Clinical Relevance of Stent Fractures for the Treatment of Long SFA Obstructions: the FESTO Study-

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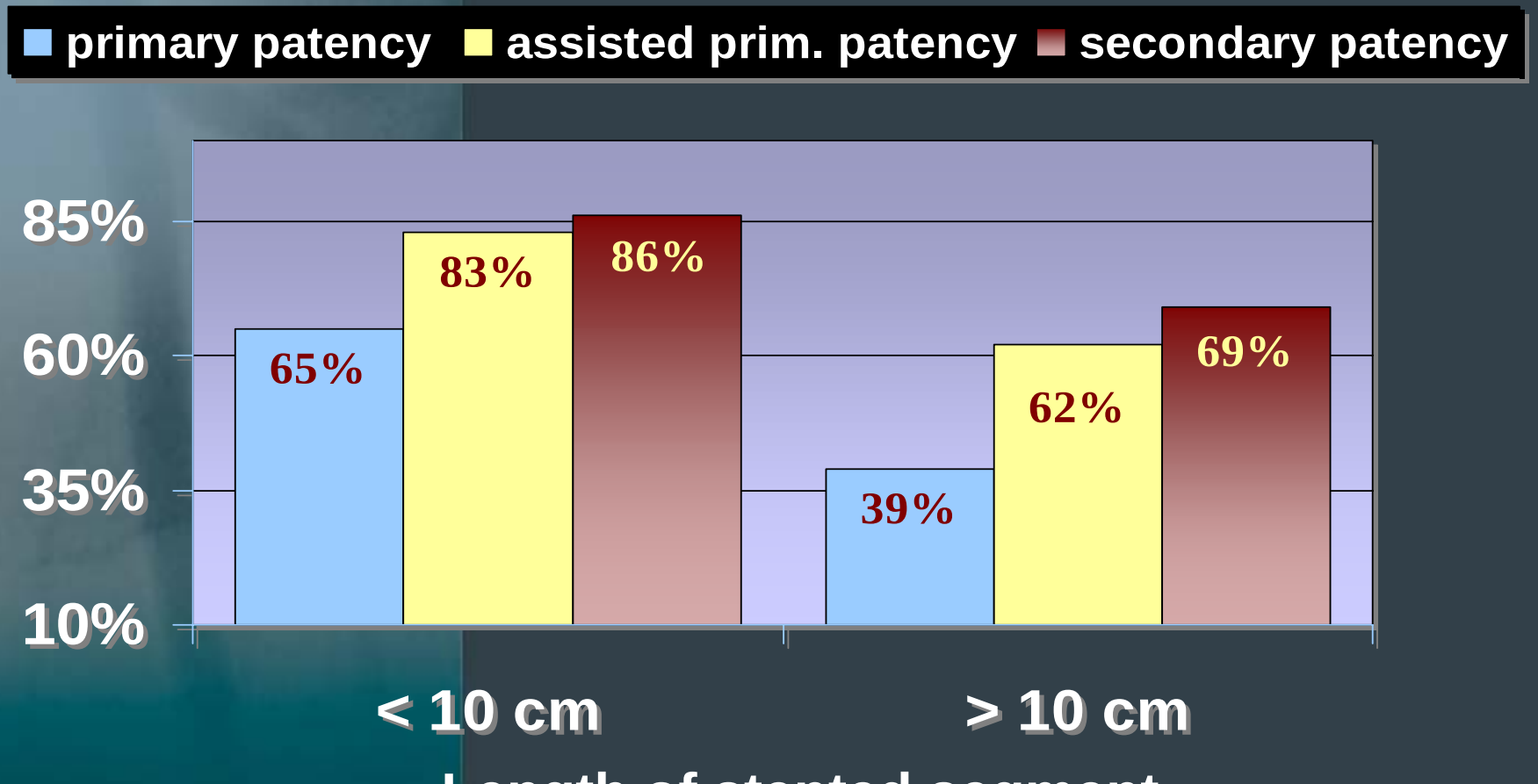
Stenting the SFA

Maintaining long-term patency after recanalization and stenting of obstructed Superficial Femoral Arteries (SFA) is still one of the most challenging aspects of endovascular therapy.

Stenting the SFA (Charite, Berlin 1997-98) N: 268

One Year Patency Rate according to stented length

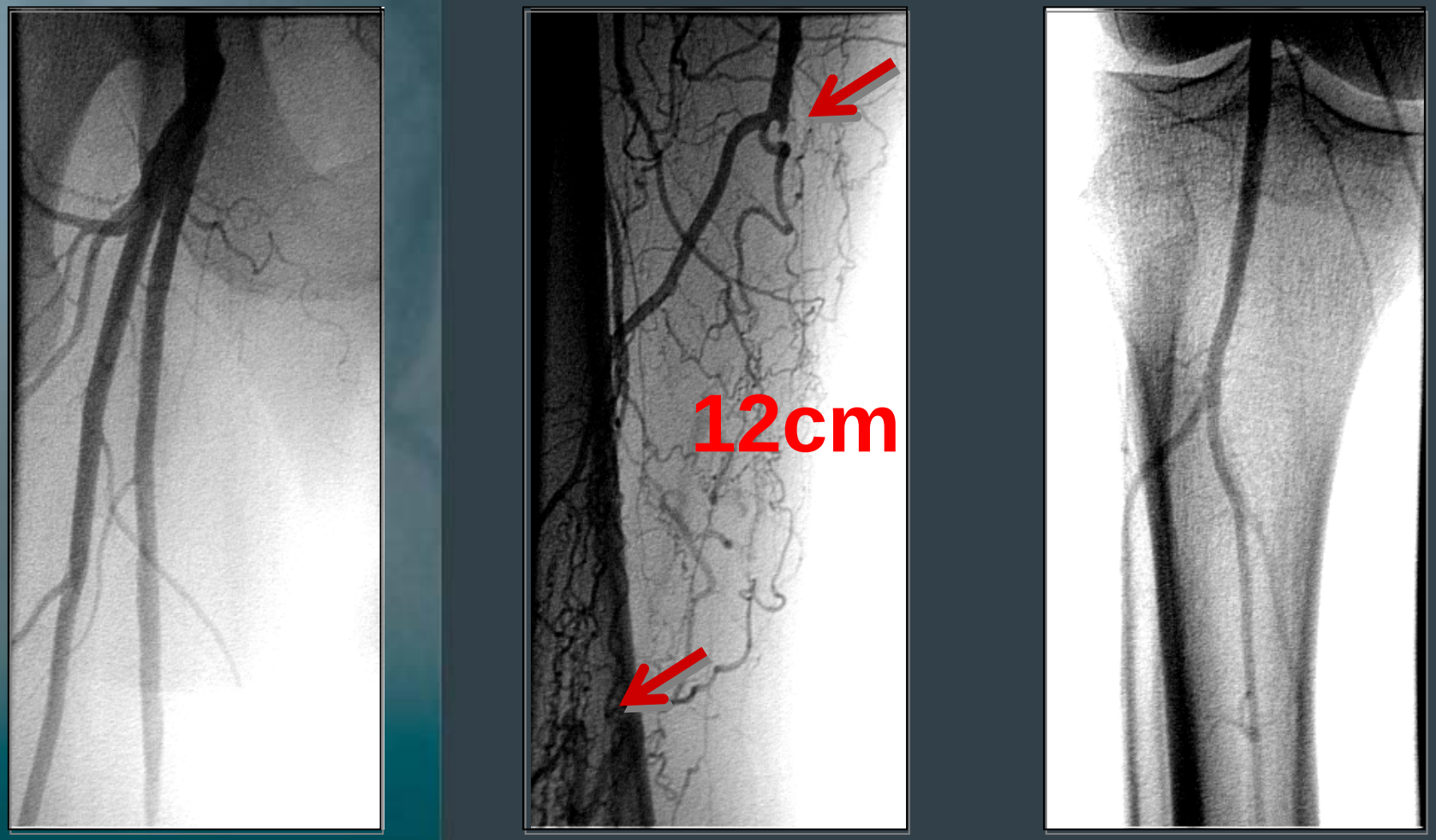


Stenting the SFA

NITINOL STENTS :

