Lower Extremity Revascularization: A data-driven analysis of SFA options

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Is claudication an acceptable endpoint?

- Lifestyle restrictions are variable but extremely limiting in many cases
- Multiple studies have clearly demonstrated a benefit in all cause and cardiovascular survival in patients who exercise regularly
- Limitations on exercise based on established atherosclerotic disease is contrary to established cardiovascular recommendations for secondary risk factor modification and relegates the patient to continued progression of atherosclerosis

Lower-extremity: therapeutics

Indications for revascularization are evolving…

- asymptomatic

1-level

- claudication

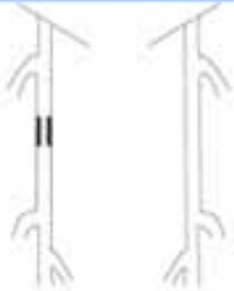
2-level

- rest-pain
- limb-threat

TASC classification of SFA disease

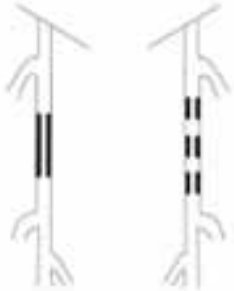
Type A Endovascular treatment of choice

- Up to 3 cm in length
- Not at origin of SFA or distal popliteal



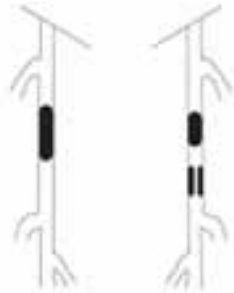
Type B Currently endovascular treatment is more often used but insufficient evidence for recommendation

- Single stenosis or occlusion 3-5 cm, not involving distal popliteal artery
- Heavily calcified stenosis up to 3 cm
- Multiple lesions < 3cm, stenosis or occlusion
- Single or multiple lesions in absence of continuous runoff



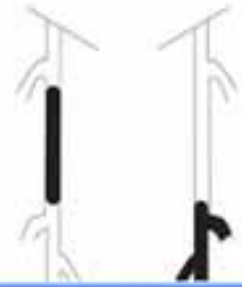
Type C Currently surgical treatment is more often used but insufficient evidence for recommendation

- Single stenosis or occlusion longer than 5 cm
- Multiple stenosis or occlusion each 3–5 cm



Type D Surgical treatment of choice

- Single CFA or SFA occlusions or complete popliteal and proximal trifurcation occlusions



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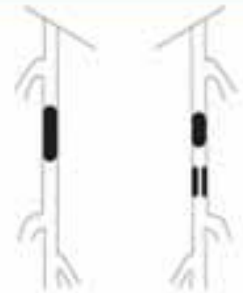

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SFA disease: surgical options

- Bypass outcomes dependent on:
  - Inflow
  - Outflow
  - Conduit used
- Recovery usually requires several weeks
- Peri-operative complications (death (4%), medical, graft, wound, etc) can be significant
- Lymphedema
- Use of saphenous venous conduits can limit future CABG options
- Collateral circulation (geniculates/surals) may be interrupted during dissection, and may increase the possibility of future limb threat with graft failure

SFA disease: surgical options

Durability of fem-pop bypass[1,2]

	1- year	3-year	5-year
Above the knee-vein	X	X	75%
Above the knee-graft	74%	56%	50%
Below the knee-vein	83%	75%	67%
Below the knee-graft	X	X	33%

After five years, 38% of patients died of unrelated causes[1]

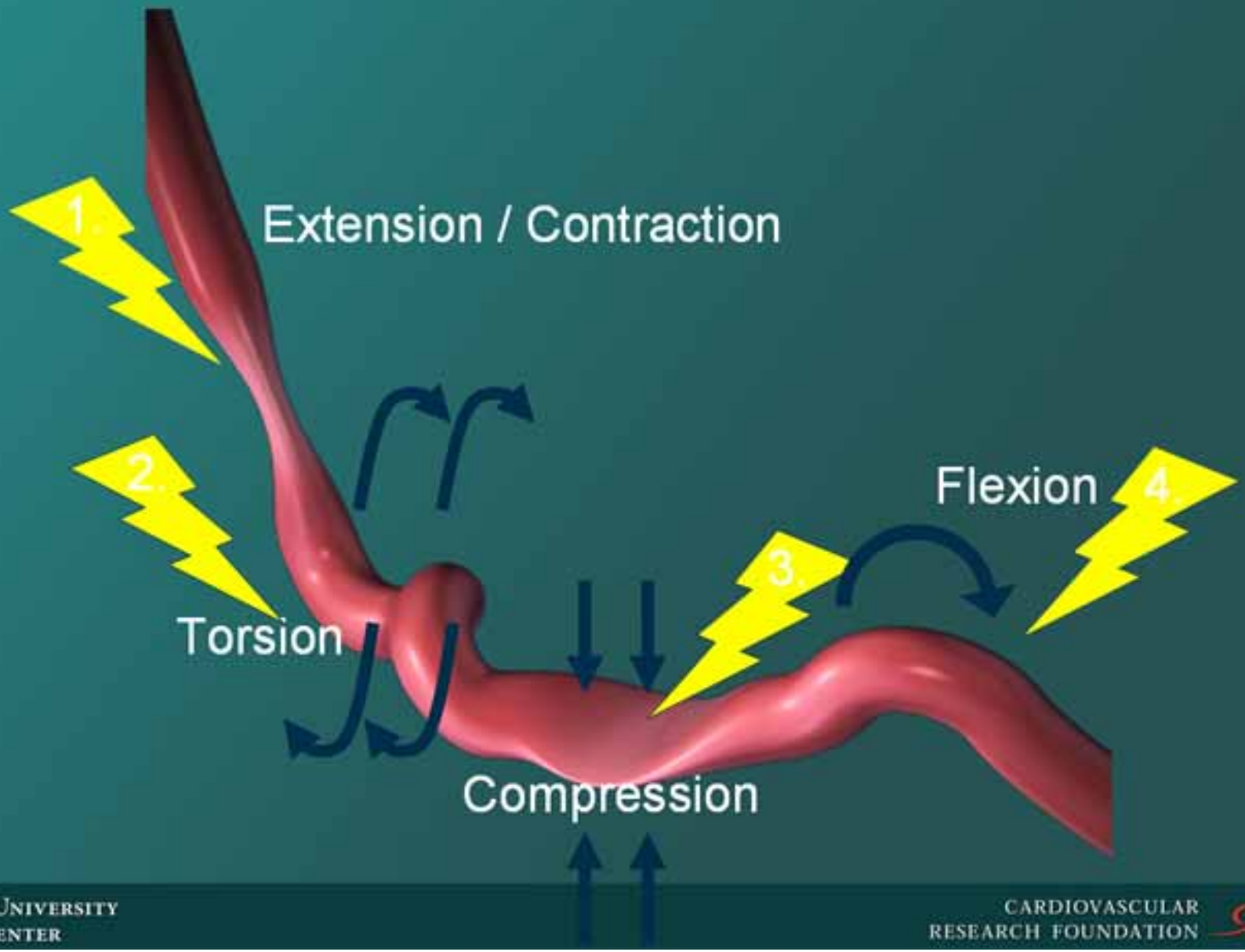
1. J Vasc Surg. 2003 Jan; 37(1):149-55
2. Am J Surg. 1997 Aug; 174(2):169-72

