Technological Advances in the Endovascular Treatment of Calcified Peripheral Lesions
Faculty Disclosure

Thomas Zeller, MD

For the 12 months preceding this presentation, I disclose the following types of financial relationships:

• **Honoraria received from:** Abbott Vascular, Angioslide, Bard Peripheral Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Cordis Corp., Covidien, Gore & Associates, Medtronic, Spectranetics, Straub Medical, TriReme, VIVA Physicians

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SFA-Stent Deployment Evaluation

*Stent Compression*

Angio AP projection

Angio LAO projection

% MLD 15%

% MLD 42%

Courtesy Andrej Schmidt
Impaired Primary Patency
due to Residual Stenosis following BMS

Residual stenosis
< 30% (- - -; Δ censored)
> 30% (---; • censored).

p< 0.05
SFA Disease has a High Prevalence of Calcium

Majority (93%) of femoral plaques are fibrocalcific (VII and VIII)\(^1\)

US SFA IDE trials have shown a range of 33% - 56% severe calcification\(^2\)

Images courtesy of Dr. Ethan Korngold, Providence St. Vincent Heart Clinic, Portland OR

2. Complete SE IFU (56%), Everflex IFU (43%), Lifestent IFU (33%), Zilver PTX IFU (35%); Supera™ Peripheral Stent System Instructions for Use.
Retrospective study to analyze DCB for SFA with emphasis on calcium

- 91 patients
- Ave Lesion Length: 57.4mm ± 49.2
- 25.3% Popliteal / 74.7% SFA
- 40.7% Moderate to Severe calcium
- CTO: 33.0%

Results

- 19% 2Yr TLR within non-calcified lesions
- 31% 2Yr TLR in unilaterally* calcified lesions
- 65% 2Yr TLR in bilaterally** calcified lesions

Within 2 years, the degree of calcium had a significant impact on the TLR rates

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*Unilateral defined as <180° (1 side of vessel only)
**Bilateral defined as ≥ 180° (both sides of vessel at same location)

1. Tepe G, Zeller et al. JEVT 2015
How to Solve the Problem?
Calcium in the SFA
How to Solve the Problem?

• Plaque removal (atherectomy)
  – Hawk series
  – Jetstream
  – Diamondback, Rotablator

• Plaque modulation
  – Lithotripsy (Shockwave)
  – Focal force balloons?

• Plaque shift / compression
  – Supera stent
Atherectomy Devices for Calcified lesions

• **A**: Directional Atherectomy
  – TurboHawk
  – HawkOne

• **B&C**: Rotational Atherectomy
  – Jetstream
  – Phoenix

• **D**: Orbital Atherectomy
  – Diamondback
  – Rotablator
DEFINITIVE Ca++ demonstrated calcified disease can be treated with DA and embolic protection

- Bail-out stent rate: 4.1%
- Flow-limiting dissection rate: 1.5%
- Achieved maximal lumen gain

1. Roberts Cath Cardiovasc Interven 84:236-244(2014)
2. Data on file
WHAT DOES DAART (=DA + DCB) EVIDENCE TELL US?

DEFINITIVE AR

### Inclusion Criteria
- RCC 2-4
- ≥ 70% stenosis of SFA and/or popliteal artery
- Lesion Length 7-15cm
- Reference Vessel ≥ 4mm and ≤ 7mm

### Exclusion Criteria
- In-stent restenosis
- Aneurysmal target vessel
- Multiple lesions in target limb that require treatment

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**General and Angiographic Criteria Assessment**

Lesion severely calcified?*

- NO
  - DAART (n=48)
  - DCB (n=54)
- YES
  - DAART Severe Ca+ (n=19)

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WHAT DOES DAART (=DA +DCB) EVIDENCE TELL US?

