Unique Considerations for SFA Disease

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Biomechanik

The SFA Applies Dynamic Forces

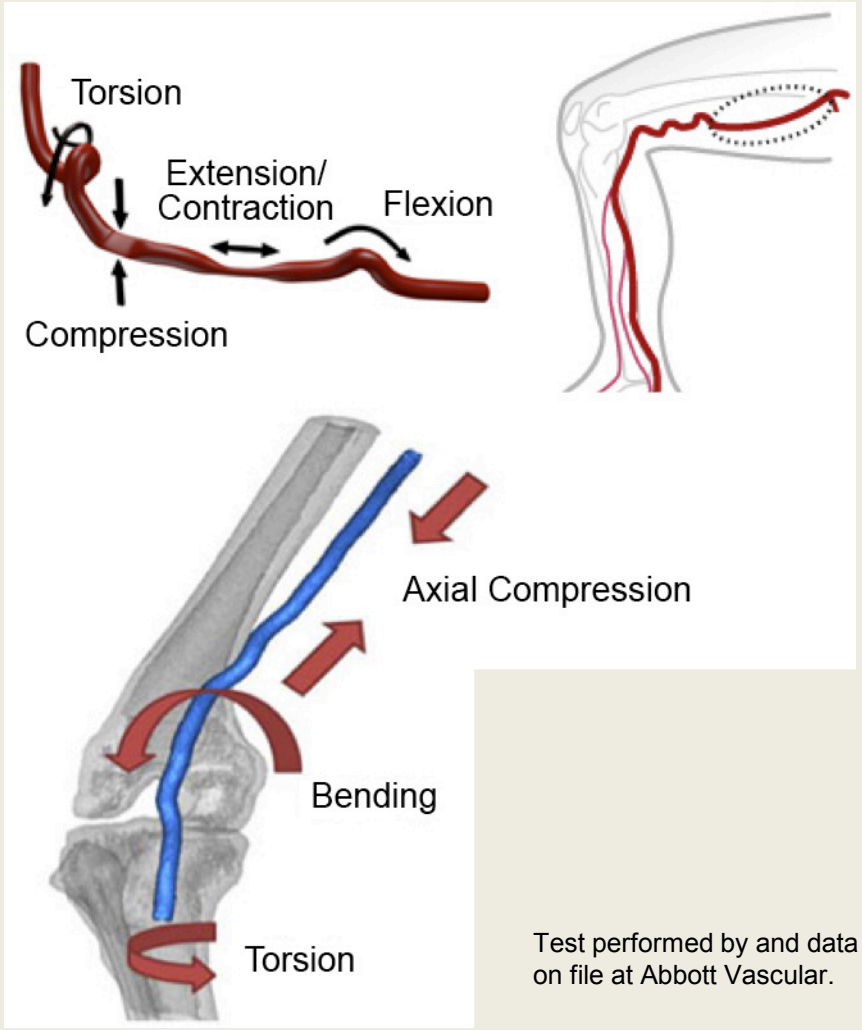
SFA Challenges

Shortening

Increased Curvature

Twist

Flexion

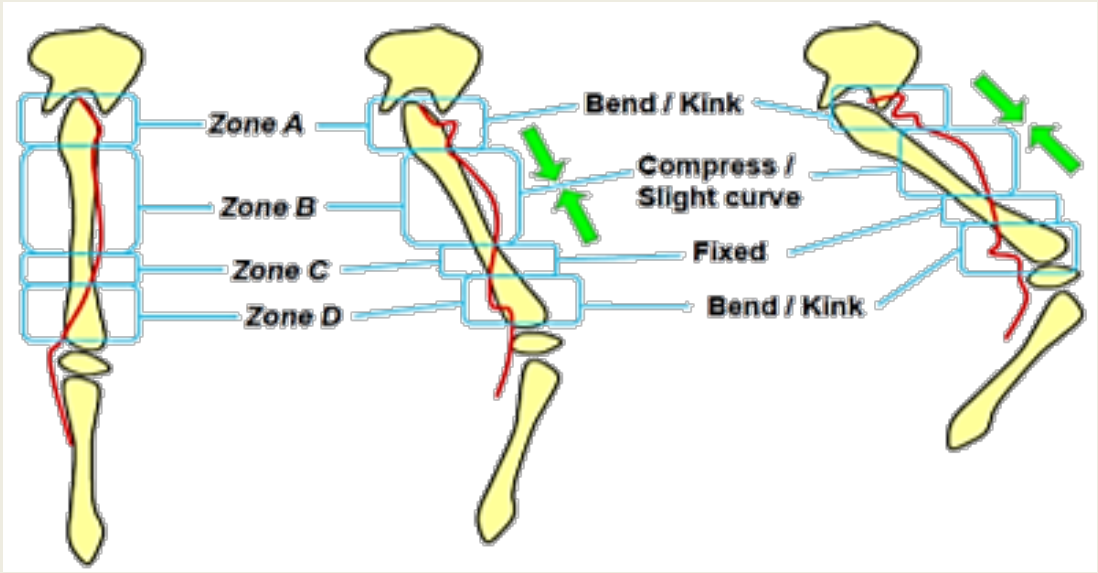


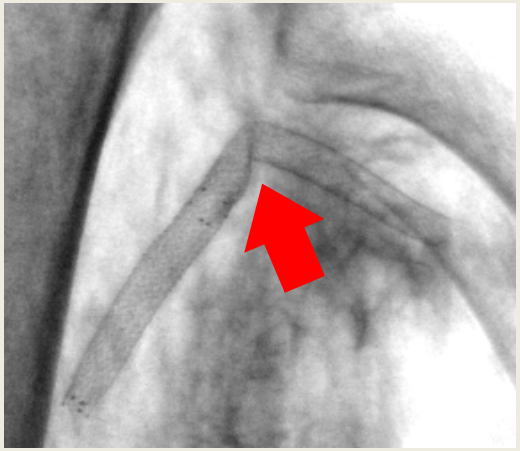
SFA, superficial femoral artery.
Klein AJ et al. *Catheter Cardiovasc Interv.* 2009;74(5):787-98.

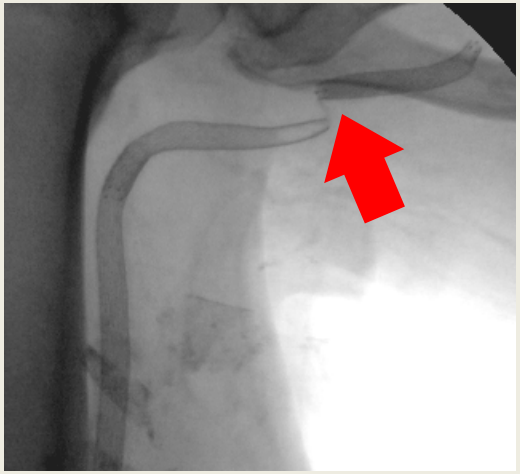
Test performed by and data on file at Abbott Vascular.

SFA: The Bad Conduit

- **up to 23% axial compression and 90° bending in native dist SFA/PP**







- **Relevant and cyclic mechanical stress continuosly beared by either the stent or by the non-stented vessel portion**

H. Bob Smouse, ISET 2008

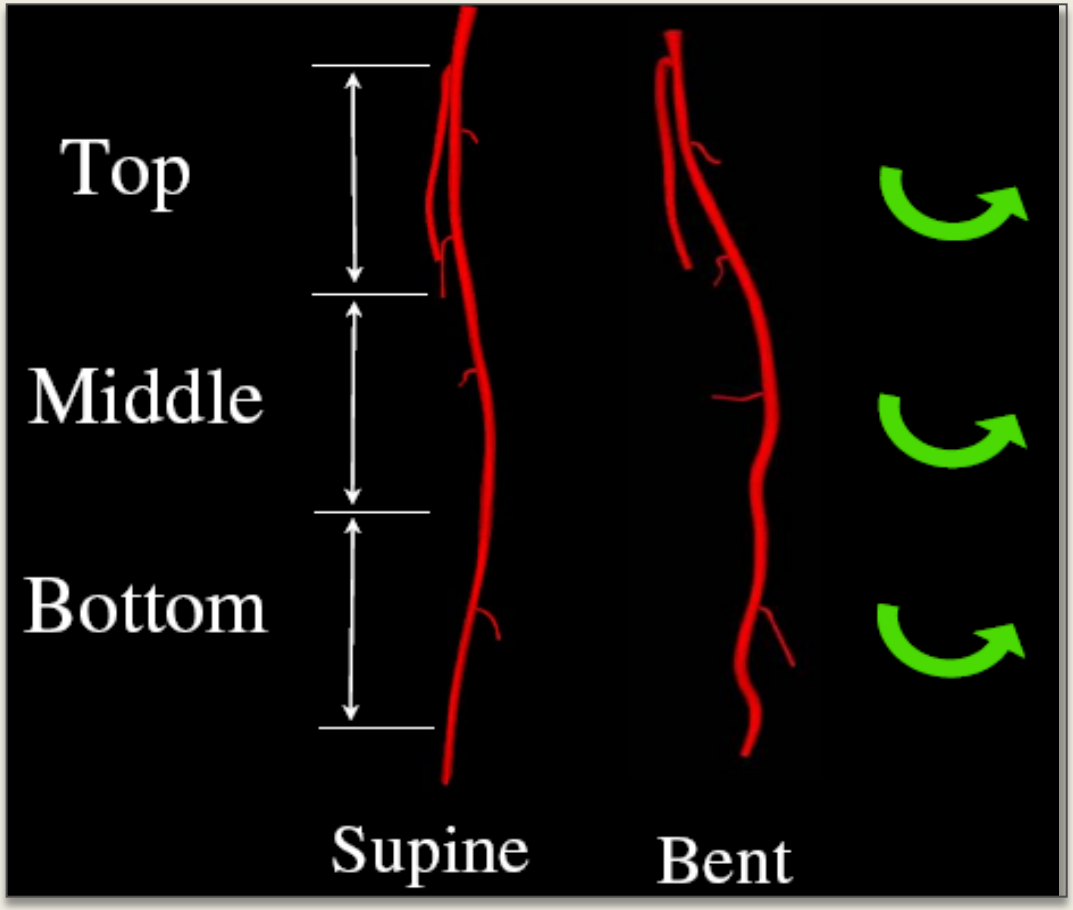
Twisting Deformation

Twist/cm

1.4 ± 1.2°/cm
2.1 (0.1-5.4°/cm)‡

2.1 ± 2.9°/cm
2.1 (0.1-5.4°/cm)‡

2.8 ± 4.4°/cm



Cheng CP et al. *J Vasc Interv Radiol.* 2006
‡Ansari F et al. *J Vasc Surg.* 2013

