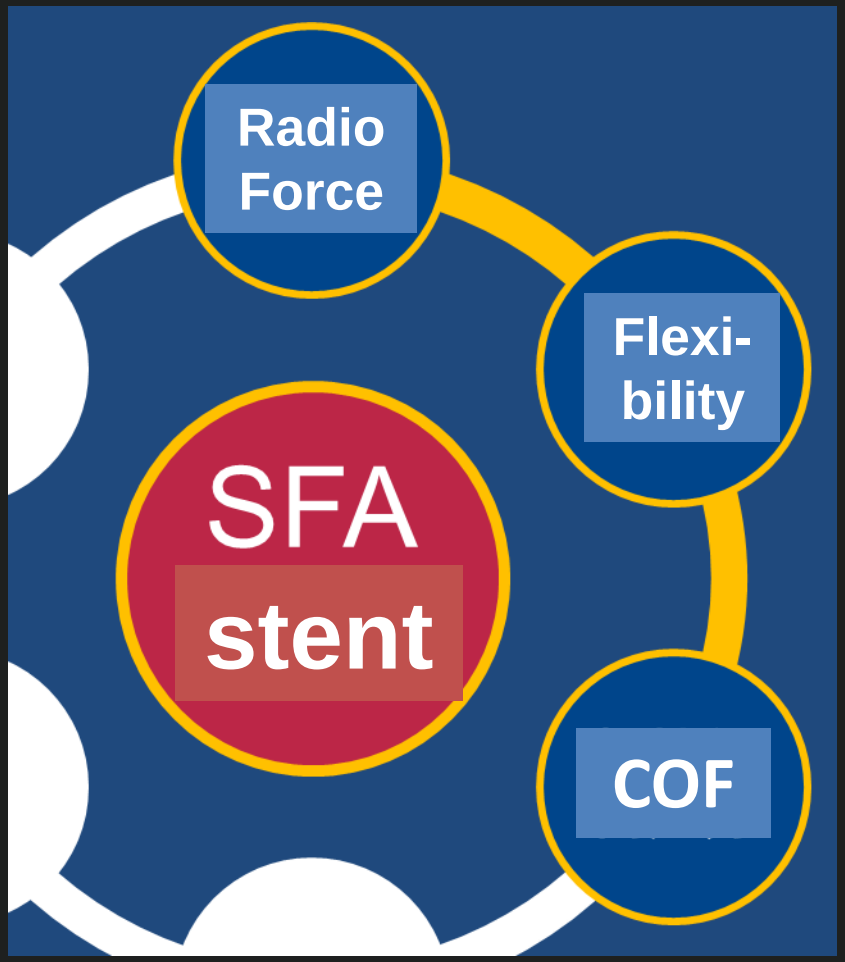
SFA Stent - *2. Flexibility*

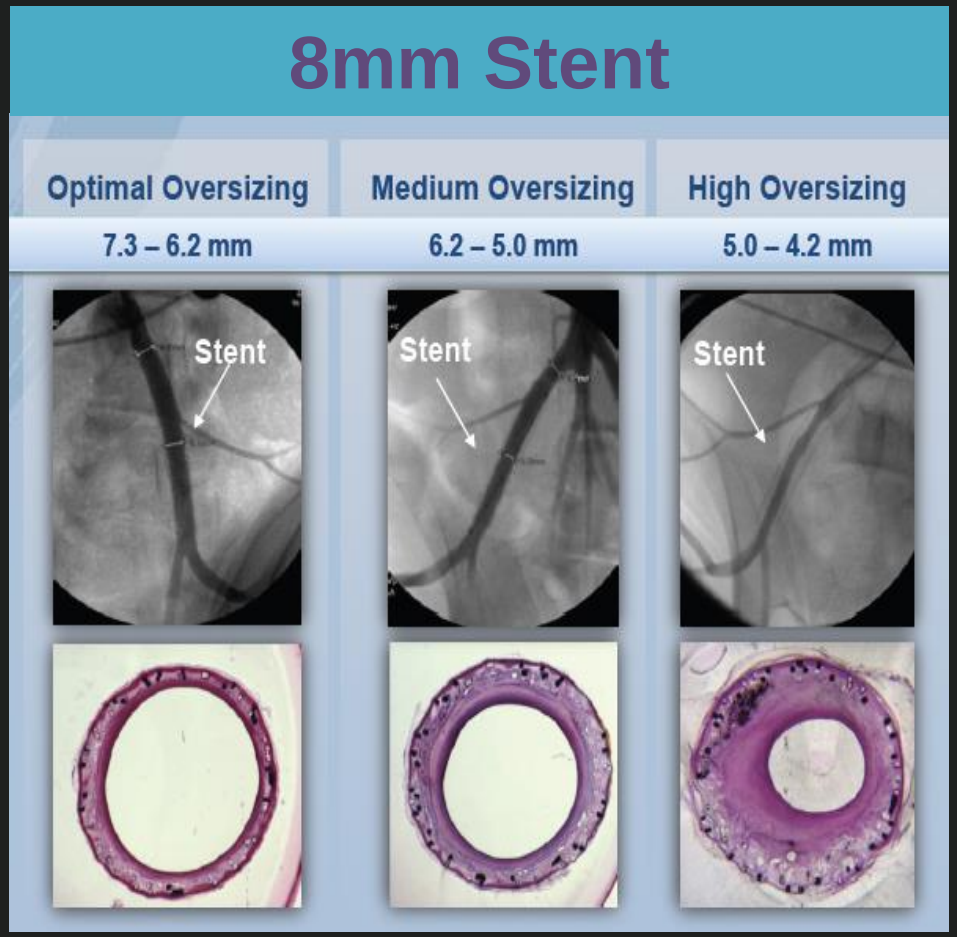




Tamashiro et al, 2015

SFA Stent - 3.Chronic Radial Force





Scheinert D. Prof. LINC AP 2014

Radial Force after stenting

- Chronic Outward Force (COF)
- Radial Resistive Force (RRF)
- Crush Resistance (CR)

Literatures of High COF

Ballyk PD et al. Intramural stress increases exponentially with stent diameter: a stress threshold for neointimal hyperplasia. J Vasc Interv Radiol. 2006 Jul;17(7):1139-45

- to evaluate the impact of stent oversizing on resultant arterial wall stress concentrations and examine the concept of a “stress threshold” for neointimal hyperplasia development
- stent “oversizing” results in an exponential increase in stresses on the vessel wall (intramural)
- intramural stress injury beyond a certain threshold may cause early restenosis by triggering neointimal hyperplasia

Freeman JW et al. A link between stent radial forces and vascular wall remodeling: the discovery of an optimal stent radial force for minimal vessel restenosis. Connect Tissue Res. 2010 Aug;51(4):314-26

