Mimetic stent technology – providing safe, sustained, and optimal care

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Disclosure

Speaker name:
Erwin Blessing

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): Honorarium: Abbott

- [ ] I do not have any potential conflict of interest
SFA challenges

THE SFA AND PROXIMAL POPLITEAL ENVIRONMENT IS COMPLEX AND CHALLENGING

25% shortening

SFA Dynamics Vary Across Regions of the Artery Greatest Risk of Stent Failure at Hunter’s Canal

60° twisting

3 lbs compression

64° bending
Strength—its high resistance to compression\textsuperscript{17}

Low chronic outward force against vessel walls\textsuperscript{18}

High flexibility,\textsuperscript{19} which allows for fracture resistance\textsuperscript{2}

\begin{itemize}
  \item LOW COF\textsuperscript{1}
  \item MINIMAL VESSEL INJURY\textsuperscript{2}
  \item FRACTURES AT 1 YEAR ACROSS ALL STUDIES\textsuperscript{2,3,24-38}
\end{itemize}
Supera™ - features

Laser-cut stent 6 mm 5 lbs
Standard laser-cut stent experiences lumen compression

Supera™ Stent maintains a round lumen with 5 lbs of force applied

SNS 7 x 200
Proximal

Supera™ Stent 6 mm 5 lbs

SNS 5.5 x 120
Distal

Same patient with SNS and Supera™ Stent

SEEING IS BELIEVING

Source: Angiogram and IVUS images courtesy of Dr. Andrej Schmidt.
Tipps and tricks: how to start?

TASC A or B lesions
Mid or distal SFA or popliteal artery
Supera™: how to continue?

Supera™ in TASC C and D CTO Lesions in CLI patients after subintimal crossing (Supersub-Study, PI: Luis Palena)

Feasibility and 1-Year outcomes of subintimal revascularization with supera® stenting of long femoropopliteal occlusions in critical limb ischemia: The "Supersub" Study.

Palena LM¹, Diaz-Sandoval LJ², Sultato E¹, Brigato C¹, Candeo A¹, Brocco E¹, Manzi M¹.
Supera™ – Clinical data

**SUPERB Freedom from Loss of Primary Patency at 12 Months**

![Graph showing freedom from loss of primary patency over days post index procedure.](image)

- **Interval**: [0, 90), [90, 180), [180, 270), [270, 360), [360, 390), ≥391
- **# At Risk**: 264, 242, 234, 215, 188, 169
- **# Events**: 1, 4, 14, 13, 16, 0
- **# Censored**: 21, 4, 5, 14, 3, 6
- **Survival Rate**: 1.000, 0.996, 0.979, 0.920, 0.863, 0.789
- **Standard Error**: 0.000, 0.004, 0.009, 0.018, 0.023, 0.027

Clinical data on file at Abbott Vascular.

* Survival rate at beginning of time period.

Supera™ – Clinical data

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.

- 83.3% (p=0.480), 81.8% (p=0.266) for Moderate (21-40%) and Minimal (11-20%) compression/elongation.
- 90.5% (p=0.026) for Nominal (±10%) compression/elongation.
- 73.7% (p=0.029) for Minimal (11-20%) and 74.4% (p<0.001) for Moderate (21-40%) compression/elongation.
- 57.7% (p<0.001) for Severe (>40%) compression/elongation.

Source: Data on file at Abbott Vascular.