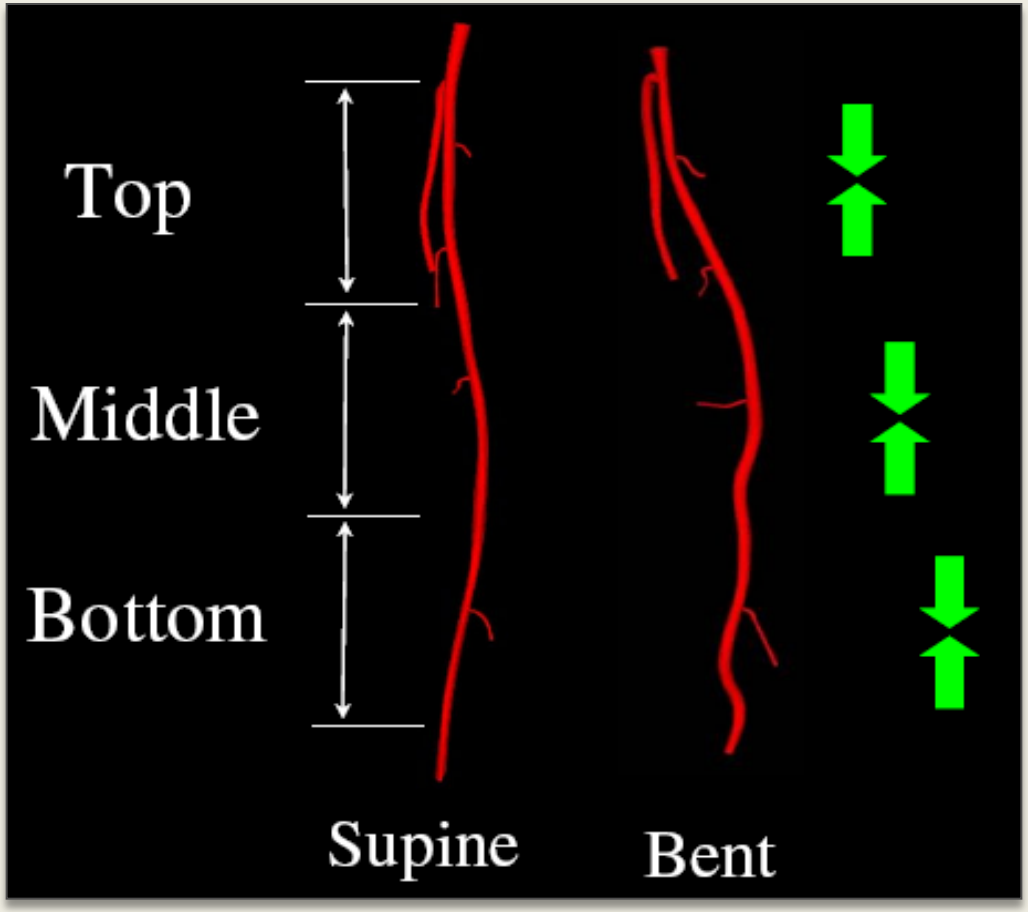
Axial Shortening

Length Change, %

6.4 ± 4.9%
4 (0-11%)‡

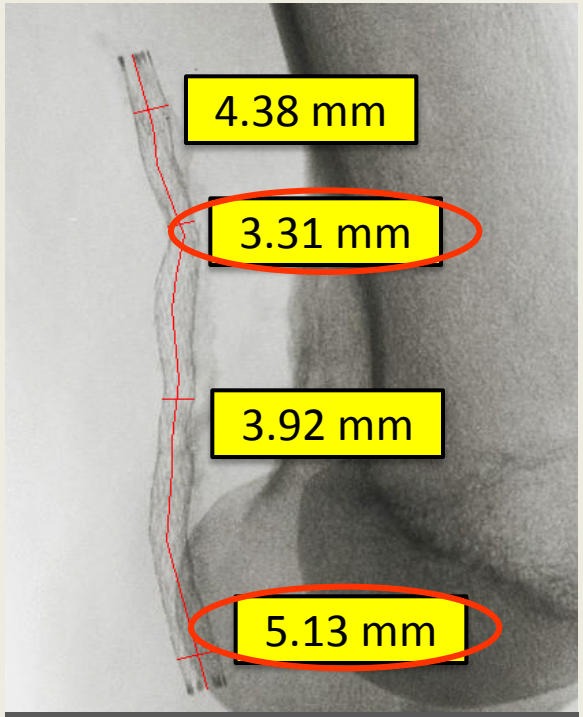
7.7 ± 1.9%
4 (0-11%)‡

7.4 ± 4.3%
8.1 (1.8-21.5%)‡



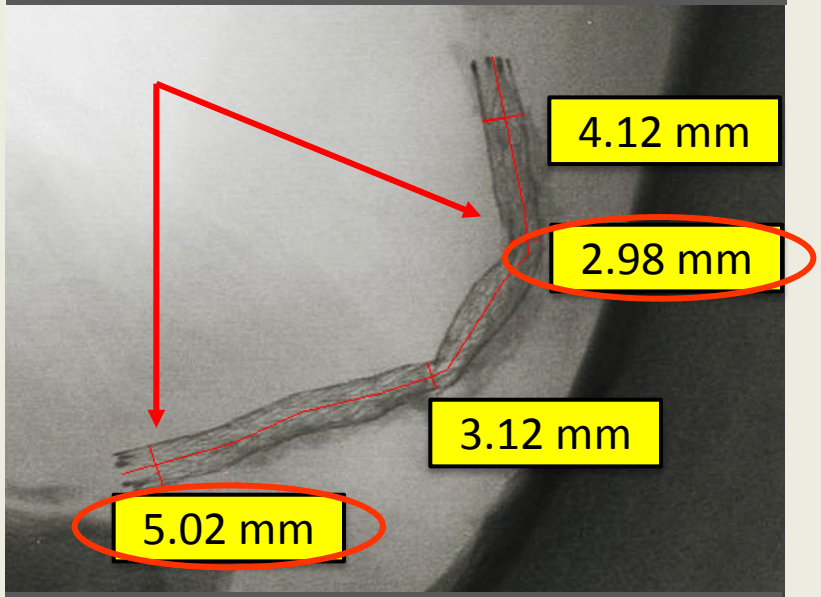
Cheng CP et al. *J Vasc Interv Radiol.* 2006
‡Ansari F et al. *J Vasc Surg.* 2013

In SFA & Popliteal Stent/Vessel Diameter Changes with Leg Motion



Stent-vessel diameter range: 5.13 - 3.31 mm

Change in vessel diameter causes variable and increasing chronic outward force



Stent-vessel diameter range: 5.02 - 2.98 mm

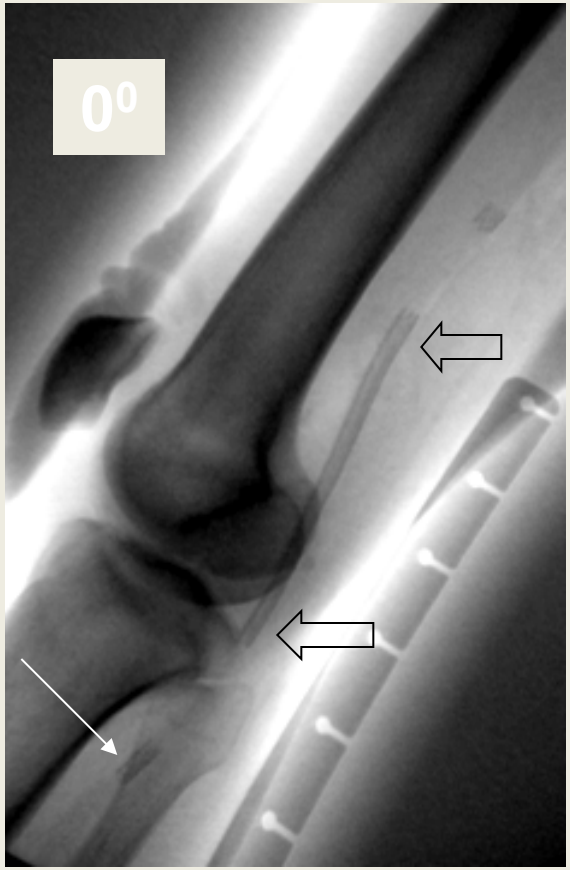
Nikanorov A et al. 2009

Fracture of self-expanding nitinol stents stressed in vitro under simulated intravascular conditions

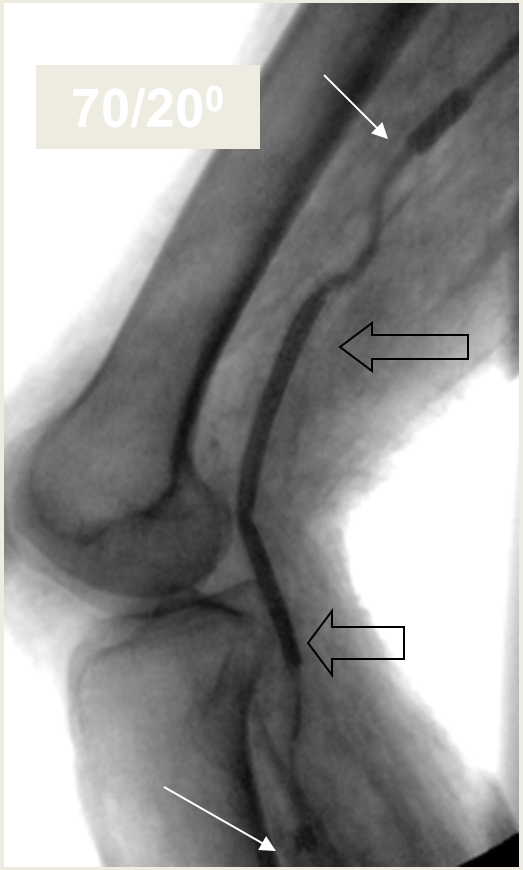
Alexander Nikanorov, MD, PhD,[a] H. Bob Smouse, MD,[b] Karim Osman, MS,[a] Michael Bialas, ME,[a] Sanjay Shrivastava, PhD,[a] and Lewis B. Schwartz, MD,[a] *Santa Clara, Calif; and Peoria, Ill*