SFA disease: endovascular options

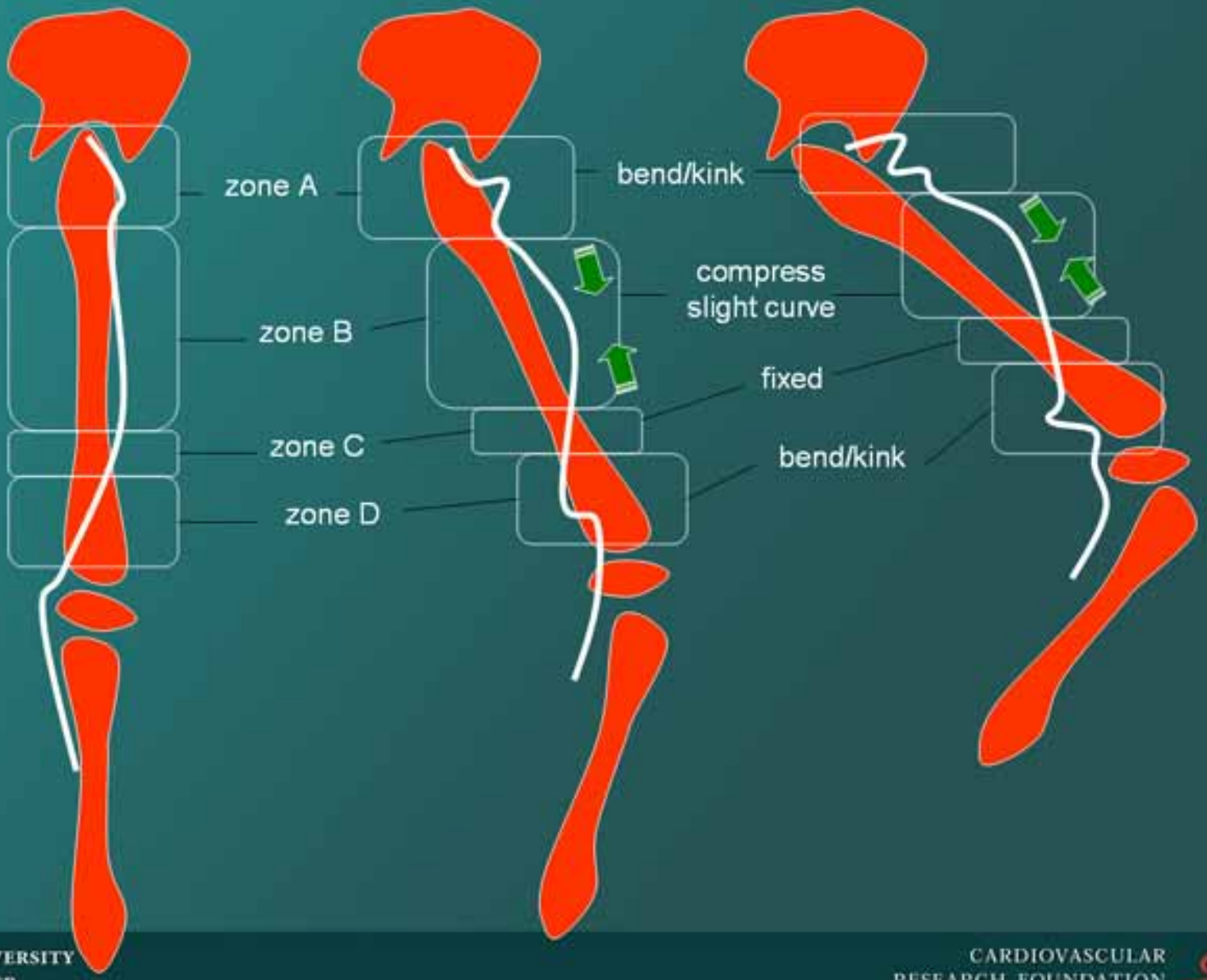
- PTA
- Stenting
  - Bare metal*
  - DES*
  - Covered stents
    - Hemobahn
    - aSpire
- Brachytherapy
- Cryotherapy
- Atherectomy
- Extravascular bypass

*randomized data

SFA: mechanical challenges



SFA: dynamics in motion



SFA: Hostile territory

Distal SFA-popliteal during knee flexion

SFA therapeutic decisions: problems with data-driven approach

- Data-analysis challenges
- Lack of available randomized multicenter data

SFA therapy: challenges in data analysis

- Understanding the factors potentially confounding factors in restenosis outcomes assessment
- Device platform differences
- Data collection

Coronary restenosis profiles

TAXUS IV – Impact of Vessel Size & Lesion Length

TLR (12-month)