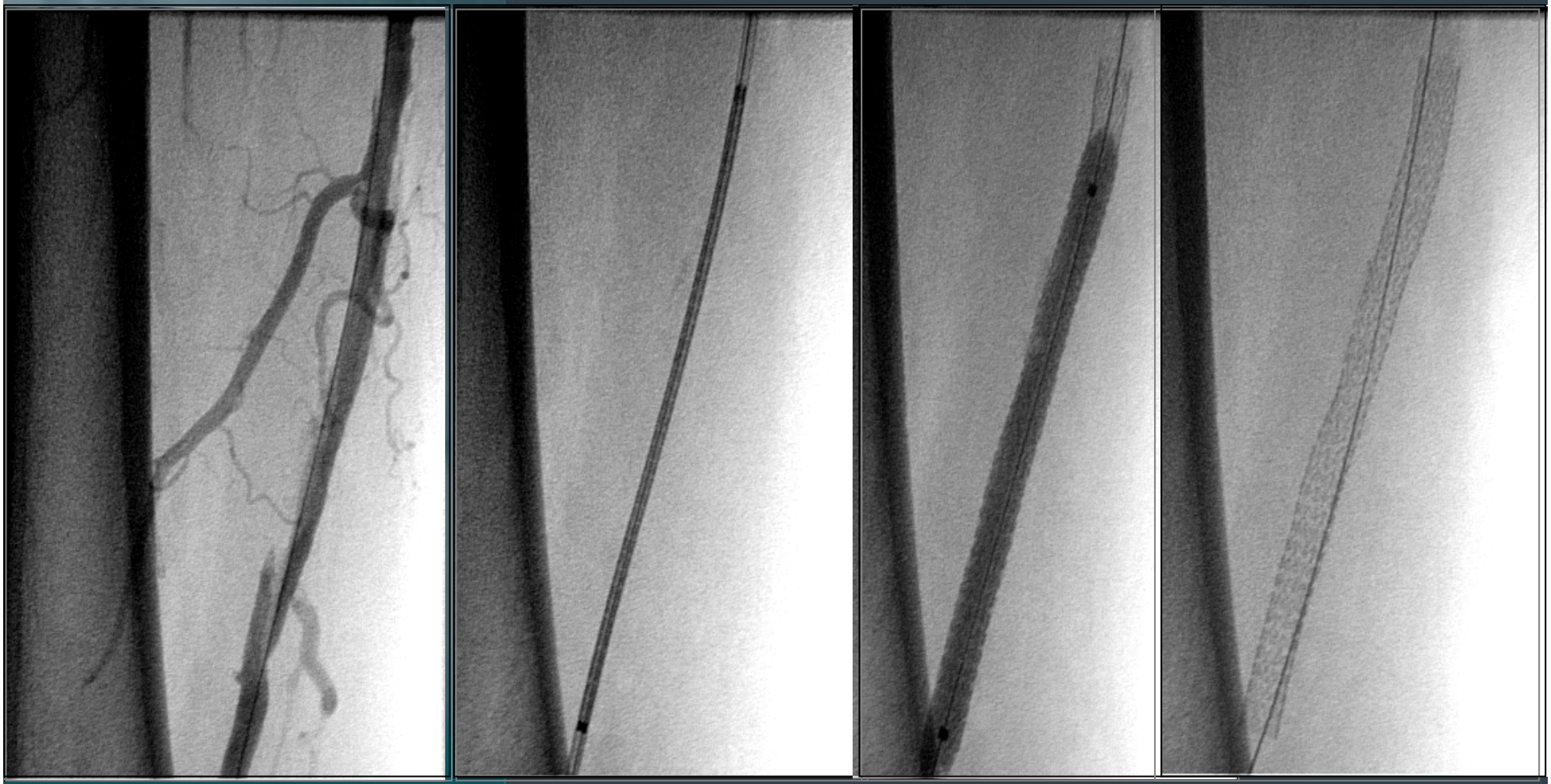
THE BREAKTHROUGH ?

Occlusion of the right SFA Ⅰ



Occlusion of the right SFA II

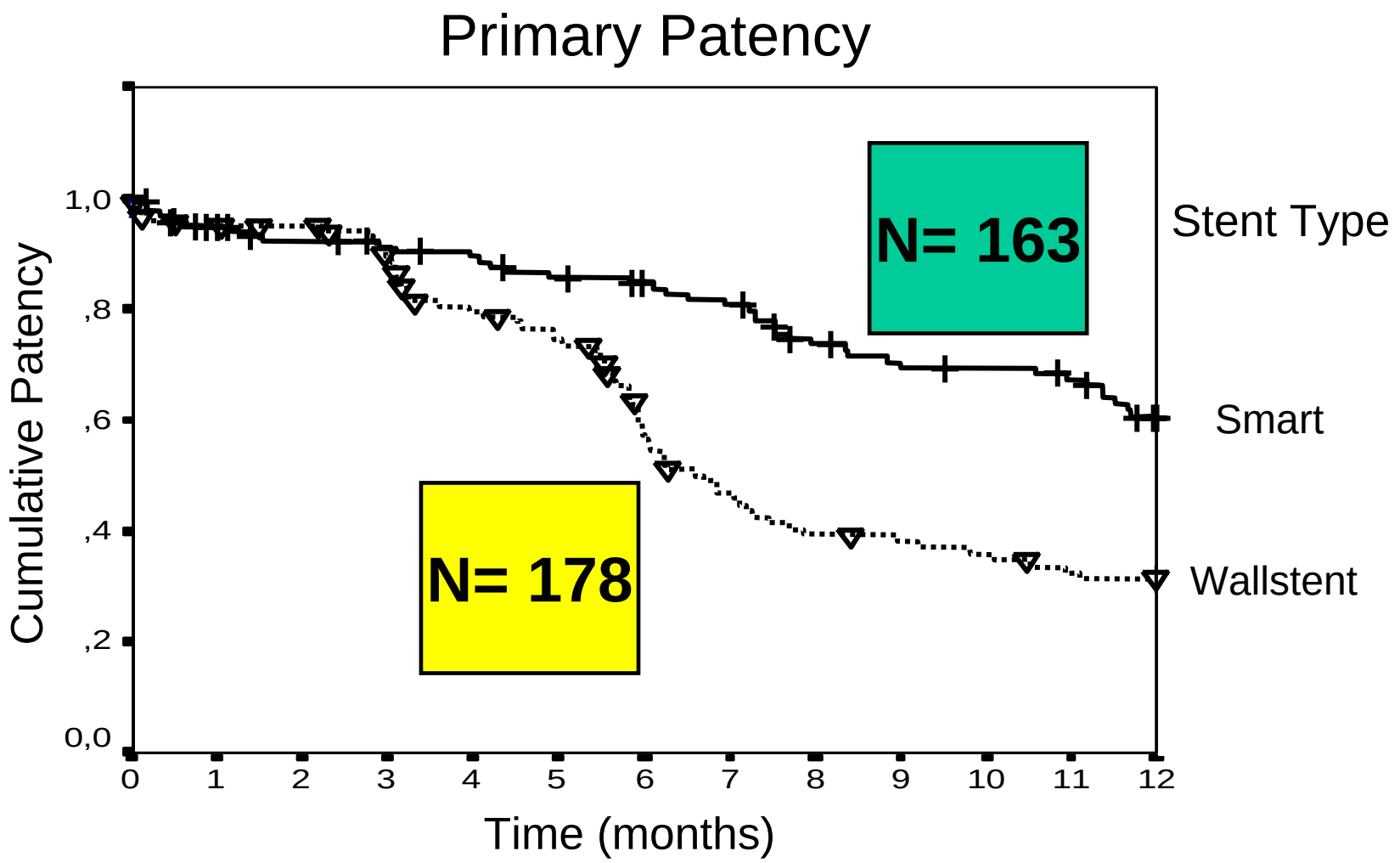
Occlusion of the right SFA III



Self-expanding Nitinol Stent

- According to some recent non randomized studies, the results using Nitinol stents are generally superior to the results reported in the past using ballon-expandable and self-expandable stainless-steel stents.

SMART vs. Wallstent in the SFA



Stenting Long SFA Lesions

- The high incidence of restenoses has been generally considered a consequence of intimal hyperplasia following
  - the incresed vessel wall stress induced by the stent
  - and/or the uncontrolled progression of the sclerotic disease.

- **Triggered by the SIROCCO I observation and by the unclear clinical impact of the phenomenon of stent fractures a systematic x-ray evaluation of all patients after SFA stent implantation was initiated**

- **121 treated legs with a total of 261 implanted stents could be investigated.**

- **Mean length of stented segment 15.7 cm**

Scheinert et al. J Am Coll Cardiol Jan 18,2005

- **Stenting only on indication:**
  - **Persistent diameter reduction > 50 % after prolonged ballon inflation.**
  - **Flow limiting dissection after PTA**

Scheinert et al. J Am Coll Cardiol Jan 18,2005

Results X-Ray Screening
10.7mo follow-up

- Fractures in 45 of 121 treated legs:

37.2%

- Fractures in 64 of 261 implanted stents:

24.5%

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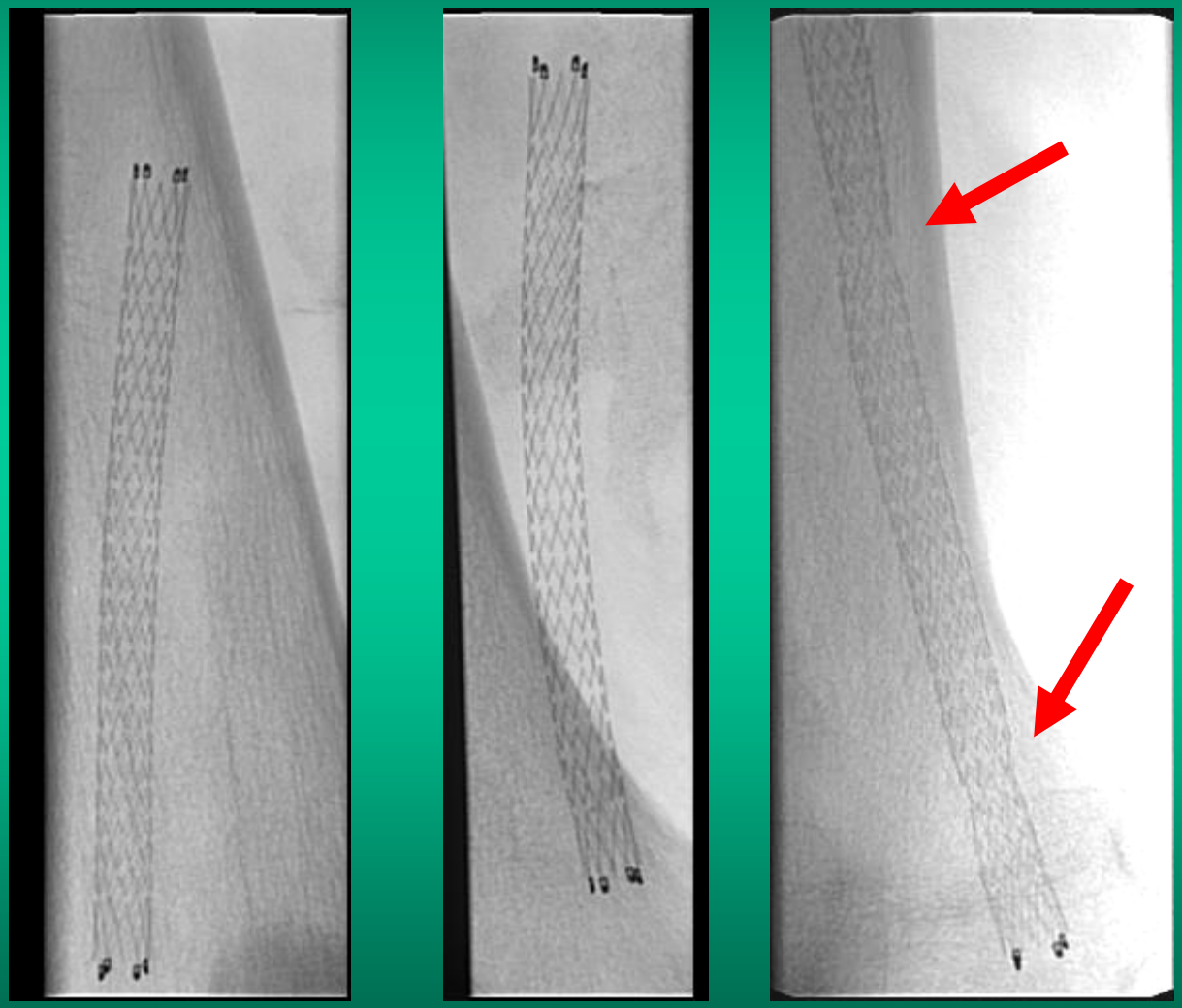
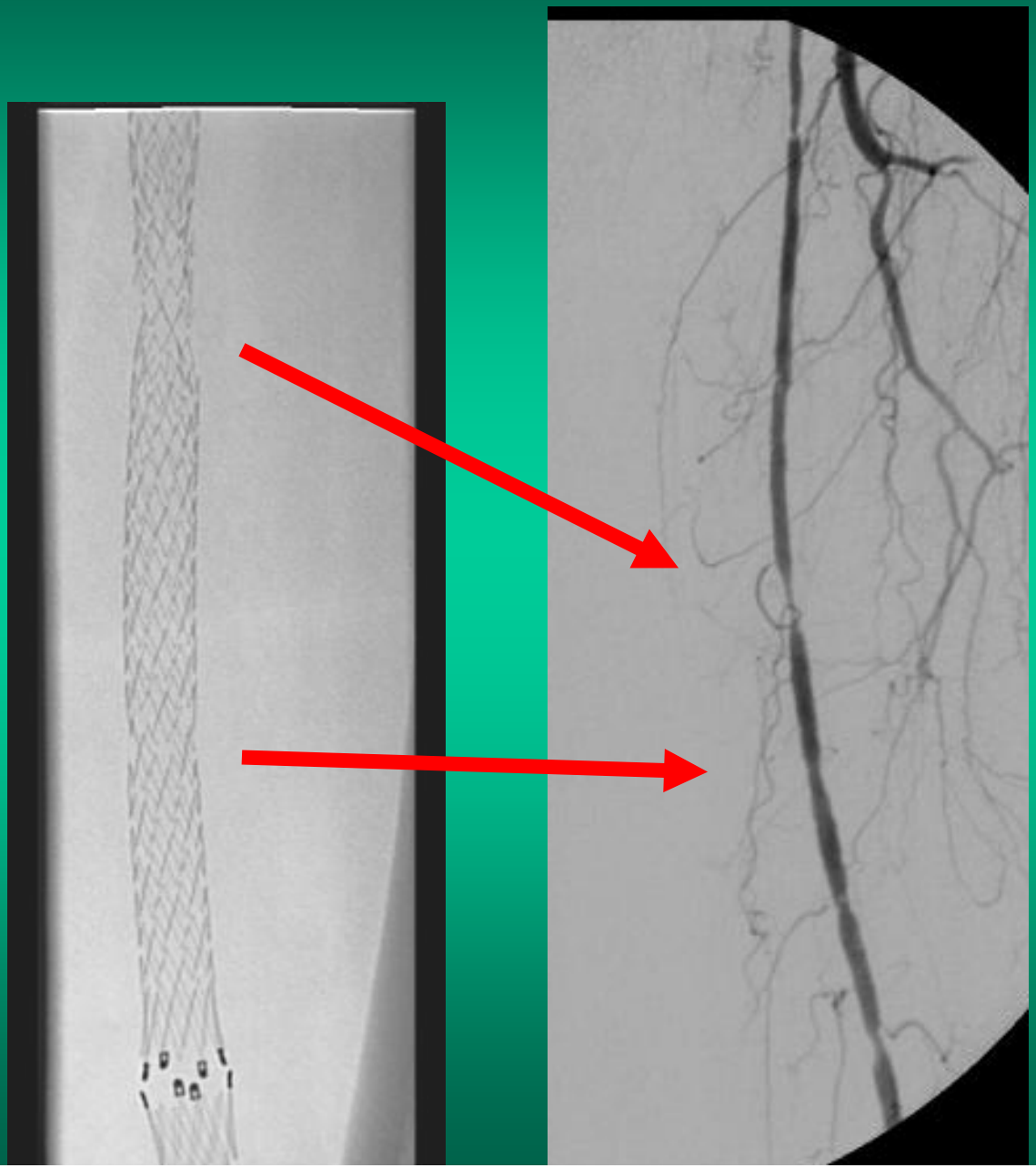
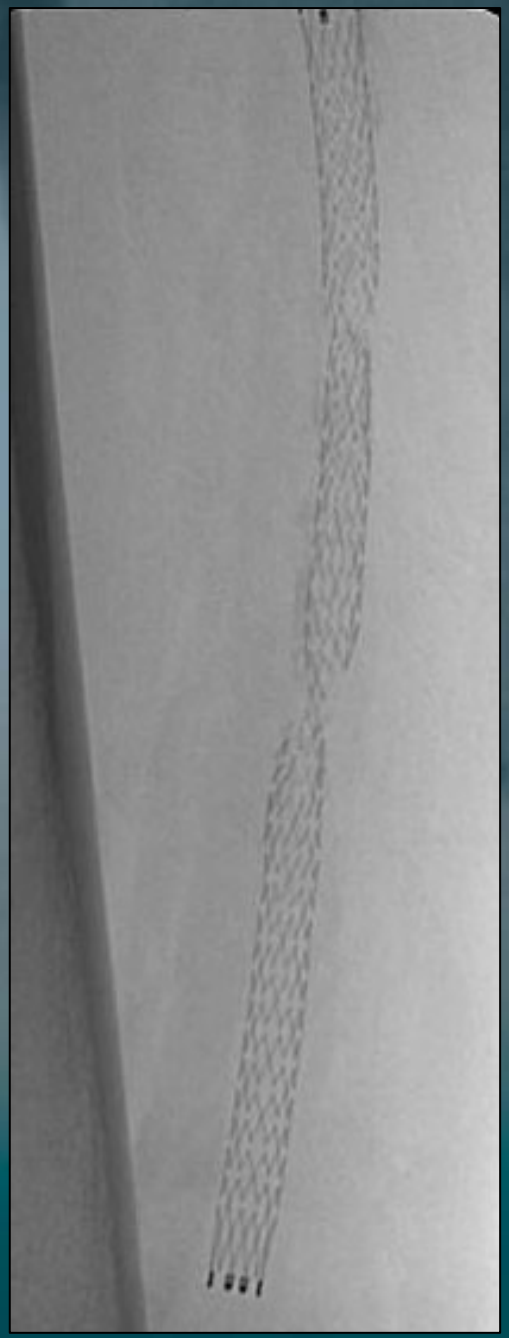
Minor Fracture



Moderate Fracture





Severe
Stent fractures
and
In-stent restenoses

Results of X-Ray Screening

- Fracture classification
  - –**Minor** (single strut fracture)

    in 31 cases **48.4%**
  - –**Moderate** (fracture of > 1 strut)

    in 17 cases **26.6%**
  - –**Severe** (separation of segments)

    in 16 cases **25.0%**

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Results of X-Ray Screening

- **Prevalence of stent fractures and length of the stented segments**:
  - **< 8 cm segment length** **13.2%** (5/38 legs)
  - **>8 <16 cm segment length** **42.4%** (14/33)
  - >16cm (3 or more stents) **52.0%** (26/50)

