Role of BMS, Woven Nitinol Stents, DCBs, DES, and Atherectomy for Various SFA/Pop Lesions: What Works For Which Lesion And What Is The Evidence?

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Disclosures
• Consulting, Speakers Program, Advisory Boards or Proctoring:
  • Boston Scientific
  • Medtronic
  • Abbott Vascular
  • Cook Medical

Endovascular Lower Extremity Intervention
What works and for which lesions?

Problem with “evidence-based approach” to percutaneous treatment of femoropopliteal disease:
• Lack of comparative outcome data
• Devices within a category may not be equivalent

Despite these issues, we do have reasonable quality evidence to make some concrete statements about the right way and wrong way to treat the SFA and popliteal

Endovascular Lower Extremity Intervention
What Are the Available Treatment Options?

1. Balloon Angioplasty
2. Laser-cut Nitinol Stents
3. Drug-coated Stents
4. Percutaneous Atherectomy
5. Drug-coated Balloons
6. “Next-generation” Nitinol Stents

Endovascular Lower Extremity Intervention
What is the Quality of Existing Data?

• Randomized controlled clinical trials
• Prospective multi-center registries
  • Recognition of “real world” results
  • Core lab adjudication / accurate lesion characterization

Endovascular Lower Extremity Intervention
What works and for which lesions?

Balloon Angioplasty vs Nitinol Stents
Endovascular Lower Extremity Intervention: Balloon Angioplasty

- 1964 Charles Dotter introduces concept of arterial remodeling
- 1977 Andreas Gruntzig performs first peripheral angioplasty
- 1980-90's Development of OTW & RX balloon angioplasty systems

Disadvantages
- Elastic recoil of vessel
- Flow-limiting dissections
- Intimal hyperplasia / Restenosis

Endovascular Lower Extremity Intervention: Laser-Cut Nitinol Stents

- Biliary stents initially used off-label for the SFA
- Laser cut from nitinol tubes, constrained in deployment catheter
- Preserve flow in cases of flow-limiting dissections and reduces late lumen loss (demonstrated in RCT)

Endovascular Lower Extremity Intervention: What Works, and for How Long?

- PTA and BMS in SFA
  - 12-Month Primary Patency
  - Bare Metal Laser-Cut Nitinol Stents in the SFA: 60-80% Primary Patency
    - Good safety profile
    - Minimal recovery
  - Balloon angioplasty in the SFA: 30-50% Primary Patency

- Stenting of the SFA has better patency than angioplasty alone

Endovascular Lower Extremity Intervention: BMS vs Drug-Coated Stents (Zilver PTX)

- Paclitaxol coated Zilver Nitinol stent (Zilver PTX)
- Multicenter RCT
- Primary Randomization:
  - PTA vs Zilver PTX
  - Secondary Randomization:
    - Provisional BMS vs Provisional Zilver PTX for Suboptimal PTA

- Primary endpoints included Primary Patency (PSVR 2.0) and Freedom from TLR
- Follow-up of primary endpoints out to 5 years

Endovascular Lower Extremity Intervention: What works and for which lesions?

- BMS Nitinol Stents vs Drug-Coated Stents
Endovascular Lower Extremity Intervention: 
**BMS vs Drug-Coated Stents (Zilver PTX)**

Baseline Lesion Characteristics

<table>
<thead>
<tr>
<th>Lesion</th>
<th>PTA</th>
<th>Zilver PTX</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion length (mm)</td>
<td>251</td>
<td>267</td>
<td></td>
</tr>
<tr>
<td>Normal to normal lesion length</td>
<td>63</td>
<td>65</td>
<td>0.25</td>
</tr>
<tr>
<td>Normal to severe lesion length</td>
<td>67</td>
<td>55</td>
<td>0.71</td>
</tr>
<tr>
<td>Diameter stenosis (%)</td>
<td>78</td>
<td>86</td>
<td>0.38</td>
</tr>
<tr>
<td>Total re-occlusions</td>
<td>27%</td>
<td>33%</td>
<td>0.33</td>
</tr>
<tr>
<td>Diaries re-occlusion</td>
<td>96%</td>
<td>100%</td>
<td>0.66</td>
</tr>
<tr>
<td>Lesion classification</td>
<td>None</td>
<td>5%</td>
<td>&lt;0.01*</td>
</tr>
</tbody>
</table>

**Evidence:** RCT data, followed to 5 years

**Conclusions:**
- Primary stent implantation and bailout stent implantation is associated with improved primary patency at 1-5 years compared to BMS
- **Caveats:**
  - Implication for re-interventions v. non-stent
  - Comparison to BMS Zilver or angioplasty alone