- Added benefit of DA in lesions ≥10 cm (RCT)
- Added benefit of DA in severely calcified lesions (All DAART)

Per Core Lab Assessment. “All Severe Ca++ “ group includes all patients with severe calcium (including randomized and non-randomized).
DEFINITIVE AR Study – Extension
Achieving optimal lumen gain (≤30% residual stenosis) following DA leads towards improved outcomes

Freedom from TLR at 24 Months: ≤30% residual stenosis

- 83.3%
- 55.2%

Δ +28.1%

≤30% Residual Stenosis Post-DA

Zeller T, et al. Presentation at VIVA 2016,
Intravascular Lithotripsy (IVL)

Shockwave Lithoplasty Balloon
Shockwave Peripheral Intravascular Lithotripsy (IVL) System

Generator

Connector Cable

Lithoplasty Catheter
Peripheral IVL

Iliac

Pre IVL  Post IVL

CFA

Pre IVL  Post IVL

SFA/POP

Pre IVL  Post IVL

BTK

Pre IVL  Post IVL
DISRUPT PAD Effectiveness*

- 100% procedural success with a 24% residual stenosis
- Compelling 6 month results in a challenging lesion cohort

*By angiographic and DUS core labs
DISRUPT PAD Procedural Success by Subgroups

Pre and Post % Diameter Stenosis

Achieves consistent successful procedural outcomes in calcified lesions regardless of lesion complexity or location.

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Pre (%)</th>
<th>Post (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Subjects</td>
<td>77.8</td>
<td>75.6</td>
</tr>
<tr>
<td>SFA</td>
<td>80.8</td>
<td>73.5</td>
</tr>
<tr>
<td>Popliteal</td>
<td>80.9</td>
<td>80.9</td>
</tr>
<tr>
<td>Moderate Ca</td>
<td>75.1</td>
<td>77.3</td>
</tr>
<tr>
<td>Severe Ca</td>
<td>82.4</td>
<td>69.9</td>
</tr>
<tr>
<td>Lesion &lt;5 cm</td>
<td>23.8</td>
<td>22.5</td>
</tr>
<tr>
<td>Lesion 5–10 cm</td>
<td>25.1</td>
<td>25.0</td>
</tr>
<tr>
<td>Lesion &gt;10 cm</td>
<td>22.1</td>
<td>23.1</td>
</tr>
<tr>
<td>Concentric</td>
<td>27.5</td>
<td>23.8</td>
</tr>
<tr>
<td>Eccentric</td>
<td>24.1</td>
<td>24.1</td>
</tr>
</tbody>
</table>

N: 95 70 24 42 52 33 39 23 78 17
IVL Case Example: Severely Calcified SFA Lesion

Heavily calcified sub-total SFA occlusion

5.5 x 60mm IVL Catheter, 120 pulses

Post IVL

Post 6.0mm DCB treatment
# DISRUPT II 1-Year Outcomes

## Performance Results

<table>
<thead>
<tr>
<th>Performance Results</th>
<th>30 days</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target lesion patency*</td>
<td>100% (56/56)</td>
<td>72.7% (40/55)</td>
<td>69.8% (30/43)</td>
</tr>
<tr>
<td>Freedom from TLR</td>
<td>100% (58/58)</td>
<td>98.3% (57/58)</td>
<td>79.3% (46/58)</td>
</tr>
<tr>
<td>Primary Patency</td>
<td>100% (56/56)</td>
<td>71.4% (40/56)</td>
<td>54.5% (30/55)</td>
</tr>
</tbody>
</table>

*B: Baseline, TLR: Target lesion revascularization
Figure 3: Optimal IVL technique was associated with significant improvement in clinical patency. Primary patency by DUS at 12-months was 54.5% (35/55) for intent-to-treat versus 62.9% (22/35) for those with optimal technique. Clinically-driven TLR at 12-months was 20.7% for intent-to-treat versus 8.6% for those with optimal technique. Optimal technique was defined as correct balloon sizing and avoidance of therapeutic miss.
Figure 3E. Case example with optimized technique 1. Pre-procedure angiography: Popliteal lesion with vessel diameter of 4.1 mm, stenosis of 100%. 2. Treatment with 5.0 mm x 60 mm IVL catheter, Optimal technique with balloon sizing 1.1:1 and complete therapeutic coverage (appropriate overlap). 3. Residual stenosis of 13% and acute gain of 3.5mm.
## DISRUPT II 1-Year Outcomes
### Safety Results

