Importance of debulking and other lesion preparation strategies with all drug eluting treatments: why it is critical?

Veith Symposium
New York City, November 14th, 2018
Erwin Blessing, MD, FESC

Conflicts of interest
None

Lesion preparation
Debulking

Why and how to prep the vessel?
TurboHawk™ and SilverHawk™

Why and how to prep the vessel?
Optimizing PTA with prolonged balloon inflations reduces dissection severity and rate and need for further intervention

- Inflation times of 180 seconds improve immediate infrapopliteal PTA results vs. a short dilation strategy
- Significantly fewer major dissections and a modest reduction of residual stenoses are observed


<table>
<thead>
<tr>
<th>Inflation Time (sec)</th>
<th>Major dissection (grades 3-4)</th>
<th>Minor or no dissection (grades 1 and 2)</th>
<th>Further interventions (Stent, repeat dilation, dilation with larger diameter)</th>
<th>Residual stenosis (&gt;30%)</th>
<th>Complication (embolization, thrombosis)</th>
<th>Mean ankle-brachial index (before, after intervention)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>16</td>
<td>21</td>
<td>20</td>
<td>12</td>
<td>1</td>
<td>0.66, 0.85</td>
</tr>
<tr>
<td>180</td>
<td>5</td>
<td>32</td>
<td>9</td>
<td>5</td>
<td>1</td>
<td>0.87, 0.94</td>
</tr>
</tbody>
</table>

Primary Patency (K-M) by Percent Compression/Elongation at 12 months

- Moderate (21-40%)
- Minimal (11-20%)
- Nominal (±10%)
- Severe (>40%)

Supporting the role of plaque scoring for vessel prep in calcific lesions and the hypothesis that degree of calcium does not predict patency

Why and how to prep the vessel?

Images used with permission of Cagent Vascular, Cook, Medtronic
Blessing E., Lugenbiel I., Holden A. The evidence to support the use of focal force balloon technology to improve outcome in the treatment of lower extremity arterial occlusive disease. JCVS. 2018

Plaque Scoring in calcified SFA

Images from the PANTHER Registry

Plaque Scoring in calcified SFA

Insights form the PANTHER Registry

Supporting the role of plaque scoring for vessel prep in calcific lesions and the hypothesis that degree of calcium does not predict patency

- ASC Technical Success* = 100% (w/out pre-dil)
- Overall Primary Patency = 82.2% (60/60)

* successful scoring = ability to cross the lesion and inflate the ASC at least at NP w/out balloon rupture
Disrupt III (IVL plus DCB vs. POBA plus DCB in calcified lesions)

Why and how to prep the vessel?

Lesion preparation
Debulking

Why and how to prep the vessel?
Case example directional atherectomy

Restenosis after 2x surgery
Silverhawk™
After Silverhawk™
After In.Pact™ Admiral

Why and how to prep the vessel?
Case example directional atherectomy

18 months follow up

PESTO-AFC (DAART vs. Surgery in CF)

This study is currently recruiting participants. (see Contacts and Locations)
Enrollment: November 2016 by Herz-Zentrum Bad Krozingen
Sponsor: Herz-Zentrum Bad Krozingen

ClinicalTrials.gov Identifier: NCT02517827
First received: August 3, 2015
Last updated: November 12, 2016
Last verified: November 2016
**Why and how to prep the vessel?**

Case example orbital atherectomy

<table>
<thead>
<tr>
<th>Pre</th>
<th>Diamondback</th>
<th>Post</th>
<th>Lutonix</th>
<th>Final</th>
</tr>
</thead>
</table>

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**OPTIMIZE:**

RCT For OAS+DCB vs. DCB Alone In BTK Lesions

**Study Details:**
- Pilot study
- Prospective, 1:1 Randomization
- Below knee lesions
- 2-year follow-up

**Active Sites:**
- Austria (Prof. Brodmann/Deutschmann & Dr. Werner)
- Germany (Prof. Zeller, Prof. Töpe, Prof. Andrassy, Prof. Blessing, Prof. Stoubart)
- Switzerland (Dr. Banyai)

**Purpose:** Demonstrate the ability of the OAS to prepare calcified, BTK lesions for optimal DCB deployment

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**Conclusions**

- Lesion preparation (prolonged inflation, high pressure dilatation, specialty balloon angioplasty, intravascular lithotripsy, debulking etc.) gained increasing recognition
- DCBs work less well in heavily calcified lesions
- Angioplasty of long lesions is plagued by high bail-out stent rates
- Debuing plus DCB offers a safe and effective treatment option in selected cases (‘no stent zones’, bifurcations, young patients, severely calcified lesions etc.)
- Specialty balloons might offer an (less expensive) alternative to debulking devices also for calcified lesions. However, RCT or even head-to-head comparisons are lacking