Why DCBs should be first line therapy for most femoropopliteal lesions

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- **Honoraria received from:** Abbott Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Philips-Spectranetics, TriReme, Veryan, Shockwave, Biotronik, B. Braun
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- **Common stock:** QT Medical
DCB FIH/Proof of Concept Evidence

DCB 5-year Freedom from TLR

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

Log-rank $P = 0.0196$

Number at risk:
- IN.PACT DCB: 220, 198, 173, 149, 121, 58
- Standard PTA: 111, 88, 77, 72, 67, 22

Time After Index Procedure (Months)

Laird J. VIVA 2018.

ACOART I Trial
Kaplan-Meier Freedom From TLR

$\Delta 18.4\%$

Scheinert D, LINC NY June 2019
DCB vs DES 5-Year Freedom from TLR

ACOART I Trial

Kaplan-Meier Freedom From TLR

Scheinert D, LINC NY June 2019

Zilver PTX vs Standard Care

Log-rank p < 0.01

Dake M. VIVA 2015

83.1%  Δ18.4% 67.6%  Δ15.5%
IN.PACT SFA RCT 5-Year Follow-up

IN.PACT SFA Trial Through the Years

CD-TLR Rates

4. Schneider P. VIVA 2017
IN.PACT Global Study: Full Clinical Cohort
4-Year Effectiveness Outcomes

Freedom from CD-TLR through 4 Years

3-Yr. FF CD-TLR = 76.9\%^{1}
4-Yr. FF CD-TLR = 73.4\%^{2} \Delta 3.5\%

1. G. Tepe IN.PACT Global 3-year Results CIRSE 2019
2. Zeller T IN.PACT Global 4-year Results VIVA 2019
IN.PACT Global Study: Clinical Cohort
Claudicant vs CLI: Reintervention

Freedom from CD-TLR through 4 Years

Log-rank p-value = 0.005

Time After Index Procedure (Months)

Number at risk:
- 1246 RCC 2/3
- 1095 RCC 4/5
- 923
- 793
- 691
- 156
- 116
- 91
- 71
- 54

Freedom from CD-TLR:
- 100%
- 90%
- 80%
- 70%
- 60%
- 50%
- 40%
- 30%
- 20%
- 10%
- 0%
# DCB “Real-World” Registries

## Follow-up
- Global: 691 subjects
  - Complete follow-up: 107 & 102 subjects for safety & effectiveness, respectively; Core lab-adjudicated
- Long Lesion: 157 subjects
  - Complete follow-up; Core lab-adjudicated
- CTO: 126 subjects
  - Complete follow-up; Core lab-adjudicated
- ISR: 131 subjects
  - Complete follow-up; Core lab-adjudicated
- Clinical: 1406 subjects
  - Complete follow-up; Core lab-adjudicated
- ILLUMENATE Global: 371 subjects
  - Complete follow-up; Core lab-adjudicated

## 12-mo Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Global</th>
<th>Long Lesion</th>
<th>CTO</th>
<th>ISR</th>
<th>Clinical</th>
<th>ILLUMENATE Global</th>
</tr>
</thead>
<tbody>
<tr>
<td>1° Patency (%)</td>
<td>NR</td>
<td>68.9%</td>
<td>91.1%</td>
<td>85.3%</td>
<td>88.7%</td>
<td>NR</td>
</tr>
<tr>
<td>FF TLR/CD-TLR (%)</td>
<td>94.3%</td>
<td>87.8%</td>
<td>94.0%</td>
<td>89.1%</td>
<td>92.9%</td>
<td>92.6%</td>
</tr>
<tr>
<td>Bail-out Stent (%)</td>
<td>25.2%</td>
<td>39.8%</td>
<td>40.4%</td>
<td>46.8%</td>
<td>14.5%</td>
<td>25.3%</td>
</tr>
<tr>
<td>Amputations (%)</td>
<td>0.5% (3/632)</td>
<td>NR</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.2% (3/1311)</td>
<td>0.3% (1/371)</td>
</tr>
</tbody>
</table>