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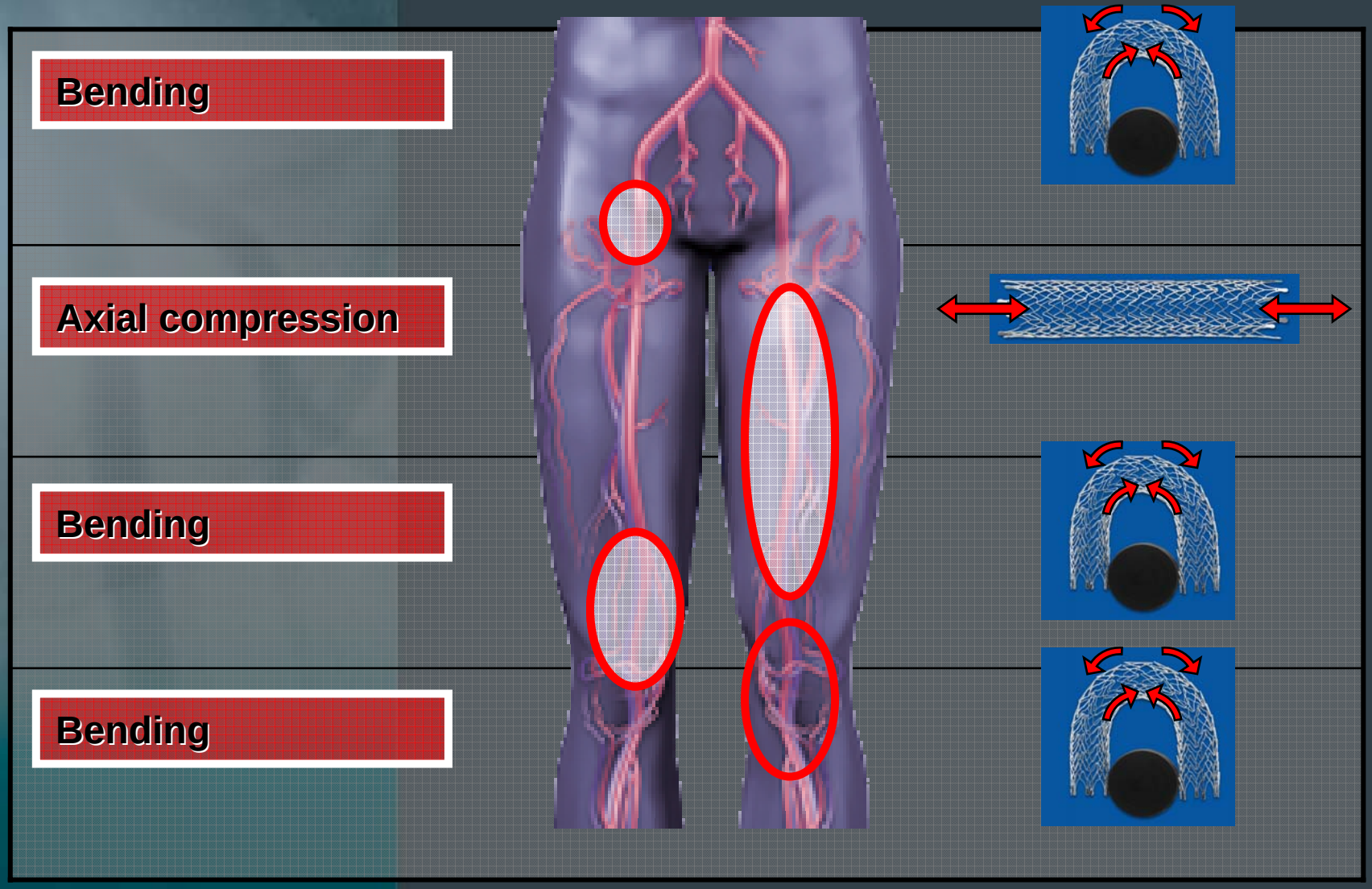
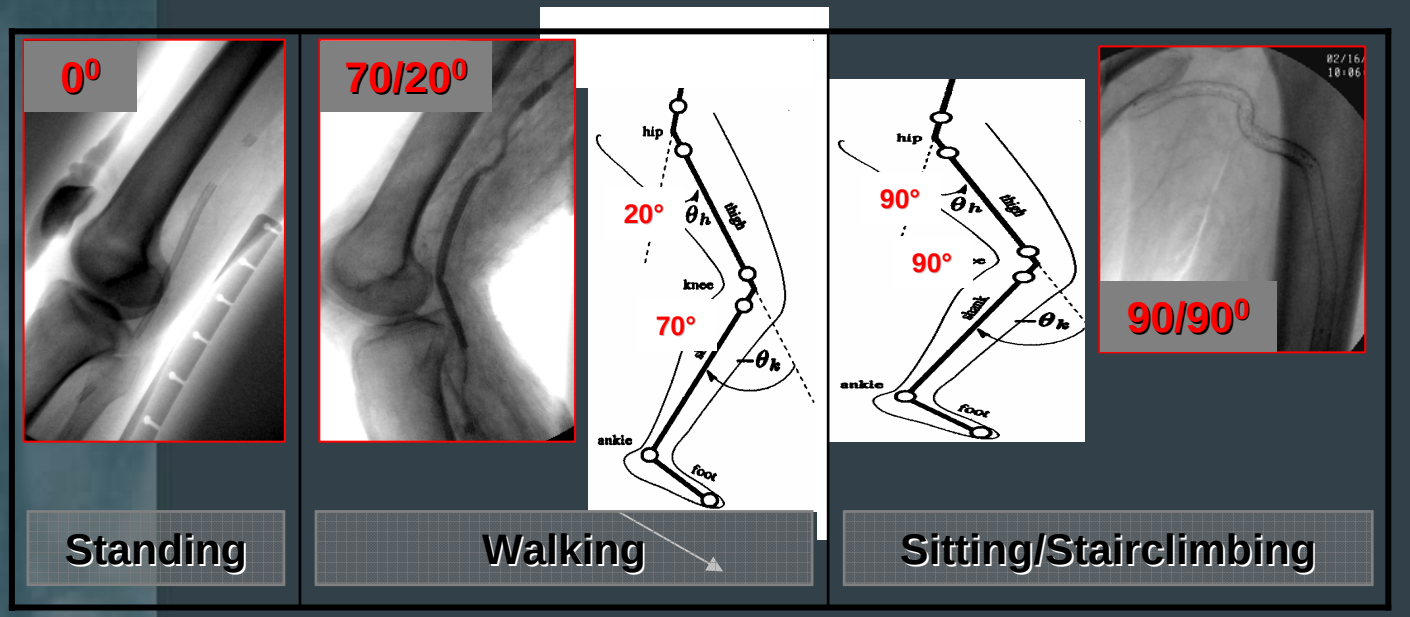
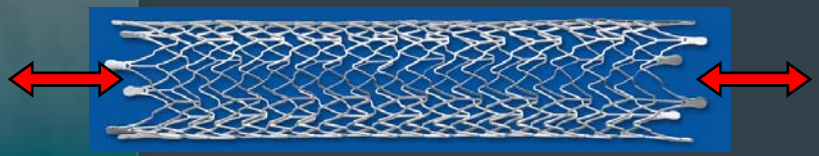
Level Dependent Stress of the Superficial Femoral Artery



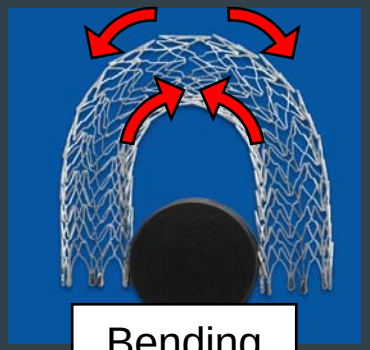
Superficial femoral artery: A mechanical model

Cadaver study on stented and unstented arteries





Axial compression/extension



Bending

Results of X-Ray Screening

- Distribution of fractures along the SFA

  – Proximal segment 19.4%
  – Middle segment 28.4%
  – Distal segment 23.7%

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Results of X-Ray Screening

- Clinical Impact of Stent Fractures:
  - Restenosis >50% at 32 fracture sites 32.8%
  - Stent occlusion at 22 fracture sites 34.4%
  - **No** reobstruction at 21 fracture sites 32.8%

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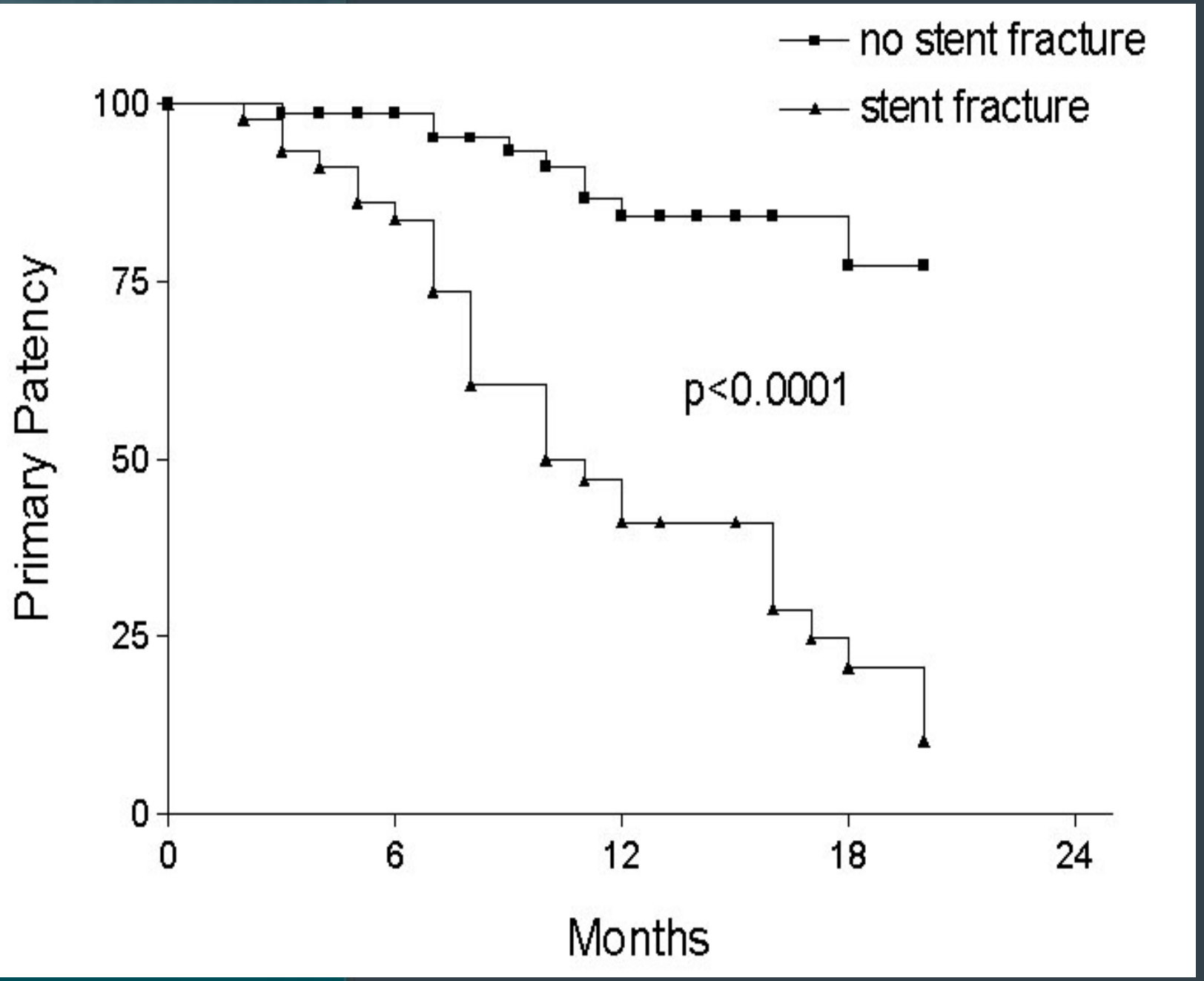