JOURNAL OF VASCULAR SURGERY
■ 2008

Ex vivo Studies



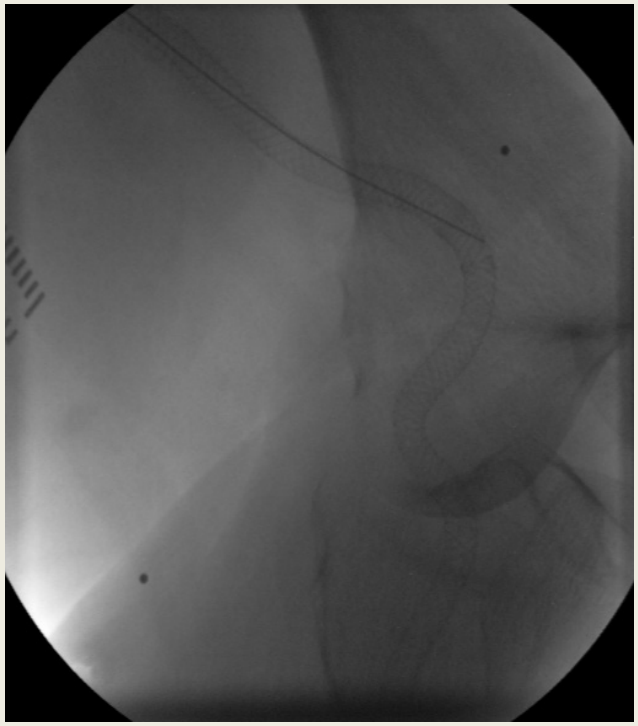
Standing



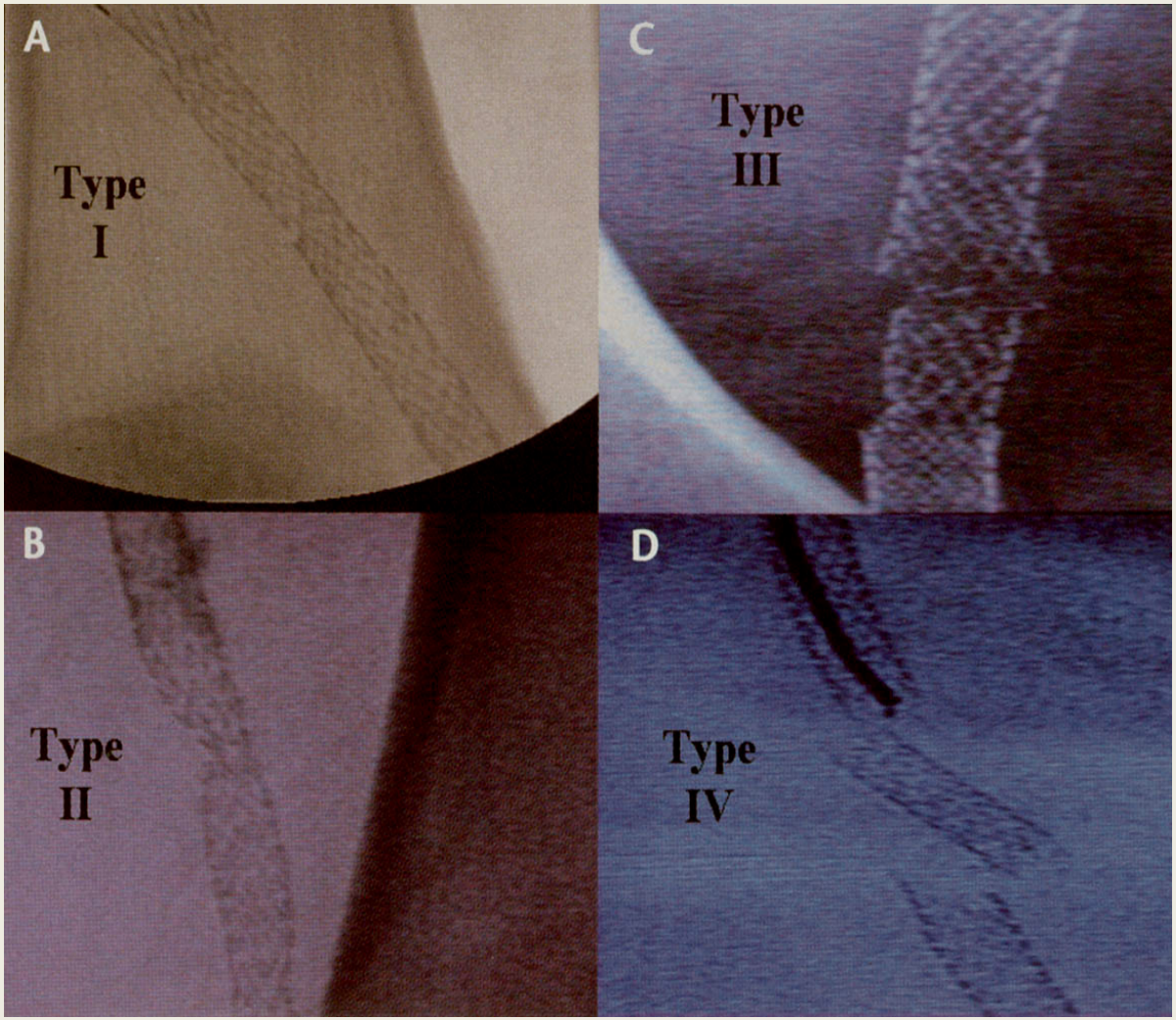
Walking

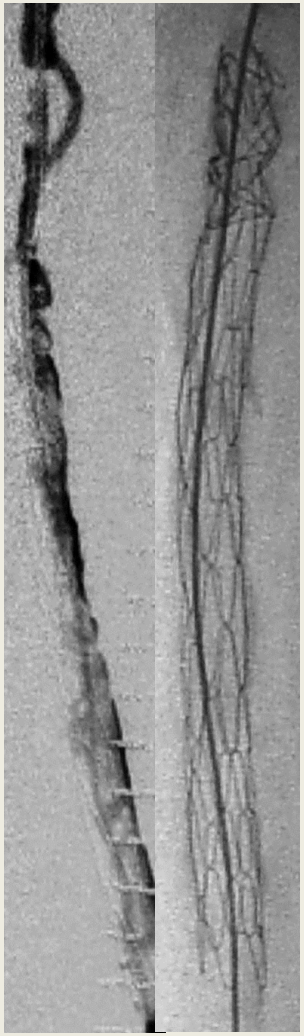
Sitting

Interwoven Stent (SUPERA)



Stress Results in Fracture!

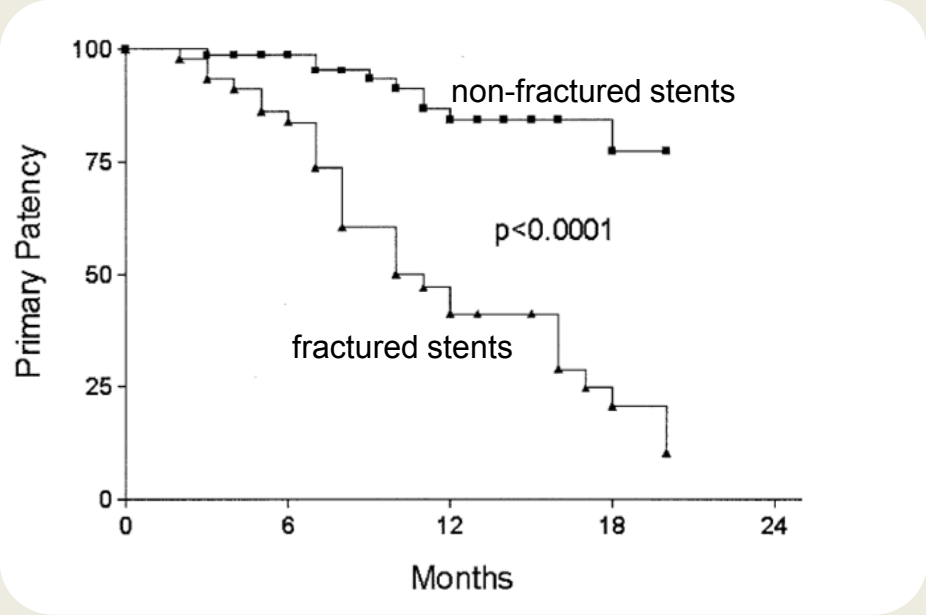




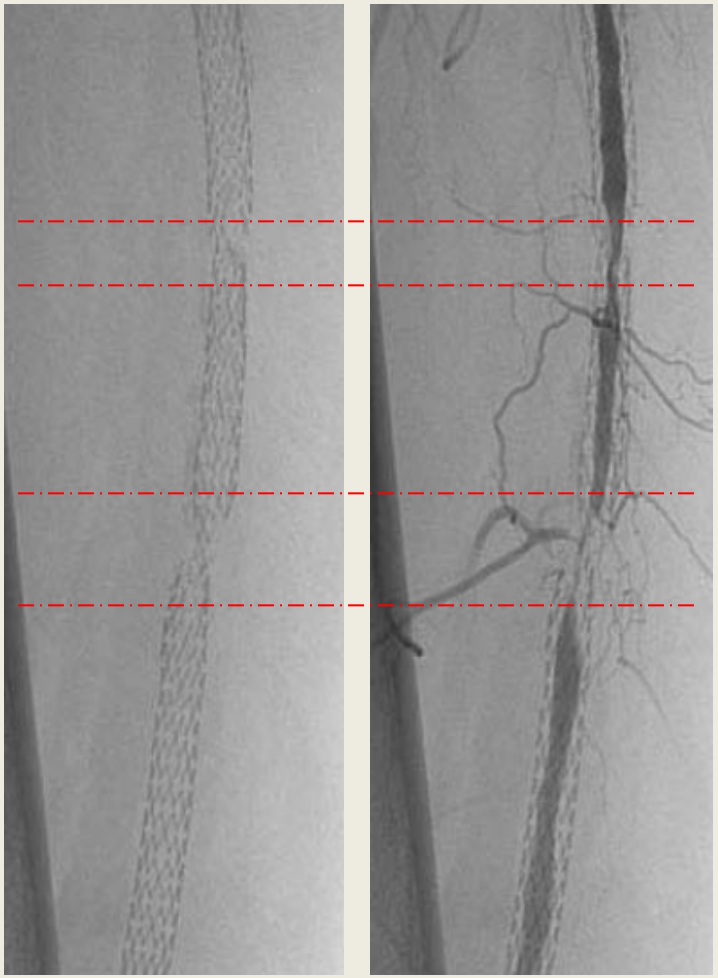
Allie et al., *Endovascular Today*, 2004

SFA: Stent Fractures

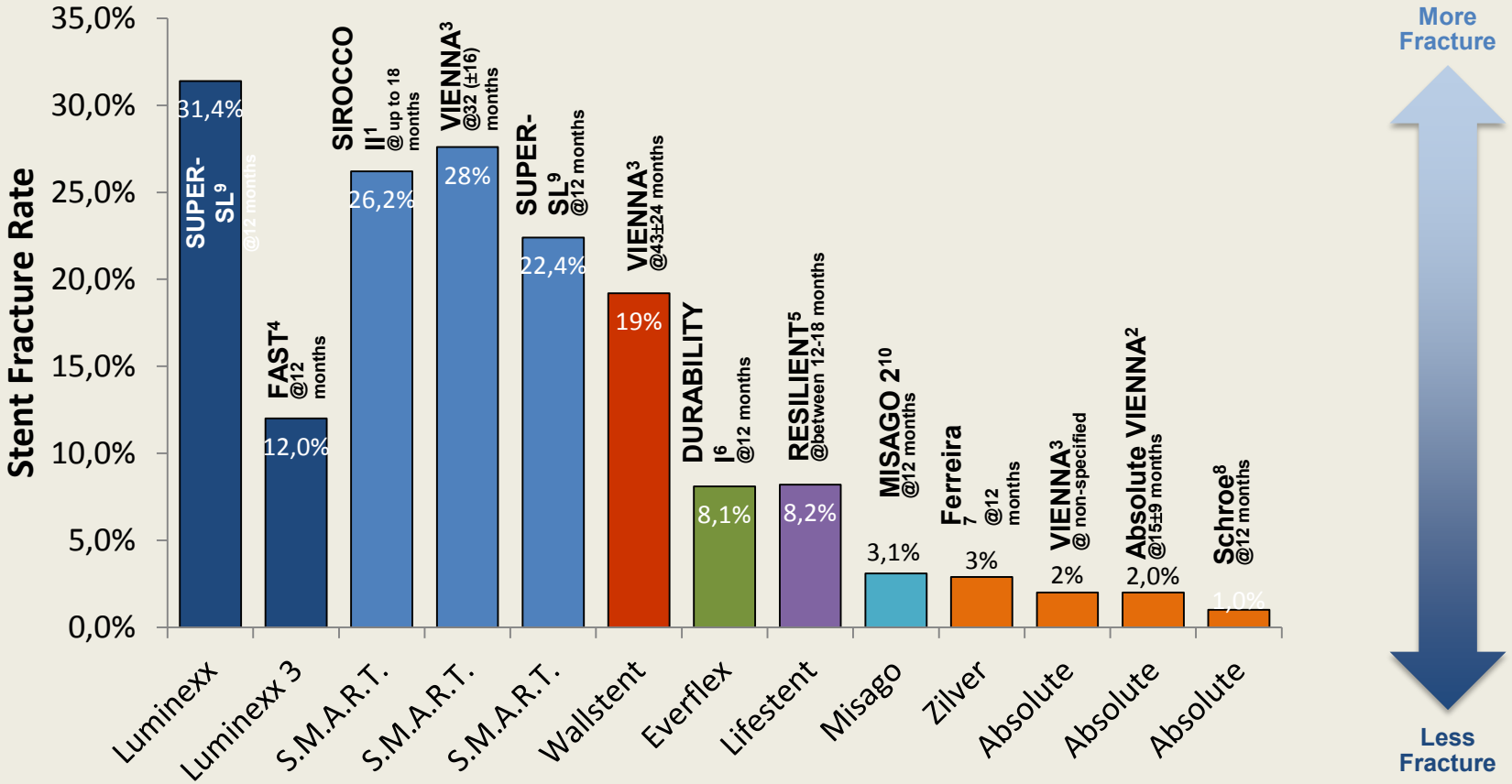
- **Stent fractures may occur**
- **may be associated with restenosis**
- **Long term incidence and implications remain unknown**



