SUPERB Trial Data: A Vasculomimetic Stent is the Treatment of Choice for Highly Calcific Long SFA Disease

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DISCLOSURES

Consultant/Medical/Scientific Boards
- Abbott
- Boston Scientific
- Cardiva
- Cook Medical
- CR Bard
- Lake Regional Medical
- Medtronic
- Spectranetics

PVD Training
- Abbott
- Bard
- Boston Scientific
- Spectranetics
- TriReme Medical

Stockholders
- CardioProlific
- Cardiva
- Spectranetics
- Vasamed

Speaker’s Bureau
- Abbott
- Bard
- Boehringer-Ingelheim
- Bristol-Myers-Squibb/Sanofi
- Cardiva
- Cook Medical
- Cordis
- DSI/Lilly
- Gore
- ACHL/Merck
- Spectranetics
Limitations of Standard Nitinol Stents (SNS)
Fractures – especially in Proximal Popliteal Artery

In a single center study evaluating stent fracture in 93 patients, Scheinert et al. found that stent fracture was associated with reduced patency with the following stents: S.M.A.R.T.®, SelfX and Luminexx™.

Primary stent patency rates for fractured and non-fractured stents

![Graph showing Kaplan-Meier primary patency rates for fractured and non-fractured stents with a beta of p<0.0001.]

In the graph, the Kaplan-Meier primary patency rates for fractured and non-fractured stents are compared over 12 months. The rates are significantly different, with a p-value of p<0.0001.
Traditional self-expanding stents try to achieve preset diameter by exerting outward force on the vessel.

Oversizing Leads to Chronic Outward Force

- Self-expanding stents are oversized to the vessel to assure wall apposition
- Oversizing causes the stent to exert COF on the vessel
- Too much COF may lead to chronic stent-vessel irritation

Oversizing Can Lead to In-Stent Restenosis

Example: 8 mm stent

**Oversized stent to vessel ratio:**

**Optimal Oversizing**
1.1 – 1.3 : 1

**Medium Oversizing**
1.3 – 1.6 : 1

**High Oversizing**
1.6 – 1.9 : 1

Preclinical animal model at 180 days

High Compression Resistance is a Desirable Attribute

Compression resistance:

- Is the ability of a self-expanding stent to resist vessel recoil or crush\(^1\)
- Allows vessels to optimize lumen diameter and maintain open, round lumens\(^2\)
- Compression Resistance is different than Chronic Outward Force\(^1,3\)

Limitations of Standard Nitinol Stents

Low Compression Resistance

OCT and IVUS of two standard nitinol stents in SFAs

- Tube design lacks longitudinal flexibility
- Low compression resistance results in D shaped lumen


Limited ability to stand up to calcium

Courtesy of: Dr. David Cohen, Valley Hospital, New Jersey, USA
Vascular Mimetic Technology Offers Beneficial Attributes

Comparative Attributes of Current SFA Treatment Modalities

<table>
<thead>
<tr>
<th></th>
<th>Addresses Dissection</th>
<th>Provides Scaffolding</th>
<th>Not a Permanent Implant</th>
<th>Resists Acute Recoil</th>
<th>Minimizes Chronic Outward Force</th>
<th>Flexibility with Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA</td>
<td>--</td>
<td>--</td>
<td>++</td>
<td>--</td>
<td>++</td>
<td>N/A</td>
</tr>
<tr>
<td>SNS</td>
<td>+</td>
<td>+</td>
<td>--</td>
<td>+</td>
<td>--</td>
<td>-</td>
</tr>
<tr>
<td>D-SES</td>
<td>+</td>
<td>+</td>
<td>--</td>
<td>+</td>
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<td>-</td>
</tr>
<tr>
<td>Ather.</td>
<td>--</td>
<td>--</td>
<td>++</td>
<td>--</td>
<td>++</td>
<td>N/A</td>
</tr>
<tr>
<td>VMT</td>
<td>+</td>
<td>+</td>
<td>--</td>
<td>++</td>
<td>+</td>
<td>+</td>
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Supera® Vascular Mimetic Implant: A New Class of SFA Technology

• Mimics the natural structure and movement of the anatomy¹
  - Optimizes luminal gain: maintains a round open lumen in challenging anatomy

• Provides strength and flexibility² for a durable solution³
  - > 4x compression resistance than standard nitinol stents
  - High fracture resistance
  - Minimal chronic outward force

¹ Data on file at Abbott Vascular. ² Strength is defined as compression resistance, flexibility is defined as kink resistance measured in a tube. Data on file at Abbott Vascular. ³ Supera® Peripheral Stent System Instructions for Use. Data on file at Abbott Vascular.
The Supera® implant has 20 lb. compression resistance\(^2\)

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.
1-year Results:
- Primary Patency (K-M) of 86.3%
- Zero fractures
- Significant improvement in ABI at 12 months versus baseline and 89% of patients have improved more than 1 Rutherford-Becker clinical category at 12 months

