What is needed in the future for SFA treatment?

Jochen Bauer
Manager R&D Innovation and Technology, Abbott Vascular, Switzerland
Lesion preparation is important

Stent sizing is important – do not grossly oversize

Not all self-expanding stents are the same
  – Low chronic outward force is important
  – Strut/cell movement during longitudinal compression is important

DES can effectively mask the effects above, as long as it is being eluted and present in tissue.
  – Without the active agent, in the presence of constant irritation, patency inevitably decreases.
### Drug Eluting BVS

<table>
<thead>
<tr>
<th>Bioresorbable Scaffold</th>
<th>Bioresorbable Coating</th>
<th>Everolimus</th>
<th>Esprit Delivery System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poly(L-lactide) (PLLA)</td>
<td>Poly(D,L-lactide) (PDLLA) coating</td>
<td>100 μg/cm²</td>
<td>Balloon-expandable delivery system</td>
</tr>
<tr>
<td>Naturally resorbed, fully metabolized</td>
<td>Naturally resorbed, fully metabolized</td>
<td></td>
<td>035” OTW platform</td>
</tr>
<tr>
<td>Designed for SFA and Iliac Arteries</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BVS for the peripheral arteries in an investigational device outside the U.S. Not available for sale. All illustrations are artists' renditions. Illustrations created by Abbott.
• Lumen stabilization and scaffold disappearance are the key ingredients for a durable SFA therapy
• Combining endovascular legacy with deep coronary BVS experience creates a specialized platform to address long term SFA needs

BVS for the peripheral arteries in an investigational device outside the U.S. Not available for sale.

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Intentionally Employing Natural Polylactide Degradation

Hydrolysis occurs via random chain scission of the ester bond

\[
R-O-R' + H_2O \rightarrow R-OH + HO-R', \text{ where } R,R' = \left(\begin{array}{c}
\text{CHO} \\
\text{CH}_3
\end{array}\right)_n
\]

Hydrolysis randomly cleaves amorphous tie chains, leading to a decrease in molecular weight without altering radial strength.

When enough tie chains are broken, the device begins losing radial strength.
Porcine iliac model of PVI

Hip Extension vs. Flexion

Images are on file at Abbott Vascular. BVS for SFA and BTK is currently in development at Abbott Vascular. Neither approved nor available for sale. Not to be reproduced, distributed or excerpted.
Peripheral Bioresorbable Vascular Scaffold (BVS)

Acute implantation in a porcine iliac artery

Oversized Nitinol SES

BVS

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ABSORB BTK is currently in development at Abbott Vascular. Neither approved nor available for sale.

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Peripheral Bioresorbable Vascular Scaffold (BVS)
6 mos. after implantation in a porcine iliac artery

Oversized Nitinol SES

BVS

Images are on file with Abbott Vascular.

ABSORB BTK is currently in development at Abbott Vascular. Neither approved nor available for sale.

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Chronic Deformation Effects on Neointima

Leg flexion causes stent deformation and neointimal formation

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Photos taken by and on file at Abbott Vascular. Tests performed by and data on file at Abbott Vascular. Representative preclinical data from porcine coronary arteries, 2x objective.

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Crush Recovery Comparison: Balloon Expandable Stent vs. Bioresorbable Scaffold

* This video demonstrates the physical properties and capabilities of PLLA-based bioresorbable scaffolds.
ESPRIT I Trial Design

A single *de novo* lesion in the superficial femoral (SFA) or iliac arteries in patients with symptomatic claudication (Rutherford Becker Category 1-3)

- Prospective, Single Arm, Multi-Center OUS trial evaluating the Esprit BVS (N=35)
- One target lesion treated with a single 6.0 x 58 mm Esprit BVS
- Vessel diameter from ≥ 5.5 – ≤ 6.5 mm, segment length ≤ 50 mm

**Trial Objective:**
Evaluate safety and performance of the Esprit BVS in subjects with symptomatic atherosclerotic disease of the SFA or iliac arteries

**Endpoints:**
Procedural, clinical, functional, hemodynamic, angiographic, IVUS, non-invasive imaging in-hospital and at F/U time points indicated
ESPRIT I  FEMORAL
Pre- and post-procedure subtracted angiograms

Pre-procedure

Post-PTA

Post-scaffold
### ESPRIT I Acute Success

<table>
<thead>
<tr>
<th><strong>Device Success</strong></th>
<th>Esprit (N=35)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achievement of successful delivery and deployment of the study device(s) at the intended target lesion and successful withdrawal of the delivery catheter.</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Technical Success</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Attainment of a final residual stenosis of &lt; 30% at the intended target lesion(s).</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Clinical Success</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Attainment of a final residual stenosis of &lt; 30% using the study device(s) and/or any adjunctive device at all intended target lesion(s) without complications within 2 days after the index procedure or at hospital discharge, whichever is sooner.</td>
<td>100.0%</td>
</tr>
</tbody>
</table>
## ESPRIT I Functional and Hemodynamic Results

<table>
<thead>
<tr>
<th></th>
<th>ESPRIT baseline (N=35)</th>
<th>ESPRIT 1-month (N=34)</th>
<th>ESPRIT 6-month (N=34)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rutherford 0</strong></td>
<td>0 %</td>
<td>84.9 %</td>
<td>67.6 %</td>
</tr>
<tr>
<td>(no claudication)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Rutherford 1</strong></td>
<td>8.6 %</td>
<td>12.1 %</td>
<td>23.5 %</td>
</tr>
<tr>
<td>(mild claudication)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Rutherford 2</strong></td>
<td>34.3 %</td>
<td>3.0 %</td>
<td>8.8 %</td>
</tr>
<tr>
<td>(moderate claudication)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Rutherford 3</strong></td>
<td>57.1 %</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>(severe claudication)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ankle-Brachial Index</strong>*</td>
<td>0.75</td>
<td>1.00</td>
<td>0.99</td>
</tr>
</tbody>
</table>


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# ESPRIT I Key Study Endpoints

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Esprit BVS (N=34*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>deaths (%)</td>
<td>0.0</td>
</tr>
<tr>
<td>any amputation of treated limb (%)</td>
<td>0.0</td>
</tr>
<tr>
<td>bypass surgery of treated limb (%)</td>
<td>0.0</td>
</tr>
<tr>
<td>scaffold thrombosis (%)</td>
<td>0.0</td>
</tr>
<tr>
<td>target lesion revascularization (TLR) (%)</td>
<td>0.0</td>
</tr>
<tr>
<td>target vessel revascularization (TVR) (%)</td>
<td>0.0</td>
</tr>
<tr>
<td>target extremity revascularization (TER) (%)</td>
<td>0.0</td>
</tr>
</tbody>
</table>

*One subject withdrew consent for further follow-up*

Conclusions

- Self expanding metallic stents can impart chronic injury through oversizing / chronic outward

- Fully resorbable scaffolds have the potential to
  - Sustain lumen dimensions while vessel wall heals
  - Disappear mechanically and not cause chronic injury
  - Fully resorb to restore mechanical integrity to the vessel wall

Scheinert D. ESPRIT I Clinical Study 30-day results: LINC Course 2013.
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