Step by step SFA/pop treatment algorithm
Thomas Zeller, MD

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- **Common stock**: QT Medical
Chronic Femoro-Popliteal TASC II A&B lesions
DEB in SFA Evidence

Proof-of-Concept

7 Trials / 6 DEB Technologies; 6-month LLL (Primary Endpoint)

- **PACCOCATH**
  - PTX 3µgr/mm² + Ultravist
  - p<0.001

- **LUTONIX**
  - PTX 2µgr/mm² + Polysorbate & Sorbitol
  - p=0.031

- **LUTONIX**
  - PTX 2µgr/mm² + Polysorbate & Sorbitol
  - p=0.016

- **IN.PACT**
  - PTX 3µgr/mm² + Urea
  - p=0.001

- **PASSEO 18 LUX**
  - PTX 3µgr/mm² + BTHC
  - p=0.033

- **ADVANCE PTX**
  - PTX 3µgr/mm² NO Excipient
  - p=0.12

- **CVI**
  - PTX/Excipient (?)
  - p=NS

- **DEL in SFA**
  - Evidence
  - Proof-of-Concept

Long-term Outcome of DCB in TASC A & B lesions

Significant and sustained TLR reduction up to 5 years

THUNDER:
Freedom from CD-TLR through 5 Years

IN.PACT SFA Trial:
Freedom from CD-TLR through 5 Years

Tepe G et al. JACC CI 2015;8:102-108
Laird J. VIVA 2018.
REAL PTX: Primary Patency @ 36 months
Stratification for lesion length - ITT

Short lesions (1 to 10 cm)

Follow up @ 1 years
KM estimates ±SE
ZilverPTX 0.90±0.07
DCB 0.91±0.06

Follow up @ 2 years
KM estimates ±SE
ZilverPTX 0.84±0.09
DCB 0.81±0.09

Follow up @ 3 years
KM estimates ±SE
ZilverPTX 0.77±0.09
DCB 0.64±0.11

+ Censored
Logrank p=0.4524

Bausback Y et al JACC 2018
DCB vs DES 5-year Freedom from TLR

IN.PACT SFA Trial:
Freedom from CD-TLR through 5 Years

5-year Freedom from TLR
Zilver® PTX® vs Standard Care

Laird J. VIVA 2018.

Effectiveness Primary Patency at 12 Months

Kaplan-Meier Analysis of Primary Patency

Cumulative Event-Free (%)

Log-rank p=0.0119

Months Since Procedure

Error bars are 95% CI.

Primary patency defined as duplex ultrasound PSVR ≤2.4, in the absence of clinically-driven target lesion revascularization or bypass of the target lesion, as assessed by the DUS core lab.

Eluvia 88.5%
Zilver PTX 79.5%
SUPERB
3-Year Outcomes Stratified to Deployment Technique

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

Freedom from TLR (K-M) by Percent Compression / Elongation at 12, 24, and 36 months

- Moderate (21-40%): n=6
- Minimal (11-20%): n=22
- Nominal (± 10%): n=74
- Minimal (11-20%): n=38
- Moderate (21-40%): n=39
- Severe (>40%): n=26

Clinical data on file at Abbott Vascular.
TASC A Lesions

**Directional Atherectomy vs. BMS vs. POBA**

De novo lesions, 4.5cm length

- Zeller et al. JACC 2006;48:1573-1578

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![Bar chart showing 1-yr patency for Silverhawk, POBA, and stent.](image)
DEFINITIVE LE

Primary Patency by Lesion Length

Mean length:
- < 4 cm: 2.2 cm
- 4-9.9 cm: 6.5 cm
- ≥ 10 cm: 14.4 cm

Number of lesions:
- < 4 cm: 220
- 4-9.9 cm: 307
- ≥ 10 cm: 214

Patency:
- < 4 cm: 81%
- 4-9.9 cm: 83%
- ≥ 10 cm: 67%
Predilatation of the SFA lesion with an undersized balloon

(Usual treatment path before DCB)

- In case of severe dissection / recoil
  - DES
  - Directional Atherectomy & DCB?

- Good result
  - DCB according to the RVD + 1 mm
  - Additional BMS on indication
Shockwave Peripheral Intravascular Lithotripsy (IVL) System

Generator

Connector Cable

Lithoplasty Catheter
DISRUPT PAD Effectiveness*

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

**% Stenosis**

- Pre-Proc: 23.8%
- Post-Proc: 77.8%

**Patency**

<table>
<thead>
<tr>
<th>TLR</th>
<th>30 days</th>
<th>6 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.0%</td>
<td>3.2%</td>
</tr>
</tbody>
</table>

