Vessel preparation with scoring balloons prior to DCB or stenting

Deep dive session: lower limb interventions

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Disclosure

Speaker name:
Erwin Blessing

I have the following potential conflicts of interest to report:

- [ ] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [x] Other(s): speakers honoraria (Spectranetics, Medtronic)

- [ ] I do not have any potential conflict of interest
Restenosis following interventions

Predictors:

– Lesion length\(^1\)
– Diabetes\(^2\)
– Occlusions\(^3\)
– Calcification

DCB use in calcified lesions

12-month Results

Group A: < 3 cm
Group B: > 3 cm

Fanelli, Cardiovasc Intervent Radiol 2014
Scoring balloons in calcified lesions

• Inadequate penetration of the drug into the media/adventitia and therefore poorer outcome?

• Does a lesion preparation prior DCB improve penetration of the drug and therefore patency?

• Lesion preparation mandatory prior implantation of dedicated interwoven stents
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Optimal Deployment Leads To Low Re-intervention Rate Out to 3 Years

SUPERB Freedom From TLR at 1, 2, and 3 Years

<table>
<thead>
<tr>
<th>Freedom from TLR (K-M) by Percent Compression/Elongation at 12, 24, and 36 months</th>
<th>Moderate (21-40%)</th>
<th>Minimal (11-20%)</th>
<th>Nominal (± 10%)</th>
<th>Minimal (11-20%)</th>
<th>Moderate (21-40%)</th>
<th>Severe (&gt;40%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 months</td>
<td>90%</td>
<td>91%</td>
<td>97%</td>
<td>84%</td>
<td>87%</td>
<td>77%</td>
</tr>
<tr>
<td>24 months</td>
<td>90%</td>
<td>87%</td>
<td>96%</td>
<td>78%</td>
<td>82%</td>
<td>63%</td>
</tr>
<tr>
<td>36 months</td>
<td>90%</td>
<td>94%</td>
<td>94%</td>
<td>78%</td>
<td>78%</td>
<td>42%</td>
</tr>
</tbody>
</table>

n: 6, 22, 74, 38, 39, 26

Clinical data on file at Abbott Vascular.
VascuTrak (Bard)

**Scoring Balloon Catheter**

**Mechanism of Action**

- Two external wires deliver Focused Force along the length of the balloon, for dilatation at low inflation pressures.
- Low inflation pressure angioplasty reduces the potential for balloon-induced over-dilation of the vessel and offers controlled plaque modification, even in calcified lesions.
- Focused Force is applied in two parallel planes, unlike standard balloons with unconcentrated circumferential dilatation forces.
Scoring Balloon Catheter

Flextome Cutting Balloon
(Boston Scientific)
Scoring Balloon Catheter

Chocolate
(TriReme Medical)
Scoring Balloon Catheter

*AngioSculpt (Biotronik/Spectranetics)*

*Semi-compliant* nylon balloon with an external *nitinol* shape memory helical scoring edge
Angiosculpt plus DCB

90 year old female patient
Claudicant (walking capacity 50 m)
CVRF: Art. HTN, HLP
PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

101 patients

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Age (years)</td>
<td>71.9 ± 9.3</td>
</tr>
<tr>
<td>Gender (m/f)</td>
<td>76/25</td>
</tr>
<tr>
<td>Arterial hypertension, n (%)</td>
<td>94 (93.1)</td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>45 (44.6)</td>
</tr>
<tr>
<td>Aktive smoking, n (%)</td>
<td>25 (24.7)</td>
</tr>
<tr>
<td>Hyperlipidemia, n (%)</td>
<td>74 (93.1)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26.9 ± 4.5</td>
</tr>
<tr>
<td>Ankle Brachial Index</td>
<td>0.63 ± 0.22</td>
</tr>
<tr>
<td>Claudicants, n (%)</td>
<td>66 (65.3)</td>
</tr>
<tr>
<td>Critical Limb Ischemia, n (%)</td>
<td>35 (34.7)</td>
</tr>
</tbody>
</table>
PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

124 lesions

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<table>
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</tr>
</thead>
<tbody>
<tr>
<td>Occlusions (%)</td>
<td>20 (16.1)</td>
</tr>
<tr>
<td>Lesion length (cm)</td>
<td>7.4±5.9</td>
</tr>
<tr>
<td>Degree of Stenosis (%)</td>
<td>85.5</td>
</tr>
<tr>
<td>Degree of Calcification, n (%)</td>
<td></td>
</tr>
<tr>
<td>1 (mild)</td>
<td>27 (21.8)</td>
</tr>
<tr>
<td>2 (moderate)</td>
<td>43 (34.7)</td>
</tr>
<tr>
<td>3 (severe)</td>
<td>54 (43.5)</td>
</tr>
</tbody>
</table>

Lesion Localization:
- iliacal, (%)           2.5
- femoral (%)             78.6
- popliteal (%)           18.9
PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

Treatment strategy

124 lesions

Non randomized – by discretion of the interventionalist!!!
PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

Overall cohort
124 lesions

![Graph showing patency over months]

- Primary Patency: 91.8%
- Secondary Patency: 81.2%
PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

Calcification
124 lesions

- Mild (1) - 81.8%
- Moderate (2) - 81.3%
- Severe (3) - 78.9%

Graph showing primary patency over time with different degrees of calcification.
PANTHER Evaluation of treatment of femoropopliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

Lesion length
124 lesions
PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

<table>
<thead>
<tr>
<th>Lesion length (cm)</th>
<th>Angiosculpt</th>
<th>Angiosculpt + DCB</th>
<th>Angiosculpt + Supera Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occlusions (%)</td>
<td>2.2</td>
<td>17.5</td>
<td>31.6</td>
</tr>
<tr>
<td></td>
<td>6.1</td>
<td>5.9</td>
<td>10.1</td>
</tr>
<tr>
<td>124 lesions</td>
<td></td>
<td></td>
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</tbody>
</table>
PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry

Angiosculpt PTA in calcified femoropopliteal lesions

Clinical outcome

101 patients

6 Months

12 Months

- **p<0.01
- *** p<0.0001

![Graph showing Rutherford-Becker Class change](image)

![Graph showing Ankle-Brachial Index change](image)
Conclusions

- DCBs seem to work less well in heavily calcified lesions
- Improved penetration of drug after lesion preparation?
- Encouraging register data for scoring balloons in short and moderate long calcified femoropopliteal lesions
- Calcification was no predictor for loss of 12-month patency as long as lesion preparation was performed
- Scoring balloons seem to be an adequate tool for lesion preparation prior implantation of interwoven stents (less perforations?)
Vessel preparation with scoring balloons prior to DCB or stenting

Deep dive session: lower limb interventions

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