Challenges: Confounding factors

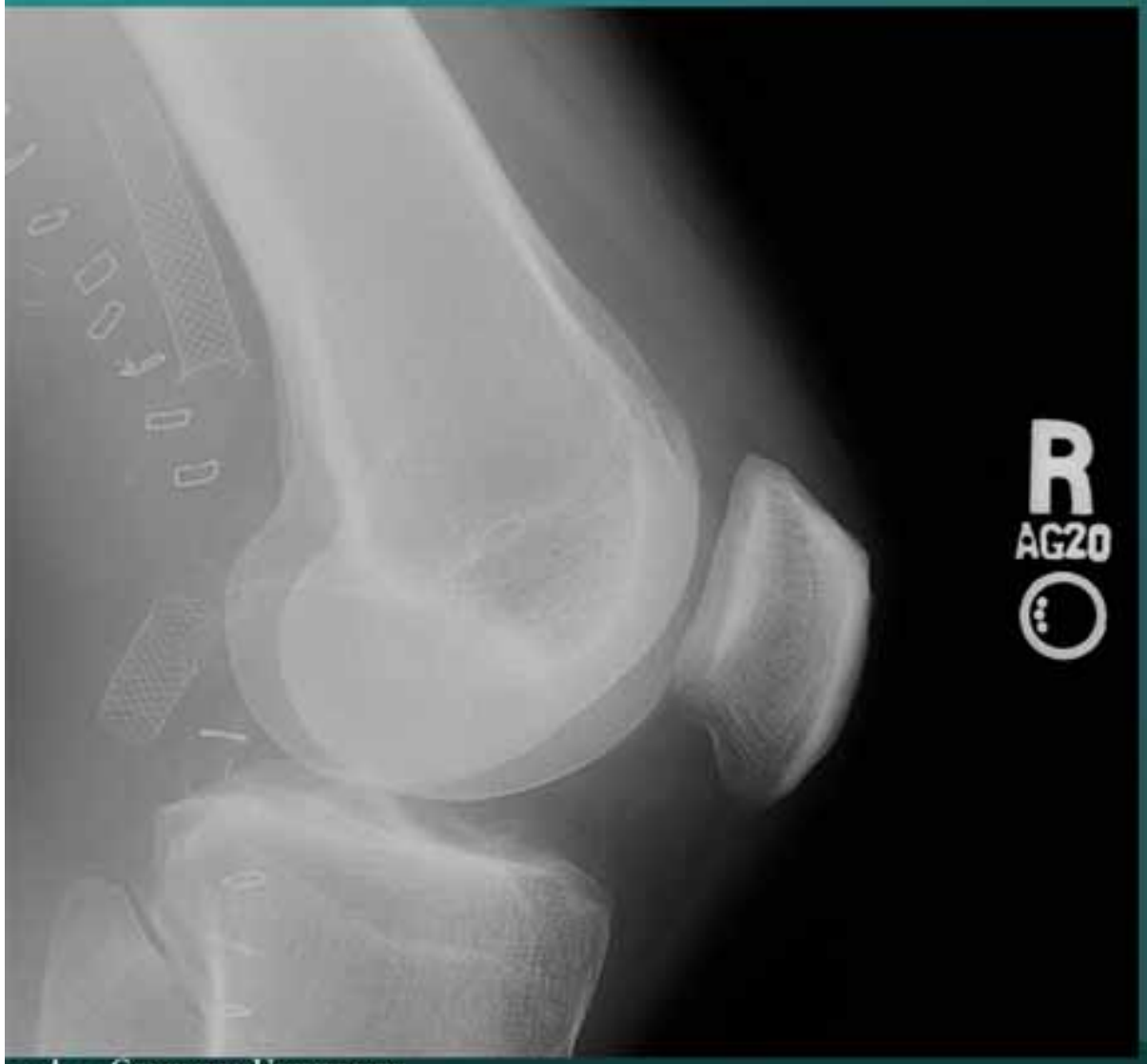
Understanding the factors potentially confounding factors in restenosis outcomes assessment:

- Length of disease
- Occlusion vs. stenosis
- Inflow/Run-off status
- Diabetic status
- Tobacco status
- Vessel diameter
- Atheroma volume

Challenges: Device platform is not "inert"

- Platform performance differences
  - Nitinol
    - Slotted tube vs. spiral
  - Woven SS
- Rate of stent fracture in self-expanding platforms
  - Clinical relevance
    - Effects on restenosis
    - Distal effects
- Possible confounding effects of adjunctive therapy
  - Debulking