Scheinert et al, JACC 2005



Stent Fracture Rates Differ by Stent Design: Clinical Rates of Stent Fracture in the SFA



[1]Duda SH, et al. *J Endovasc Ther.* 2006;13:701-710. [2]Schillinger M, et al. *N Engl J Med.* 2006 May 4;354(18):1879-88. [3]Schlager O, et al. *J Endovasc Ther.* 2005 Dec;12(6):676-84. [4]Krankenberg H, et al. *Circulation.* 2007 Jul 17;116(3):285-92. [5]Bard LifeStent B05680 vers. 6/12-10 US Instructions for Use. [6]Scheinert D. TCT, 2008, Washington D.C., United States. [7]Ferreira M, et al. *Eur J Vasc Endovasc Surg.* 2007 Dec;34(6):702-8. [8]Schroë H, et al. CIRSE, 2008, Copenhagen, Denmark; [9]Duda S. LINC 2009. Leipzig, Germany. [10] Schulte KL et. al. *J Endovasc Ther.* 2012 Dec;19(6):774-84.

Weitere Ursachen für Stent-FX

- Anzahl der Stents
- Überlappungszonen
- Technische Aspekte (Freisetzung der Stents)

<u>Aber:</u>

Stent-Fx und Restenose— Korrelation??

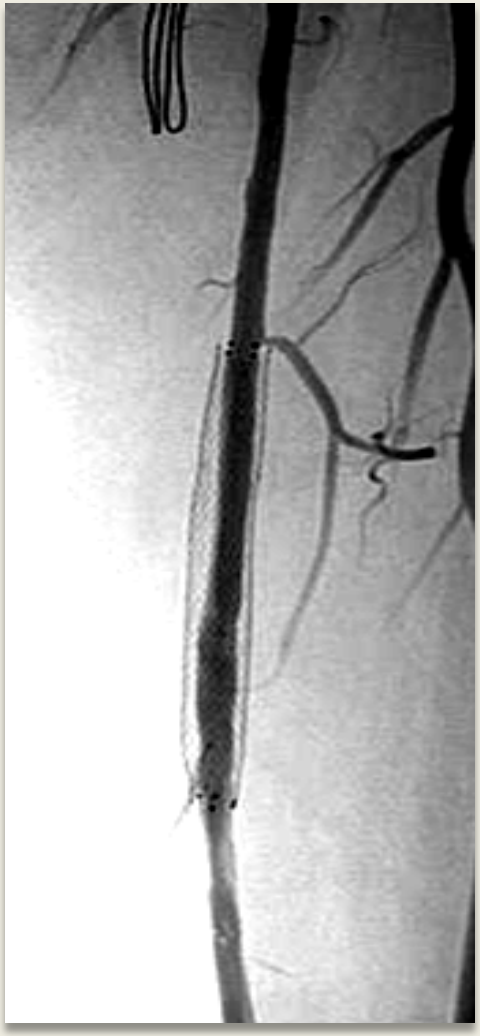
Selbst wenn ja, ist die Stent-Fx bedingte Restenose fast zu vernachlässigen.

Laird JR circcardiovasc inter. 2010
Müller-Hülsbeck S JEVT 2010
Nikanorov A J vasc surg 2008

Oversizing

What Is the Effect of Oversizing?

ISR



Post Atherectomy

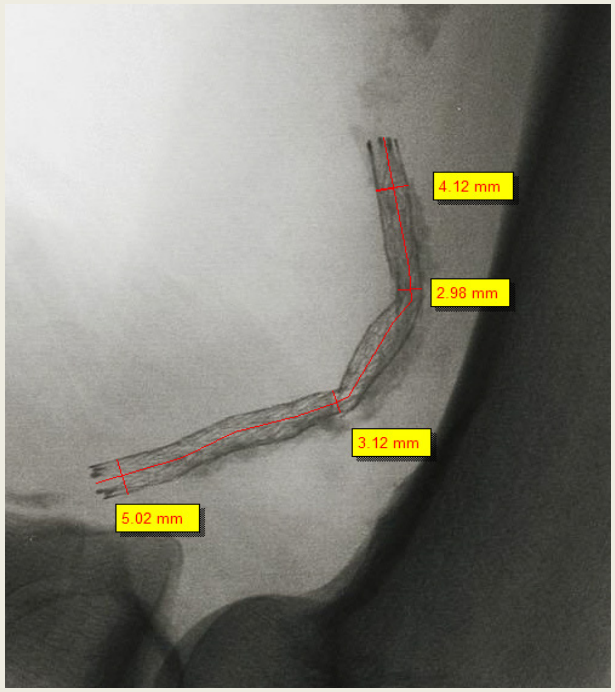
Stent Oversizing
Leads to Chronic Outward Force (COF)

- Self-expanding stents are oversized to the vessel to assure wall apposition
- Oversizing causes the stent to exert COF on the vessel
- Stents have individual COF at same diameter
- Too much COF may lead to chronic stent-vessel irritation

Stents Must be Designed for a Broad Range of Vessel Diameters

Bent Leg: 6 mm stent

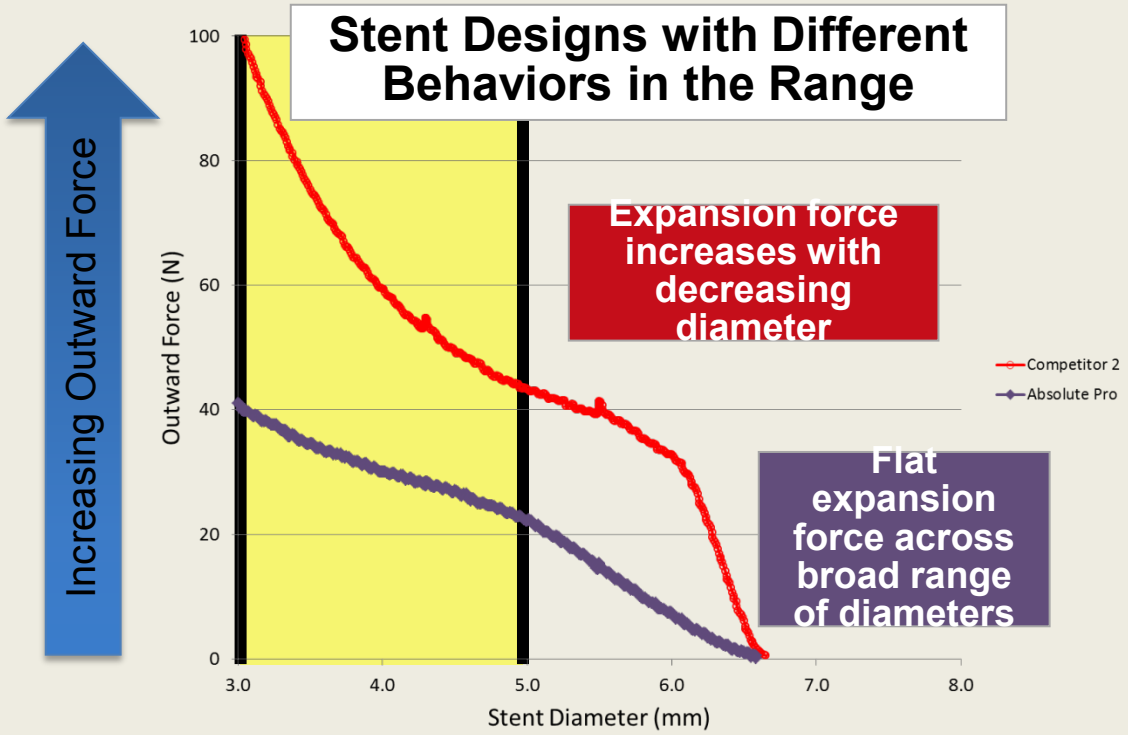
Stent-vessel diameter range, 5.02 - 2.98 mm



COF, chronic outward force.
Test(s) performed by and data on file at Abbott Vascular.
Nikanorov A et al. J *Vasc Surg*. 2009; 5 supplement: S24.

Ideal Stent Design

- Flat expansion force curve across a broad range of zero
- Less concern for precise vessel sizing to minimize COF

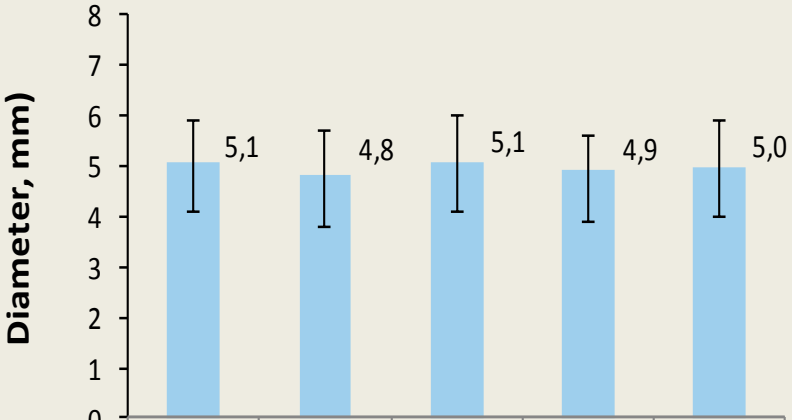


Nikanorov A et al. 2009

How Common Is SFA Oversizing?