*By angiographic and DUS core labs

Brodmann M et al. CCI 2018
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>
<th>50% Primary Performance</th>
<th>30% Exploratory Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Subjects</td>
<td>77.8</td>
<td>75.6</td>
<td>50% Primary Performance</td>
<td>30% Exploratory Performance</td>
</tr>
<tr>
<td>SFA</td>
<td>80.8</td>
<td>75.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Popliteal</td>
<td>73.5</td>
<td>75.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate Ca</td>
<td>22.1</td>
<td>22.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe Ca</td>
<td>25.0</td>
<td>25.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion &lt;5 cm</td>
<td>22.1</td>
<td>22.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion 5–10 cm</td>
<td>23.1</td>
<td>23.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion &gt;10 cm</td>
<td>27.5</td>
<td>27.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concentric</td>
<td>79.5</td>
<td>69.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eccentric</td>
<td>77.3</td>
<td>82.4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lesion Length</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;5 cm</td>
<td>95</td>
</tr>
<tr>
<td>5–10 cm</td>
<td>70</td>
</tr>
<tr>
<td>&gt;10 cm</td>
<td>24</td>
</tr>
<tr>
<td>All Subjects</td>
<td>42</td>
</tr>
</tbody>
</table>

Brodmann M et al. CCI 2018
Data on file at Abbott Vascular.

**Supera Has Strong Clinical Outcomes in Calcification**

**SUPERB Data - Severe Calcification**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patency (VIVA 12 months)</td>
<td>88.9%</td>
</tr>
<tr>
<td>Freedom from TLR at 1 year (K-M)</td>
<td>94.5%</td>
</tr>
<tr>
<td>Freedom from TLR at 2 years (K-M)</td>
<td>91.6%</td>
</tr>
</tbody>
</table>

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

Femoropopliteal Lesions (severe calcium)

Predilatation of the SFA lesion with a vessel prep device
(Lithotrypsy, cutting balloon, flex catheter)

- In case of suboptimal result
  - DES or Supera
  - Atherectomy & DCB

- Good result
  - DCB according to the RVD + 1 mm
  - Dedicated calcium stent on indication
Chronic Femoro-Popliteal TASC II C&D lesions
IN.PACT Global Long Lesion Imaging Cohort: Kaplan-Meier Estimate of Primary Patency

Provisional Stent
- LL 15-25 cm: 33.3% (33/99)
- LL > 25 cm: 52.6% (30/57)

Lesion Length: 26.40 ± 8.61 cm
# BMS & DES - Published Results in SFA/Pop TASC C& D Lesions

<table>
<thead>
<tr>
<th>Study/Device</th>
<th>Number of Patients</th>
<th>Mean Lesion Length</th>
<th>12 Month Primary Patency</th>
<th>12 Month Stent Fracture</th>
</tr>
</thead>
<tbody>
<tr>
<td>DURABILITY-200(^1) Protégé Everflex</td>
<td>100</td>
<td>242 mm</td>
<td>64.8%</td>
<td>6.0%</td>
</tr>
<tr>
<td>STELLA Registry(^2) LifeStent</td>
<td>58</td>
<td>220 mm</td>
<td>66.0%</td>
<td>17.7%</td>
</tr>
<tr>
<td>Zilver PTX Global Registry Zilver PTX(^3)</td>
<td>135</td>
<td>226 mm</td>
<td>77.6%</td>
<td>2.1%</td>
</tr>
<tr>
<td>STELLA PTX Zilver PTX(^4)</td>
<td>45</td>
<td>252 mm</td>
<td>52.5%</td>
<td>9.0%</td>
</tr>
<tr>
<td>Viabahn TASC C&amp;D Viabahn(^5)</td>
<td>71</td>
<td>265 mm</td>
<td>67.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>SUPERB 500 Supera(^6)</td>
<td>172</td>
<td>223 mm</td>
<td>80.5%</td>
<td>0.0%</td>
</tr>
<tr>
<td>St. Louis University Supera(^7)</td>
<td>42</td>
<td>279 mm</td>
<td>80.1%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>


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.
IN.PACT vs DES in Long SFA Lesions

228-Patients Retrospective, Propensity score analysis

- Non significant difference between IN.PACT DCB and Zilver PTX in long SFA lesions
- Provisional stent rate post DCB = 18.3%

Lesions ~19 cm

Zeller T. et al. JEVT 2014
REAL PTX RCT
Primary Patency @ 36 months - ITT in middle and long lesions >10cm to 30cm

Follow up @ 1 year 2 years 3 years
KM estimates ±SE
ZilverPTX 0.74±0.07 0.56±0.08 0.45±0.08
DCB 0.74±0.06 0.49±0.08 0.26±0.07

Days
No@Risk ZilverPTX 44 34 27 16
DCB 46 36 21 10
REAL PTX RCT
Primary Patency @ 36 months – Zilver PTX vs DCB only in middle and long lesions >10cm to 30cm