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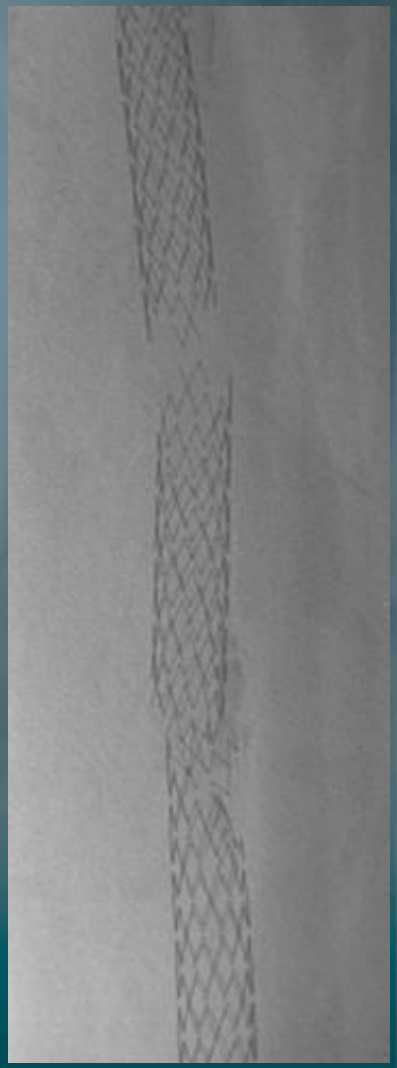
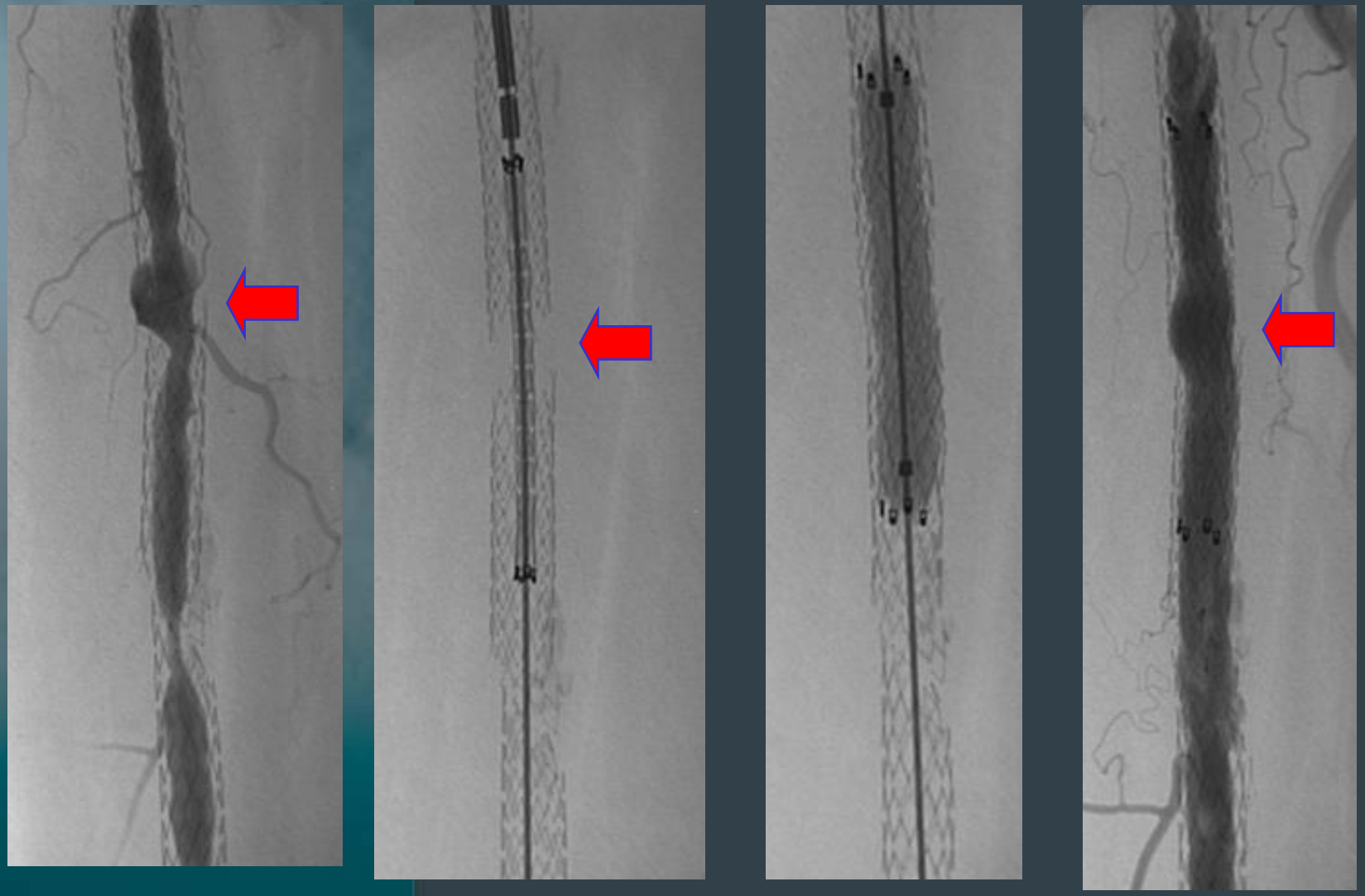
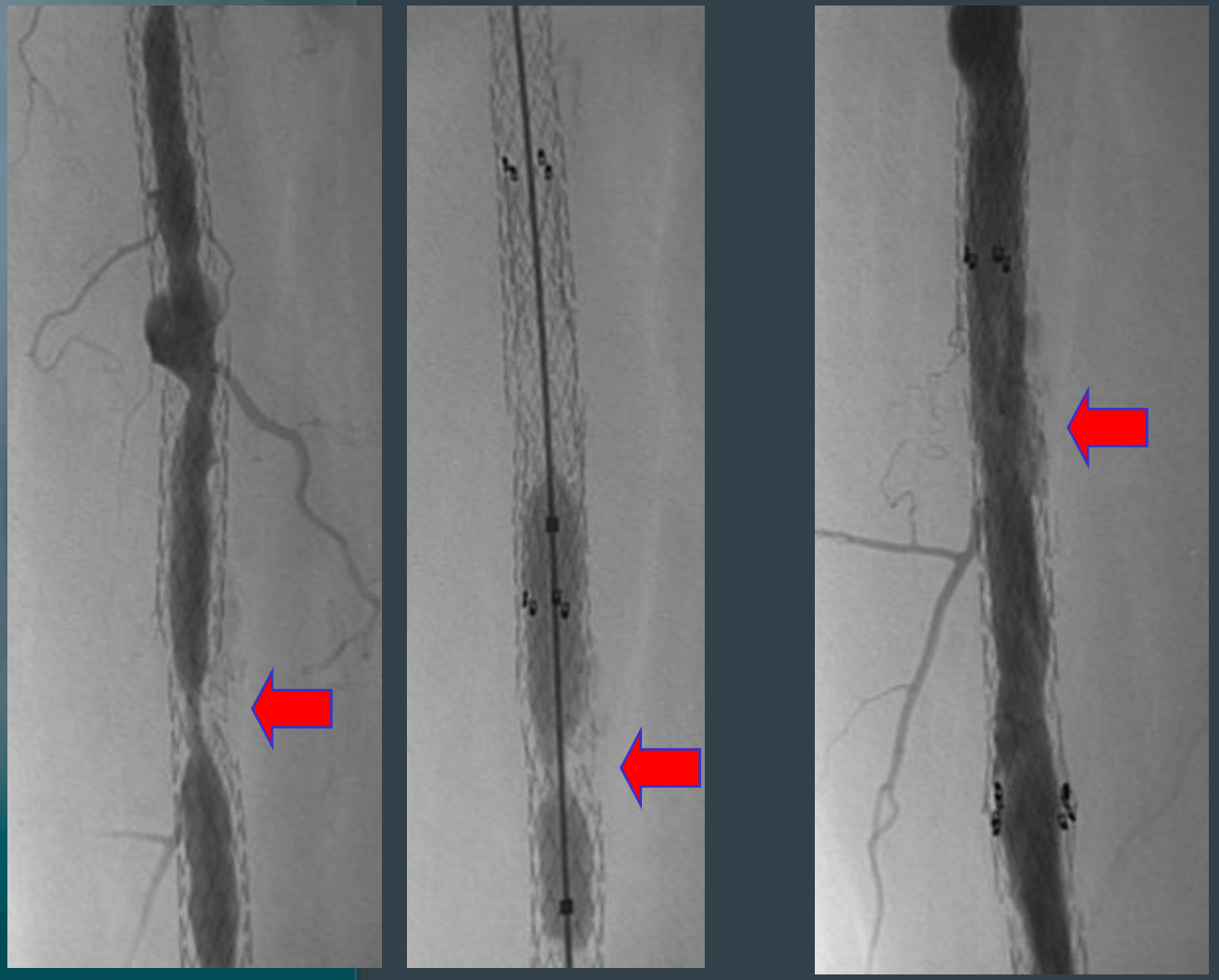
Femoropopliteal Stent-Fracture