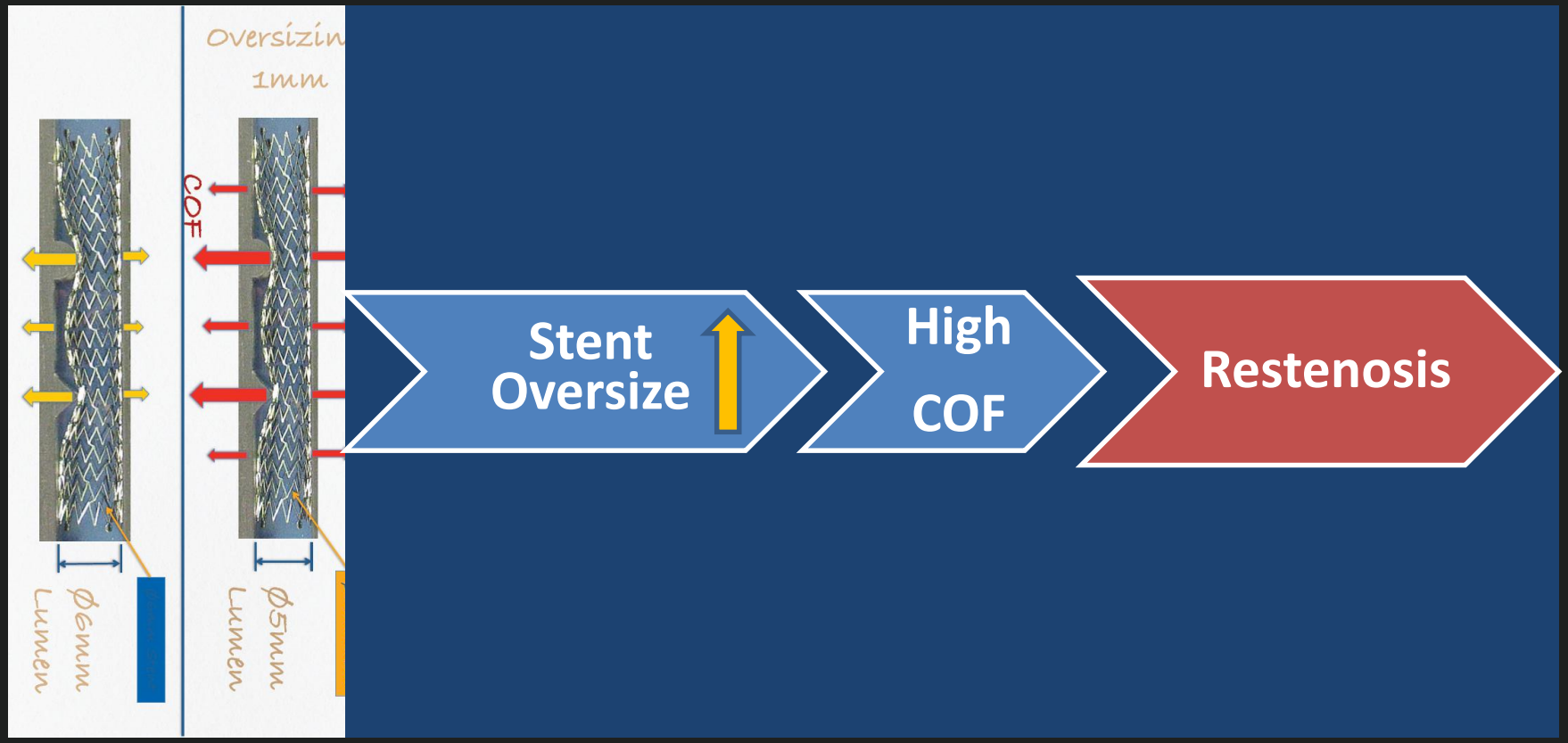
- low, high and ultrahigh radial force stents were implanted in porcine iliac arteries
- 30 days after implantation, significant increase in intimal thickness and neointimal hyperplasia with increasing stent force
- stents should not produce stress in the vessel wall greater than the end of the transitional domain of the vessel’s stress–strain curve

Zhao HQ et al. Late stent expansion and neointimal proliferation of oversized Nitinol stents in peripheral arteries. Cardiovasc Intervent Radiol. 2009 Jul;32(4):720-6

- 8mm diameter SE stents implanted in Yucatan swine Ilio-femoral arteries, stent to artery ratio (oversizing) varied from ratio of 1.2 to 1.9 (7.1 – 4.7mm)
- at 6 months all stents expanded to nominal diameter (8mm)
- severe stent oversizing (>1.4) results in exuberant neointimal proliferation and luminal stenosis

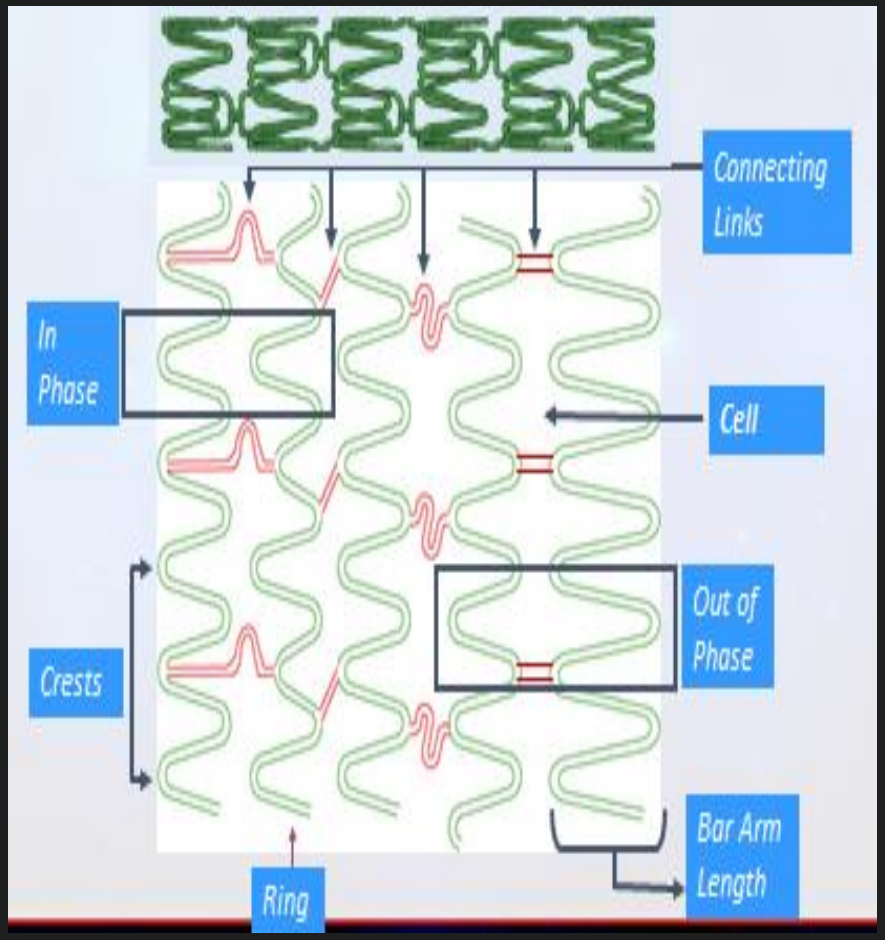
High COF cause neointimal hyperplasia and restenosis