2-year Results:
- 84% Freedom from TLR
- 0.5% fracture

Source: Supera® Peripheral Stent System Instructions for Use.
1. PSVR < 2.0,
2. Garcia, L., SUPERB Pivotal IDE Trial, 12-Month Results, TCT 2012 for Ankle-Brachial Index improvements.
3. One patient (1/200, 0.5%) experienced a Type III fracture at 24 months. The patient had a revascularization with directional atherectomy for in-stent restenosis at 9 months post index procedure. At 12-month follow up there was no evidence of a stent fracture. Additional in-stent restenoses were treated twice more with directional atherectomy between the 12- and 24-month evaluations. At 24 months, a type III fracture was noted in x-ray in the region of the earlier restenoses. There was no report of a major adverse event at 24 months.
Percent of Lesions without Restenosis by
Lesion Length
(12 months SUPERB IDE Trial)

<table>
<thead>
<tr>
<th>Lesion Length</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shortest Lesions (35.4 ±12.3 mm)</td>
<td>87.7%</td>
</tr>
<tr>
<td>Middle Lesions (73.5 ±10.8 mm)</td>
<td>84.6%</td>
</tr>
<tr>
<td>Longest Lesions (126.1 ±33.4 mm)</td>
<td>87.7%</td>
</tr>
</tbody>
</table>

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

Source: Supera® Peripheral Stent System Summary of Safety and Effectiveness Data (SSED).
Optimal deployment leads to durable freedom from Target Lesion Revascularization, maintained out to 2 years.

Freedom from TLR at 1 year and 2 years

<table>
<thead>
<tr>
<th>Compression / Elongation</th>
<th>1 Year (K-M)</th>
<th>2 Years (K-M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nominal (±10%)</td>
<td>97%</td>
<td>96%</td>
</tr>
<tr>
<td>Moderate Compression (21-40%)</td>
<td>90%</td>
<td>90%</td>
</tr>
<tr>
<td>Minimal Compression (11-20%)</td>
<td>91%</td>
<td>87%</td>
</tr>
<tr>
<td>Minimal Elongation (11-20%)</td>
<td>84%</td>
<td>77%</td>
</tr>
<tr>
<td>Moderate Elongation (21-40%)</td>
<td>87%</td>
<td>82%</td>
</tr>
<tr>
<td>Severe Elongation (&gt;40%)</td>
<td>77%</td>
<td>84%</td>
</tr>
</tbody>
</table>

Clinical data on file at Abbott Vascular.
Pre-dilate; Size 1:1; Deploy Slowly: The 3 Keys for Optimal Supera Deployments

1. **Pre-dilate**
   - Pre-dilate the lesion to ≥ 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
Closing Remarks / Thank You
Greater than 4x Compression Resistance Optimizes Luminal Gain and Maintains Circular Geometry

Supera® implant vs. Standard Nitinol Stent in the SFA

Video courtesy of Dr. Sahil Parikh. On file at Abbott Vascular.
Supera® Offers a Unique Solution!\(^1\)

**Advantages**

- High radial strength (>4x)\(^1\)
- Low chronic outward force (1:1 sizing)\(^2\)
- Mimics the natural structure and movement of the anatomy\(^3\)
- Durable/low fracture design\(^4,5\)
- Kink resistant\(^6\)
- Stands up to calcium (no recoil)\(^7\)
- No difference in restenosis rates between 12 cm and 3.5 cm lesions\(^5\)
- Low re-intervention rate out to 2 years\(^8\)

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1. 20 lbs compression resistance for 5.5 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 lbs applied. Data on file at Abbott Vascular.
2. Data on file at Abbott Vascular: Report Chronic Outward Force (COF) for Peripheral Self-Expanding Stents, Competitive Study RPT2097692
4. 1,152 patient analyzed retrospectively, see Scheinert et al., Real world perspectives of treating complex SFA-Pop lesions. Results from the SUPERA-500 (including Leipzig SFA, Leipzig Popliteal and S500 LL) Registry, LINC 2013, 495 patients; Goverde et al., AURORRA-registry: Experience with high radial force interwoven nitinol stents in femoro-popliteal arteries, LINC 2013, 117 patients; Molenaar et al., Interwoven self-expanding nitinol stents for long complex SFA and popliteal lesions CWZ, LINC 2012, 178 patients; Goltz et al., Endovascular Treatment of Popliteal Artery Segments P1 and P2 in Patients with Critical Limb Ischemia. J Endovasc Ther 2012;19:450-456, 40 patients; Chan et al., HK Single-centre Results of Femoro-popliteal Revascularization using Helical Interwoven Nitinol Stents, LINC 2013, 75 patients; Pacanowski et al., RESTORE: Interwoven Stents in the Real World, The Initial United States Experience with the Use of the Supera Stent in the SFA and Popliteal Artery, LINC 2013, 147 patients; Kovach, R., SAKE, Supera Interwoven Nitinol Stent Outcomes in Above-Knee Interventions: A Single Center Experience, LINC 2013, 100 patients.
5. Supera Peripheral Stent System Instructions for Use.
7. Metzger, C. A Mechanical Problem Should Be Treated Mechanically. LINC 2013.