Are Long Stents Still the First Choice in Long SFA CTO?

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Disclosures

• Consultant / Speaker / Proctor / Advisory Board

  – Bayer
  – Bolton
  – Boston Scientific
  – Cook
  – CR Bard

  – Medtronic
  – Shockwave Medical
  – Philips
  – W.L. Gore & Associates
72y, Female
Heavy smoker
Diabetic
Hypertension

Bilateral claudication <50 mt
  Rt > Lt

Worsening of the symptoms in the last 6 mos

ABI: Rt 0.5
  Lt 0.7

Medical therapy:
  - Statins 40 mg/d
  - Oral hypoglycemic drug
  - Aspirin
72y, Female
Heavy smoker
Diabetic
Hypertension

Bilateral claudication <50 mt
    Rt > Lt

Worsening of the symptoms in the last 6 mos

ABI: Rt 0.5
    Lt 0.7

**USCD**: occlusion of the Rt SFA
    occlusion of the Lt SFA

**CTA**
Retrograde Lt CFA access
US guidance

Cross-over

- 6 Fr / 45 cm Destination  
  (Terumo)
- 0.035» hydrophilic GW  
  (Terumo)
- 4Fr / 65 cm RIM catheter  
  (Cordis)

**TASC D: >20 CM**

**Calcium grade: 2A (180° / <3cm)**
- 4Fr CXI support catheter (Cook)
- 0.035» hydrophilic GW (Terumo)

Pre–dilatation
Admiral
Ø 4 mm (Medtronic)
Pre-dilatation
Admiral
Ø 4 mm
(Medtronic)
In.Pact Admiral
Ø 5 mm
(Medtronic)

Inflation Time: 3 min
DCB in Long Lesions

6 trials with fem-pop lesions > 20 cm
- 3 DCB (In.Pact) trials (2 with independent corelab adj.)
- 3 BMS trials

![Baseline characteristics chart]

1. D. Scheinert - Drug Coated Balloon Treatment for Patients with Intermittent Claudication: New Insights from the IN.PACT Global Study Long Lesion (≥ 15 cm) Imaging Cohort. Oral presentation EuroPCR 2015
What about Long Lesions?

Long lesions may trigger higher (10~40%) provisional stent rates, however a DCB + prov. Stent strategy does better than 100% elective (long) stenting

1 year Primary Patency (by Kaplan Meier)

1. D. Scheinert - Drug Coated Balloon Treatment for Patients with Intermittent Claudication: New Insights from the IN.PACT Global Study Long Lesion (≥ 15 cm) Imaging Cohort. Oral presentation EuroPCR 2015
Investigator initiated, multicenter prospective, single-arm study
Indipendent Clinical Events Committee

- \( N = 105 \)
- Rutherford 2 to 4
- RVD: 4 – 7 mm
- Stenosis or occlusion \( \geq 150 \) mm
- Multiple lesions with <3cm distance
- 1 patent crural vessel
• **Treated lesion length = 251±71 mm**
  - **Pre.dilatation:** uncoated balloon; 0.5-1 mm undersized; inflation time 2 min
  - **DCB:** In.Pact Admiral (Medtronic) 1:1 RVD; inflation time 3 min; 3-12 atm
  - **Post-dilatation:** uncoated balloon >3min or spot stenting (persistent stenosis >50% or dissection)

• **Post-dilatation: 49.6%**

• **Stent rate: 10.9%**
  
  flow limiting dissection: 6.7%
  persistent stenosis: 8.6%
In.Pact SFA Long: 2-year Primary Patency

Lesion length: 251.71 ± 78.9 mm
IN.PACT Global (LL&CTO) + Severe Calcium

<table>
<thead>
<tr>
<th>IN.PACT Global IMG Cohorts</th>
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<tbody>
<tr>
<td>N=72 Subjects</td>
</tr>
<tr>
<td>N=81 Lesions</td>
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<table>
<thead>
<tr>
<th>Lesion Type: % (n)</th>
<th>81.5% (66/81)</th>
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<tbody>
<tr>
<td>De novo</td>
<td>18.5% (15/81)</td>
</tr>
<tr>
<td>Restenotic (non-stented)</td>
<td></td>
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| Lesion Length (cm ± SD)       | 24.73 ± 10.82   |

| Total Occlusions % (n)        | 60.3% (47/78)   |

<table>
<thead>
<tr>
<th>Calcification¹ % (n)</th>
<th>100% (78/78)</th>
</tr>
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<tr>
<td>Severe Grade 4 % (n)</td>
<td>56.4% (44/78)</td>
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<thead>
<tr>
<th>TASC A-B % (n)</th>
<th>24.7% (19/77)</th>
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<tbody>
<tr>
<td>TASC C-D % (n)</td>
<td>75.3% (58/77)</td>
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| RVD (mm ± SD)                | 5.180 ± 0.600   |

| Diameter Stenosis (% ± SD)   | 90.9 ± 15.0     |

<table>
<thead>
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<th>Dissections after pre-dil:</th>
</tr>
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<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>A-C</td>
</tr>
<tr>
<td>D-F</td>
</tr>
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</table>

