SUPERA stent for Calcified Femoropopliteal Disease

Focused on Supera; Vascular Mimetic Implants
A Unique Class of SFA Technology

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Cardiovascular Center,
Korea University Guro Hospital
1. Supera case review
   1) Popliteal lesion
   2) Common femoral lesion
   3) Distal SFA lesion

2. Supera Data

3. Summary and Conclusion
Case 1. Rt popliteal calcified lesion

F/68, Rt DM foot
Baseline angiography
Intraluminal wiring; 018 Connect Flex
NC Balloon Dilation

Admiral and Mustang Ballooning (5.0X80mm)
Post Balloon Dilation and Supera

Supera 5.0X60mm
Adjuvant Ballooning and Another BMS to distal SFA
Case 2. Severely Calcified Common Femoral Artery

F/80, Claudication
Baseline Angiography
Intraluminal Wiring with 018 Connect Flex
Predilation using NC Balloon
Post-predilation
Supera-SFA to Common Femoral Artery
Final Angiography
Case 3. Distal SFA Calcified Lesion
Wiring (Intraluminal and Subintimal)
Predilation
Supera-Distal SFA to Politeal Artery

Supera 5.0X80mm
# Balloon for PTA

<table>
<thead>
<tr>
<th></th>
<th>014</th>
<th>018</th>
<th>035</th>
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<tbody>
<tr>
<td><strong>Abbott</strong></td>
<td>Armada14</td>
<td>Fox cross</td>
<td>Armada35</td>
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<tr>
<td><strong>Boston</strong></td>
<td>Coyote (M)</td>
<td>Advance 14 (M)</td>
<td>Mustang (NC)</td>
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<tr>
<td><strong>Cook</strong></td>
<td>Advance 14 (M)</td>
<td>Advance 18</td>
<td>Advance 35</td>
</tr>
<tr>
<td><strong>Cordis</strong></td>
<td>Sleek (M)</td>
<td>Savvy</td>
<td>PowerFlex</td>
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<tr>
<td><strong>Medtronic</strong></td>
<td>Amphirion (M)</td>
<td>InPact (DCB)</td>
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<tr>
<td><strong>Covidien</strong></td>
<td>Nanocross</td>
<td>Evercross</td>
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<tr>
<td><strong>Biotronik</strong></td>
<td>Passeo 14</td>
<td>Passeo 18</td>
<td>Passeo 35, Passeo 35-HP (NC)</td>
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<tr>
<td><strong>Bard</strong></td>
<td>Rival, Conquest (NC)</td>
<td></td>
<td>Lutonix (DCB)</td>
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*M; monorail type available  
NC; Non-compliant balloon  
DEB; Drug-eluting balloon
# Stents for PTA

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<tr>
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<th>014/018</th>
<th>035</th>
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<tbody>
<tr>
<td>Abbott</td>
<td>Xpert (SES), <strong>Supera</strong></td>
<td>Absolute Pro</td>
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<tr>
<td>Bard</td>
<td></td>
<td>LifeStent</td>
</tr>
<tr>
<td>Cordis</td>
<td>Precise (SES)-Carotid Palmaz Blue/Genesis (BES)-Renal</td>
<td><strong>Smart</strong></td>
</tr>
<tr>
<td>Gore</td>
<td></td>
<td><strong>Viabahn</strong> (Stentgraft)</td>
</tr>
<tr>
<td>Cook</td>
<td></td>
<td>Zilver, Zilver PTX (DES)</td>
</tr>
<tr>
<td>Medtronic</td>
<td>Maris deep (SES); 014 &amp; 018 Chromis Deep (BES)</td>
<td>Complete SE</td>
</tr>
<tr>
<td>Boston</td>
<td></td>
<td>Wall Stent, Epic, Inova, Eluvia (DES)</td>
</tr>
<tr>
<td>Covidien</td>
<td></td>
<td>Protege</td>
</tr>
<tr>
<td>Biotronic</td>
<td>Pulsar (018)</td>
<td>Pulsar (035)</td>
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<tr>
<td>Terumo</td>
<td></td>
<td>Misago</td>
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*SES; Self-expanding stent, BES; Balloon-expandable stent, DES; Drug-eluting stent  **BTK stents; disappeared in the market
1. Cutting balloon (Boston)
2. Scoring Balloon; *Vascutrak* *(Bard)*, AngioSculpt (Spectranetics) or NSE balloon (Goodman)--pending
3. Directional Atherectomy Device
   ; Silverhawk, *Turbohawk*, HawkOne (Covidien)
4. *Jetstream* (Boston)
5. Rotablator (Boston)
SUPERB Results