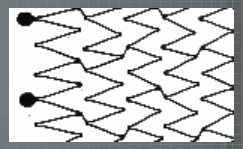
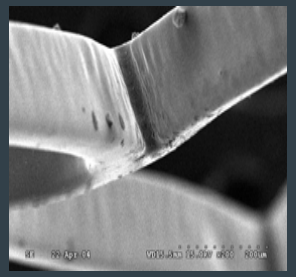
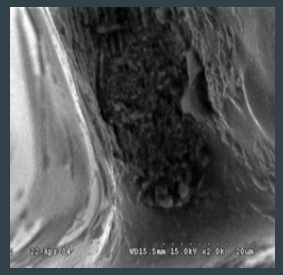
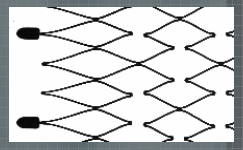
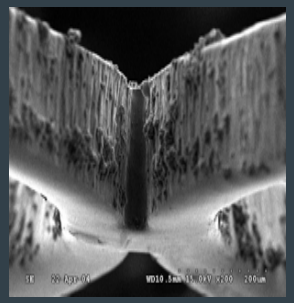
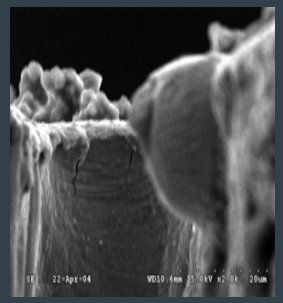
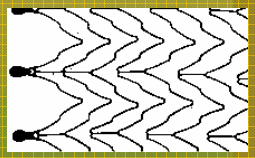
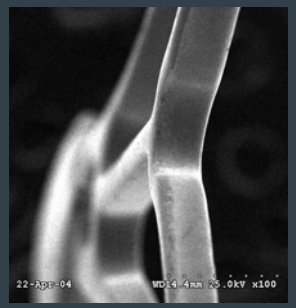
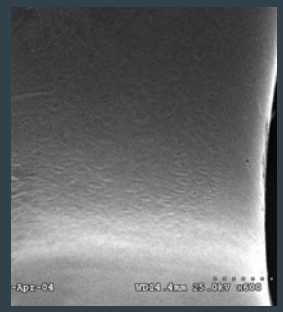
Treatment of the Aneurysm with a Covered Stent



Treatment of the Stenosis with PTA

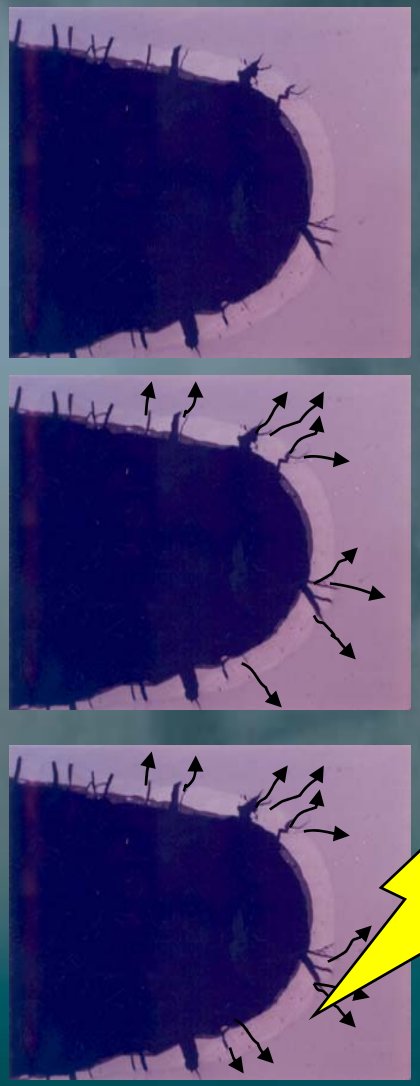


Nitinol stents : Surface finishing

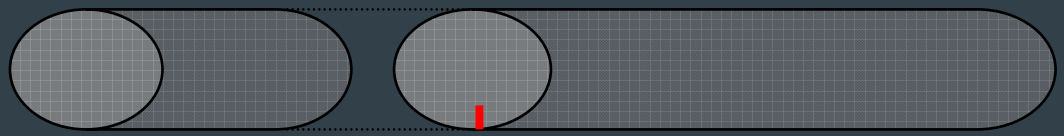
Stent A 	 
Stent B 	 
Stent C 	 

Stent fractures

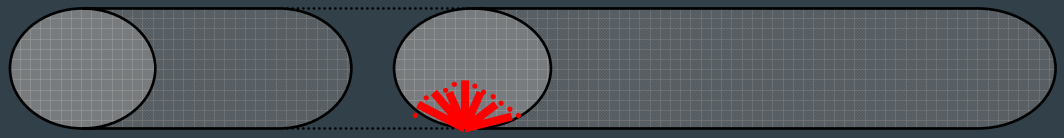
Role of surface defects and microcracks



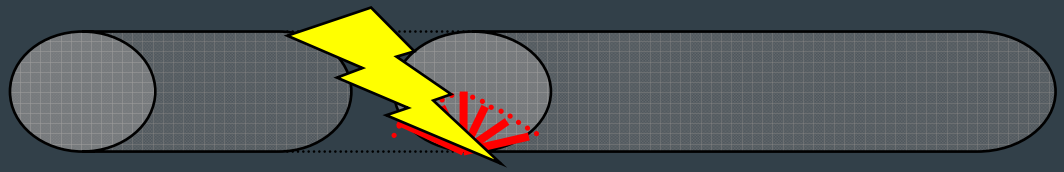
Under repeated and cyclical stresses...



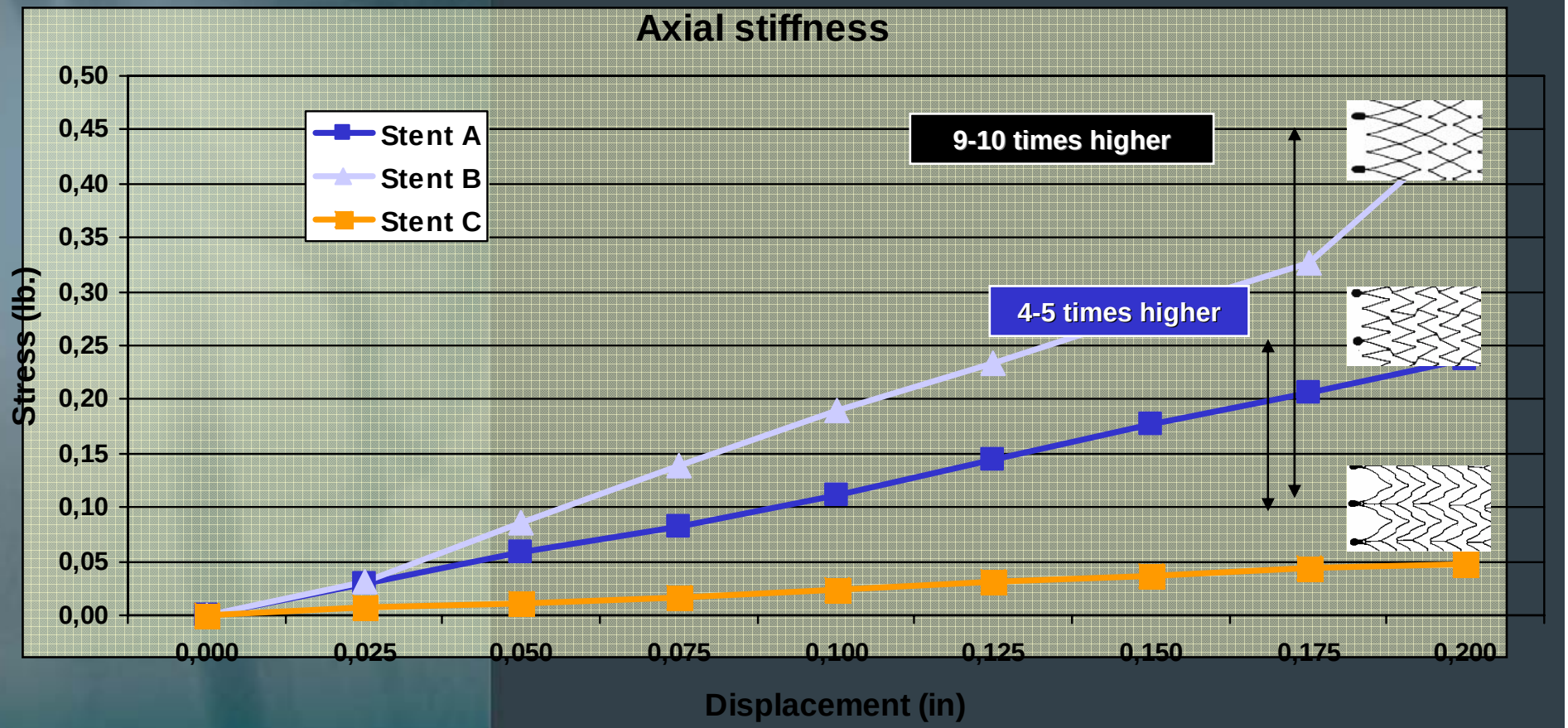
...microcracks propagate...

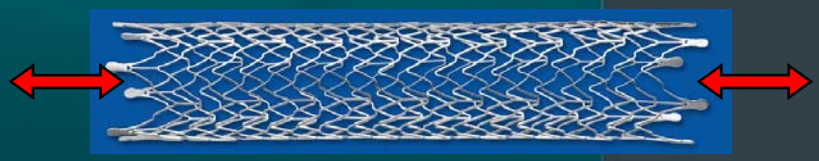


...until the remaining contact area of the stent yields and fails



Pattern design
Role of axial stiffness





↑ Axial stiffness ⇒

⇒ ↑ Crack propagation rate


Is it still reasonable to
treat long SFA-lesions
with stents?

