Fempop Treatment: Long stents vs. short stents

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Faculty Disclosure

*Thomas Zeller, MD*

For the 12 months preceding this presentation, I disclose the following types of financial relationships:

- **Honoraria received from:** Abbott Vascular, Bard Peripheral Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Philips-Spectranetics, TriReme, Veryan, Shockwave
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- **Common Stock:** Veryan, QT Medical
12-month Restenosis vs. Lesion Length:
Data from Randomized Trials

![Graph showing binary restenosis at 12 months (%) vs. length of the lesion (cm). The graph compares PTA and Stent treatments, with lines for FAST, RESILIENT, ASTRON, and ABSOLUTE devices.](image-url)
12-month Restenosis vs. Lesion Length: Data from Randomized Trials

- FemPac
- ZILVER PTX
- RESILIENT
- SUPERA
- DURABILITY I
- THUNDER
- ABSOLUTE
- DURABILITY
- VIBRANT Vlabans
- VIBRANT BMS

Stent Studies
Drug-eluting Balloon Studies

Lesion Length (cm)

1. Werk et al. Circ 2008;118,
2. Tepe et al. NEJM 2008;358:889-99,
3. Ramee MEET 2008,
5. Schillinger, NEJM 2006;354:1879-88
6. Braunlich LINC 2010
7. Ansel, LINC 2010
8. Bosiers, CIRSE 2010
Every Aspect of Stent Design and Placement Has Some Association with Restenosis

- Mesh configuration
- Chronic outward force (stent oversizing)
- Stent material (nitinol > elgiloy > stainless steel)
- Strut thickness (coronaries)
- Stent length
- Stent overlap

Endovascular Treatment of SFA-ISR

How to best treat?

- How to approach ISR?
  1. POBA
  2. Cutting balloon
  3. Atherectomy
     1. Laser
     2. Silverhawk
     3. Pathway
  4. DCB
  5. DES
  6. Endoprosthesis
  7. Bypass-Surgery
Outcomes of Spot Stenting Versus Long Stenting After Intentional Subintimal Approach for Long Chronic Total Occlusions of the Femoropopliteal Artery

Sung-Jin Hong, MD, Young-Guk Ko, MD, Dong-Ho Shin, MD, MPH, Jung-Sun Kim, MD, Byeong-Reuk Kim, MD, Donghoon Choi, MD, Myeong-Ki Hong, MD, Yangsoo Jang, MD

Figure 1: Restenotic Patterns

- Total limbs: n=196
  - Spot stenting: n=129
    - Loss of patency: n=37 (29%)
      - Out-stent: n=9 (24%)
        - Type 1: n=4 (11%)
        - Type 2: n=10 (27%)
        - Type 3: n=23 (62%)
      - In-stent: n=28 (76%)
        - Type 1: n=2 (7%)
        - Type 2: n=9 (30%)
        - Type 3: n=19 (63%)
  - Long stenting: n=67
    - Patent: n=37 (55%)
      - In-stent: n=30 (100%)
        - Type 1: n=2 (7%)
        - Type 2: n=9 (30%)
        - Type 3: n=19 (63%)
      - Loss of patency: n=30 (45%)