Safety and efficacy demonstrated with the Supera implant

1-year Results:
- Primary Patency (K-M) of 86.3%\(^1\)
- Zero fractures
- Significant improvement in ABI at 12 months versus baseline\(^2\) 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\(^3\)

Source: Clinical data on file at Abbott Vascular.
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.
SFA IDE Trial 12 Month Results Patency (VIVA Criteria (Binary Proportion (BP)))

#### Results

**Primary Patency by Binary Proportion**

- **Supera:** 79%
- **Complete SE:** 73%
- **S.M.A.R.T EverFlex:** 68%
- **EverFlex:** 67%

<table>
<thead>
<tr>
<th>Stent</th>
<th>Patients</th>
<th>Avg Lesion Length (cm)</th>
<th>Fracture Rate (%)</th>
<th>Occlusion (%)</th>
<th>CD-TLR (%)</th>
<th>Primary Patency (%) (K-M)</th>
<th>PSVR</th>
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<tbody>
<tr>
<td>Supera</td>
<td>264</td>
<td>7.8</td>
<td>0</td>
<td>25</td>
<td>10.6*</td>
<td>86.3</td>
<td>2.0</td>
</tr>
<tr>
<td>Complete SE</td>
<td>196</td>
<td>6.1</td>
<td>0</td>
<td>30</td>
<td>8.4</td>
<td>90.9</td>
<td>2.0</td>
</tr>
<tr>
<td>S.M.A.R.T</td>
<td>250</td>
<td>7.7</td>
<td>2.0</td>
<td>24</td>
<td>12.4</td>
<td>81.7</td>
<td>2.0</td>
</tr>
<tr>
<td>EverFlex</td>
<td>287</td>
<td>8.9</td>
<td>0.4</td>
<td>48</td>
<td>13.9*</td>
<td>77.2</td>
<td>2.0</td>
</tr>
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</table>

**Note:**
- Results from Clinical Trials are not directly comparable. Information provided are for educational purposes only.
- Primary Patency by Binary Proportion
- Primary Patency (% (K-M))

* By Kaplan-Meier estimated TLR
Limitations of SFA Technologies

Performance Decreases as Lesion Get Longer

Good results in short lesions with SES, PTA, and DES...

Worse results in long SFA lesions...

DCB, drug-coated balloon; DES, drug-eluting stent; SES, self-expanding stent; SFA, superficial femoral artery.

Modified from Shroë H. Superficial femoral artery PTA or stenting? 5-Year results. CIRSE 2011; Munich, Germany.
Consistent Data Even in Very Long Lesions

2. SUPERA 500: Scheinert, D. Results from the SUPERA 500 Registry, LINC 2013.
3. SUPERA 500 Long Lesions: Scheinert, D. Results from the SUPERA 500 Registry. LINC 2013.
4. COMPLETE SE: IFU, Complete SE.
6. ZILVER PTX IFU/SEED.
7. RESILIENT: IFU, LifeStent.
10. DURABILITY II: Everflex Instructions for Use.
Excellent Freedom From Clinically Driven TLR Through 3 Years

Data differences depicted between these trials may not be statistically significant or clinically meaningful and different clinical trials may include differences in the demographics of the patient populations.

Supra® Has Strong Clinical Outcomes in Calcification at 3 Years

Freedom from TLR % Over Time in Severe Calcium

- 12 months: 95%
- 24 months: 92%
- 36 months: 88%

SUPERNB Data - Severe Calcification

- % of Lesions with Severe Calcification (SUPERNB Trial): 45% (n=118)
- Patency (VIVA 12 months): 89%