Follow up @

<table>
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<th>KM estimates ±SE</th>
<th>ZilverPTX</th>
<th>1 year</th>
<th>2 years</th>
<th>3 years</th>
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<tr>
<td>ZilverPTX</td>
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<td>0.56±0.08</td>
<td>0.45±0.08</td>
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</tr>
<tr>
<td>DCB only</td>
<td>0.75±0.08</td>
<td>0.32±0.09</td>
<td>0.21±0.09</td>
<td></td>
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Days

<table>
<thead>
<tr>
<th>Days</th>
<th>150</th>
<th>320</th>
<th>670</th>
<th>1035</th>
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<tr>
<td>No@Risk</td>
<td>ZilverPTX</td>
<td>44</td>
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TASC II C&D SFA Lesions

*Viabahn*

- Achilles' heel of SFA stenting: Neo-intimal hyperplasia
Primary patency rate >20 cm vs. ≤20 cm lesion length

P=0.01

P=0.057
25cm Viabahn
12M Data – Primary Patency & Freedom from TLR

Mean lesion length 26.5cm
Total occlusions 93%

67%

78.2%
Treatment Algorithm in TASC C & D Femoropopliteal Lesions (not severely calcified)

Predilatation of the SFA-lesion with a standard balloon

(Usual treatment-path before DCB)

In case of severe dissection / recoil

DES / Supera / Viabahn

Good result

DCB according to the RVD + 1mm

? Atherectomy & DCB ?

? DES & DCB ?

BMS / Tack on indication
Treatment Algorithm in TASC C & D Femoropopliteal Lesions (severely calcified)

Predilatation of the SFA-lesion with a dedicated vessel prep device (lithotripsy, flex catheter)

- In case of severe dissection / recoil
  - Aggressive dilatation (non-compliant balloon & Supera (& Viabahn?))

- Good result
  - DES or Supera

- ? Atherectomy & DCB ?
- ? DES ?
Leaving Nothing Behind
Proposed Fem-pop treatment algorithm including “spot atherectomy”

1. **TASC A – D lesions**
   - Pre-dilatation with 1:1 sized balloon or plaque modulation device
     - Flow-limiting dissection or residual stenosis >50%?
       - Yes: **Directional Atherectomy**
       - No: **DCB**

2. Flow-limiting dissection or residual stenosis >50%?
   - Yes: **YES**
   - No: **BMS**
Instant Restenosis

- Stent-struts
- Neointimal hyperplasia
DEB in SFA In-Stent Restenosis

**IN.PACT ISR**
(E.Stabile et al. JACC 2012)

- **39-Patient Registry**
- **92.2% Primary Patency**
- **92.2% freedom from TLR**

**DEBATE ISR**
(F.Liistro et al. JEVT 2014)

- **44-Patient Registry vs. historical PTA cohort**
- **Restenosis**
  - **19.5% (DEB) vs. 71.8% (PTA)**
  - **(p<0.001)**

**FAIR**
(H.Krankenberg LINC 2014)

- **119-Patient RCT**
- **Freedom from TLR:**
  - **90.8% (DEB) vs. 52.6% (PTA)**
  - **(p=0.0001)**

**12-month TLR and restenosis**

- **ISR length: 8.2 cm**
- **ISR length: 13.2 cm**
- **ISR length: 8.3 cm**
- **12-month freedom from TLR**

**Patient Registry**

**12-month freedom from TLR**

**T-Statistics**

- **p=0.046**
- **p<0.001**
- **p=0.001**
ISR and DEB

- At 3 year follow-up complete catch-up
- No difference between DEB and POBA
Treatment of Femoropopliteal In-Stent Restenosis With Paclitaxel-Eluting Stents

Thomas Zeller, MD,* Michael D. Dake, MD,† Gunnar Tepe, MD,‡ Klaus Brechtel, MD,‡ Elias Noory, MD,* Ulrich Beschorner, MD,* Patricia L. Kultgen, PhD,§ Aljoscha Rastan, MD*

Bad Krozingen and Rosenheim, Germany; Stanford, California; and West Lafayette, Indiana

Zilver PTX*
No in-stent restenosis

Zilver PTX*
In-stent restenosis
Treatment Algorithm in ISR Femoropopliteal Lesions

- Occlusion
  - Mechanical Thrombectomy or Atherectomy
  - DCB according to stent diameter & provisional stenting (double dose?)
    - Second Choice: DES or Viabahn

- Stenosis
Subacute Occlusions (potentially thrombotic)
Acute & Subacute SFA-Occlusions
Mechanical Thrombectomy & Rotational Aspiration
Atherectomy
Treatment Algorithm in Thrombotic Femoro-Popliteal Lesions

1\textsuperscript{st} choice: Mechanical Thrombectomy
2\textsuperscript{nd} choice: Rotational Aspiration Atherectomy / Laser

In case of residual thrombus:
- Local lysis
- DCB

Good result:
- DCB according to RVD + 1mm
- Additional BMS if necessary
Step by step SFA/pop treatment algorithm