The restenotic patterns were similar between groups (p = 0.830).
<table>
<thead>
<tr>
<th></th>
<th>Spot Stenting 129 Limbs</th>
<th>Long Stenting 67 Limbs</th>
<th>p Value*</th>
<th>p Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean lesion length, cm</td>
<td>25.7 ± 8.6</td>
<td>24.2 ± 7.8</td>
<td>0.225</td>
<td>0.224</td>
</tr>
<tr>
<td>Proximal SFA</td>
<td>107 (83)</td>
<td>52 (78)</td>
<td>0.365</td>
<td>0.364</td>
</tr>
<tr>
<td>Lesions with P2 or P3 segment involvement</td>
<td>21 (16)</td>
<td>15 (22)</td>
<td>0.295</td>
<td>0.262</td>
</tr>
<tr>
<td>Lesion type, TASC II</td>
<td></td>
<td></td>
<td>0.007</td>
<td>0.020</td>
</tr>
<tr>
<td>B</td>
<td>3 (2)</td>
<td>8 (12)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>25 (19)</td>
<td>14 (21)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>101 (78)</td>
<td>45 (67)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcified lesion</td>
<td>36 (28)</td>
<td>24 (36)</td>
<td>0.254</td>
<td>0.258</td>
</tr>
<tr>
<td>Right side</td>
<td>57 (44)</td>
<td>33 (49)</td>
<td>0.499</td>
<td>0.483</td>
</tr>
<tr>
<td>Distal run-off vessels ≤1</td>
<td>45 (35)</td>
<td>28 (42)</td>
<td>0.343</td>
<td>0.338</td>
</tr>
<tr>
<td>Pre-procedural ABI</td>
<td>0.48 ± 0.17</td>
<td>0.45 ± 0.19</td>
<td>0.494</td>
<td>0.482</td>
</tr>
<tr>
<td>Use of re-entry device</td>
<td>5 (4)</td>
<td>5 (7)</td>
<td>0.314</td>
<td>0.284</td>
</tr>
</tbody>
</table>

Number of stents
- 1: 112 (87), 16 (24)
- 2: 17 (13), 42 (63)
- 3: 52 (40), 6 (9)

Mean stent diameter, mm
- 10.3 ± 3.6, 24.6 ± 8.7
- 7 ± 0.7, 6.5 ± 0.5
- 6.2 ± 1.0, 5.8 ± 0.9

Stent-to-artery ratio
- 1.2 ± 0.2, 1.1 ± 0.2

Distal stent diameter, mm
- 6: 23 (18), 29 (43)
- 7: 54 (42), 32 (48)
- 8: 52 (40), 6 (9)

Stent type
- S.M.A.R.T.: 110 (85), 51 (76)
- Zilver: 8 (6), 3 (5)
- Absolute Pro: 3 (2), 5 (8)
- Complete SE: 2 (2), 4 (6)
- Protect Everflex: 6 (5), 4 (6)

Extent of popliteal artery stent coverage
- <0.001, <0.001

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<th>Long Stenting 67 Limbs</th>
<th>p Value*</th>
<th>p Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-procedural ABI</td>
<td>0.82 ± 0.18</td>
<td>0.86 ± 0.18</td>
<td>0.262</td>
<td>0.281</td>
</tr>
<tr>
<td>Immediate procedural complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure-related deaths</td>
<td>0</td>
<td>0</td>
<td>1.000</td>
<td>1.000</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>7 (5)</td>
<td>2 (3)</td>
<td>0.721</td>
<td>0.446</td>
</tr>
<tr>
<td>Arterial perforation</td>
<td>2 (2)</td>
<td>1 (2)</td>
<td>1.000</td>
<td>0.975</td>
</tr>
</tbody>
</table>

Stent fracture‡
- No fracture: 38 (78), 18 (67)
- Type 1: 5 (10), 3 (11)
- Type 2: 2 (4), 3 (11)
- Type 3: 4 (8), 2 (7)
- Type 4: 0, 1 (4)
- Type 5: 0, 0
FIGURE 2  Kaplan-Meier Survival Curves and Adjusted Survival Curves Using IPTW

The spot stenting group had higher (A) primary patency rates and (B) target lesion revascularization (TLR)-free survival rates than the long stenting group. There was a graded relationship between the primary patency and the extent of popliteal artery coverage (C). These findings were consistent after adjustment using inverse probability of treatment weighting (IPTW) (D-F).
### FIGURE 3  Univariate Analysis of Risk Factors for Restenosis