COF - *Stent Oversize Rate*



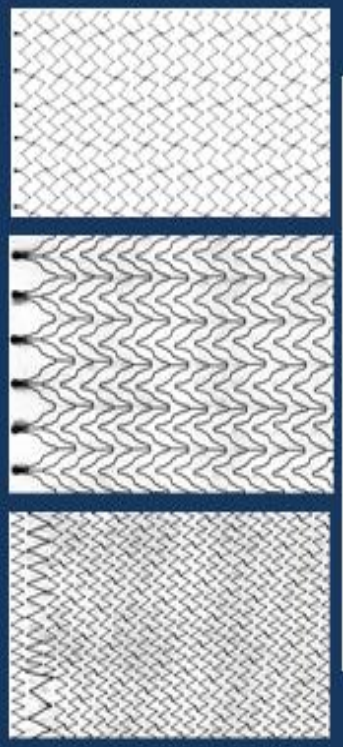
http://gefaessmedizin.ch/PDF%20Dateien/AFS_Vortrag_Graz_Final.pdf

COF – *Stent Design*



These 2D images show very different design structures

- Many design parameters influence final COF
- Main factors are
  - design itself
  - strut thickness
  - strut width
  - number of connectors
  - segment length

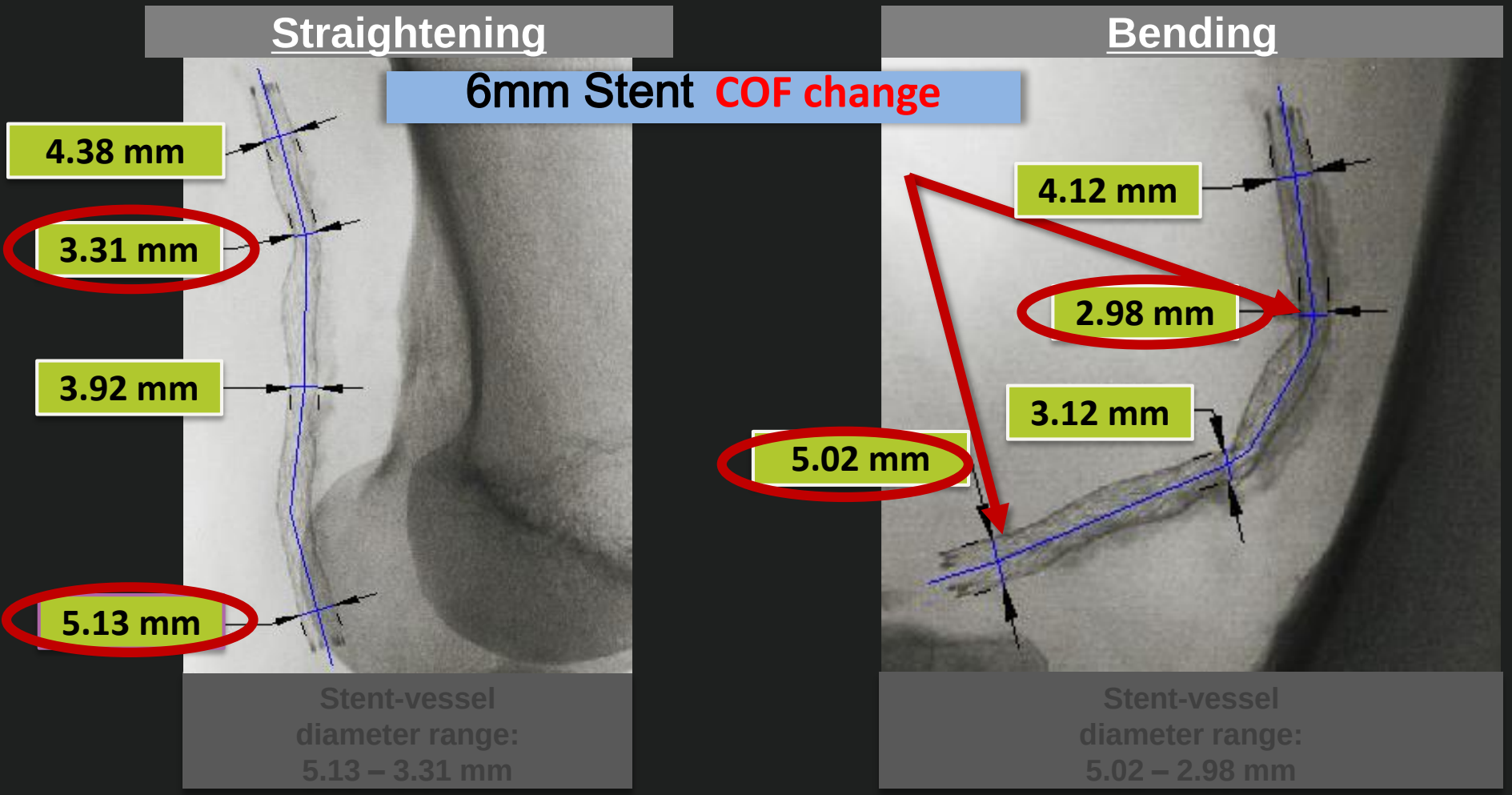


BIOTRONIK Pulsar-18
Strut thickness: 140 µm
Strut width: 85 µm

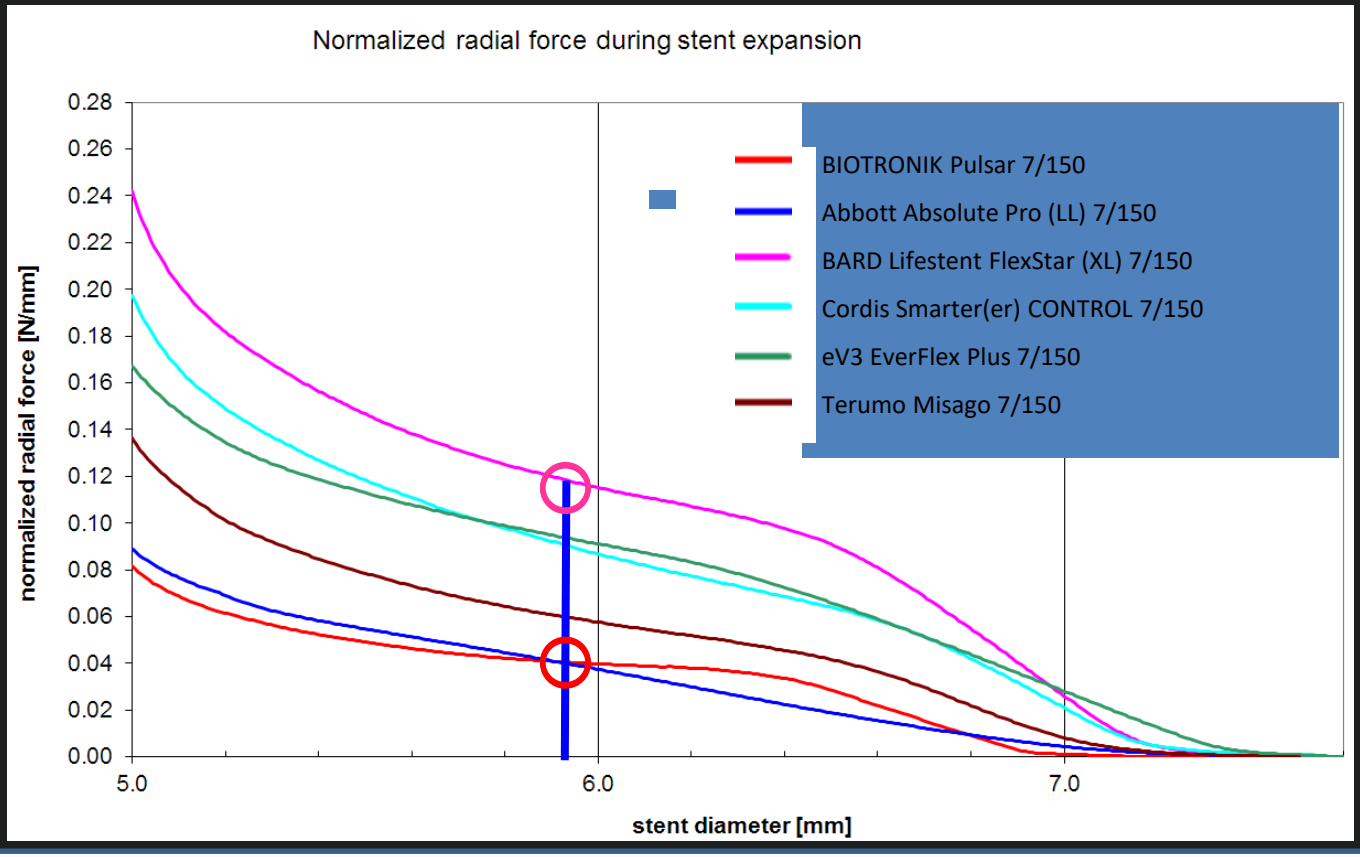
Abbott Absolute PRO
Strut thickness: 230 µm
Strut width: 110 µm

