STENT FRACTURES IN SFA

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Stenting the SFA

NITINOL STENTS:

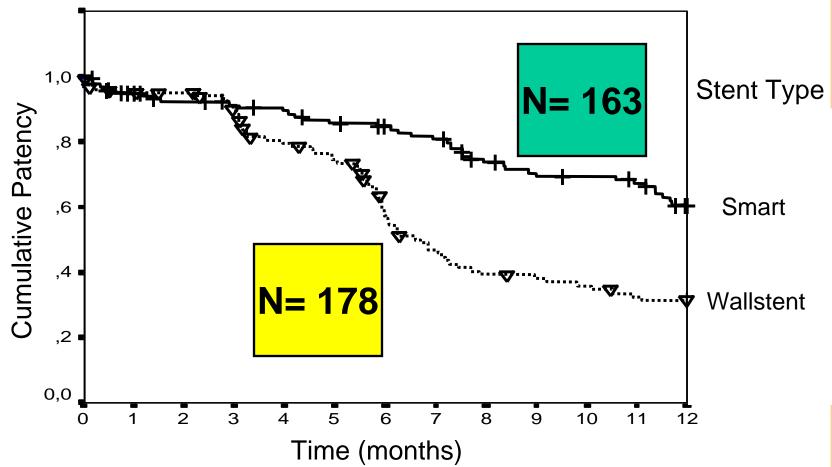
THE BREAKTHROUGH ?

Self-expanding Nitinol Stent

 According to some recent <u>NON</u> randomized studies, the results using Nitinol stents are generally superior to the results reported in the past using ballonexpandable and self-expandable stainless-steel stents.

SMART vs. Wallstent in the SFA

Primary Patency



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

Stenting (only) on indication:

–Persistent diameter reduction > 50 % after prolonged ballon inflation.

-Flow limiting dissection after PTA

Results X-Ray Screening 10.7mo follow-up

• Fractures in 45 of 121 treated legs:

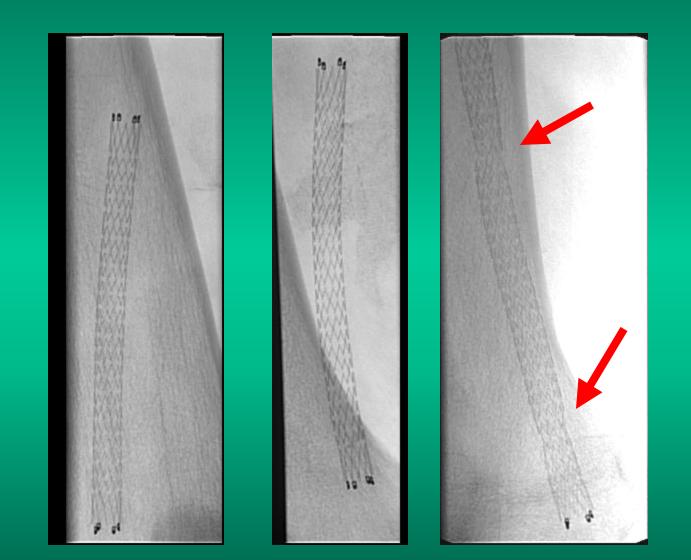
37.2%

• Fractures in 64 of 261 implanted stents:

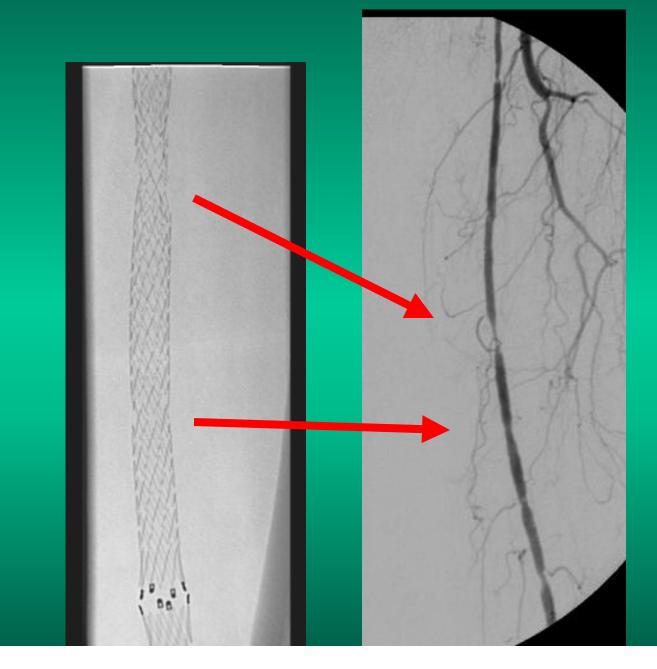
24.5%

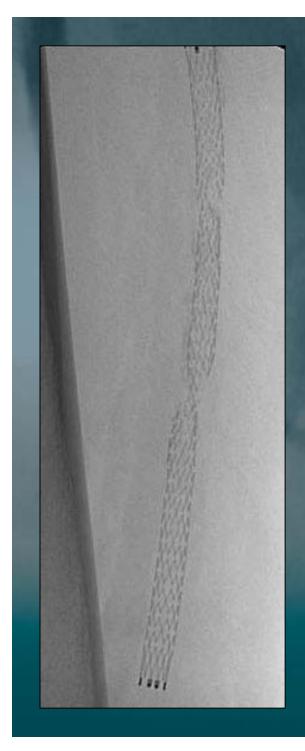
Results of X-Ray Screening Fracture classification -Minor (single strut fracture) 48.4% in 31 cases -Moderate (fracture of > 1 strut) 26.6% in 17 cases -Severe (separation of segments) 25.0% in 16 cases Scheinert et al. J Am Coll Cardiol Jan 18,2005

Minor Fracture



Moderate Fracture





Severe Stent fractures and In-stent restenoses

Results of X-Ray Screening

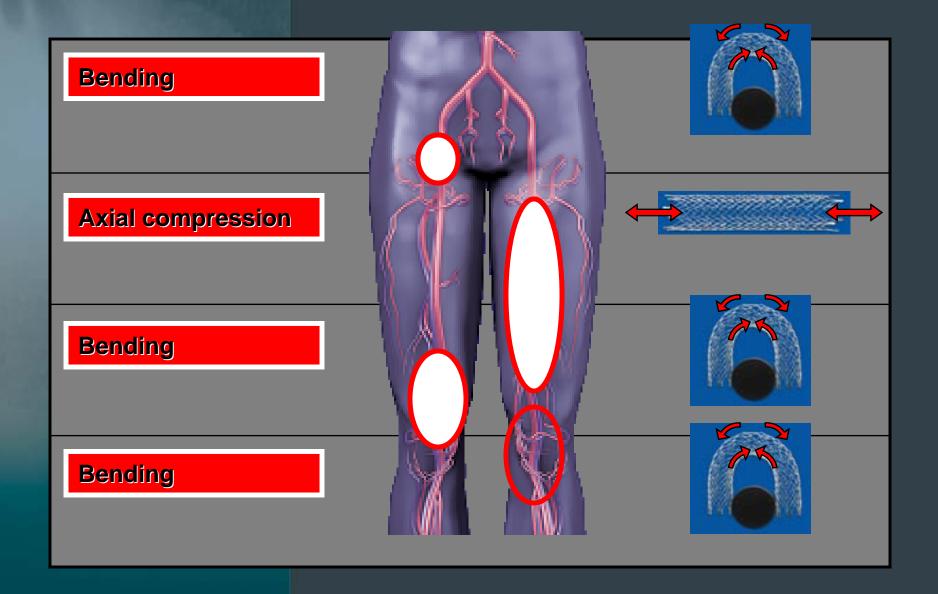
 Prevalence of stent fractures and length of the stented segments:

- < 8 cm segment length (13.2%)(5/38 legs)</p>

- >8 <16 cm segment length(42.4%)(14/33)</p>

- >16cm (3 or more stents) (52.0%) (26/50)

Level Dependent Stress of the Superficial Femoral Artery



Results of X-Ray Screening
Distribution of fractures along the SFA

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

Results of X-Ray Screening

Clinical Impact of Stent Fractures:

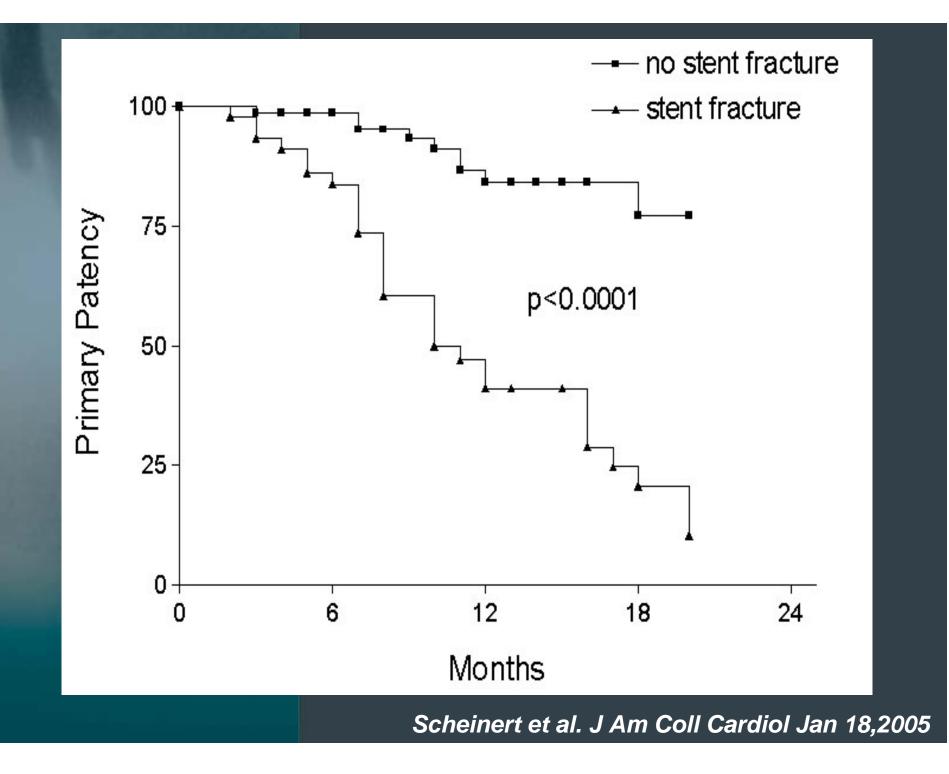
– Restenosis >50% at 32 fracture sites 32.8%