Data on file at Abbott Vascular.
0 Stent Fractures at 12 Months in SUPERB

Assessed by core lab review of AP and lateral X-ray views

<table>
<thead>
<tr>
<th>Stent Fracture</th>
<th>12 Months (N=243)</th>
<th>24 Months (N=200)</th>
<th>36 Months (N=162)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single strut</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Multiple strut</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Complete fracture/fragments aligned</td>
<td>0.0%</td>
<td>0.5%*</td>
<td>0.6%*</td>
</tr>
<tr>
<td>Complete fracture/fragments mal-aligned</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Spiral fracture</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
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</table>

Source: Supera Peripheral Stent System, Clinical data on file at Abbott Vascular. Image from SUPERB trial. Data on file at Abbott Vascular. Image courtesy of Dr. Hans Biemans, Rivas Hospital Gorinchem, the Netherlands. Evaluated by X-ray [anterior-posterior (AP) and lateral views in both straight and flexed knee positions] per an independent core lab. * One subject experienced a Type III fracture at 24 months after three directional atherectomy procedures to treat in-stent restenosis.
Results of DCB in Complex Pathology: *Calcified Lesions*

- Paclitaxel must transfer from balloon into vessel wall
- Extensive calcification or thrombus may act as a barrier to drug diffusion

Primary patency & late lumen loss were both negatively impacted by increasing calcification, with the worst results in patients with circumferential calcification (Fanelli F, et al. Cardiovasc Int Radiol 2014)

DCB vs. Existing Modalities for SFA/Pop Interventions

Supera works well in the challenging clinical scenarios of calcium, acute recoil, and long lesions.

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>Supera</th>
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<tbody>
<tr>
<td><strong>Severe Calcification</strong></td>
<td>Excluded from and/or low rates of in trials(^1,2); calcium represents a barrier to optimal drug absorption.(^3)</td>
<td>5% TLR(^*) in Severe Calcium at 1 year in SUPERB(^4)</td>
</tr>
<tr>
<td><strong>Acute Recoil or Dissections</strong></td>
<td>Stent/Implant needed to treat. (Flow-limiting dissections can occur up to 40% of time(^6))</td>
<td>&gt;4x the compression resistance of SNS(^5)</td>
</tr>
<tr>
<td><strong>Long Lesions</strong></td>
<td>Data not yet available in US</td>
<td>High freedom from restenosis is consistent across all lesion lengths in SUPERB(^4)</td>
</tr>
</tbody>
</table>

1 Lutonix FDA Executive Summary
2 IN.PACT Admiral Summary of Safety and Effectiveness Data
4 SUPERB 3 Year Garcia VIVA 2014
5 Data on file at Abbott Vascular.

*TLR by KM
Supera Outperforms BMS and DCB in Real World Patients

- Real world data of patients undergoing femoropoliteal interventions
- Different patterns of disease progression observed with DCB, conventional and interwoven nitinol stents
- Limitations of non-randomized data

The Leipzig experience with DCB, conventional, and interwoven nitinol stents for complex SFA disease. S. Steiner. LINC 2015
Patients and Lesions in the “Real World”

TASC D Femoropopliteal Occlusions

In-stent Re-stenosis and Occlusions

Long-segment Disease with Extensive Calcification

Images Courtesy of Dr. Brian G. DeRubertis
Proper Sizing, Preparation, and 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

- **Moderate (21-40%)**: 83.3% (p=0.480, n=6)
- **Minimal (11-20%)**: 81.8% (p=0.268, n=22)
- **Nominal (± 10%)**: 90.5% (p=0.268, n=74)
- **Minimal (11-20%)**: 73.7% (p=0.026, n=38)
- **Moderate (21-40%)**: 74.4% (p=0.029, n=39)
- **Severe (>40%)**: 57.7% (p=<.001, n=26)

Source: Data on file at Abbott Vascular.
Dr Rha’s Indication for Supera

1. No stent zone; CFA and Popliteal Artery; Try with DAART first, if bailout stenting is needed, Supera is the choice (Limitations in larger diameter CFA..)

2. Heavily calcified SFA lesion; debulking, DCB and provisional Supera stenting

3. Diffuse long SFA, particularly mid to distal SFA without optimal balloon response
   1) Acute recoil and dissection; DCB+Supera
   2) Expecting good stent expansion without significant calcium: DES
Save the Date!!

CCI Guro Live 2017

October 19~21, 2017

Korea University Guro Hospital, Seoul, Korea
Thank You for Your Attention!

Korea University Guro Hospital, Seoul, Korea