Bard Lifestent Flexstar (XL)
Strut thickness: 205 µm
Strut width: 100 µm

SFA-POP diameter change Location & Exercise



Stent COF changes in different oversizing



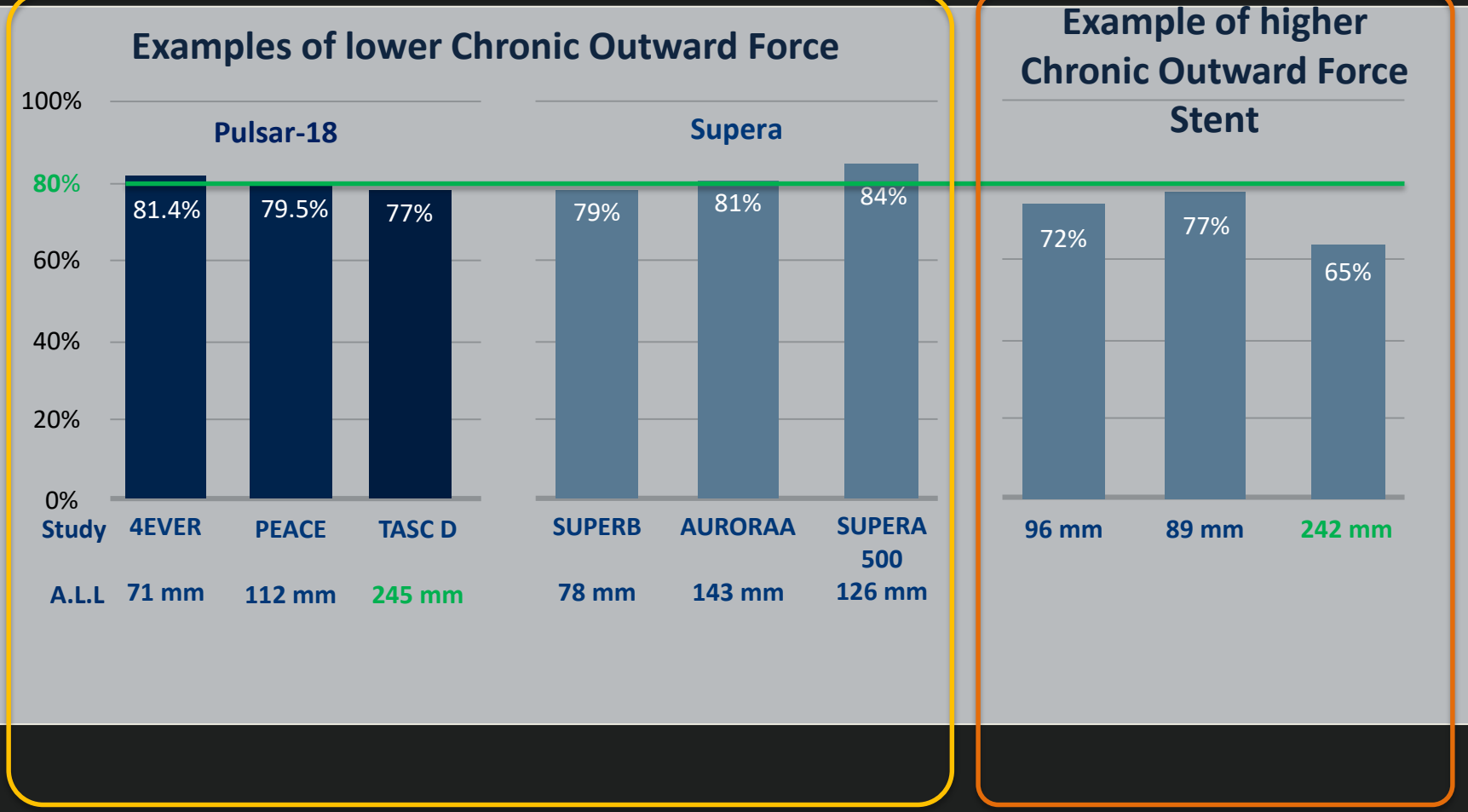
- 7mm stent in 6mm vessel (1mm oversizing), COF of Pulsar (red line) & Absolute PRO (LL) (blue line) similar

- **Oversizing Pulsar/Absolute PRO (LL) stents makes smaller difference to COF than other stents**