Wallstent fracture

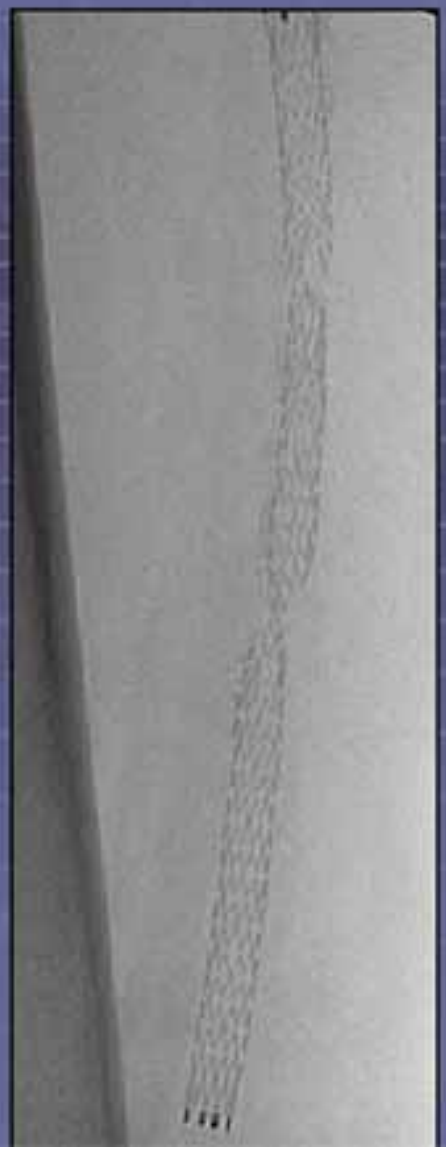


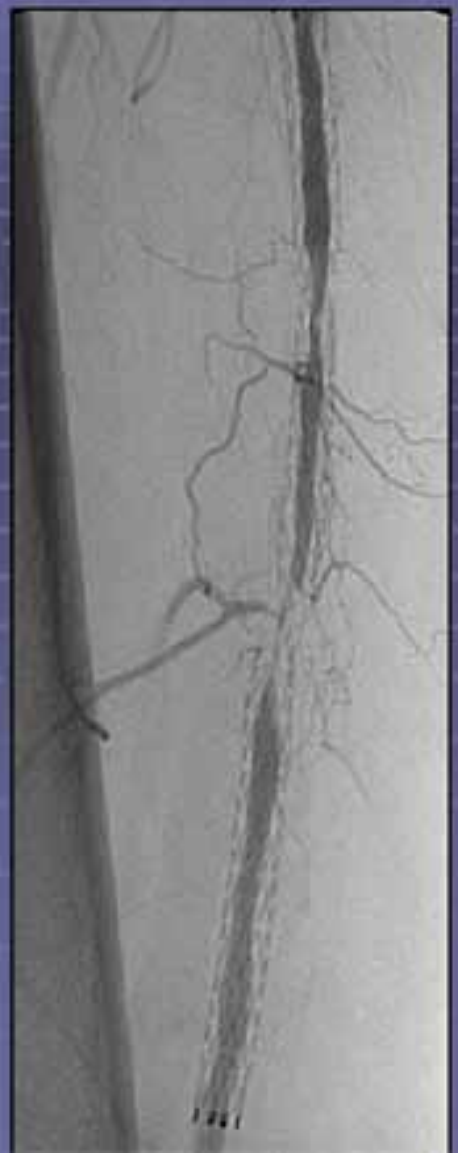
Wallstent fracture

Wallstent fracture

Wallstent fracture

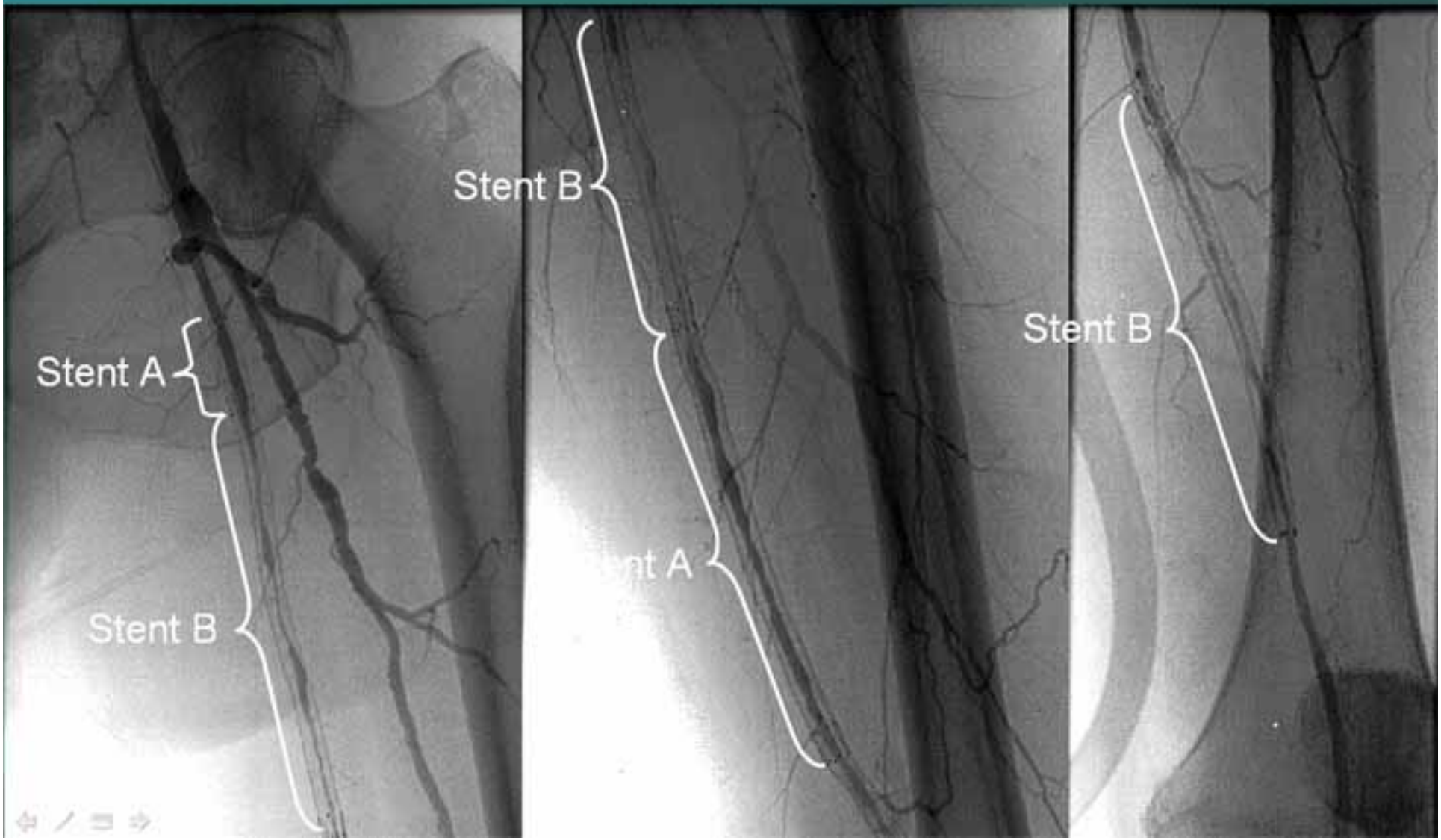
FESTO: Effects of nitinol stent fracture