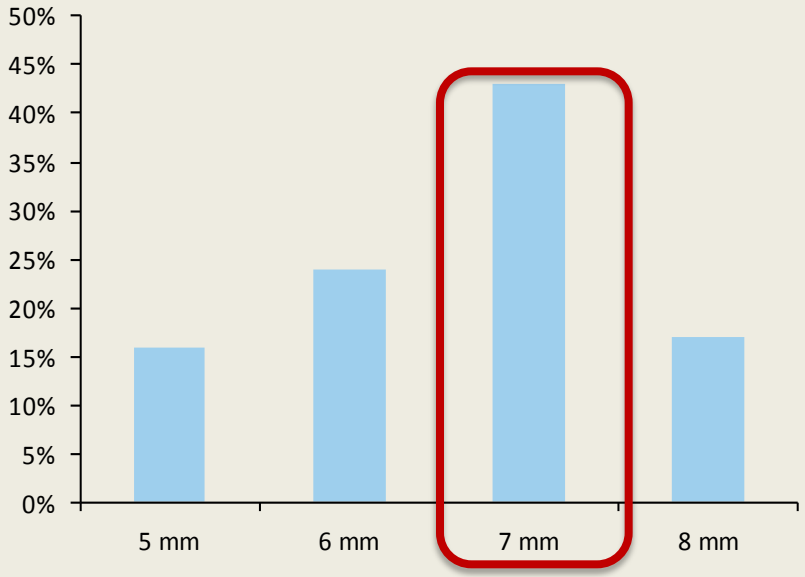
- Average reference vessel diameter of SFA is 5 mm
- Most commonly used stent diameter in SFA is 7 mm

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

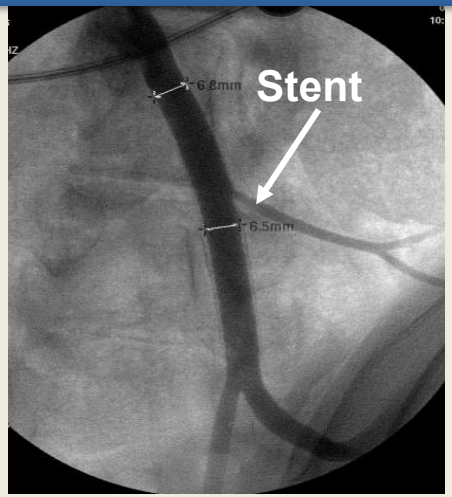
Stent Diameter Use in SFA, %

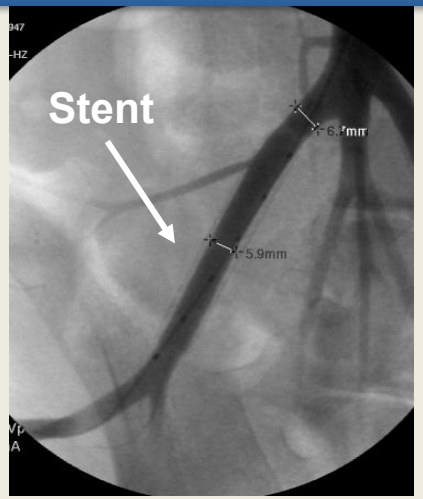


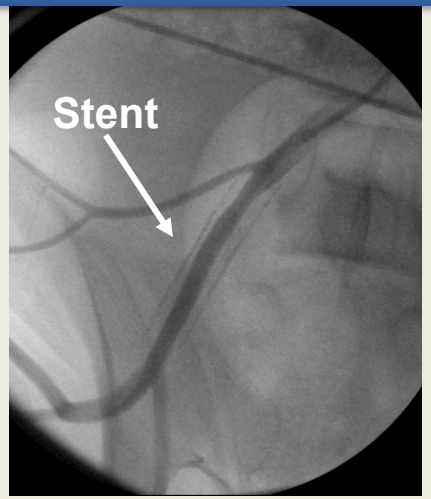
Source: Clinical data from US product Instructions for Use (IFU) except where noted.
1- Garcia L. Superb Trial 12 Month Results. Presented at TCT 2012. Miami, FL.

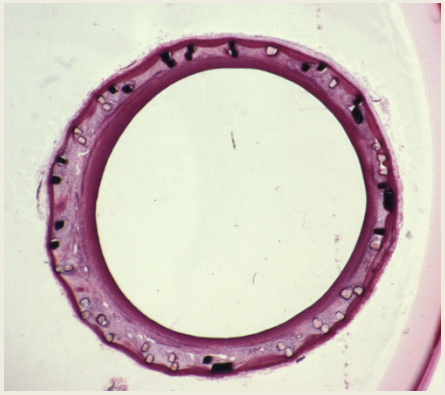
Oversizing Can Lead to Chronic Stent-Vessel Irritation

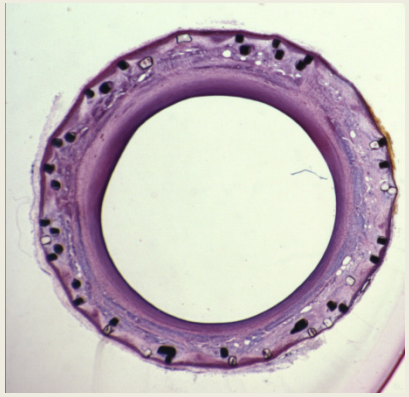
	Optimal Oversizing	Medium Oversizing	High Oversizing
Example: 8 mm stent	7.3 – 6.2 mm	6.2 – 5.0 mm	5.0 – 4.2 mm









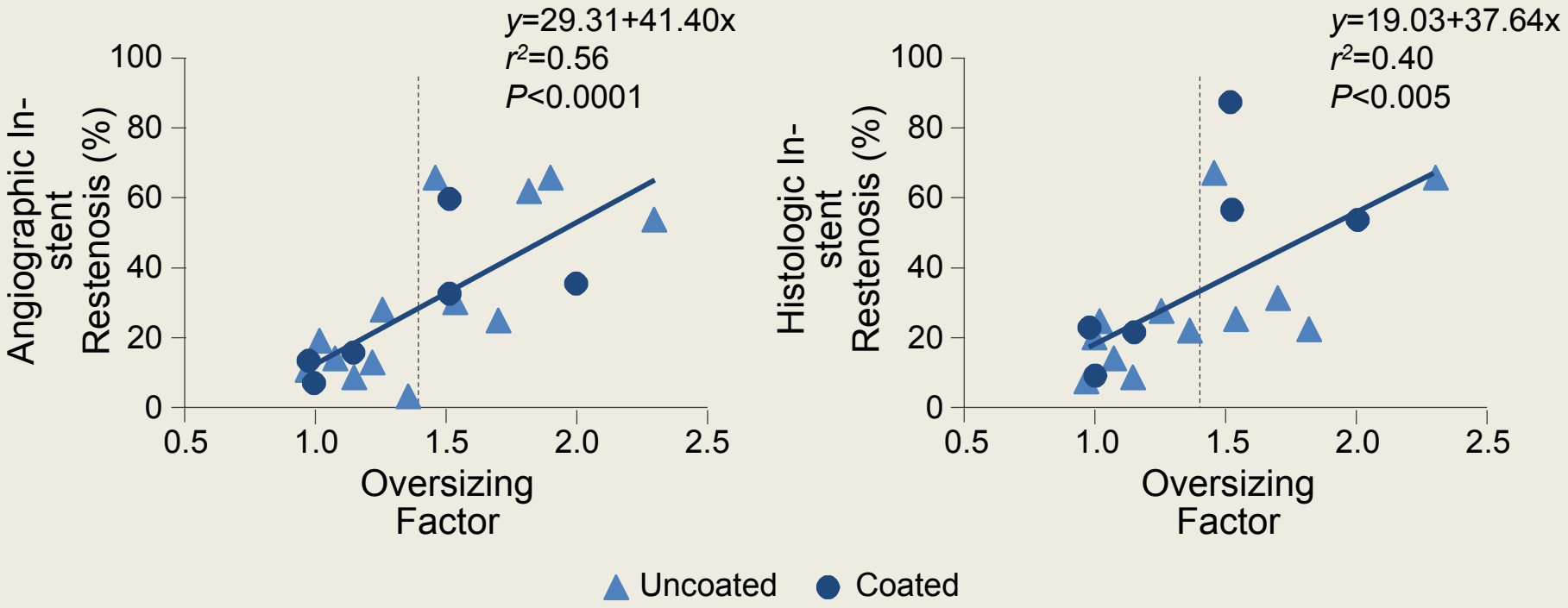


Preclinical animal model.

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

Oversizing Leads to In-Stent Restenosis

5-Month Restenosis in Porcine Illiofemoral Arteries



Preclinical animal model.

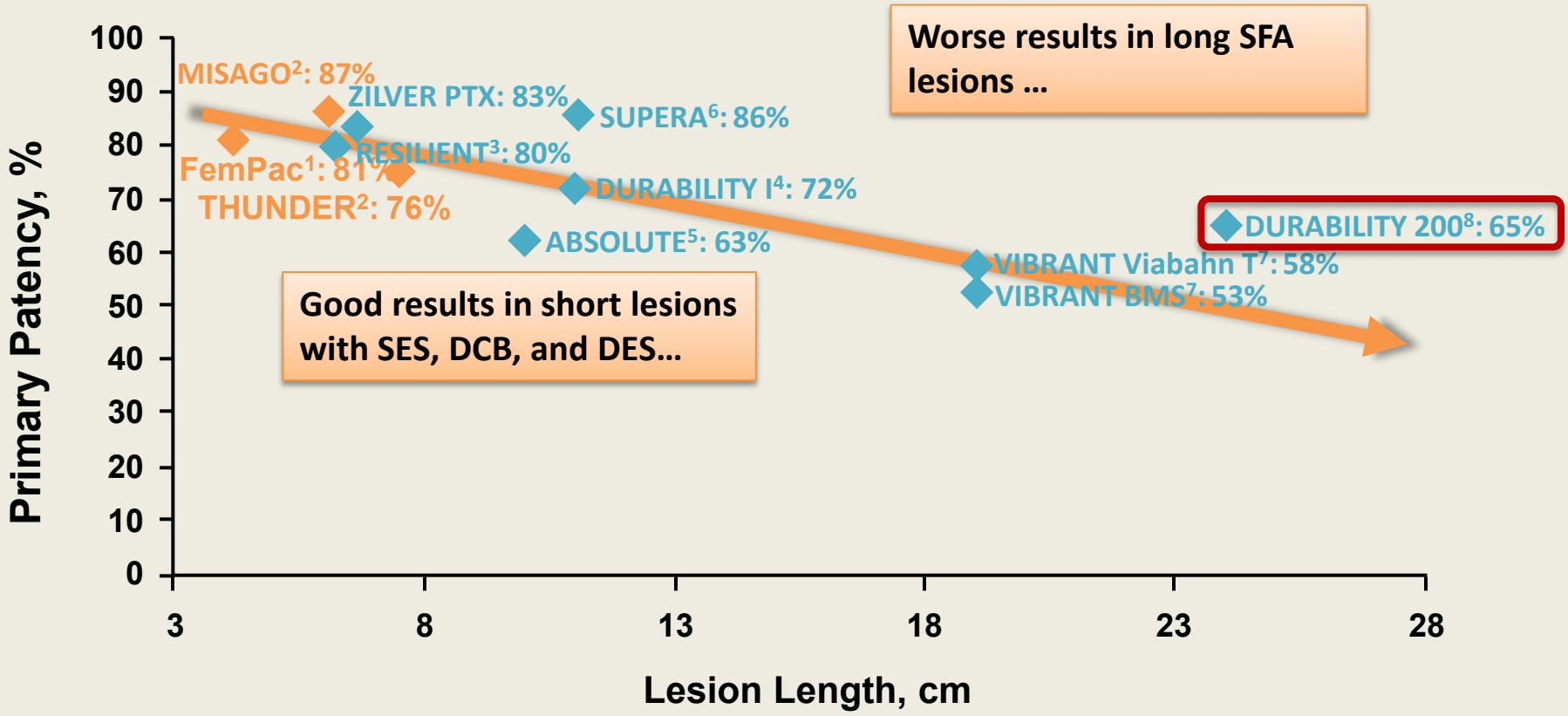
Saguner AM, T et al. *Cardiovasc Intervent Radiol.* 2012 Aug;35:906-13.