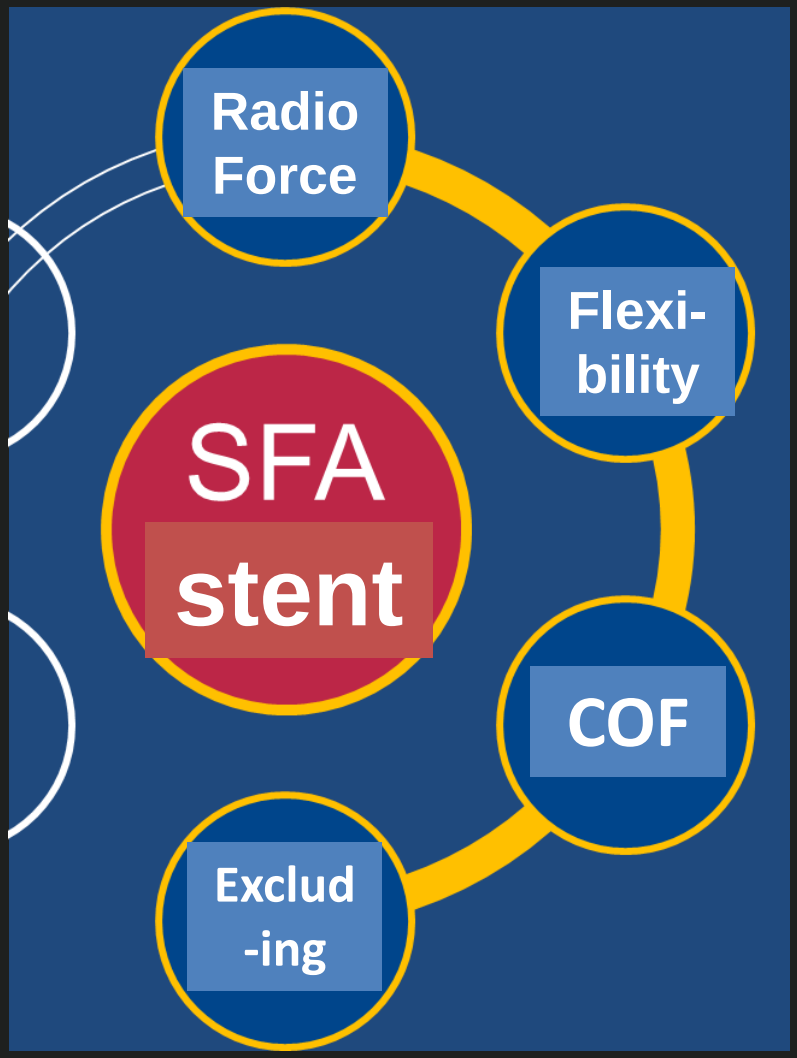
Source: IIB(P)71-2011

COF - Patency of Stent

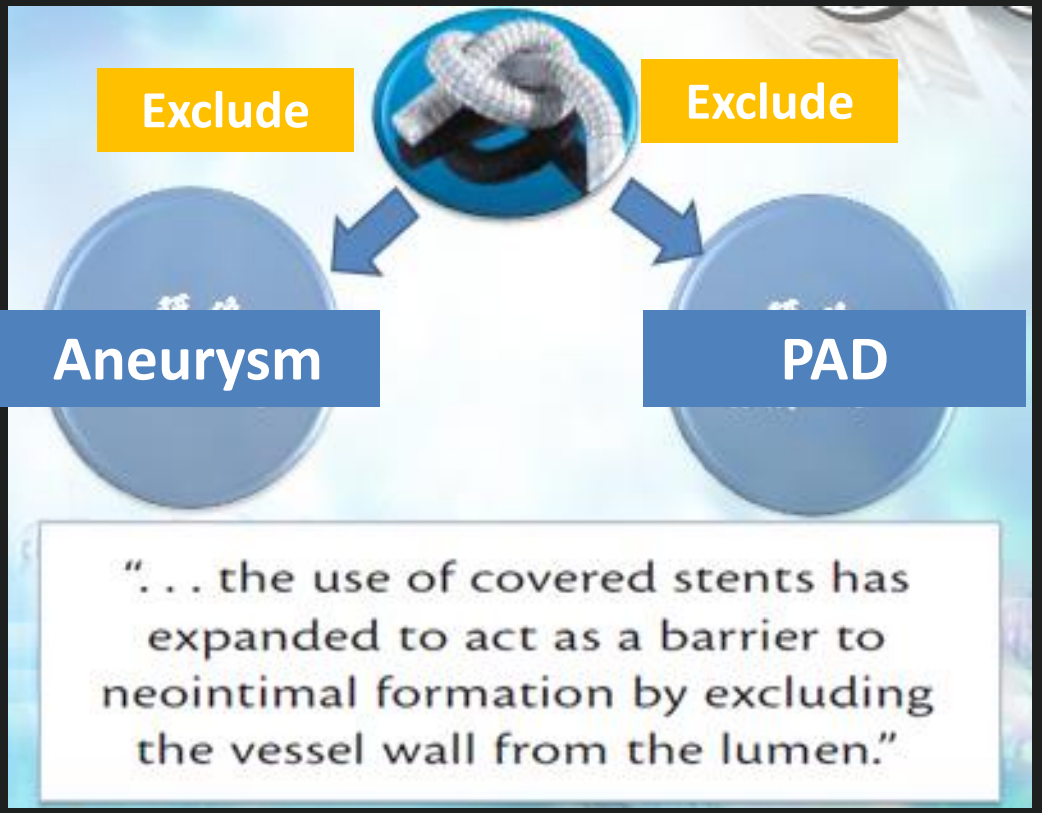
Primary Patency Rates at 12m. Selected SFA trial outcomes