Severe
Stent fractures
and
In-stent
restenoses

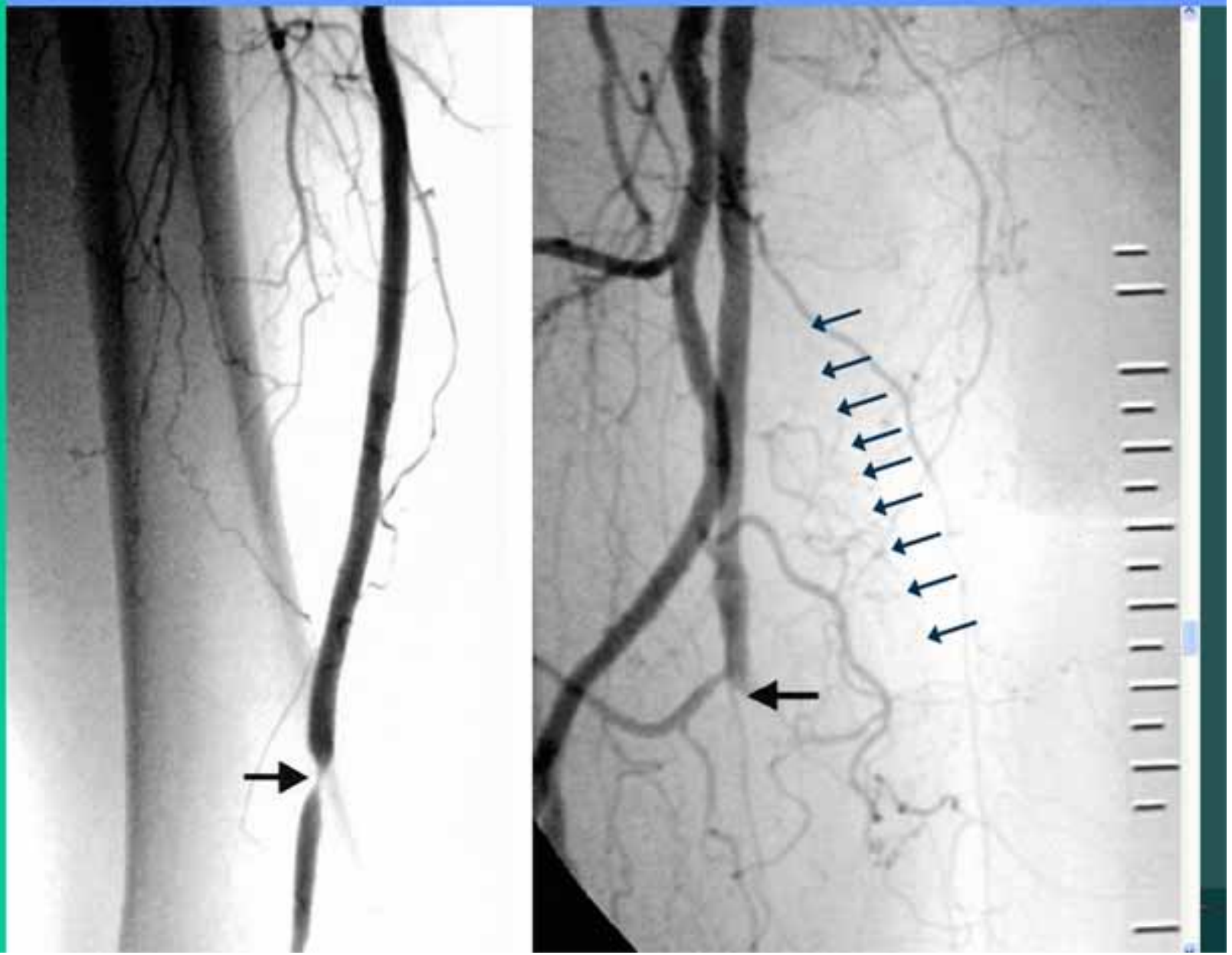
Differential stent effects?



Challenges: Data collection

- Data collection
  - Endpoint definitions of success
    - Anatomic
      - Binary restenosis (>50%)
      - Discrete vs. diffuse vs. volume definitions
    - Clinical
      - Walking distance
      - ABI
  - Quantifying (and understanding) restenosis
    - Angiographic
    - Duplex
    - Intravascular ultrasound
  - Time course defining durability of intervention
  - Consistent and standardized reporting structure

Focal vs. discrete restenosis: do they count the same?



Legacy stent results in SFA lesions

	Mean lesion length	Stent	1^0 patency (1 year)	2^0 patency (1 year)
White et al 1995	3.7 cm	Wallstent and Strecker	75%	89%
Marin et al 1995	?	Wallstent	61%	84%
Gray et al 1997	16.5 cm	Wallstent and Palmaz	22%	46%
Conroy et al 2000	13.5 cm	Wallstent	47%	79%
Gordon et al 2001	14.4 cm	Wallstent	55%	82%