– Stent occlusion at 22 fracture sites

34.4%

32.8%

-No reobstruction at 21 fracture sites

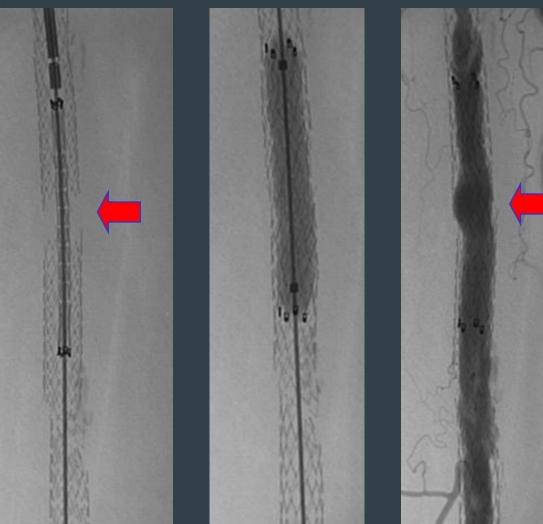


Femoropopliteal Stent-Fracture

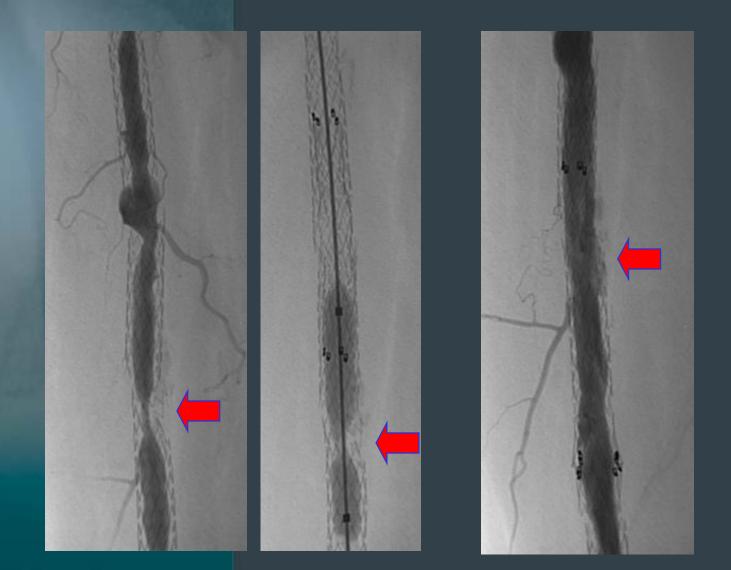


Treatment of the Aneurysm with a Covered Stent





Treatment of the Stenosis with PTA



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** %

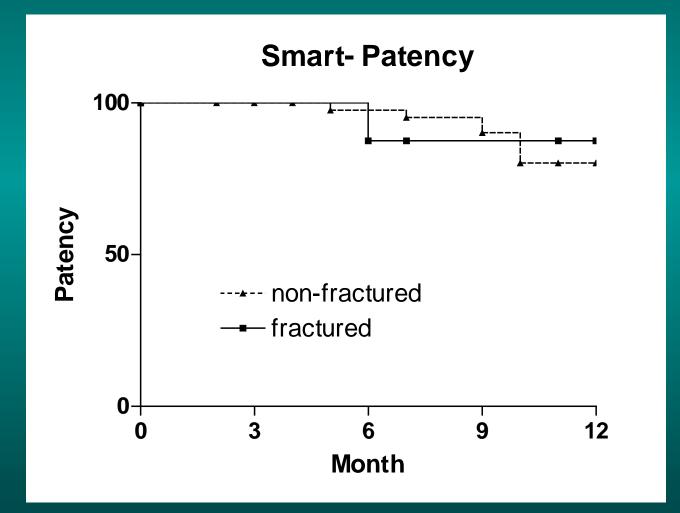
• Primary patency rate

- 6 months 96.3 %
- 12 months 82.1 %

Fracture rate 15.1%



Results of X-Ray Screening



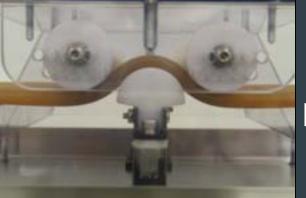


Test Capabilities for SFA Stents

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.