SFA Stent - *4. Excluding the lesion*

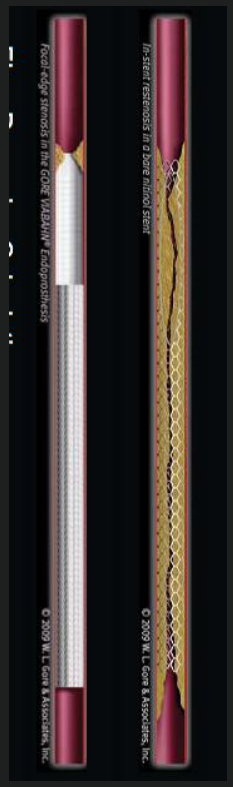


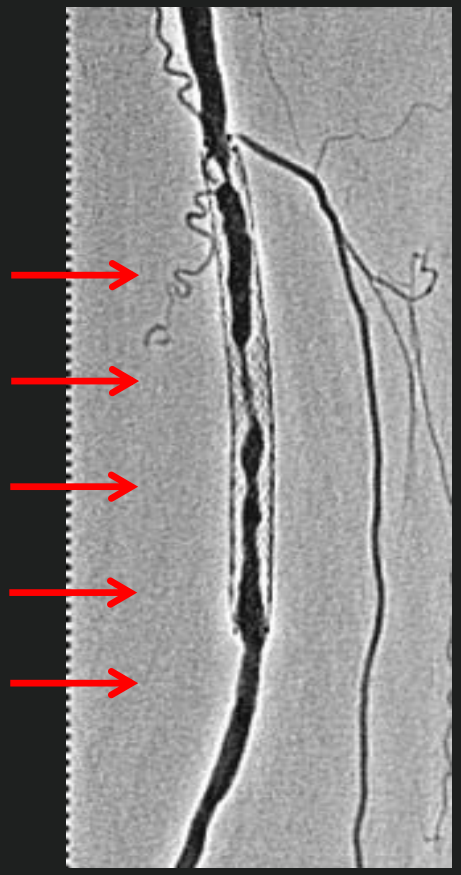
Covered Stent



Cover Stent: Edge restenosis

Cover -





Bare -

Cover Stent: VIASTAR Trial

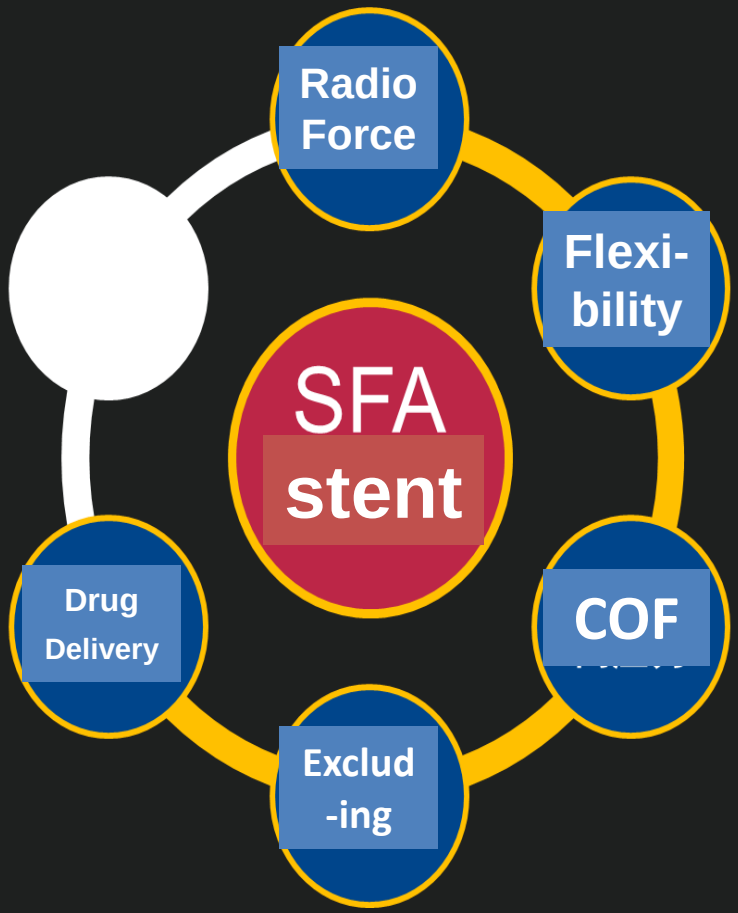
- **(Viabahn Endoprosthesis With PROPATEN Bioactive Surface [VIA] Versus Bare Nitinol Stent in the Treatment SFA Long Lesions)**

Number with 12-month follow-up	GORE® VIABAHN® Endoprosthesis n = 57	Bare Metal Stent n = 52	p-value
Restenoses * (>50%)	9 (16%)	22 (42%)	0.003
Occlusions	6 (11%)	4 (8%)	0.74
Acute Limb Ischemia (ALI)	1 (1.5%)	0	1.0

* GORE® VIABAHN® Endoprosthesis group: only edge stenoses observed.
* BMS group: diffuse in-stent restenosis observed most commonly.

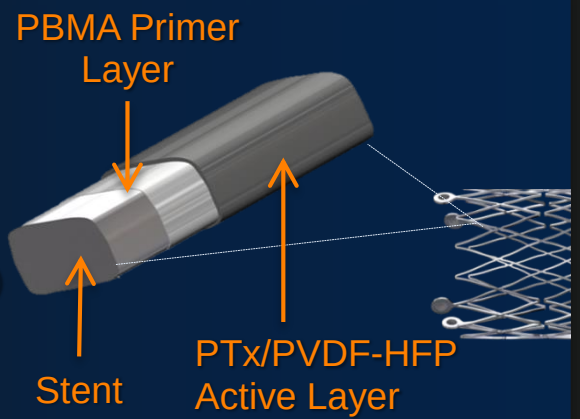
J Am Coll Cardiol. 2013;62(15):1320-1327

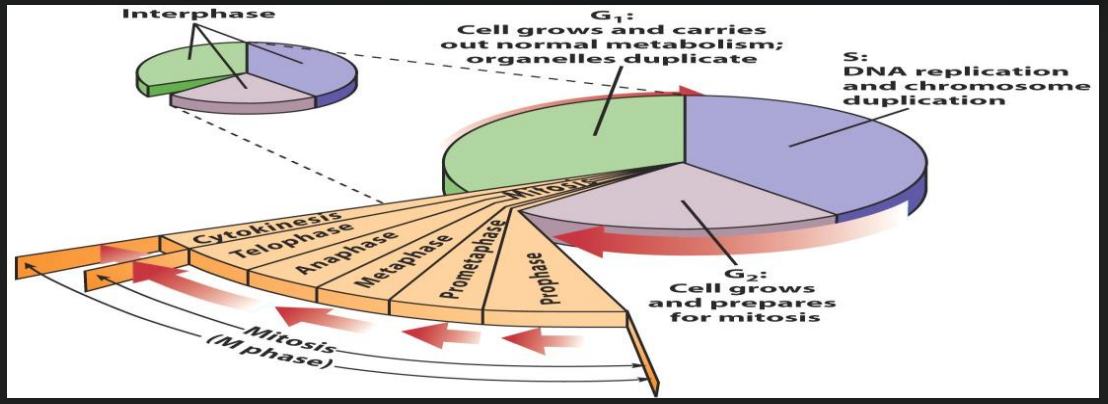
SFA Stent - *5. Local drug delivery*



Primer Layer (PBMA)
Promotes adhesion of active layer to stent

Active Layer (PTx/PVDF-HFP)
Controls release of Paclitaxel

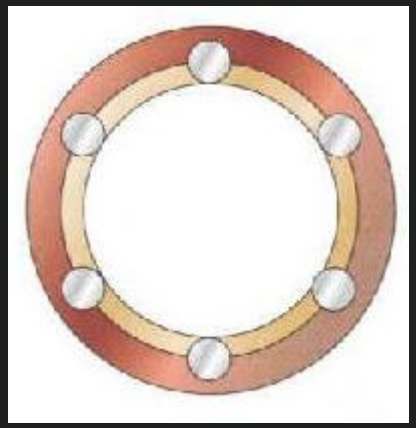




SFA Stent - *6. Strut (width)*

- **Dedicated design for small vessels – <u>not</u> a large vessel stent in smaller diameters**
- **Flow optimization due to thinner struts[1]**