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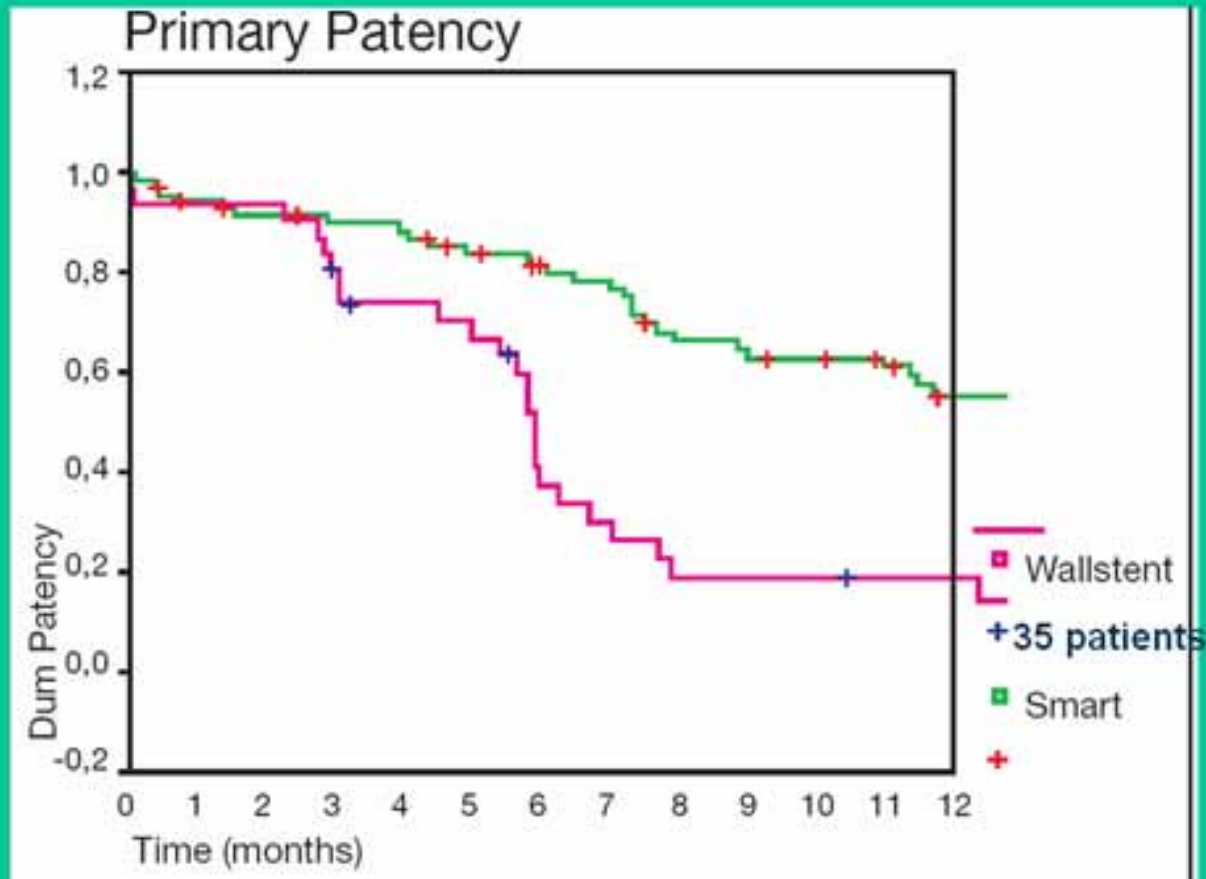
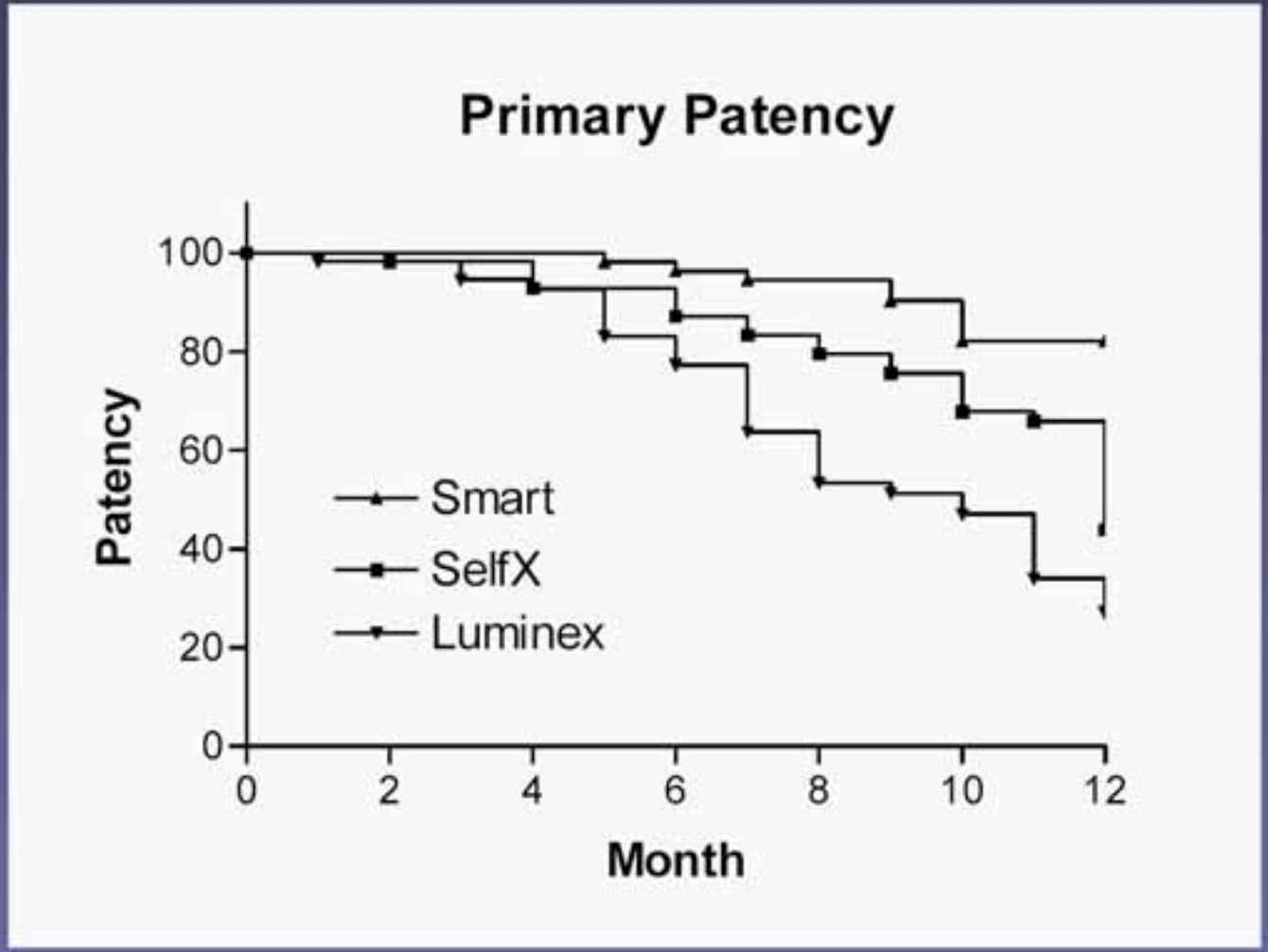
Biamino retrospective