<table>
<thead>
<tr>
<th>Variables</th>
<th>HR (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.02 (0.99–1.05)</td>
<td>0.209</td>
</tr>
<tr>
<td>Female</td>
<td>1.23 (0.68–2.21)</td>
<td>0.495</td>
</tr>
<tr>
<td>Body mass index</td>
<td>0.92 (0.86–0.99)</td>
<td>0.019</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1.48 (0.90–2.42)</td>
<td>0.123</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.87 (0.51–1.46)</td>
<td>0.593</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>0.98 (0.53–1.79)</td>
<td>0.934</td>
</tr>
<tr>
<td>Critical limb ischemia</td>
<td>2.07 (1.28–3.34)</td>
<td>0.003</td>
</tr>
<tr>
<td>Non-use of clopidogrel</td>
<td>2.10 (1.21–3.65)</td>
<td>0.008</td>
</tr>
<tr>
<td>Non-use of cilostazol</td>
<td>1.57 (0.94–2.63)</td>
<td>0.086</td>
</tr>
<tr>
<td>Non-use of statin</td>
<td>1.25 (0.77–2.02)</td>
<td>0.365</td>
</tr>
<tr>
<td>Non-use of ACE inhibitor or ARB</td>
<td>1.61 (0.95–2.71)</td>
<td>0.076</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>1.00 (0.99–1.00)</td>
<td>0.456</td>
</tr>
<tr>
<td>Initial P2 or P3 segment involvement</td>
<td>1.44 (0.81–2.56)</td>
<td>0.214</td>
</tr>
<tr>
<td>Distal run-off vessels ≤1</td>
<td>2.31 (1.42–3.74)</td>
<td>0.001</td>
</tr>
<tr>
<td>Vessel diameter (mm)</td>
<td>0.79 (0.59–1.07)</td>
<td>0.128</td>
</tr>
<tr>
<td>Stent diameter (mm)</td>
<td>0.63 (0.45–0.90)</td>
<td>0.010</td>
</tr>
<tr>
<td>Stent-to-artery ratio</td>
<td>0.72 (0.17–3.02)</td>
<td>0.658</td>
</tr>
<tr>
<td>Stent fracture</td>
<td>0.95 (0.49–1.85)</td>
<td>0.887</td>
</tr>
<tr>
<td>Postprocedural ABI</td>
<td>0.08 (0.02–0.28)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Extent of popliteal artery coverage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coverage of P1 segment</td>
<td>1.67 (0.90–3.10)</td>
<td>0.105</td>
</tr>
<tr>
<td>Coverage of P2 or P3 segment</td>
<td>3.03 (1.47–6.22)</td>
<td>0.003</td>
</tr>
<tr>
<td>Long stenting</td>
<td>2.20 (1.35–3.59)</td>
<td>0.002</td>
</tr>
</tbody>
</table>

The circles represent the hazard ratios (HR). The error bars show the 95% confidence intervals (CI). ABI = ankle-brachial index; ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker.
Limitations of Stents

Stent Fracture

A
Type I

B
Type II

C
Type III

D
Type IV
Angiographic Characterization of Dissections: NHLBI Modification

A. Minor radiolucent areas
B. Linear dissection
C. Contrast outside the lumen
D. Spiral dissection
E. Persistent filling defects
F. Total occlusion w/o distal antegrade flow
VascuFlex® Multi-LOC

- Multiple Stent Delivery System (MSDS)
- 6 individual stents on top of one delivery system:

  - Stent-diameter: 5-8 mm
  - Stent-length: 13 mm (6 / system),
  - Delivery system: 6F-system (0.035” guide wire)
  - Shaft lengths: 80 cm / 130 cm

- Indication:
  - pAVK → SFA and popliteal artery (p1-p3 segment)
“Tacking” – A new modality

**GOAL:**
- Provide anatomic result of stent
- Minimize injury – Minimize hyperplasia
- Maintain physiologic vessel compliance
- Operator control
  - Placement
  - Number of tacks
  - Timing
- Maintain options for future reintervention
Right SFA occlusion

predilatation

5/300mm PTA

6 mm DCB
Right SFA after DCB

5/300mm PTA after 11 6mm-Ministents

Final result
Conclusion

- Long distant stent implantation is associated with
  - Reduced patency
  - Increased fracture rate
  - Impairment of vessel physiology and anatomy during leg motion
- Multiple short stents might overcome the limitations of a full metal jacket
- Prospective studies are on the way (LOCOMOTIVE, TOBA series)
Fempop Treatment:
Long stents vs. short stents

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