Stenting the SFA

NITINOL STENTS: THE BREAKTHROUGH?
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 balloon-expandable and self-expandable stainless-steel stents.
SMART vs. Wallstent in the SFA

Primary Patency

Cumulative Patency

Time (months)

N = 163

Stent Type

Smart

Wallstent

N = 178
Stenting Long SFA Lesions

• The high incidence of restenoses has been generally considered a consequence of intimal hyperplasia following
  
  – the increased 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 balloon 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%

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

• Fractures in 64 of 261 implanted stents:
  24.5%
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%

Scheinert et al. J Am Coll Cardiol Jan 18, 2005
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)
  - > 8 < 16 cm segment length: 42.4% (14/33)
  - > 16 cm (3 or more stents): 52.0% (26/50)

Scheinert et al. J Am Coll Cardiol Jan 18, 2005
<table>
<thead>
<tr>
<th>Level Dependent Stress of the Superficial Femoral Artery</th>
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<td><strong>Bending</strong></td>
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<td><strong>Axial compression</strong></td>
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Results of X-Ray Screening

• Distribution of fractures along the SFA
  – Proximal segment 19.4%
  – Middle segment 28.4%
  – Distal segment 23.7%

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

Scheinert et al. J Am Coll Cardiol Jan 18, 2005
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The figure shows a Kaplan-Meier survival curve comparing primary patency between patients with no stent fracture and those with stent fracture. The curve indicates a statistically significant difference in patency over time, with a p-value of <0.0001.
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?
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

![Graph showing Smart-Patency over months with non-fractured and fractured lines.](image)

- **X-axis:** Month
- **Y-axis:** Patency
- **Legend:**
  - Dashed line: non-fractured
  - Solid line: fractured
Test Capabilities for SFA Stents

- Pulsative fatigue testing
- Stretch and twist testing
- Flexation testing
I can stent the SFA, but Nitinol stents are not perfect and all stents are not equal !!!!!!!!
Before thinking about DES for the SFA, changes in the **mechanical performance** of the Nitinol stents are mandatory.