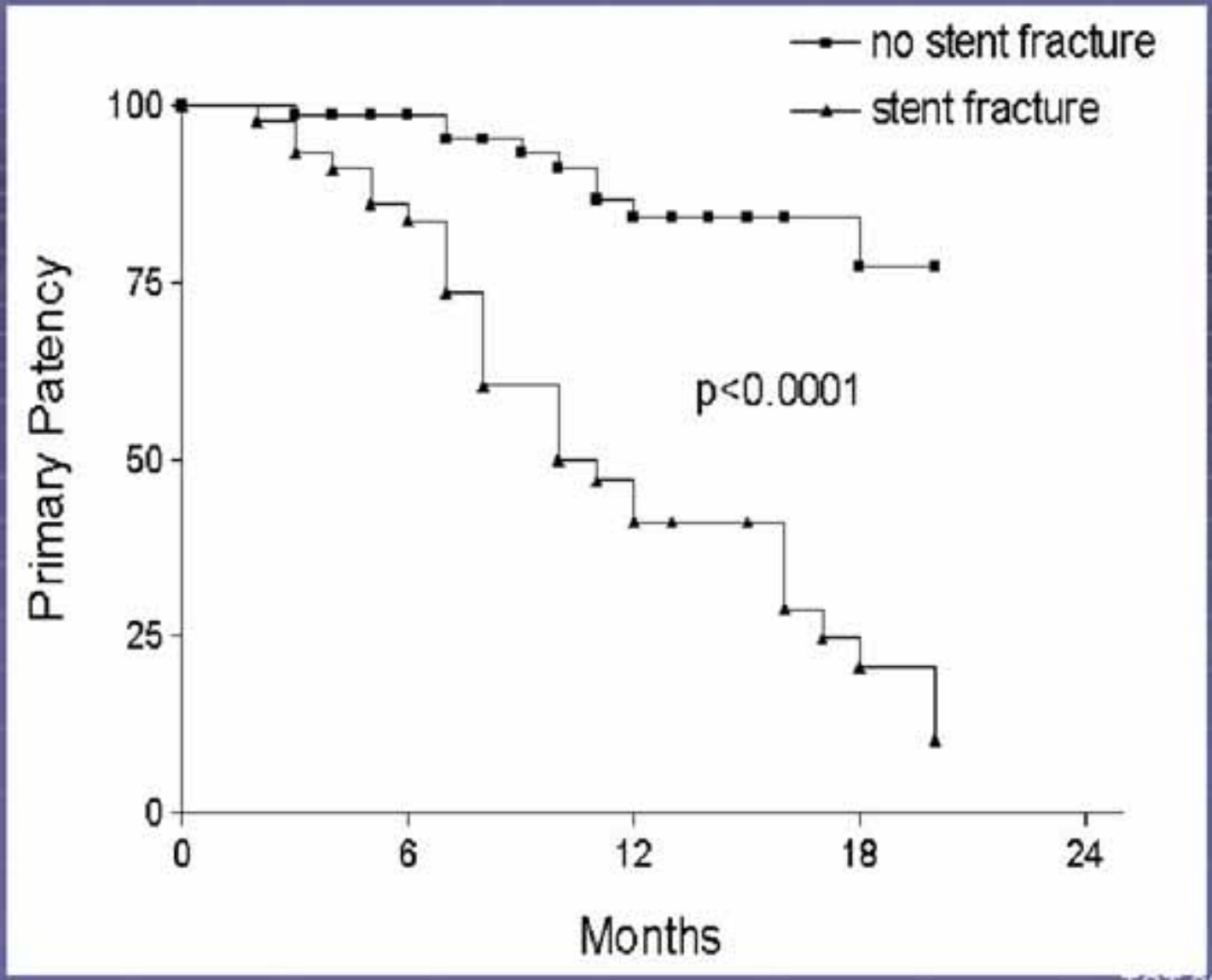
	Smart	Wallstent
6 months:	81.7±4.7%	37.2 ± 9.1%
12 months:	55.0 ± 6.5%	18.6 ± 7.4%