Large vessel stent
e.g. Astron, Smart, E-Luminexx etc…



Large vessel

Small vessel stent
e.g. Pulsar,, Superflex-418, Xpert

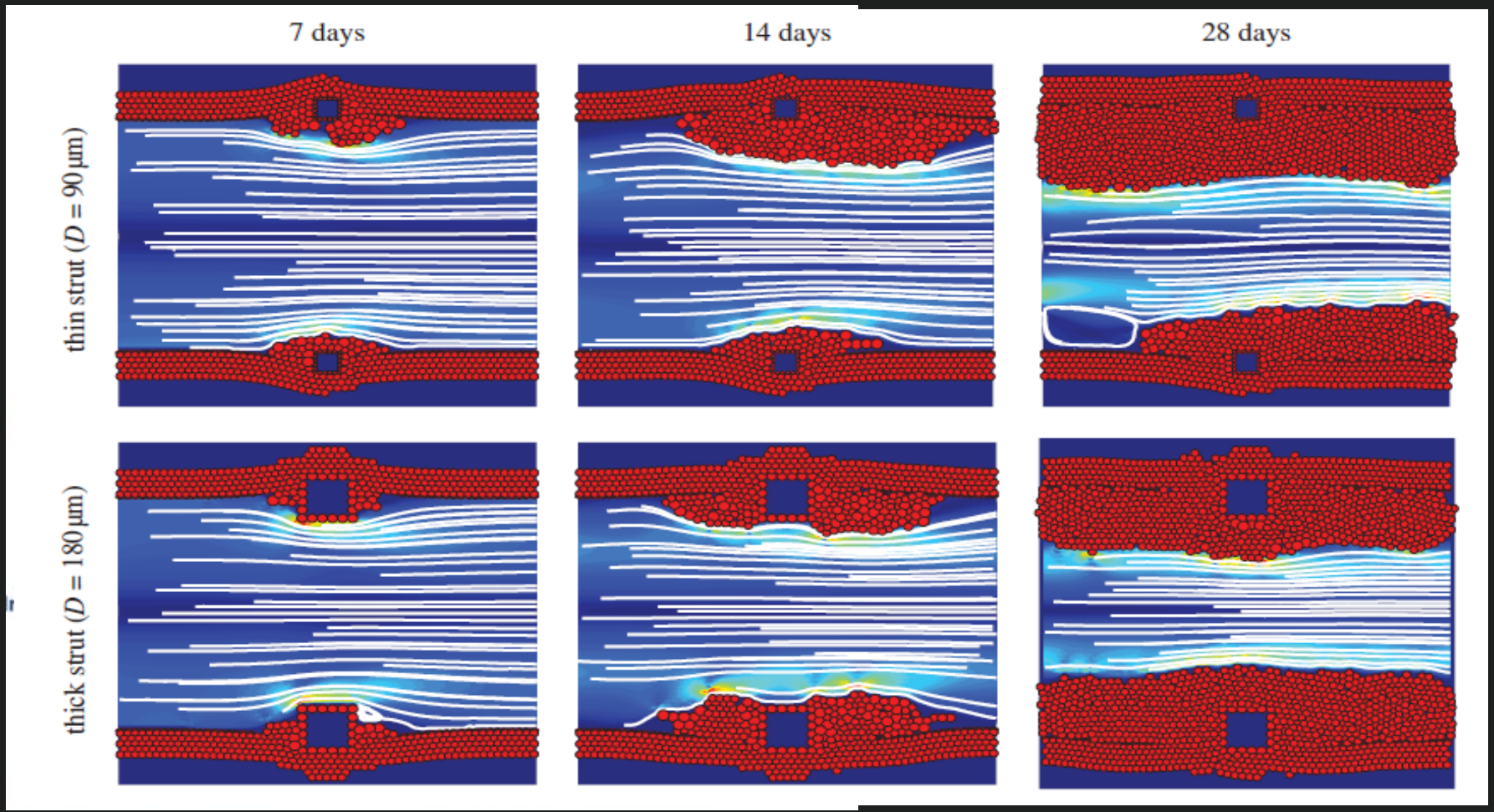
Small vessel

Small vessel

Strut thickness / Lumen Optimization
Strut thickness / width 140µm - 228µm

1 BIOTRONIK data on file

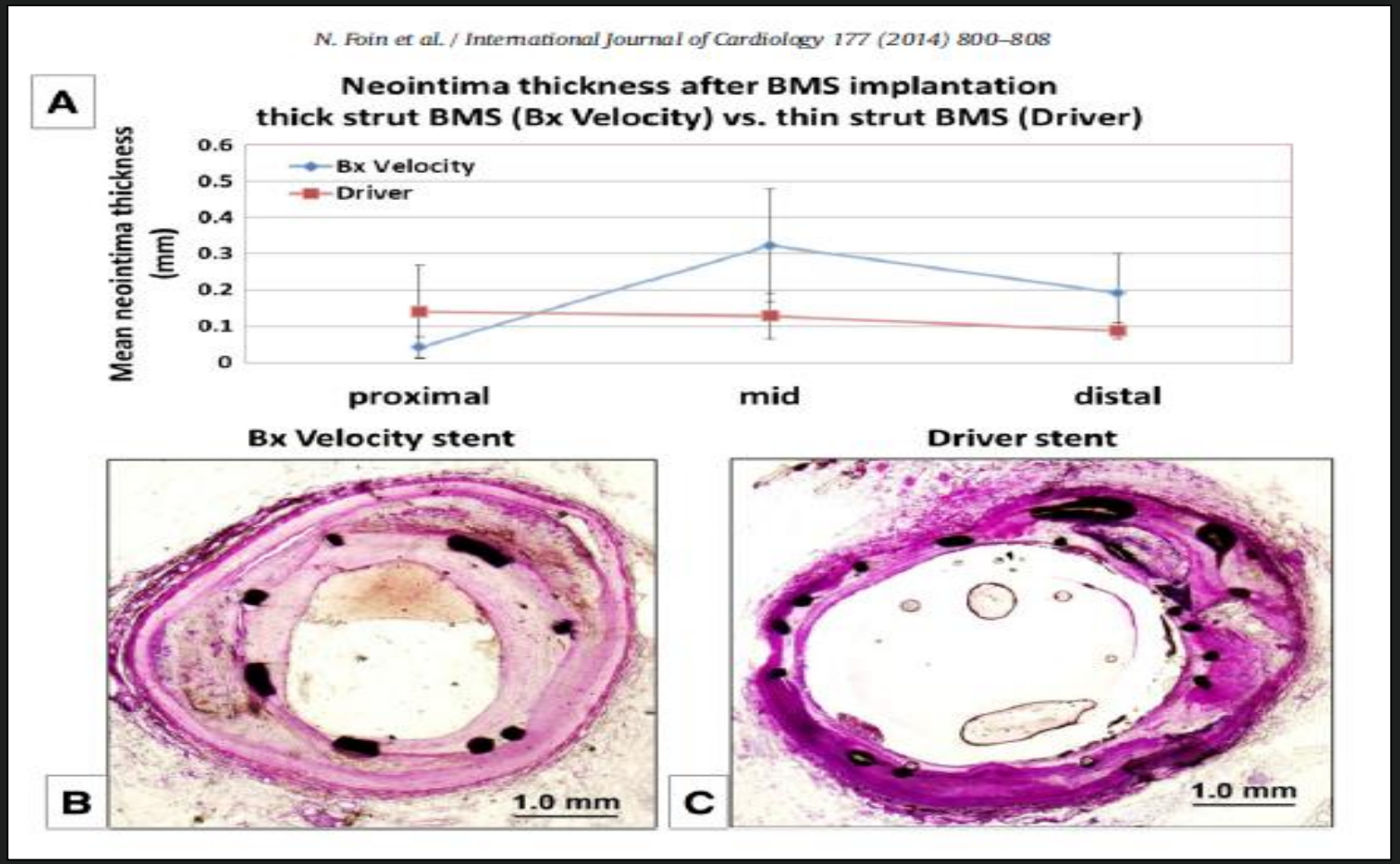
SFA Stent - *6. Strut (width)*



Interface Focus (2011) 1, 365–373

International Journal of Cardiology 177 (2014) 800–808

SFA Stent - *6. Strut (width)*



International Journal of Cardiology 177 (2014) 800–808

SFA Stent - *6. Strut*

(Close/Semi-close/Open Cell)

LINC

DEBAS

SELF-EXPANDING NITINOL STENTS COMBINED WITH DCB

24-MONTH FOLLOW-UP OF THE DEBAS STUDY

B. PATRICE MWIPATAYI, MMed, FCS (SA), FRACS
Department of Vascular Surgery, RPH
School of Surgery, University of Western Australia Perth