Supera™ – Clinical data

Optimal Deployment Leads To Low Re-intervention Rate Out to 3 Years

SUPEROB Freedom From TLR at 1, 2, and 3 Years

- 90% at 12 months
- 90% at 24 months
- 90% at 36 months

- 91% at 12 months
- 87% at 24 months
- 87% at 36 months

- 84% at 12 months
- 78% at 24 months
- 82% at 36 months

- 77% at 12 months
- 63% at 24 months
- 42% at 36 months

## TABLE V. Rutherford Becker Clinical Category Changes

<table>
<thead>
<tr>
<th>Rutherford Becker Scale</th>
<th>1 M</th>
<th>12 M</th>
<th>24 M</th>
<th>36 M</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>P-value for comparison of clinical category between follow-up and baseline (by Friedman)</strong></td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Clinical improvement compared with baseline</td>
<td></td>
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</tr>
<tr>
<td>Grade +3 markedly improved</td>
<td>68.0% (176/259)</td>
<td>53.5% (123/230)</td>
<td>56.7% (115/203)</td>
<td>65.9% (110/167)</td>
</tr>
<tr>
<td>Grade +2 moderately improved</td>
<td>23.2% (60/259)</td>
<td>24.3% (56/230)</td>
<td>25.1% (51/203)</td>
<td>19.8% (33/167)</td>
</tr>
<tr>
<td>Grade +1 minimally improved</td>
<td>6.2% (16/259)</td>
<td>11.3% (26/230)</td>
<td>7.4% (15/203)</td>
<td>6.6% (11/167)</td>
</tr>
<tr>
<td>Grade 0 no change</td>
<td>2.7% (7/259)</td>
<td>8.3% (19/230)</td>
<td>4.4% (9/203)</td>
<td>6.0% (10/167)</td>
</tr>
<tr>
<td>Grade −1 mildly worse</td>
<td>0.0% (0/259)</td>
<td>1.3% (3/230)</td>
<td>1.5% (3/203)</td>
<td>0.6% (1/167)</td>
</tr>
<tr>
<td>Grade −2 moderately worsening</td>
<td>0.0% (0/259)</td>
<td>0.9% (2/230)</td>
<td>3.4% (7/203)</td>
<td>0.0% (0/167)</td>
</tr>
<tr>
<td>Grade −3 Markedly Worsening</td>
<td>0.0% (0/259)</td>
<td>0.4% (1/230)</td>
<td>1.5% (3/203)</td>
<td>1.2% (2/167)</td>
</tr>
<tr>
<td>Limb ischemia improvement(^a)</td>
<td>97.3% (252/259)</td>
<td>89.1% (205/230)</td>
<td>89.2% (181/203)</td>
<td>92.2% (154/167)</td>
</tr>
</tbody>
</table>

\(^a\)Limb ischemia improvement is defined as an improvement in the Rutherford-Becker Clinical Scale of greater than or equal to one category.
Supera™ – Clinical data

Supera Outperforms BMS and DCB in Real World Patients

**Supera - BMS**
- Matched Cohort: Supera 130 ± 83, BMS 139 ± 100, P-Value 0.2
- Instant restenosis, %: 16, 16, 0.9

**Supera - DCB**
- Matched Cohort: Supera 143 ± 92, DCB 157 ± 102, P-Value 0.09
- Instant restenosis, %: 16, 17, 0.6

- K-M curve with 95% Confidence Interval

- Real world data of patients undergoing femoropopliteal 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

J Endovasc Ther. 2016. Steiner et al.
# Table 1. Summary of clinical studies on the SUPERA stent use in femoropopliteal arterial disease