May 2002
Euro PCR

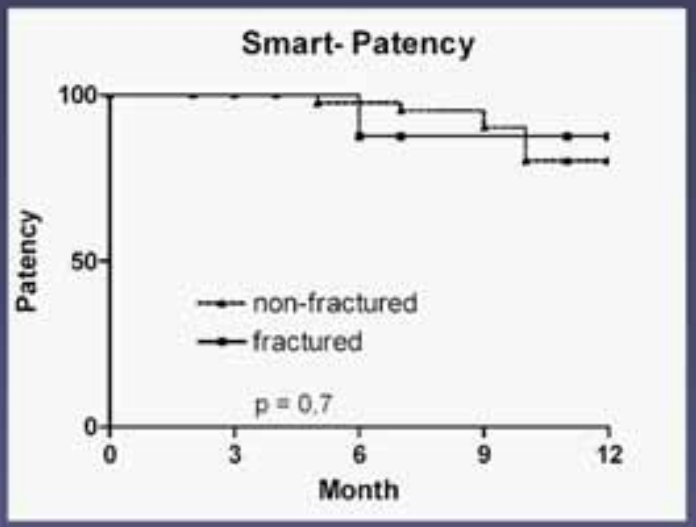
FESTO: Differential stent patency

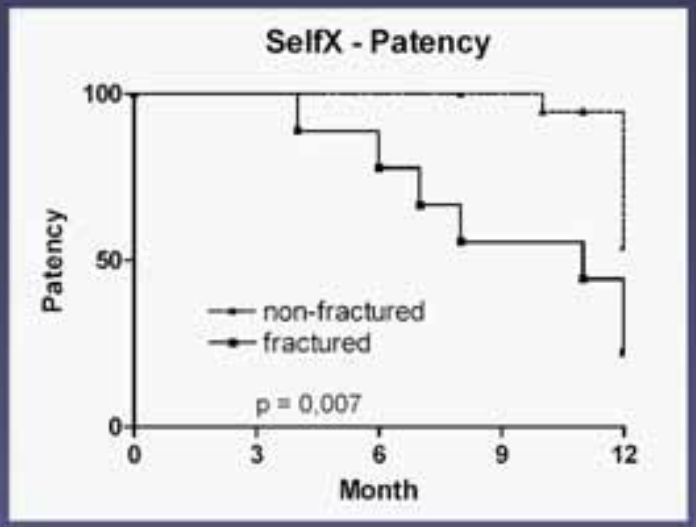


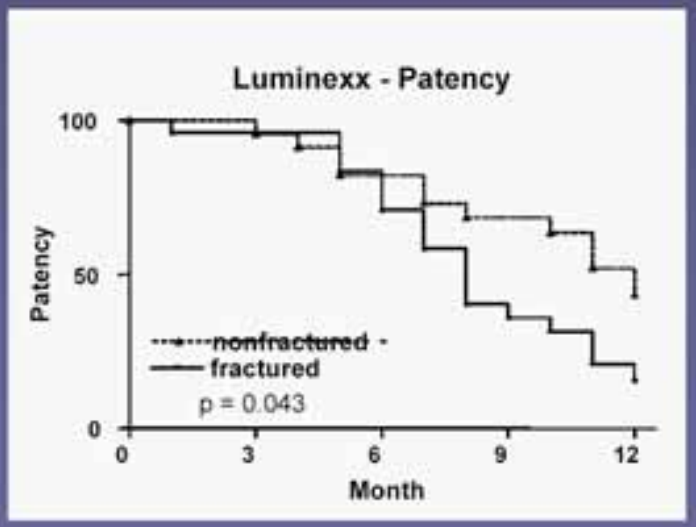
FESTO: Stent fracture and patency



FESTO: Fracture and patency by stent







Impact of stent fracture on stent patency

SIROCCO Outcomes

9-Month Duplex Ultrasound

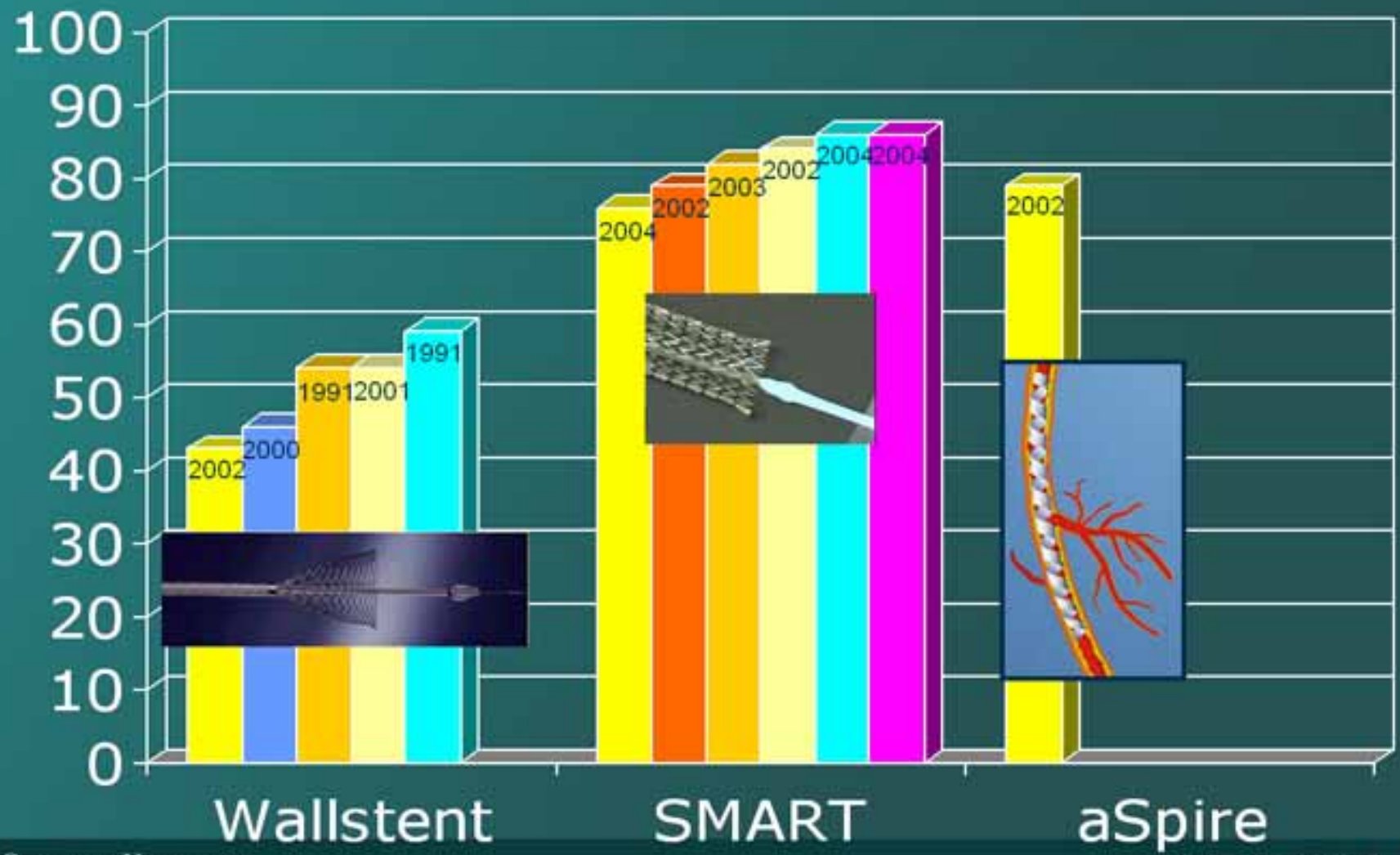
	Sirolimus	SMART Control	*P* value
	(n=26)	(n=23)	
Lesion length:	8.6 cm	7.6 cm	
In-stent			
Binary restenosis	2 (7.7%)	2 (8.7%)	1.00
Occlusion	0	1 (4.3%)	0.47
Total	2 (7.7%)	3 (13.0%)	0.66
In-Lesion			
Binary restenosis	6 (23.1%)	4 (17.4%)	0.73
Occlusion	0	1 (4.3 %)	0.47
Total	6 (23.1%)	5 (21.7%)	1.00

BLASTER Efficacy Results

Parameter	SMART with Abciximab	SMART without Abciximab	All Patients
Duplex Primary Restenosis	22.0%	13%	17%
9 Month Assisted Primary Patency	96.0%	100.0%	97.6%

- ~ 100 patients
- Stenosis/occlusion (50%) length: 11cm-12cm
- Length of stented segment: 17.8 cm
- 98% Rx'd with <3 stents

Nitinol revolution?



Possible objections to SFA stenting

- Collateral compromise
- Acute thrombosis
- Durability/Stent fracture
- In-stent restenosis management
- Follow-up surgical option issues

SFA disease: covered stents

- Hemobahn (WL Gore) randomized data
  - 28 patients randomized to PTA or ePTFE covered stent
  - Baseline characteristics were similar between groups including ABI's, lesion length (focal-to-moderate), run-off status etc.
  - Results:
    - Post-procedure ABI's better in the stent group
    - 6 month patency 93% in ePTFE vs. 42% in PTA
    - 2 year patency 87% vs. 25%
    - *Transient thigh pain requiring meds in 20% of ePTFE group, with one thrombotic complication

Conclusion

- Analysis of data is encumbered by
  - the lack of Level 1 data
  - the lack of uniform reporting, including accounting for confounding differences in lesion/patient characteristics, and standard time interval defining success, etc
  - small sample sizes
  - possible differences in stent performance and durability
- An "endovascular first" approach is an imperfect, but viable option
- That said, there appear to be enough broadly improving restenosis data in SFA intervention to support this change in the approach to SFA disease (and its ongoing, in-depth study)