Endovascular Lower Extremity Intervention: 
**Bypass vs Drug-Coated Stents (ZilverPass RCT)**

**ZilverPASS Trial:**
ZilverPTX vs Prosthetic BPG in TASC C & D Lesions
- Multicenter RCT in Belgium, Germany, Italy, Brazil
- Randomized 1:1 to ZilverPTX vs prosthetic bypass graft
- Enrolled 199 patients, interim results on 119 (LINC 2017, DeLoose)
- Same outcome assessment (PSVR < 2.4 lesion or in bypass)

**Evidence:** RCT data (in progress)

**Conclusions:**
- Interim results suggest equivalent primary patency and TLR rates at one year
- **Caveats:**
  - Study ongoing
  - Long-term data not available
  - Prosthetic bypass only

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Drug-coated stents may provide equivalent patency and TLR with less morbidity at 12 months than prosthetic bypass (full results forthcoming)
Endovascular Lower Extremity Intervention

*What works and for which lesions?*

**Percutaneous Atherectomy vs ????????**

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**Endovascular Lower Extremity Intervention:
Percutaneous Atherectomy: Overview of Data**

<table>
<thead>
<tr>
<th></th>
<th>DEFINITIVE LE</th>
<th>Confirm Reg</th>
<th>Compliance360</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Patients</td>
<td>799 (25% CLI)</td>
<td>1109 (100% CLI)</td>
<td>65</td>
</tr>
<tr>
<td>Published</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Multicenter</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Location</td>
<td>SFA/pop/Tib</td>
<td>SFA/pop/Tib</td>
<td>SFA/pop/Tib</td>
</tr>
<tr>
<td>Lesion Description</td>
<td>Yes (7.4cm)</td>
<td>Yes (7.9cm)</td>
<td>Yes (5.6cm)</td>
</tr>
<tr>
<td>Angio Core lab</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Duplex Core lab</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>12mo Primary Patency</td>
<td>Yes (71%)</td>
<td>No</td>
<td>81% (30% w/7T re)</td>
</tr>
<tr>
<td>12mo Freedom TLR</td>
<td>Not reported</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Bailout Stent Rate</td>
<td>3%</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Complications reported</td>
<td>7.6% (3.8% embol)</td>
<td>14.8%</td>
<td>n/a</td>
</tr>
</tbody>
</table>

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**DEFINITIVE LE Trial (Prospective Registry)**

- **Diabetes**
  - 78%
  - 77%
  - 78%

- **Non-Diabetes**
  - 78%
  - 77%
  - 78%

Primary Patency in Claudicants

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**Laser Atherectomy – RCT and Registries**

<table>
<thead>
<tr>
<th></th>
<th>PATENT Spectranetics Laser ISR Study (German)</th>
<th>EXCITE ISR Trial with Spectranetics Laser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized</td>
<td>No</td>
<td>Yes (2:1 vs angioplasty)</td>
</tr>
<tr>
<td>Patients</td>
<td>99 patients (83% Claudicants)</td>
<td>250 pts (halted early)</td>
</tr>
<tr>
<td>Published</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Multicenter</td>
<td>Yes (German)</td>
<td>Yes</td>
</tr>
<tr>
<td>Location</td>
<td>SFA/pop</td>
<td>SFA/pop</td>
</tr>
<tr>
<td>Lesion Description</td>
<td>Yes (12.3cm ISR)</td>
<td>Yes (19.6cm ISR)</td>
</tr>
<tr>
<td>Angio Core lab</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Duplex Core lab</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>12mo Primary Patency</td>
<td>38%</td>
<td>0%</td>
</tr>
<tr>
<td>12mo Freedom TLR</td>
<td>No</td>
<td>74% vs 52% freedom TLR</td>
</tr>
<tr>
<td>Complications reported</td>
<td>23% (10% embolization)</td>
<td>8.3% embolization</td>
</tr>
</tbody>
</table>
Endovascular Lower Extremity Intervention: Percutaneous Atherectomy

- Evidence:
  - RCT for ISR
  - Prospective core lab adjudicated registry data

- Conclusions:
  - Low rates of “bail-out” stenting
  - “Stent-like” primary patency rates at 1 yr
  - Role for debulking in ISR (vs angioplasty alone)

- Caveats:
  - No long-term data
  - Embolization remains important consideration
  - * Single device represented in large studies

Endovascular Lower Extremity Intervention: What works and for which lesions?