1. Calcium definition used by both the study sites and core laboratory
1. Freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR ≤2.4) and clinically-driven target lesion revascularization through 12 months (adjudicated by a Clinical Events Committee blinded to the assigned treatment)
2. Number at risk represents the number of evaluable subjects at the beginning of the each 30-day window
Drug-Coated Balloons vs. Drug-Eluting Stents for Treatment of Long Femoropopliteal Lesions

Thomas Zeller, MD¹; Aljoscha Rastan, MD¹; Roland Macharzina, MD¹; Gunnar Tepe, MD²; Matthias Kaspar, MD¹; Jorge Chavarria, MD¹; Ulrich Beschoner, MD¹; Uwe Schwarzwalder, MD¹; Thomas Schwarz, MD¹; and Elias Noory, MD¹

Retrospective dual center study

228 patients  DCB: 131  DES: 97  (after propensity score stratification)

Lesion length (mm)

DCB: 194.46±86.3 [100–450]

DES: 195.06±64.5 [100–350]  p=0.948
“The 1-year outcome of DCB and DES angioplasty in long femoropopliteal lesions compares well with currently published outcomes for the bypass surgery gold standard treatment of these challenging lesions. Due to its ease of use and no scaffold left behind, DCB angioplasty with or without provisional bare nitinol spot stenting might be preferred over DES implantation.”
Pressure Gradient >30 mmHg
Admiral 5x40 mm
(Medtronic)
Inflation time: 3 min
Admiral 5x40 mm (Medtronic)

Inflation time: 3 min
## Optimal PTA

**Effect of Short vs Long Balloon Inflation Times on the Morphologic Results¹**

<table>
<thead>
<tr>
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<th>Inflation Time (sec)</th>
<th></th>
<th>P-Value</th>
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<tbody>
<tr>
<td></td>
<td>30</td>
<td>180</td>
<td></td>
</tr>
<tr>
<td>Major dissection (grades 3 or 4)</td>
<td>16</td>
<td>5</td>
<td>.010</td>
</tr>
<tr>
<td>Minor or no dissection (grades 1 and 2)</td>
<td>21</td>
<td>32</td>
<td>.010</td>
</tr>
<tr>
<td>Further interventions (Stent, repeat dilatation, dilation with larger diameter)</td>
<td>20</td>
<td>9</td>
<td>.017</td>
</tr>
<tr>
<td>Residual stenosis (&gt;30%)</td>
<td>12</td>
<td>5</td>
<td>.097</td>
</tr>
<tr>
<td>Complication (embolization, thrombosis)</td>
<td>1</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Mean ankle-brachial index (before, after intervention)</td>
<td>0.66, 0.87</td>
<td>0.65, 0.84</td>
<td></td>
</tr>
</tbody>
</table>

- Inflation times of 180 seconds improve immediate infrainguinal PTA results vs. a short dilation strategy
- Significantly fewer major dissections and a modest reduction of residual stenoses are observed
- Significantly fewer continued interventions

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Admiral 6x40 mm (Medtronic)

Inflation time 5 min
Post – treatment therapy:

- Clopidroglrel 65mg/die 4 weeks
- Aspirin

Clinical evaluation:

Lt claudication <50 mt
Recanalization Lt SFA 4 weeks later

2-y F.U.
ABI Rt: 0.85      Lt 0.85
2 y F.U.
Conclusions

- DCB shows excellent results in the fem-pop region when compare to standard PTA
- Continuous development in drug eluting devices
- DCB appears to be the new standard for femoral-popliteal intervention
- Level 1 Evidence support the role of DCBs as frontline therapy for fem-pop disease
- Overarching principle = DCB with “intention not to stent”
- Vessel preparation in complex lesions mandatory for both DCB and DES
- DCB command re-learning of PTA, call for more patience, longer time and high attention in interpreting final results. Not as easy and quick as a stent