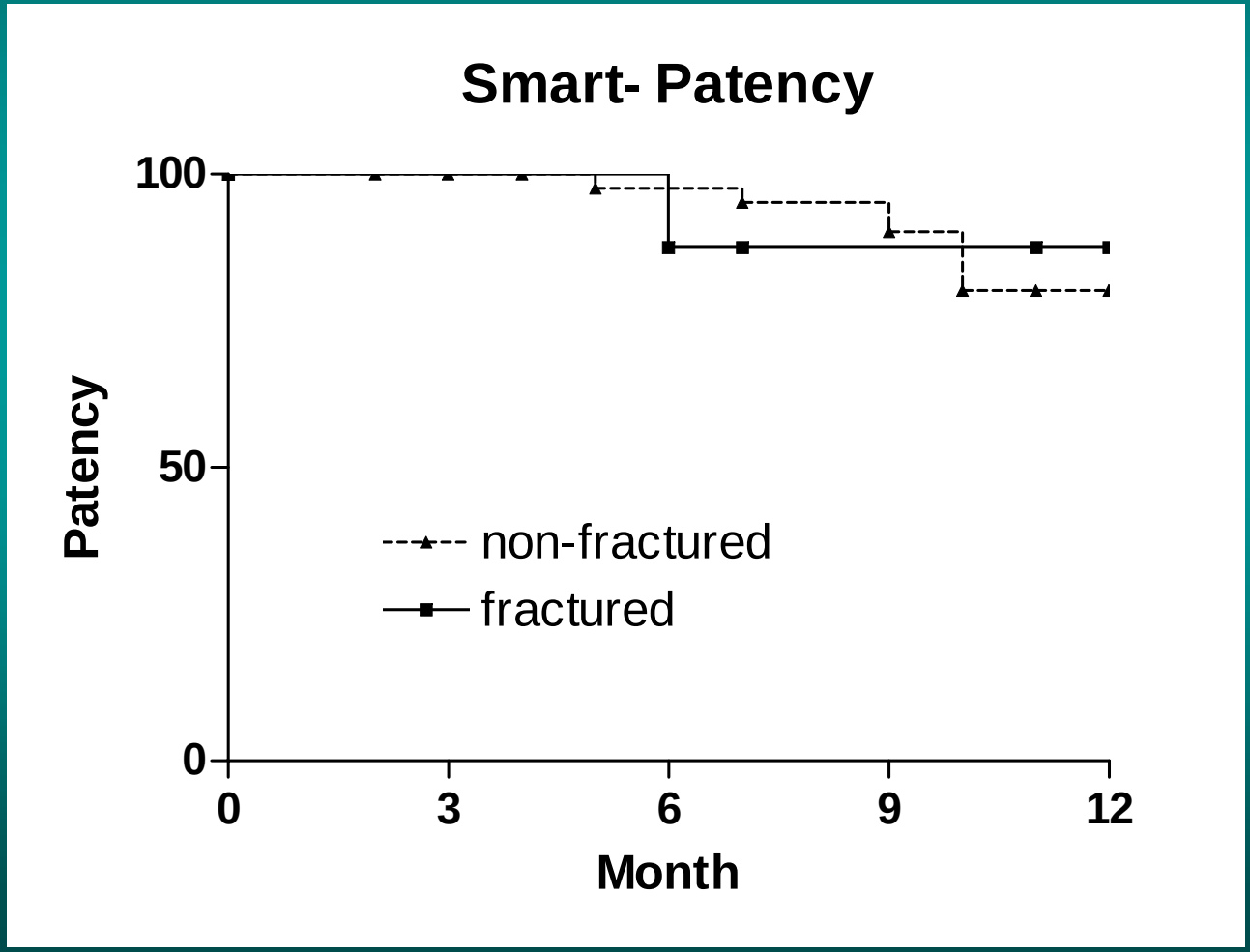
Results of Stenting
Long SFA-Lesions

- 64 patients treated with **SMART**-stents
  - Lesion length **154 +/- 63** mm
  - Total occlusions **59.4 %**
  - Diabetics **43.7 %**

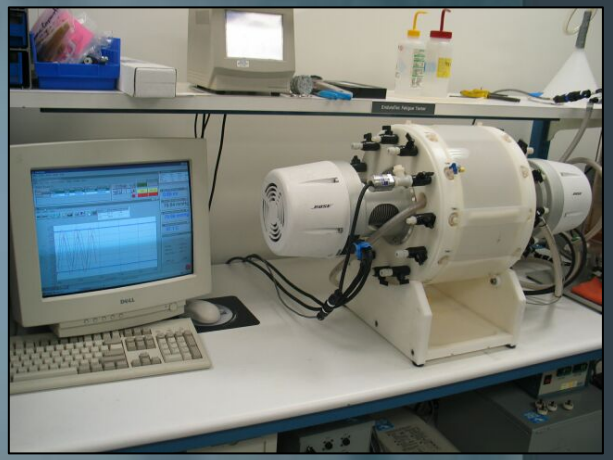
- Primary patency rate
  - 6 months **96.3 %**
  - 12 months **82.1 %**