Weitere Probleme mit Stents?

....na ja, klar.....

- Läsionslänge↑= Restenose ↑
- Behandlung der In-Stent Stenose?
- Langzeitergebnisse > 4 Jahre?

Lesion Length Impacts Primary Patency Regardless of Treatment Modality



Stent Studies

Drug-eluting Balloon Studies

1. Werk M et al. Circulation. 2008;118:1358-65.
2. Tepe G et al. *N Engl J Med.* 2008;358:689-99.
3. Ramee MEET 2008.
4. Bosiers et al. JET. 2009;13:261-9.
5. Schillinger M et al. *N Engl J Med.* 2006;354:1879-88.
6. Braunlich LINC 2010.
7. Ansel LINC 2010.
8. Bosiers CIRSE 2010.

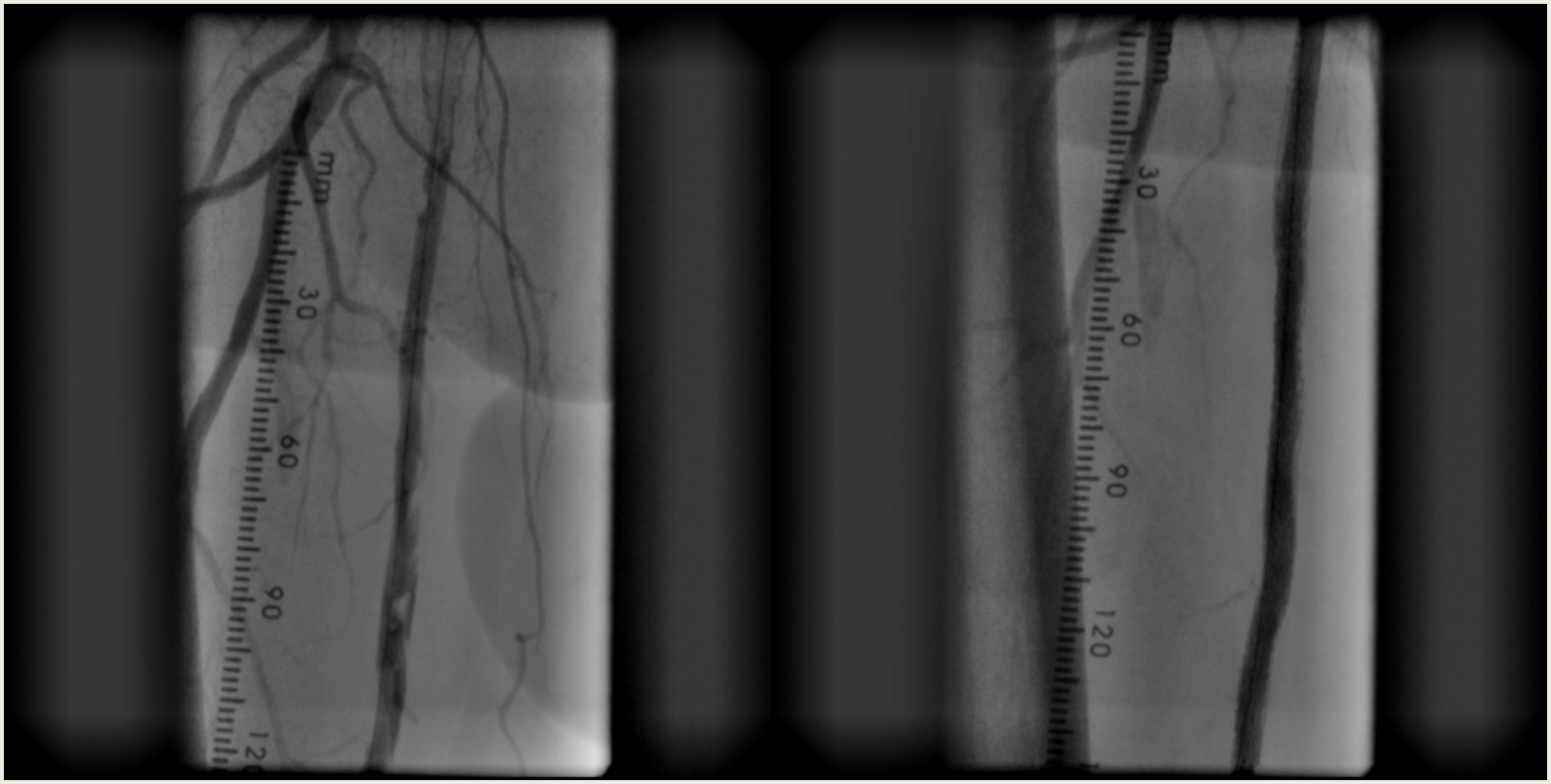
DCB, drug-coated balloon; DES, drug-eluting stent; SES, self-expanding stent; SFA, superficial femoral artery.

Long Balloon Inflation Time Improves Outcomes

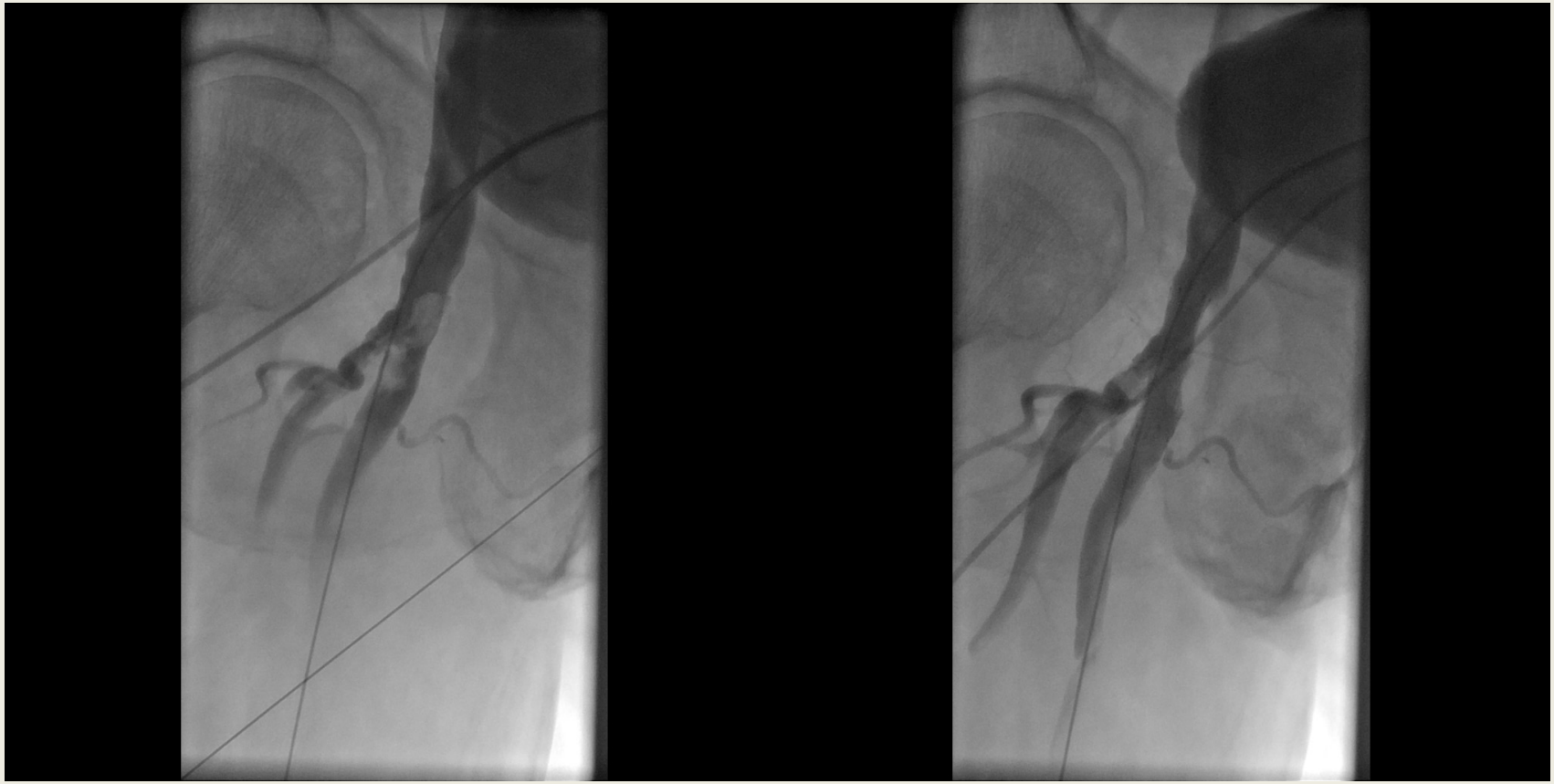
	Inflation Time (sec)		*p* Value
	30 (n = 37)	180 (n = 37)	
Major dissection (grades 3 and 4)	16	5	0.010
Minor or no dissections (grades 1 and 2)	21	32	0.010
Further interventions Stent Further dilation (prolonged dilation, dilation with larger diameter)	20 4 16	9 1 8	0.017
Residual stenosis (>30%)	12	5	
Complication (embolization, thrombosis)	1	1	
Mean ankle-brachial index (before, after intervention)	0.66, 0.87	0.65, 0.84	0.97

Zorger N et al. *J Vasc Interv Radiol.* 2002;13(4):355-9.

