Supera in calcified lesions

Ralf Langhoff, MD
Vascular Centre Sankt Gertrauden
Berlin
Sankt - Gertrauden Hospital
Charité, CC11
Academic Teaching Hospitals — Charité Berlin
Disclosure

Speaker name: Ralf Langhoff, MD

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☒ I do not have any potential conflict of interest
‘Easy‘-lesion to cross but complex to maintain patent!

Calcium is the most negative predictor for a good endovascular outcome
Case Szenario

78 year male
- Claudicant, ABI 0.7
- A.Fib
- Diabetes
- Art. Hypertension
- CAD
- 2 cm long calcified Subocclusion in a 6.5 mm SFA

What Would You Do?
Therapeutic Options
Calcium is a mechanical problem

- PTA (POBA) – not good long term results
- DCB – too much Calcium?
- Scoring Balloon – good vessel preparation
- Atherectomy – artery too large (costs)?
- Shock-Wave – not as stand alone?
- Standard Nitinol Stent – too weak
- VMI (Supera) – good results from Superb IDE
Angiosculpt 6x40 mm
Post Angiosculpt Scoring PTA
POBA for Vesselpreparation

7 x 20 mm Ballon

...the End?
Supera 6.5 x 40 mm Stent
Disrupt PAD II Trial

**Disrupt PAD II**

*By The Numbers*

- **60** Patients with HEAVILY CALCIFIED femoral-popliteal lesions
- **85%** SEVERE calcification by PARC
- **98mm** Average calcified length

Followed out to 12-months

**Compelling Safety & Performance**

in Severely Calcified Lesions*

- **0%**
  - Perforations
  - Embolization
  - Thrombus
  - No reflow
  - Abrupt closure

- **1.7%**
  - Dissection (D/E/F)*
  - Provisional stenting
  - Guidewire induced through recanalization of a CTO

- **24%**
  - Residual stenosis with average acute gain of 3.0-mm
  - Average balloon inflation pressure of 6 atm after IVI therapy

- **100%**
  - Procedural success
  - Low use of adjunctive tools

- **79%**
  - Freedom from clinically driven revascularization at 1-year
  - With simple revascularization procedures

*Core Lab and CEC Adjudicated*
Definitive AR

![Graph showing freedom from clinically-driven TLR over time after index procedure (months). The graph compares DA + DCB and DCB groups. The 2-year data points indicate 77.0% for DA + DCB and 73.2% for DCB. The table below shows the number at risk for each group at different time points: DA + DCB (48, 44, 43, 36, 16, 15) and DCB (54, 51, 48, 42, 22, 19).]
Supera® Has Strong Clinical Outcomes in Calcification at 3 Years

Freedom from TLR % Over Time in Severe Calcium

<table>
<thead>
<tr>
<th>Time</th>
<th>Freedom from TLR %</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 months</td>
<td>95%</td>
</tr>
<tr>
<td>24 months</td>
<td>92%</td>
</tr>
<tr>
<td>36 months</td>
<td>88%</td>
</tr>
</tbody>
</table>

**SUPERB Data - Severe Calcification**

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of Lesions with Severe Calcification (SUPERB Trial)</td>
<td>45% (n=118)</td>
</tr>
<tr>
<td>Patency (VIVA 12 months)</td>
<td>89%</td>
</tr>
</tbody>
</table>
Thank You For Attention!

Ralf Langhoff, MD
Vascular Centre Sankt Gertrauden
Berlin
Sankt - Gertrauden Hospital
Charité, CC11
Academic Teaching Hospitals — Charité Berlin
Supera in calcified lesions

Ralf Langhoff, MD
Vascular Centre Sankt Gertrauden
Berlin
Sankt - Gertrauden Hospital
Charité, CC11
Academic Teaching Hospitals — Charité Berlin