4F Lower Limb Intervention: Pulsar Stent Technology

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Conflict of interest

• None
4F vs. 6F How much smaller is it?

For hemostasis, the area of the hole and not the diameter is important.

- 6F = 5.6 mm²
  - This is a 81% larger hole!!
- 4F = 3.1 mm²
  - This is a 45% smaller hole!!
Why 4F?

• Because we now have the tools
  – Balloons
  – Stents
  – Long introducer sheaths
Why 4F?

• Thinner strut
  – Less material in the wall
  – Less inflammation-reduction of restenosis
  – Less fractures

• Lower radial force
  – Less trauma to internal elastic lamina
  – Less restenosis

• Smaller access
  – Shorter compression time
  – No need for closure device (cost reduction)
  – Less puncture site related complications
  – Office-based procedures
Why 4F?

• More versatility
  – Femoral
  – Popliteal
    • Failed antegrade approach
    • Obesity
  – Pedal
    • Failed antegrade approach
    • Obesity
What can we do with 4F

- All SFA and BTK
- Some iliac (4F SE stents available until 8 x 80 mm)
Long SFA occlusion
Long SFA occlusion
Long SFA occlusion
Long SFA occlusion
Occlusion external iliac artery
After 4F stenting (6 mm)
Transpopliteal Stenting of Femoral Occlusions in Patients With Critical Limb Ischemia Using a 4-French System

Marlon Spreen · Ted Vink · Bob Knippenberg · Jim Reekers · Lukas van Dijk · Jan Wever · Randolph van Eps · Hans van Overhagen
Popliteal access
Fatigue testing

- 4F & 6F (A) = 0# @ 6 million cycles
- 6F (D) = 6x Type 2 # @ 3 million cycles
- 6F (B) = Type 4 # @ 311,951 cycles
- 6F (C) = Type 3 # seen @ 84,036 cycles
- 6F (E) = Type 2 # @ 84,036 cycles

Stiffer stents and areas where stents overlap are more prone to fracture
Durability/radial force
Durability/radial force
4EVER study

4-French–Compatible Endovascular Material Is Safe and Effective in the Treatment of Femoropopliteal Occlusive Disease: Results of the 4-EVER Trial

Marc Bosiers, MD¹; Koen Deloose, MD¹; Joren Callaert, MD¹; Koen Keirse, MD²; Jürgen Verbist, MD²; Jeroen Hendriks, MD³; Patrick Lauwers, MD³; Olivier D’Archambeau, MD⁴; Dierk Scheinert, MD⁵; Giovanni Torsello, MD⁶; and Patrick Peeters, MD²

J ENDOVASC THER 2013;20:746-756
4EVER study

• 120 patients: Astron Pulsar n= 70; Pulsar-18 n=46, mixed n=4
• Average lesion length: 7.2cm ± 4.78
• 83.3% intermittent claudication; 16.7% critical limb ischemia

Bosiers M et al JET 2013;20:746-756
Access site complications

• A total of 4 patients (3.34%) presented with relevant haematoma at puncture site
  – 3 major haematoma requiring transfusion, 1 minor haematoma
  – No surgical repair required
  – 3 out of 4 patients were on Coumarine therapy

• Reduced manual compression time as compared to 6F (literature)

Bosiers M et al JET 2013;20:746-756
Primary patency @ 12 months

Bosiers M et al JET 2013;20:746-756
Primary patency @ 24 months

<table>
<thead>
<tr>
<th>time</th>
<th>baseline</th>
<th>24MFU</th>
</tr>
</thead>
<tbody>
<tr>
<td>at risk</td>
<td>120</td>
<td>63</td>
</tr>
<tr>
<td>%</td>
<td>100%</td>
<td>72.3%</td>
</tr>
</tbody>
</table>
Freedom from TLR @ 12 months

Bosiers M et al JET 2013;20:746-756
Freedom from TLR @ 24 months

Deloose K et al LINC 2014
Primary patency @ 12 months

Calcified vs. non calcified lesions

Deloose K et al LINC 2014
• Single center, prospective study of long SFA stenosis and occlusion (TASC D)
• 22 patients with 22 lesions
• Mean stented length 245 mm (range 215-315)
• Average lesion length 315 mm
• Freedom from TLR at 12 months 86%

Lichtenberg M et al, JCVS 2013;54:433-439
TASC D

Lichtenberg M et al, JCVS 2013;54:433-439
• 118 patients (all-comers)

• Primary endpoint
  – Primary patency of the Pulsar-18 SE stent at 6 and 12 months
    • Binary restenosis (duplex ultrasound ratio (PSVR) < 2.5 at the stented target lesion(s))
    • Freedom from clinically driven TLR

• Inclusion criteria
  – Rutherford 2-5
  – SFA – APOP Seg. III stenosis > 50
  – No lesion length restriction, no restriction of # of stents

• Exclusion criteria
  – In-stent re-stenosis
  – Indication for drug eluting devices

Lichtenberg M et al JET 2014;21:373-380
**Lesion Characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion length (mm)</td>
<td>111.5 ± 71.4 mm</td>
</tr>
<tr>
<td>Implanted Stents</td>
<td>151</td>
</tr>
<tr>
<td>Stents per patient</td>
<td>1.28</td>
</tr>
<tr>
<td>Pre-procedure diameter stenosis</td>
<td>93.2 ± 9.3 %</td>
</tr>
<tr>
<td>Total occlusion (CTO)</td>
<td>84 (56.8 %)</td>
</tr>
<tr>
<td>Lesion length &lt; 100 mm</td>
<td>67 (45.0 %)</td>
</tr>
<tr>
<td>Lesion length &gt; 100 mm</td>
<td>82 (55.0 %)</td>
</tr>
<tr>
<td>Popliteal Segment (I-III)</td>
<td>28 (18.7 %)</td>
</tr>
</tbody>
</table>

**TASC 2007**

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>23.5 %</td>
</tr>
<tr>
<td>B</td>
<td>24.8 %</td>
</tr>
<tr>
<td>C</td>
<td>19.5 %</td>
</tr>
<tr>
<td>D</td>
<td>32.2 %</td>
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</tbody>
</table>

Lichtenberg M et al JET 2014;21:373-380
<table>
<thead>
<tr>
<th>Category</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall subjects</td>
<td>87.4 %</td>
<td>79.5 %</td>
</tr>
<tr>
<td>Single Stents subjects</td>
<td>97.1 %</td>
<td>92.9 %</td>
</tr>
<tr>
<td>Multi-stent subjects (≥ 2 Stents)</td>
<td>85.7 %</td>
<td>80.3 %</td>
</tr>
<tr>
<td>Freedom from TLR</td>
<td>88.7 %</td>
<td>80.8 %</td>
</tr>
</tbody>
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Lichtenberg M et al JET 2014;21:373-380
4F versus 6F

12-month Primary Patency (%) vs Lesion Length (cm)

- Stents:
  1. FAST
  2. FACT
  3. RESILIENT
  4. DURABILITY
  5. ASTRON
  6. VIENNA
  7. 4EVER
  8. PEACE
  9. TASC D

References:
Bosiers M et al JET 2013; 20:746-756
Lichtenberg M et al JET 2014;21:373-380
Lichtenberg M et al, JCVS 2013;54:433-439
Conclusions

• 4F (SFA) stenting is feasible and safe
• Low profile stents have acceptable radial force, with data to support efficacy in complex lesions
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