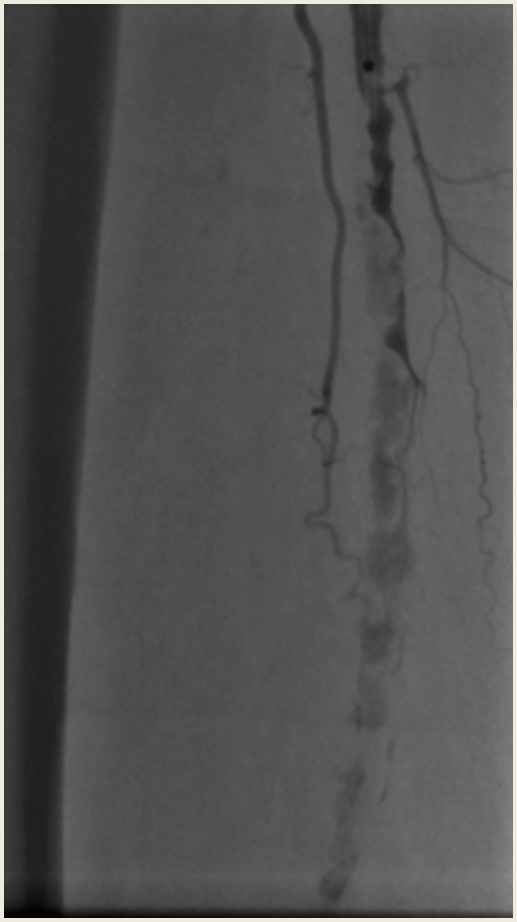
Dissektion



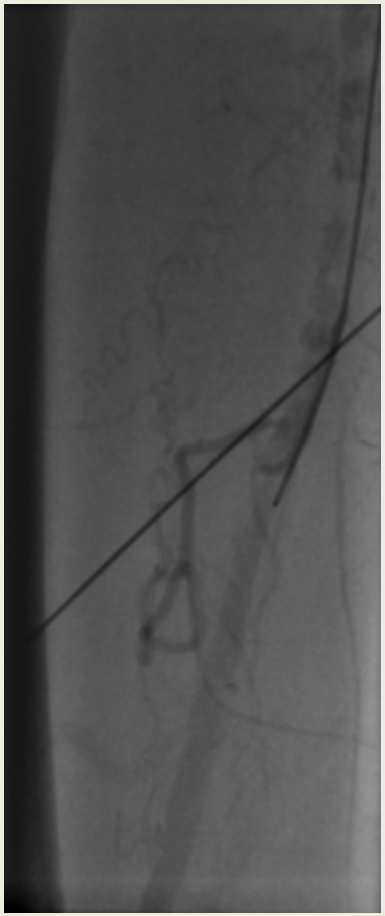
Thrombus

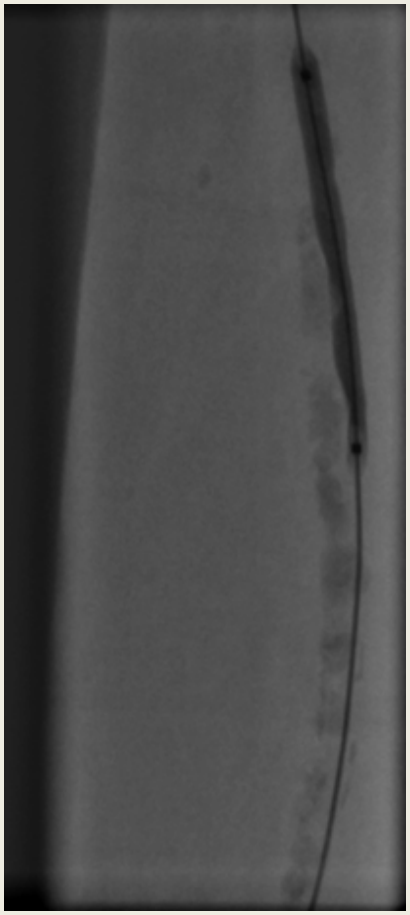


Recoil

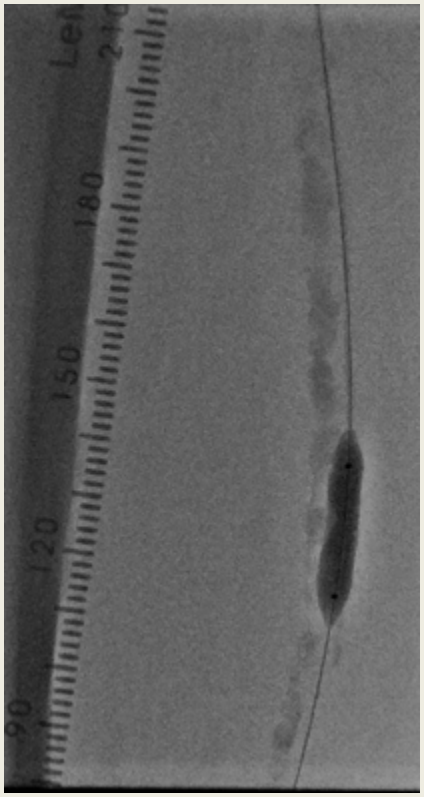


Pre-intervention





5x60mm PTA



Cutting balloon

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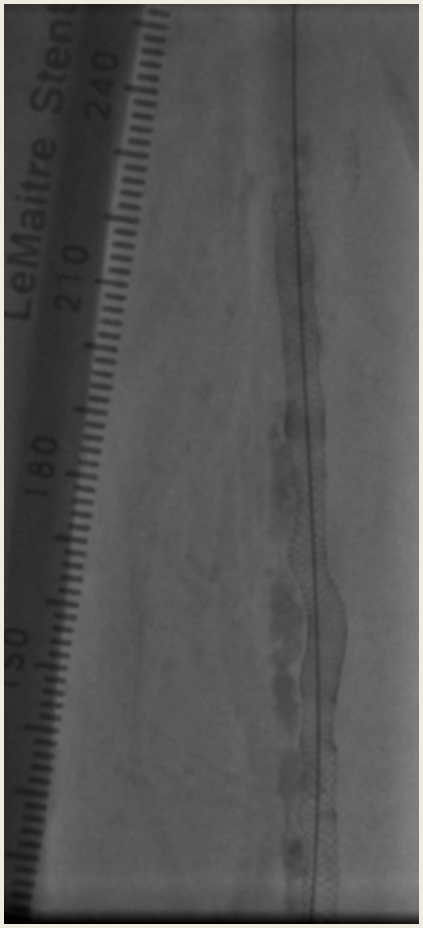
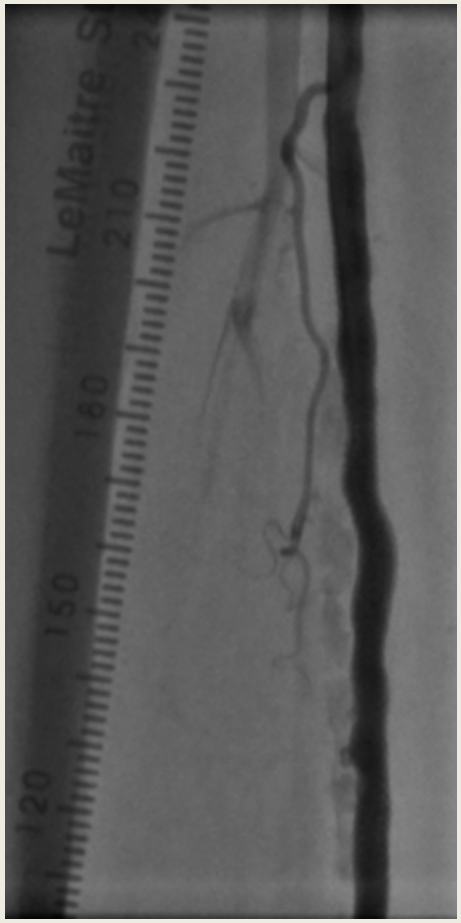
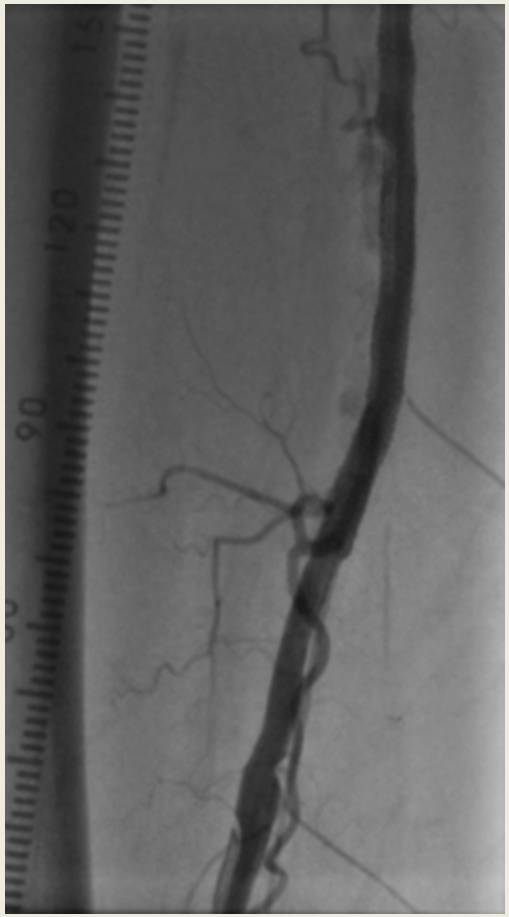
Recoil



Stent 5x150mm





Final result

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Zusammenfassung I

- Bei Stentimplantation der AFS und/oder AP besteht hoher Anspruch an das Stentdesign. (Biomechanik, Stent-FX, COF)

- Oversizing scheint die In-Stentstenoserate zu erhöhen. (noch nicht genügend Evidenz!)

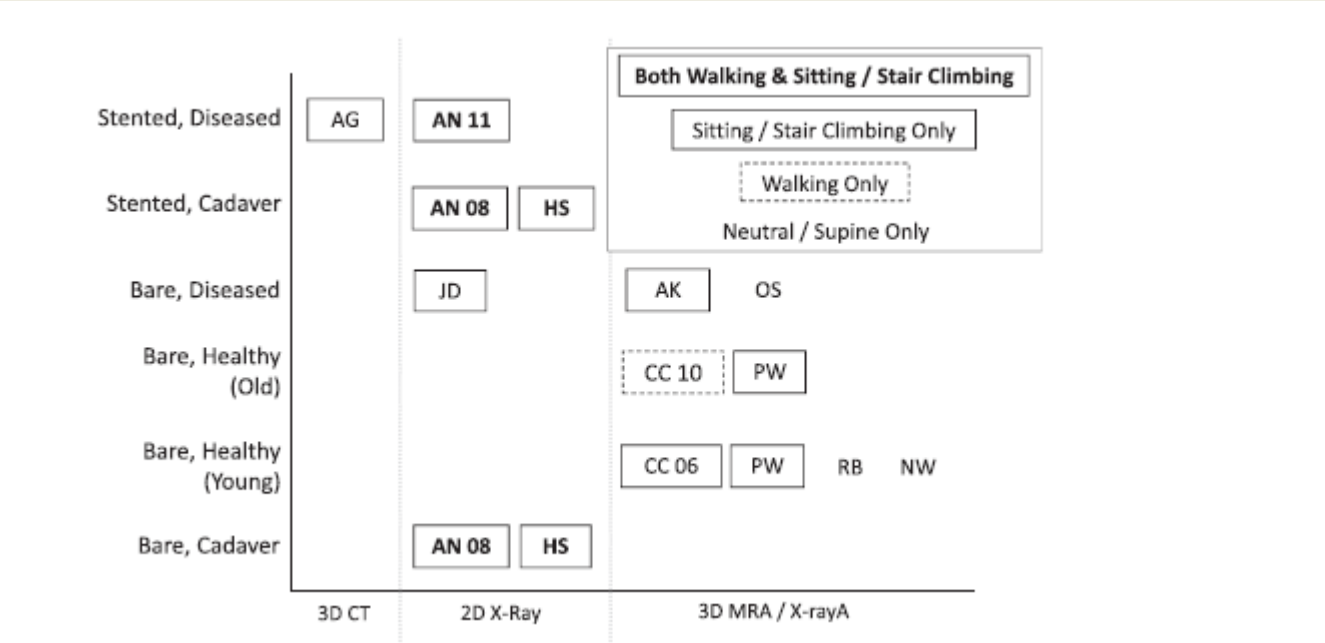
Zusammenfassung II

- Stentimplantation der AFS/AP (Länge: 8-10cm) 1-Jahres Offenheitsraten: (↑) vs. PTA; (=) vs. DEB (Randomisierte Studien fehlen!)

