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

G. Biamino

University of Leipzig – Heart Center
Department of Clinical and Interventional Angiology
Leipzig, Germany
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

- **Primary patency**
- **Assisted primary patency**
- **Secondary patency**

Length of stented segment:
- **< 10 cm**
- **> 10 cm**

- Primary patency: 65\% in < 10 cm, 62\% in > 10 cm
- Assisted primary patency: 83\% in < 10 cm, 69\% in > 10 cm
- Secondary patency: 86\% in < 10 cm, 69\% in > 10 cm
Stenting the SFA

NITINOL STENTS: THE BREAKTHROUGH?
Occlusion of the right SFA 12cm
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

Primary Patency

Cumulative Patency

Time (months)

Stent Type

Smart

Wallstent

N= 178

N= 163
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%

• Fractures in 64 of 261 implanted stents:

24.5%

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

- **Minor** (single strut fracture)
  - 31 cases, 48.4%

- **Moderate** (fracture of > 1 strut)
  - 17 cases, 26.6%

- **Severe** (separation of segments)
  - 16 cases, 25.0%

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

Scheinert et al. J Am Coll Cardiol Jan 18,2005
Level Dependent Stress of the Superficial Femoral Artery
Superficial femoral artery: A mechanical model

Cadaver study on stented and unstented arteries

Standing

Walking

Sitting/Stairclimbing

Axial compression/extension

Bending

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%

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

The graph represents the primary patency over time for two conditions: no stent fracture and stent fracture. The graph shows a clear trend where the primary patency decreases over months, with a statistically significant difference between the two conditions, indicated by "p < 0.0001."
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

↑ Axial stiffness ⇒
⇒ ↑ Crack propagation rate

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Role of axial stiffness

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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

![Graph showing Smart-Patency over months with non-fractured and fractured lines]
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

<table>
<thead>
<tr>
<th></th>
<th>Smart (n = 64)</th>
<th>SelfX (n = 58)</th>
<th>Luminexx (n = 56)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n Pat.- X-Ray</td>
<td>53 (82,8%)</td>
<td>29 (50%)</td>
<td>48 (58,7%)</td>
</tr>
<tr>
<td>X-Ray- time (Month)</td>
<td>15,5 ± 4,9</td>
<td>11 ± 4</td>
<td>9,1 ± 4,1</td>
</tr>
<tr>
<td>Stentfractur (n / %)</td>
<td>8 (15,1 %)</td>
<td>9 (31,0%)</td>
<td>25 (52,1%)</td>
</tr>
<tr>
<td>Grading</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>3 (37,5%)</td>
<td>4 (44,4%)</td>
<td>4 (16%)</td>
</tr>
<tr>
<td>2</td>
<td>3 (37,5%)</td>
<td>3 (33,3%)</td>
<td>5 (20%)</td>
</tr>
<tr>
<td>3</td>
<td>2 (25%)</td>
<td>2 (22,2%)</td>
<td>14 (56%)</td>
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</table>
Impact of stent fracture on stent patency
Primary Patency

Patency vs. Month graph showing data for Smart, SelfX, and Luminex.
# Primary Patency Rates

<table>
<thead>
<tr>
<th></th>
<th>S.M.A.R.T</th>
<th>SelfX</th>
<th>Luminex</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Months</td>
<td>100%</td>
<td>98.2%</td>
<td>94.5%</td>
</tr>
<tr>
<td>6 Months</td>
<td>96.3%</td>
<td>87.1%</td>
<td>77.2%</td>
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<tr>
<td>9 Months</td>
<td>90.3%</td>
<td>75.6%</td>
<td>51.3%</td>
</tr>
<tr>
<td>12 Months</td>
<td><strong>82.1%</strong></td>
<td><strong>43.9%</strong></td>
<td><strong>27.1%</strong></td>
</tr>
</tbody>
</table>
Superficial femoral artery
A mechanical model

Bending
Axial compression
Bending
Bending