Just stent it?
Biomimetic interwoven stents

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Disclosure

Speaker name:

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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
Dense arterial calcification is a problem

- Most calcium is located in the media not the intima
- Calcium is associated with less optimal outcomes in most interventional series
- There are many talks but NO RANDOMIZED TRIALS to guide us in the interventional therapy of calcific SFA disease.
There are no randomized controlled trials in calcified SFA intervention comparing various therapies to each other.
The SUPERA Stent

- SUPERA is an interwoven self-expanding nitinol stent
- The design incorporates 6 pairs of super-elastic nitinol wires which are interwoven in a helical pattern with a closed cell geometry
Unparalleled Strength

The Supera® implant has 20 lb. compression resistance²

References
1. Flexibility is defined as kink resistance. Supera® implant demonstrated lowest kink resistance for 5 and 6 x 100 mm implants as compared to 6 x 100 mm standard nitinol implants in a tube. Data on file at Abbott Vascular.
2. 20 lbf compression resistance for 5 x 100 mm Supera® implant to achieve 53% compression. Four times the compression resistance of all other competitors. All other products compressed 53% with less than 5 lbf applied. Data on file at Abbott Vascular.
3. 10 million cycles (equivalent of 10 years of human activity) of independent lab bending, extension, torsion and compression testing.
Supera® is a New Class of SFA Technology

Unlike Standard Nitinol Stents (SNS), Supera’s Vascular Mimetic Technology offers unparalleled strength and flexibility.

1. Flexibility is defined as kink resistance. Supera® implant demonstrated lowest kink resistance for 5.5 and 6.5 x 100 mm implants as compared to 6 x 100 mm standard nitinol stents in a tube. Data on file at Abbott Vascular.

Angio photos courtesy of Dr. Dierk Schienert (top row) and SUPERB study (bottom row). IVUS images courtesy of Dr. Dierk Scheinert and Dr. Frank Arena. Kink photos on file at Abbott Vascular.
6 MFU – X-ray

6MFU Cine
Correction of Ca++ Induced Stent Deformation

Baseline  Post BMS  Supera restores max stent lumen CSA

Courtesy of D. Cohen
Supera® Has Strong Clinical Outcomes in Calcification

**SUPERB Data - Severe Calcification**

- Patency (VIVA 12 months) - 89%
- Freedom from TLR at 1 year (K-M) - 95%
- Freedom from TLR at 2 years (K-M) - 92%

- % of Lesions with Severe Calcification (SUPERB Trial) - 45% (n=118)

Data on file at Abbott Vascular.
Patency Rates are Consistent Across Lesion Lengths

Percent of Lesions without Restenosis by Lesion Length
(12 months SUPERB IDE Trial)

<table>
<thead>
<tr>
<th>Lesion Length</th>
<th>Percent without Restenosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shortest Lesions</td>
<td>87.7%</td>
</tr>
<tr>
<td>(35.4 ± 12.3 mm)</td>
<td>n=87</td>
</tr>
<tr>
<td>Middle Lesions</td>
<td>84.6%</td>
</tr>
<tr>
<td>(73.5 ± 10.8 mm)</td>
<td>n=88</td>
</tr>
<tr>
<td>Longest Lesions</td>
<td>87.7%</td>
</tr>
<tr>
<td>(126.1 ± 33.4 mm)</td>
<td>n=87</td>
</tr>
</tbody>
</table>

Low Re-intervention Rate Out to 2 Years

Optimal deployment leads to durable freedom from Target Lesion Revascularization, maintained out to 2 years.

Freedom from TLR at 1 year and 2 years

Clinical data on file at Abbott Vascular.
Proper Sizing, Preparation, Deployment Technique Result in **Excellent Patency Rates**

High patency rates are demonstrated in cases where appropriate implant selection, vessel preparation, and deployment technique are used.

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

Source: Supera® Peripheral Stent System Summary of Safety and Effectiveness Data (SSED).
Pre-dilate; Size 1:1; Deploy Slowly: The 3 Keys for Optimal Supera Deployments

1. Pre-dilate
   - Pre-dilate the lesion to \( \geq \) the outer diameter of the implant.
   - Longer inflation times recommended.

2. Size 1:1
   - Match implant size 1:1 to vessel diameter.
   - Do not oversize the implant.

3. Deploy Slowly
   - Magnify imaging to observe cell geometry.
   - Use short, even throws of the thumb slide.
   - Open the deployment lock and fully advance thumb slide to completely release the implant.
   - Visually confirm implant detachment.
   - Retract the tip and lock the thumb slide before withdrawal.
   - Post-dilate as needed.

“The most important keys for a Supera® case are a good balloon and careful vessel preparation.”
- Dr. Peter Goverde, Vascular Surgeon, Belgium (has performed over 200 Supera cases)
Supera Limitations

• Difficult to land precisely at the SFA ostium
• Does not conform well in areas of size mismatch
• Must utilize an .018 or .014 wire
• Present maximal available length is 12cm
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