<table>
<thead>
<tr>
<th>Event</th>
<th>30 days</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major adverse events (MAE)</td>
<td>1.7%</td>
<td>1.7%</td>
<td>1.8%</td>
</tr>
<tr>
<td></td>
<td>(1/59)</td>
<td>(1/58)</td>
<td>(1/57)</td>
</tr>
<tr>
<td>Emergency surgical revascularization of target</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>limb</td>
<td>(0/59)</td>
<td>(0/58)</td>
<td>(0/57)</td>
</tr>
<tr>
<td>Unplanned target limb amputation</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>(0/59)</td>
<td>(0/58)</td>
<td>(0/57)</td>
</tr>
<tr>
<td>Symptomatic thrombus or emboli</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>(0/59)</td>
<td>(0/58)</td>
<td>(0/57)</td>
</tr>
<tr>
<td>Perforations or Gr D dissections w/ interventions</td>
<td>1.7%</td>
<td>1.7%</td>
<td>1.8%</td>
</tr>
<tr>
<td></td>
<td>(1/59)</td>
<td>(1/58)</td>
<td>(1/57)</td>
</tr>
</tbody>
</table>

*Excludes any patient that had a TLR from analysis
†3 patients did not complete DUS, 2 patients withdrew from the study
‡2 patients withdrew from the study, 1 was lost to follow up
DISRUPT II 1-Year Outcomes
Clinical Results

[Graphs and data tables showing ABI Shift, Rutherford Category Shift (%), and Walking Impairment over time.]
Compression Resistant Stent

SUPERA Interwoven Stent
1. The compression resistance for a 5.5 x 100mm Supera® implant is 20 lbf at 53% compression. This is 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.

*Stents tested include Complete SE, Astron Pulsar-18, Maris Deep, Innova, Epic, Zilver, EverFlex, LifeStent, Misago, S.M.A.R.T., SMARTFlex, Tigris, and Absolute Pro.
Fully Symmetric and Open Lumen

Case courtesy of Dr. Andrej Schmidt

IVUS confirmation of good hemodynamic flow
SUPERB Freedom from TLR
Outcomes in Calcification at 3 Years

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

Patency (VIVA 12 months) 89%

Freedom from TLR % Over Time in Severe Calcium

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

Clinical data on file at Abbott Vascular.

Information contained herein for distribution outside the U.S. only. Check the regulatory status of the device in areas where CE marking is not the regulation in force.
Key Statements from the publication

- “The Supera stent (Abbott) has a unique nitinol coil spring design and that provides excellent radial force resisting elastic recoil and the compression of calcific plaque”

- “Three-quarters of the patients (Superb) had moderate or severe calcification, and no difference in outcomes in the severe calcification cohort”.

Recommended Treatment Algorithm

- **Moderate - Severe calcification = Supera**
- **Long Lesion (>20cm) = Supera**
- **Popliteal/CFA = Supera**
Supera in Heavy Calcium

- Very heavy calcium markers
- Angio post 4.0 x 60 mm PTA
- 6.0 x 60 mm PTA 15 ATM
Supera in Heavy Calcium – Continued

Ghost image demonstrates lesion recoil and calcium

Post PTA with 6.0 by 60 mm balloon to 20 ATM

Final view of stent after post dilatation
Treatment Algorithm in Calcified Femoro-Popliteal Lesions

TASC A & B lesions

- Atherectomy & DCB
- or
- Lithotripsy & DCB

DCB according to RVD + 1mm

TASC C & D lesions

- Aggressive predilatation (Lithotripsy)
- & Supera Stent