Plain Balloon Angioplasty vs Drug-Coated Balloon Angioplasty

DCBs are associated with superior primary patency and reduced TLR rates compared to plain balloon angioplasty in simple lesions represented in IDE trials.

Endovascular Lower Extremity Intervention: Angioplasty vs Drug-Coated Balloon Angioplasty

As lesion complexity increases, so does need for scaffolding.

DCBs may maintain high primary patency rates and low TLR rates in complex lesions, but this comes with an increased bailout stent rate.
Endovascular Lower Extremity Intervention: Angioplasty vs Drug-Coated Balloon Angioplasty

- Evidence:
  - 3 RCT IDE Trials (Two published)
  - Prospective adjudicated registry data (complex lesions)
- Conclusions: DCBs (vs plain balloon angioplasty)
  - Show improved primary patency rates at 1 yr
  - Demonstrate reduced TLR rates at 1 yr
  - Conflicting results > 1yr (device specific?)
- Caveats:
  - RCT evidence includes selection bias / simple lesions
  - More complex lesions appear to do well based on prospective registries, but w/ high stent rates

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- 3 RCT IDE Trials (Two published)
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Caveats:
- RCT evidence includes selection bias / simple lesions
- More complex lesions appear to do well based on prospective registries, but w/ high stent rates
```

Endovascular Lower Extremity Intervention: Next-generation Nitinol Stents: Tigris (WL Gore)

- Tigris Stent with nitinol wire scaffold and heparin-bonded PTFE coating
- RCT 3:1 Tigris (Gore) vs Lifestent (Bard)
- 274 patients randomized

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Tigris Stent
(WL Gore)
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<table>
<thead>
<tr>
<th></th>
<th>Tigris</th>
<th>Lifestent</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Length</td>
<td>10.7 cm</td>
<td>11.8 cm</td>
<td>0.29</td>
</tr>
<tr>
<td>Stented Length</td>
<td>12.9 cm</td>
<td>14.9 cm</td>
<td>0.06</td>
</tr>
<tr>
<td>Occlusions</td>
<td>42%</td>
<td>37%</td>
<td>NS</td>
</tr>
<tr>
<td>Lesion Length</td>
<td>63%</td>
<td>67%</td>
<td>NS</td>
</tr>
<tr>
<td>2-yr Freedom from TLR</td>
<td>77%</td>
<td>81%</td>
<td>NS</td>
</tr>
<tr>
<td>Stent Fractures</td>
<td>0%</td>
<td>29%</td>
<td>&lt;0.001</td>
</tr>
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- Considerable reduction in stent fractures compared to standard laser-cut nitinol stents
- Failure to achieve improved patency rates despite absence of stent fractures

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Supera Stent
(Abbott Vascular)
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Endovascular Lower Extremity Intervention: Next-generation Nitinol Stents: Supera (Abbott)

- SUPERB Trial
  - 238 patients, prospective registry IDE trial
  - Core-lab adjudication, 78mm mean, 73% Ca++
  - No stent fractures, 86% 12m primary patency

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SUPERB Trial
```

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<td>29%</td>
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Supera vs standard laser cut nitinol stents
```

```
% Crash Resistance in standard and even test gap nitinol stents
```

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Endovascular Lower Extremity Intervention: What works and for which lesions?

“Next-Generation” Nitinol Stents
```
Endovascular Lower Extremity Intervention:
Next-generation Nitinol Stents: Supera (Abbott)

When nominally deployed:\(^1\)
- 91% 12mo Primary Patency
- 94% 36mo Freedom from TLR

Endovascular Lower Extremity Intervention:
Next-generation Nitinol Stents

- **Evidence:**
  - RCT IDE Trial (Tigris)
  - Prospective core-lab adjudicated IDE Registry (Supera)
- **Conclusions:**
  - Decreased stent fracture rates
  - Device specific
- **Caveats:**
  - Supera among best in class results in Superb Trial, but without comparator arm or any RCT data
  - Superb Trial: 3 yr results sustained for TLR, but no patency data available

Conclusions

- Evidence to judge the effectiveness of old and emerging technology is incomplete but improving
- Plain balloon angioplasty and bare-metal laser-cut nitinol stents are below the standard of care considering today’s treatment options
- Atherectomy is an effective tool for reducing bailout stent rates in fempop interventions
- Paclitaxol coating (on balloons or stents) convincingly reduces rates of restenosis
- As lesion complexity increases, the need for stenting increases and probably should be done with newer “next-generation” devices