- Als „bail-out“-Instrument (Re-coil, Dissektion, akuter Verschluss, Thrombus) gibt es zum Stent nur selten eine Alternative.

Design considerations for studies of the biomechanical environment of the femoropopliteal arteries

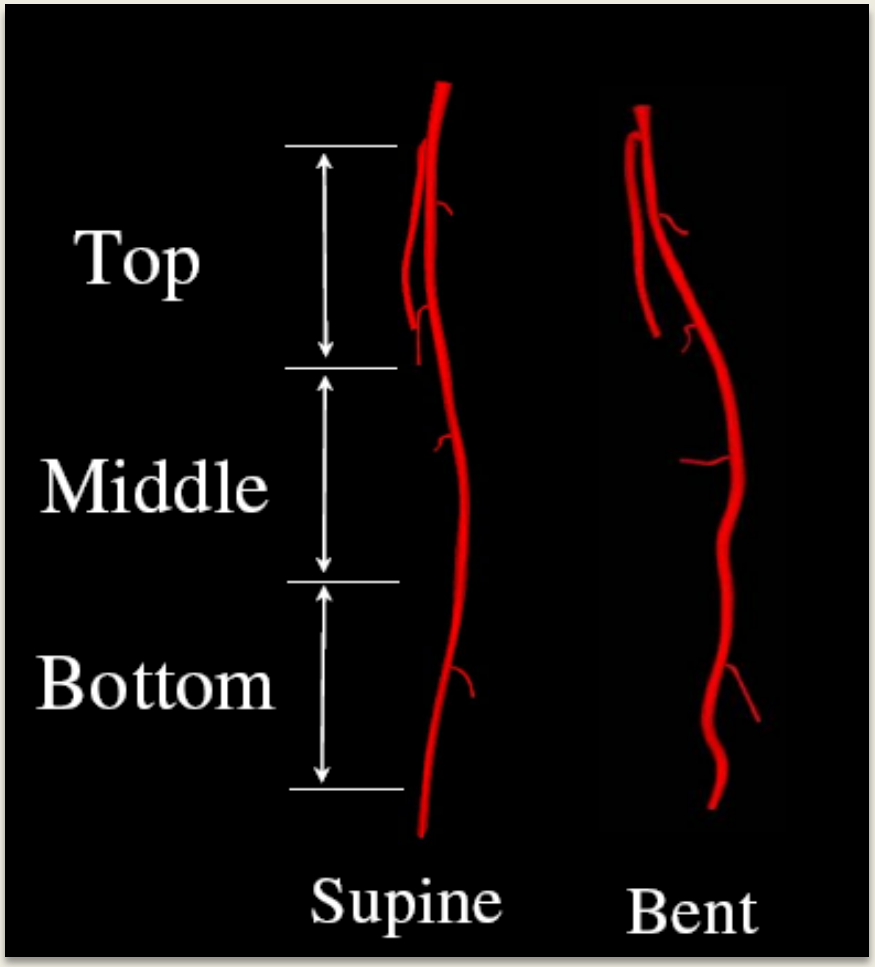
Farzana Ansari, MS,[a] Lindsay K. Pack, BSE,[b] Steven S. Brooks, MD,[b] and Tina M. Morrison, PhD,[b]
Berkeley, Calif; and Silver Spring, Md



J Vasc Surg. 2013 Sep;58(3):804-13.

Divide SFA Into Three Equal Parts

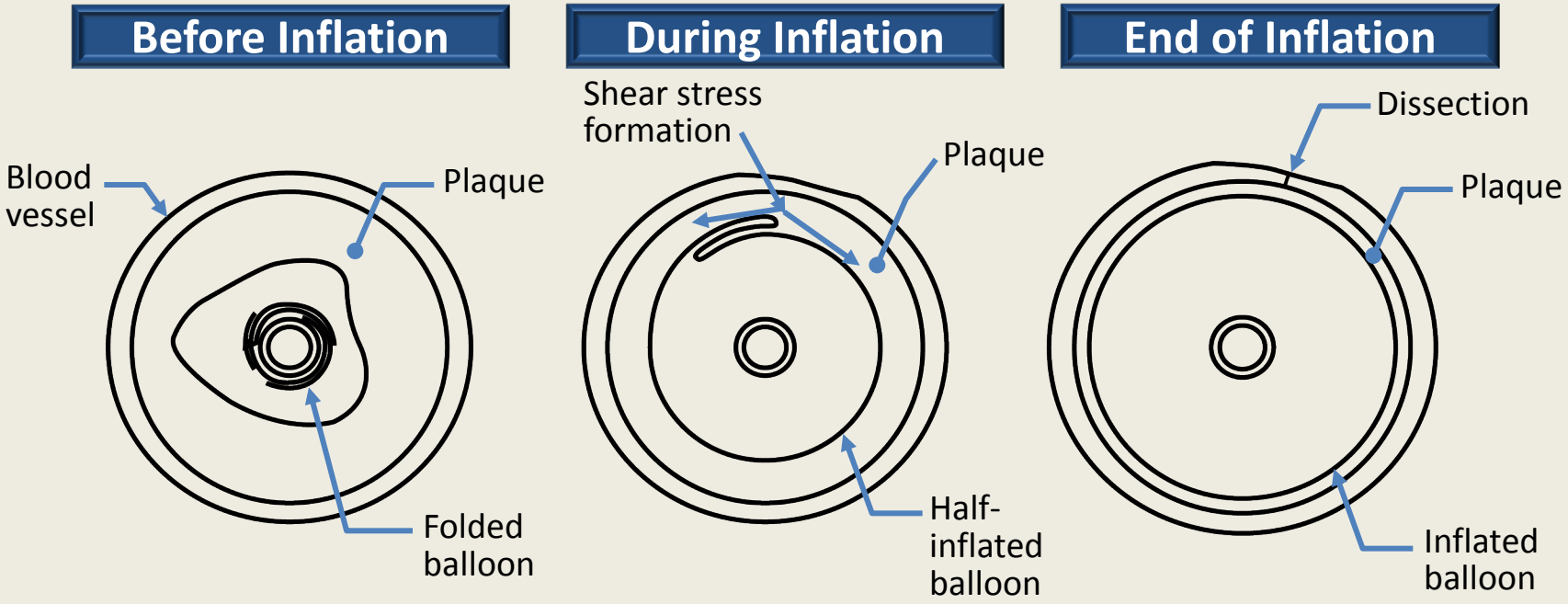
- Supine vs. bent
- Top vs. middle vs. bottom



Cheng CP et al. *J Vasc Interv Radiol.* 2006

PTA (DCB) Balloons – Not an Ideal Platform: A Stent May Still Be Needed

- Balloon expansion mechanism causes significant shear stress and trauma and can lead to
  - High dissection rate, elastic recoil and abrupt closure

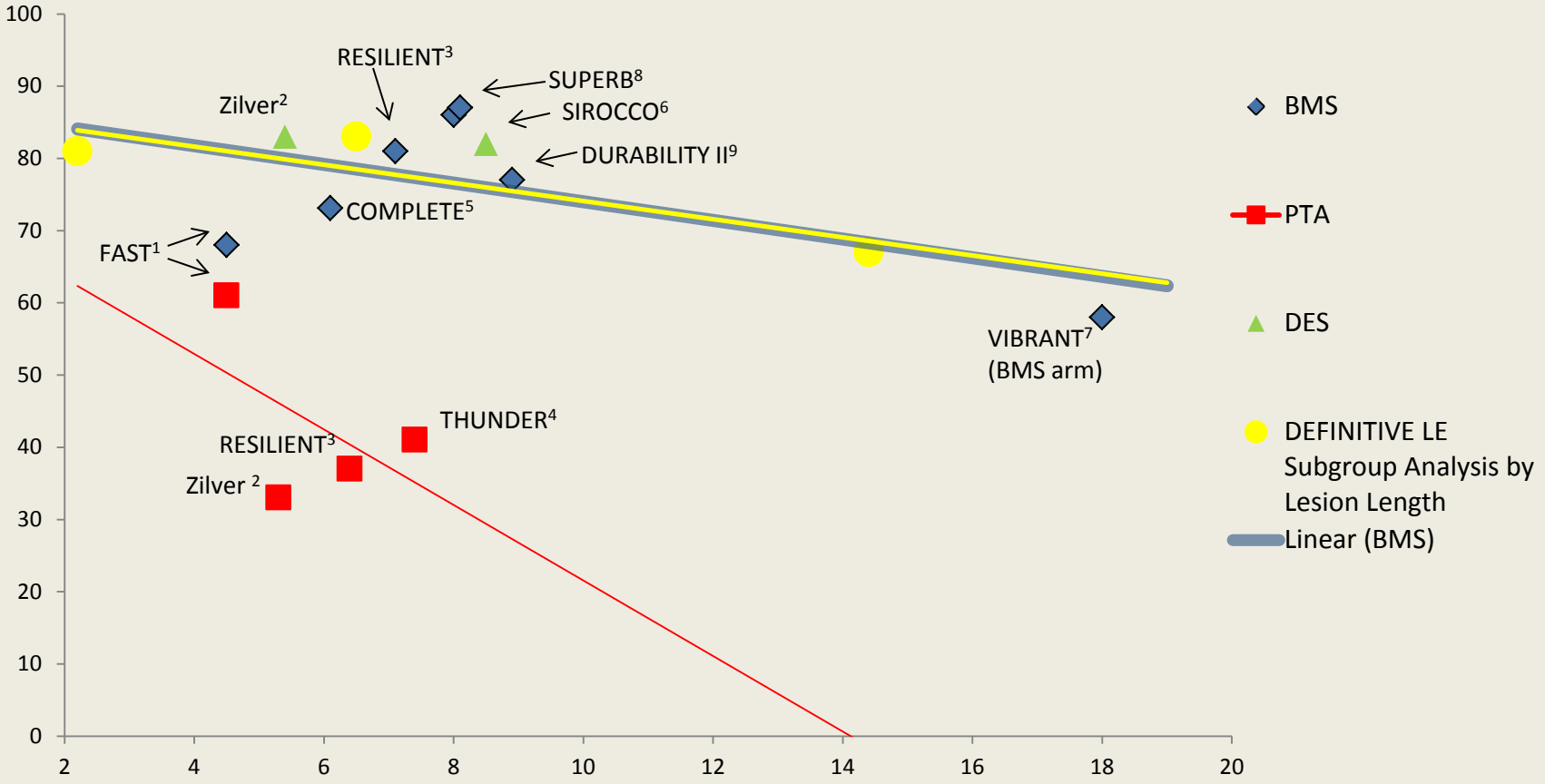


DCB, drug-coated balloon; PTA, percutaneous transluminal angioplasty.

Granada J. Drug-coated balloon technologies, I: technology considerations and controversies. Presented at: TCT 2011; San Francisco, CA.

SFA 12-Month Primary Patency

PTA, BMS, DES and DEF LE Sub-analyses by Lesion Length



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