## Key Lesion Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Global</th>
<th>Long Lesion</th>
<th>CTO</th>
<th>ISR</th>
<th>Clinical</th>
<th>ILLUMENATE Global</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length (cm)</td>
<td>10.1cm</td>
<td>21.3cm</td>
<td>26.4cm</td>
<td>22.9cm</td>
<td>17.2cm</td>
<td>12.1cm</td>
</tr>
<tr>
<td>CTO (%)</td>
<td>31.2%</td>
<td>52.1%</td>
<td>60.4%</td>
<td>100.0%</td>
<td>34.0%</td>
<td>35.5%</td>
</tr>
<tr>
<td>Ca²⁺ (%)</td>
<td>50.2%</td>
<td>78.9%²</td>
<td>71.8%</td>
<td>71.0%</td>
<td>59.1%</td>
<td>68.7%</td>
</tr>
</tbody>
</table>

2. Bard Lutonix Instructions for Use BAW1387400r3, Section 10.5. Moderate to severe calcification reported; amputations not reported (NR).
IN.PACT Global Study
Stented vs Non-Stented Analysis

Freedom from CD-TLR Through 2 Years

Number at risk represents the number of evaluable subjects at the beginning of each 60-day window.

Log-rank $P = 0.2063$

- Stented: 92.9%
- Non-Stented: 83.9%

<table>
<thead>
<tr>
<th>Time after Index Procedure (Months)</th>
<th>0</th>
<th>6</th>
<th>12</th>
<th>18</th>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stented</td>
<td>353</td>
<td>332</td>
<td>309</td>
<td>246</td>
<td></td>
</tr>
<tr>
<td>Non-Stented</td>
<td>1044</td>
<td>988</td>
<td>914</td>
<td>742</td>
<td></td>
</tr>
</tbody>
</table>

1. Zeller T. Charing Cross 2018
Primary Patency @ 36 months

ZilverPTX vs DCB only vs DCB plus Stent

Survival Probability

Follow up @ 1 year 2 years 3 years
KM estimates ±SE ZilverPTX 0.79±0.05 0.65±0.06 0.54±0.07
DCB only 0.82±0.05 0.52±0.08 0.40±0.08
DCB/Stent 0.74±0.10 0.67±0.11 0.34±0.12

Days
150 320 670 1035

No@Risk
ZilverPTX 69 53 42 27
DCB only 51 42 27 16
DCB/Stent 18 13 11 6

Logrank p=0.3644
Conclusions

- In RCT DCB demonstrated sustained benefit over POBA up to 5 years in TASC A & B lesions
- In more challenging TASC C & D lesions DCB
  - have shown promising results in real world registries up to 4 year follow independent of plain DCB angioplasty or provisional stent placement
  - In a RCT not sufficiently powered (REAL PTX) longer lesions showed a trend towards favorable outcomes for a DES full metal jacket
- Nevertheless, minimizing stent length by provisional stent placement following DCB preserves further treatment options
- Alternatively spot atherectomy of lesions areas not responsive to predilatation may further reduce the need for provisional stent placement
Treatment Algorithm in TASC A & B Femoropopliteal Lesions
(no to moderate calcium)

Predilatation of the SFA-lesion with a 1:1 sized balloon
(Usual treatment path before DCB)

- In case of severe dissection / recoil
  - DES or Supera

- Good result
  - DCB according to the RVD + 1 mm
  - Additional BMS on indication
Treatment Algorithm in TASC A & B Femoropopliteal Lesions (severe calcium)

Predilatation of the SFA-lesion with lithotripsy
(Usual treatment path before DCB)

In case of suboptimal result

DES or Supera

Good result

DCB according to the RVD + 1 mm

Dedicated calcium stent on indication
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 + 1 mm

Additional BMS on indication
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