<table>
<thead>
<tr>
<th>Study</th>
<th>STENT Design</th>
<th>Study design</th>
<th>Patients</th>
<th>Primary patency (in months)</th>
<th>Freedom from TLR (in months)</th>
<th>Fracture rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUPERA 500</td>
<td>SUPERA</td>
<td>Retrospective</td>
<td>439 (492 limbs)</td>
<td>83.3% (12 m) 72.8% (24 m)</td>
<td>0% (24 m)</td>
<td></td>
</tr>
<tr>
<td>SUPERA SFA</td>
<td>SUPERA</td>
<td>Retrospective</td>
<td>107</td>
<td>84.7% (12 m) 71.7% (18 m), 67.4% (60 m)</td>
<td>0%</td>
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<tr>
<td>Registry</td>
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<tr>
<td>SUPERA</td>
<td>SUPERA</td>
<td>Prospective,</td>
<td>264</td>
<td>86.3% (12 m) 88.9% (12 m), 83% (36 m)</td>
<td>0% (12 m), 0.6% (16 m)</td>
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<td></td>
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<td>multicenter,</td>
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<td></td>
<td></td>
<td>unblinded</td>
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<tr>
<td>St Louis</td>
<td>SUPERA</td>
<td>Retrospective</td>
<td>53</td>
<td>85.6% (12 m) 83.1% (24 m)</td>
<td>0%</td>
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<tr>
<td>University</td>
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<tr>
<td>Tucson</td>
<td>SUPERA</td>
<td>Retrospective</td>
<td>147</td>
<td>89.8% (12 m) 76.7% (36 m)</td>
<td>0%</td>
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<tr>
<td>SAKE</td>
<td>SUPERA</td>
<td>Retrospective</td>
<td>80</td>
<td>88.4% (24 m) 85.8% (primary patency defined as absence of need for TLR)</td>
<td>85.8% n/a</td>
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<tr>
<td>HONG KONG</td>
<td>SUPERA</td>
<td>Retrospective</td>
<td>153</td>
<td>81.4% (12 m) 64.6% (60 m)</td>
<td>0%</td>
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<tr>
<td>QM TURKEY</td>
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<tr>
<td>SUPERSUB</td>
<td>SUPERA</td>
<td>Retrospective</td>
<td>36</td>
<td>85.7 (12 m)</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prospective,</td>
<td>34</td>
<td>94.1% (12 m) 97.1% (12 m)</td>
<td>0%</td>
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<td></td>
<td></td>
<td>single-center, single-arm</td>
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<tr>
<td>VALLADOLID</td>
<td>SUPERA</td>
<td>Prospective,</td>
<td>46 (50 limbs)</td>
<td>89.6% (12 m)</td>
<td>0%</td>
<td>0%</td>
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<tr>
<td>Leipzig</td>
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<td>single-arm</td>
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<tr>
<td>SUPERAPoplitial artery</td>
<td></td>
<td>Retrospective</td>
<td>101 Patients (125 stents)</td>
<td>87.7% (12 m) 91.3% (12 m)</td>
<td>86.7% (24 m), 81.6% (36 m)</td>
<td>0%</td>
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<tr>
<td>Popliteal</td>
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<tr>
<td>P1 P2</td>
<td>SUPERA</td>
<td>Retrospective</td>
<td>40 Patients (34 eligible for follow-up)</td>
<td>68.4% (12 m)</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Dumanetepe M</td>
<td>SUPERA</td>
<td>Retrospective</td>
<td>36 Patients (42 limbs)</td>
<td>91.4% (6 m), 85.7% (12 m)</td>
<td>86.6% (24 m), 76.4% (24 m), 68.9% (36 m)</td>
<td>0%</td>
</tr>
<tr>
<td>SUPERAPoplitial artery versus SNS versus DCB</td>
<td></td>
<td>Retrospective</td>
<td>470</td>
<td>91.4% (6 m), 85.7% (12 m)</td>
<td>86.6% (24 m), 76.4% (24 m), 68.9% (36 m)</td>
<td>0%</td>
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<td>SNS</td>
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<td>432</td>
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<tr>
<td>DCB</td>
<td></td>
<td></td>
<td>390</td>
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<tr>
<td>SUPERAPoplitial artery versus DEB</td>
<td></td>
<td>Retrospective</td>
<td>49</td>
<td>84.8% (12 m) 79.2% (12 m)</td>
<td>88% (12 m)</td>
<td>56% (12 m)</td>
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<tr>
<td>SUPERFAST</td>
<td>SUPERA</td>
<td>Prospective study,</td>
<td>53</td>
<td>Control propensity matched stent matched</td>
<td>88% (12 m)</td>
<td>56% (12 m)</td>
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<tr>
<td>MUNICH</td>
<td>SUPERA</td>
<td>Retrospective</td>
<td>70 Patients</td>
<td>86.7% (12 m) 72.5% (12 m)</td>
<td>46% (12 m)</td>
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<tr>
<td>REGISTRY</td>
<td></td>
<td></td>
<td>85 Patients</td>
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<td></td>
<td>67 Patients</td>
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</tbody>
</table>

Ahmet Peker,1 Bantu Choudhury,2 Amandeep Tandon,3 Ioannis Krokidis,1

1 Department of Vascular Surgery, Cambridge and Abingdon, United Kingdom
2 Department of Radiology, Cambridge and Abingdon, United Kingdom
3 Department of Radiology, The London Clinic, London, United Kingdom
### Supera™ – Clinical data

<table>
<thead>
<tr>
<th></th>
<th>12 months</th>
<th>24 months</th>
<th>36 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Patency</td>
<td>68.4 - 94.1 %</td>
<td>72.8 - 88.4 %</td>
<td>68.9 - 83.0 %</td>
</tr>
<tr>
<td>Freedom from TLR</td>
<td>86.7 - 97.1 %</td>
<td>86.7 %</td>
<td>81.6 - 83.0 %</td>
</tr>
</tbody>
</table>

1 reported stent fracture (Superb Trial 36 months follow up, patient undergoing multiple instent atherectomy procedures)

Supera™: new indications?

Supera in CFA (VMI-CFA Study, PI: Koen Deloose)
Supera™: new indications?

Bifurcation Stenting CFA (Culotte-Technique)

Images: Blessing

18 months follow up
Zentralbl Chir. 2019. Tessarek

Images: Blessing
Supera™: pushing the limits
Supera™: pushing the limits

J Endovasc Ther. 2018. Palena et al.
Supera™: pushing the limits

PRESTO Technique: sheathless in surgically removed proximal SFA

Images: Blessing
Conclusions

Treatment of complex femoropopliteal lesions remains challenging.

Robust clinical data with Supera™ vascular mimetic implants, even in very complex lesions (long lesions, heavily calcified etc.)

Lesion preparation crucial to ensure proper stent deployment.

Increasing evidence to support Supera™ use even in extremely challenging settings and with potentially new indications.
Mimetic stent technology – providing safe, sustained, and optimal care

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