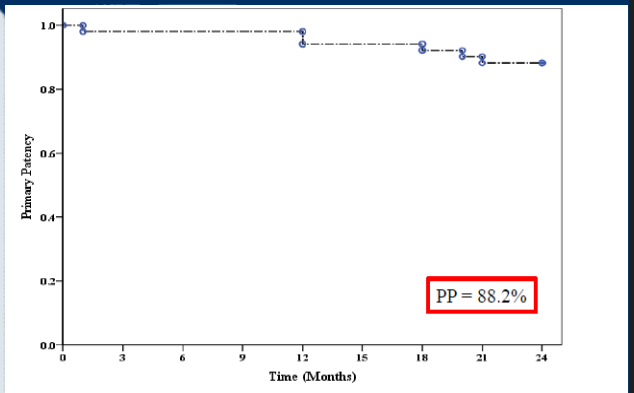
Predilate lesion

↓

Implant SE Stent in diseased segment

↓

Deliver DCB to entire stented segment



Primary Patency	
6M	98%
1yr	94.1%
2yrs	88.2%

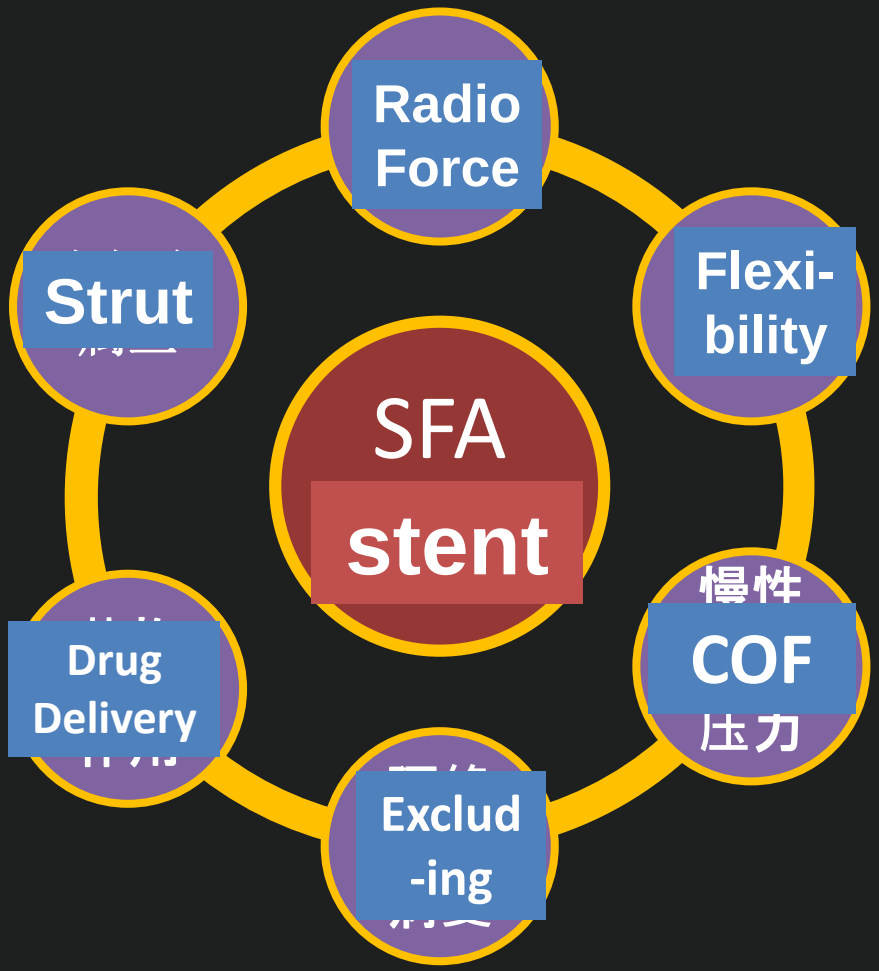
BMS + DCB

Drug Delivery

Touch Area

Product	Metal to artery ratio (wall coverage)
XACT	10.09%
Acculink	10.82%
Absolute pro	13.88%
Omnilink	13.6%
Herculink	10.4%
Xpert	11.8%

SFA Stent - *6. Strut*



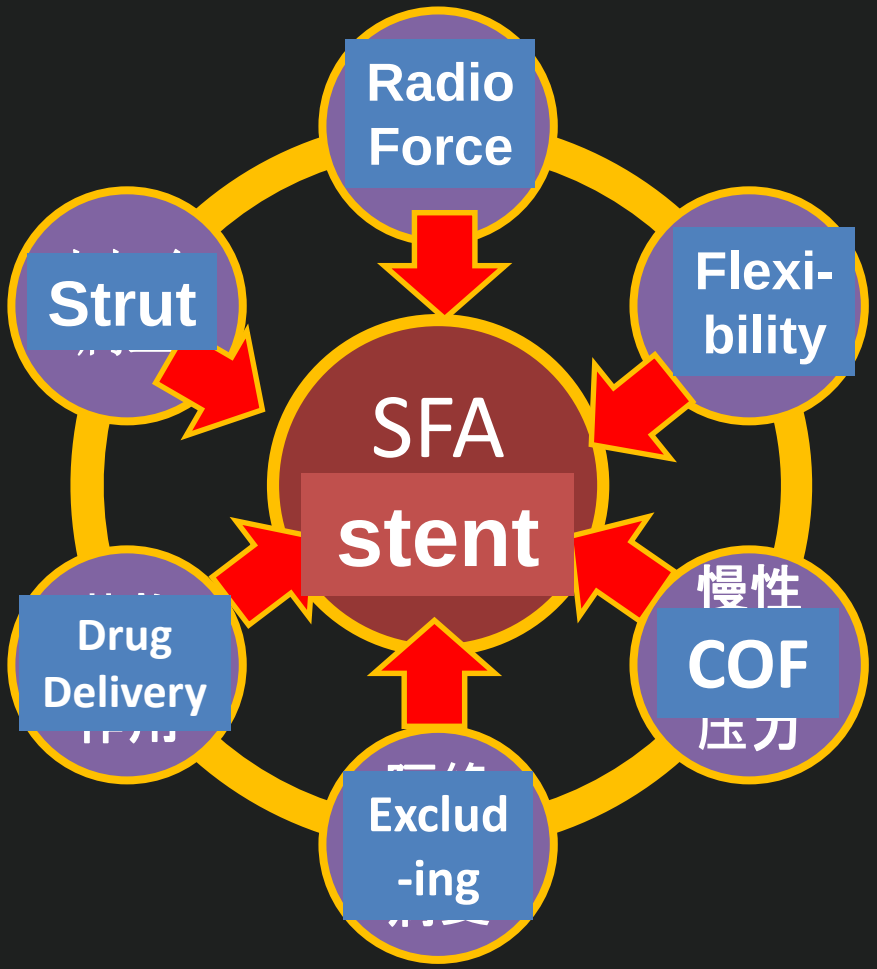
Thin

Thickness of Strut

Small

Metal wall Coverage

What is Perfect SFA Stent



Summary

- Stent is necessary in complex SFA lesion
- SFA Stent needs to adapt native artery
- Design of stent is key to clinical outcome
- Better SFA stent is always needed

Thank You

Better Endo, Better life