- Fracture rate **15.1%**

Results of X-Ray Screening

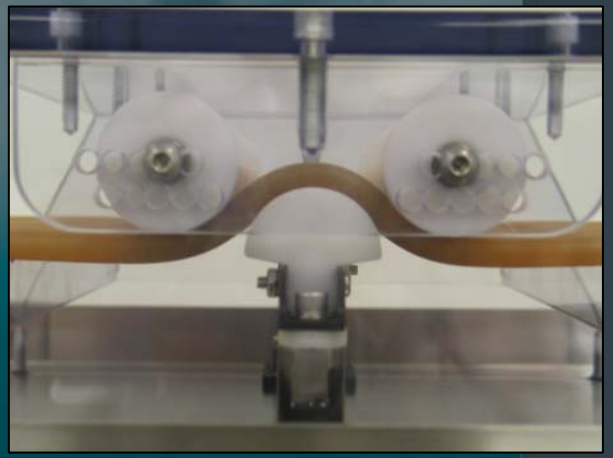


Test Capabilities for SFA Stents



Pulsative fatigue testing

Stretch and twist testing

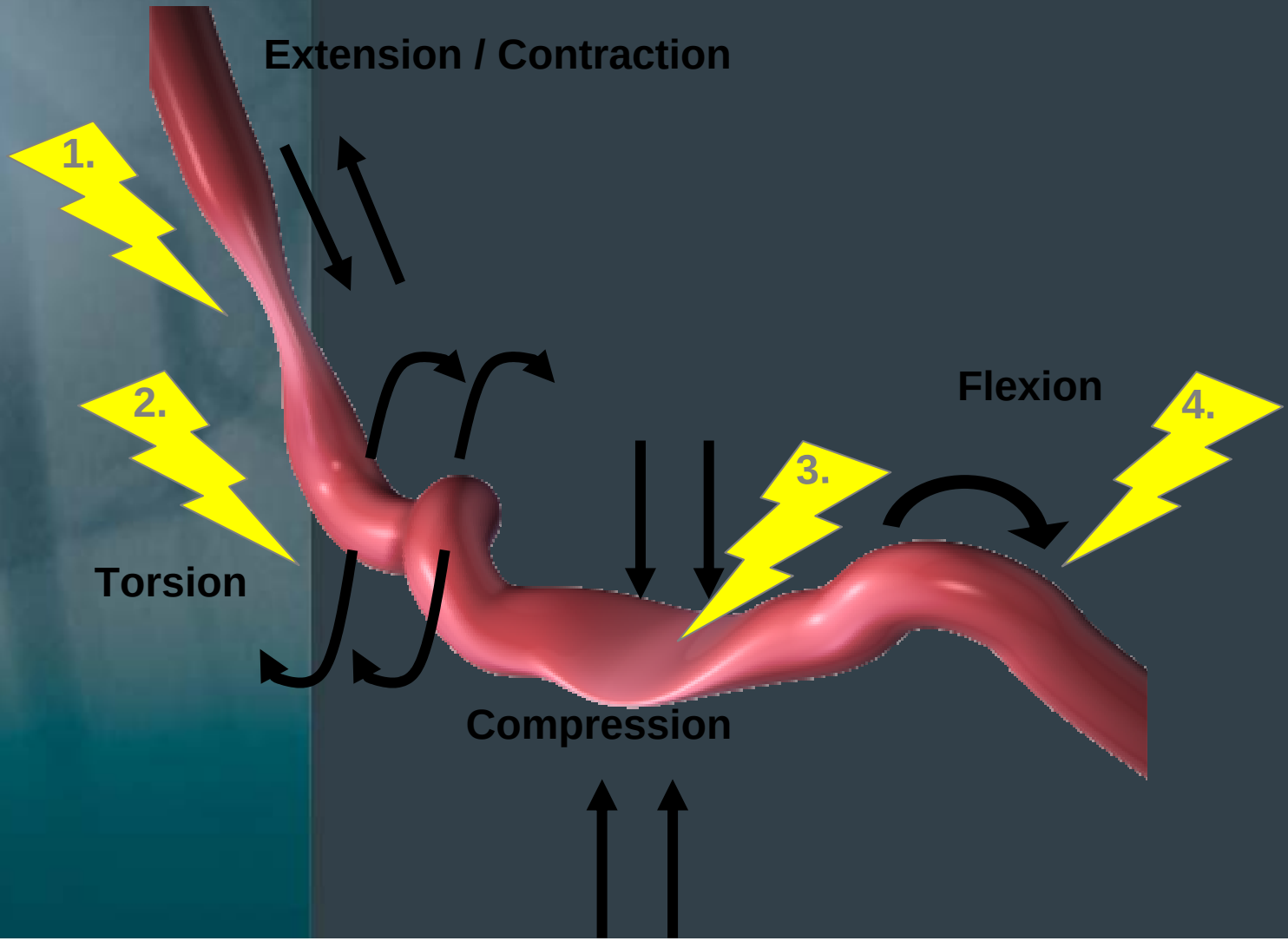


Flexation testing

Before thinking about DES for the SFA, changes in the

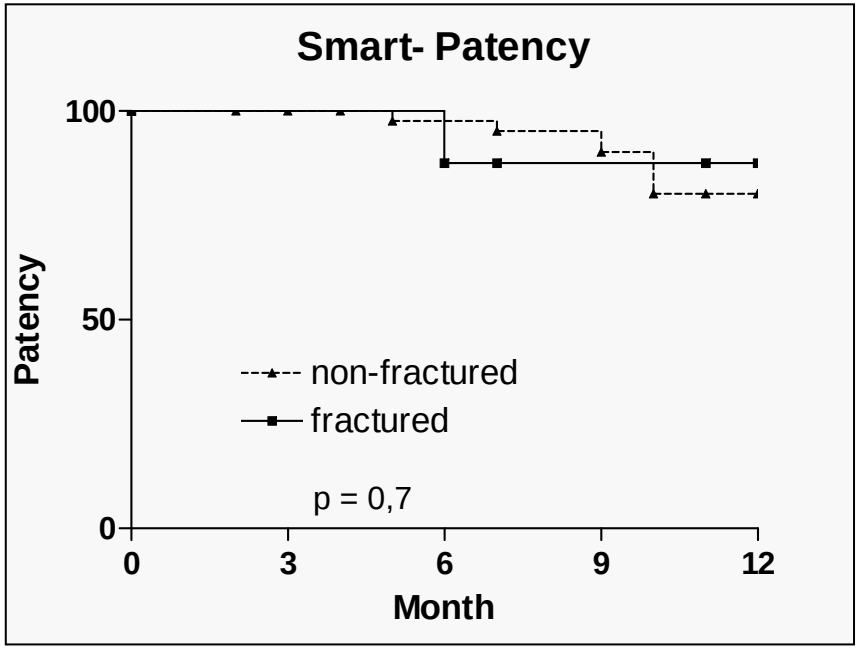
mechanical performance

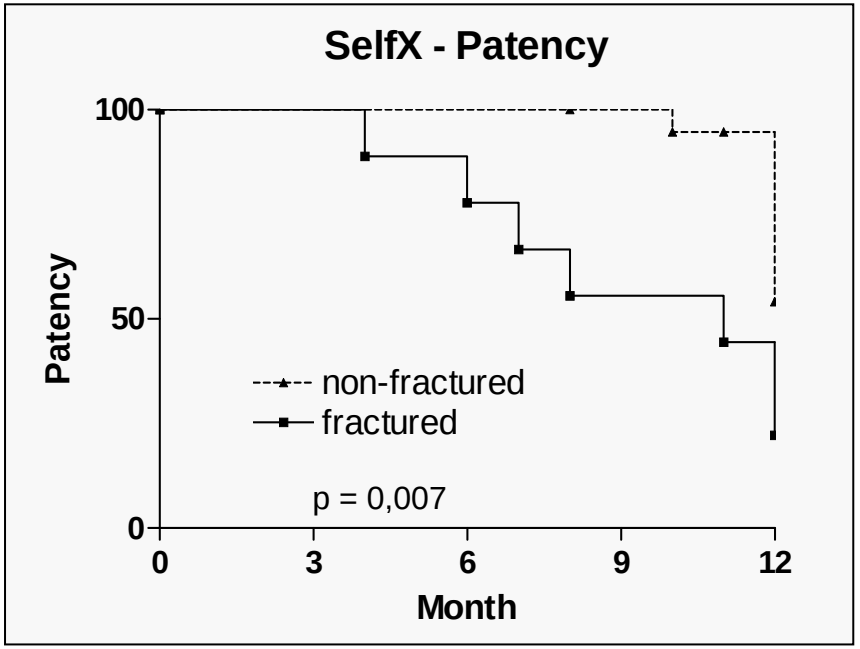
of the Nitinol stents are mandatory.

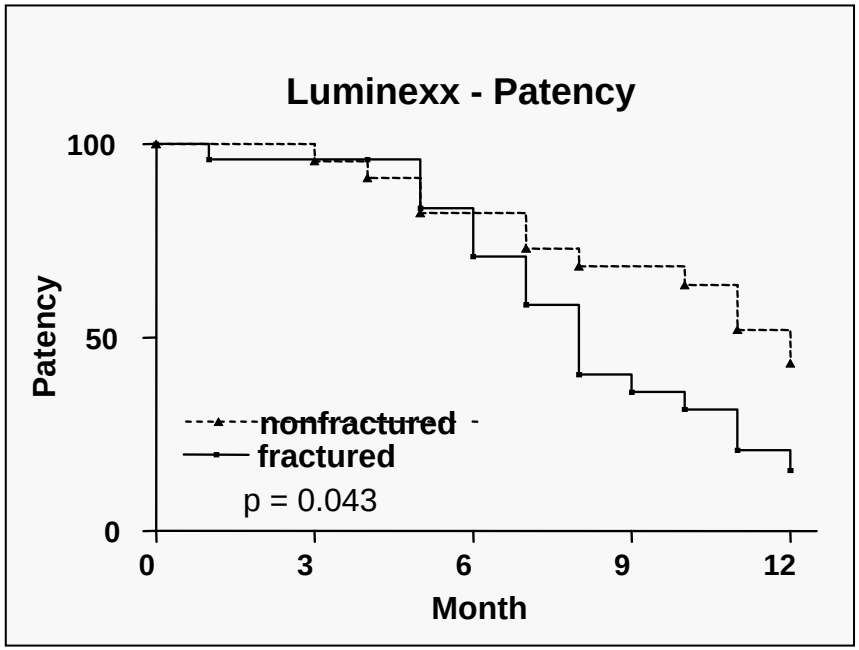


Results of X-Ray Screening

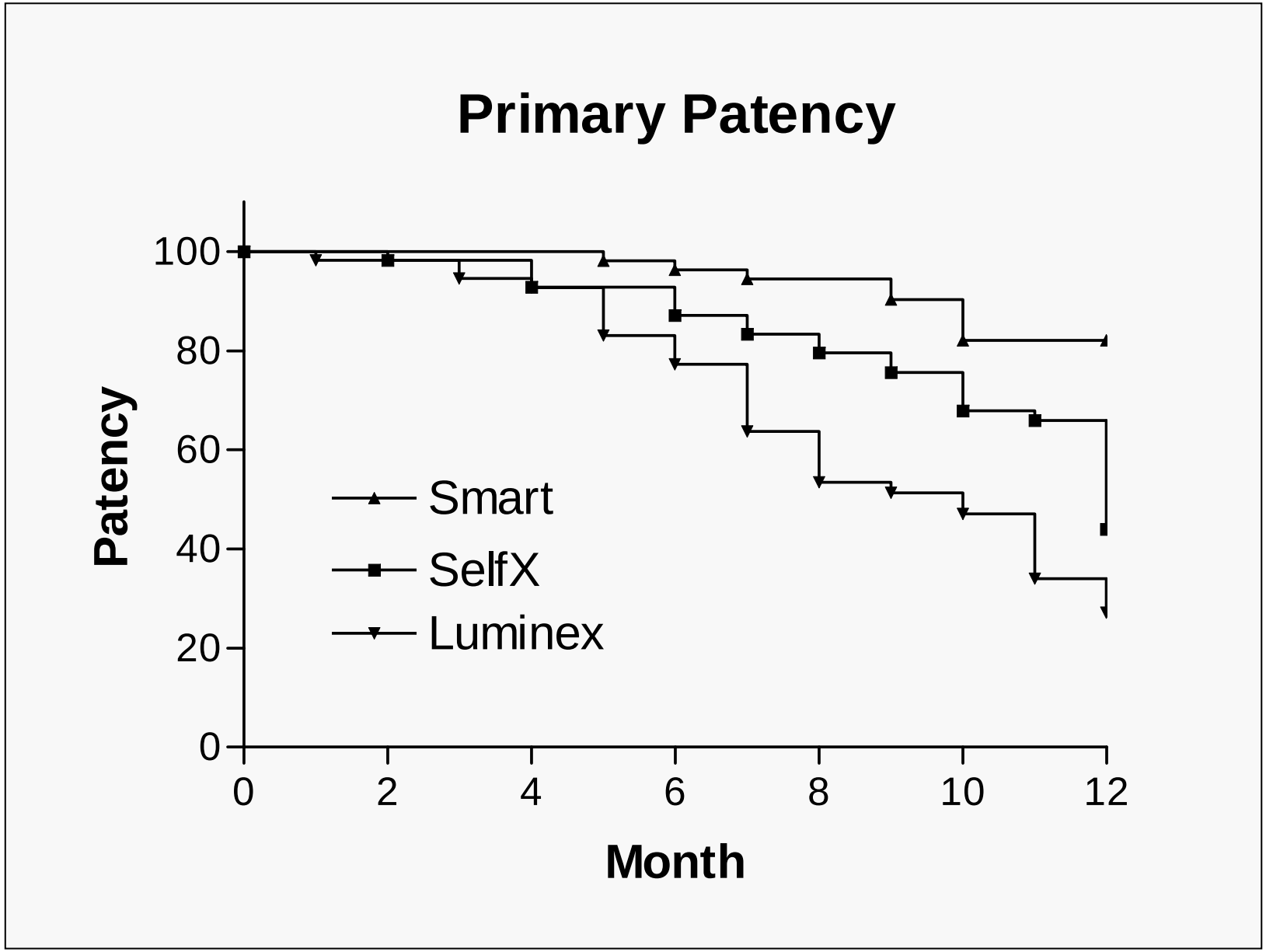
	Smart (n = 64)	**SelfX (n = 58)**	**Luminexx (n = 56)**
n Pat.- X-Ray	53 (82,8%)	29 (50%)	48 (58,7%)
X-Ray- time (Month)	15,5 ± 4,9	11 ± 4	9,1 ± 4,1
Stentfractur (n / %)	8 (15,1 %)	9 (31,0%)	25 (52,1%)
Grading 1 2 3	 3 (37,5%) 3 (37,5%) 2 (25%)	 4 (44,4%) 3 (33,3%) 2 (22,2%)	 4 (16%) 5 (20%) 14 (56%)







Impact of stent fracture on stent patency


Primary Patency
Patency
100
80
60
40
20
0
0
2
4
6
8
10
12
Month
Smart
SelfX
Luminex

Primary Patency Rates

	S.M.A.R.T	SelfX	Luminex
3 Months	100%	98,2%	94,5%
6 Months	96,3%	87,1%	77,2%
9 Months	90,3%	75,6%	51,3%
12 Months	82,1%	43,9%	27,1%

Superficial femoral artery
A mechanical model

Bending

Axial compression

Bending

Bending