Present Role of DCBs and DESs for SFA Lesions: Updated Treatment Algorithm and How to Deal with Severe Calcifications

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SFA Treatment is a Diverse Field

Examples of Core Lab-adjudicated 12-month patency results demonstrate a range of performance within classes of therapies.

- PTA: 32.8 – 61.4%
- DCB: 73.5 – 91.1%
- Atherectomy: 54.3 – 78.0%
- Stent: 55.1 – 90.9%
- Stent-Graft: 63.0 – 92.9%
- DES: 53.0 – 70.9%

Core Lab-Adjudicated 12-month Patency Rates

Calcium and DCB

Evidence (in-vivo and ex-vivo) indicates Calcium as potential barrier to optimal drug absorption. Circumferential Calcium strongest contributor

- Post-hoc analysis of a large patient dataset (N=571) treated with Stellarex DCB
- Pooled analysis from 2 prospective studies:
  - ILLUMENATE GLOBAL single-arm, full cohort (N=371) [1]
  - ILLUMENATE PIVOTAL randomized trial, DCB arm (N=200) [2]


Impact of Severe Calcification on Procedural Characteristics and 12-month Outcomes Following Femoropopliteal Treatment with the Stellarex Drug-Coated Balloon

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Disclosures

- Consultant / Speaker / Proctor / Advisory Board
  - Bayer
  - Bolton
  - Boston Scientific
  - Cook
  - Medtronic
  - Shockwave Medical
  - Philips
  - W.L. Gore & Associates

Patency rates are presented for demonstration purposes only; values reflect different patency definitions, reporting methods, follow-up intervals, and patient and lesion characteristics. Lesion lengths (cm) are also presented. Please see References slide for list of citations.


- 41.8% of Ca++ meeting the PACS Grade 4 definition, bilateral calcification extending ≥5cm [1]
### Procedural Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Non-Severely Calcified (N=314)</th>
<th>Severely Calcified (N=242)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Dilatation</td>
<td>98.9%</td>
<td>98.8%</td>
<td>1</td>
</tr>
<tr>
<td>Pre-Dilatation Max Pressure (atm/lesion)</td>
<td>8.8</td>
<td>9.5</td>
<td>0.005</td>
</tr>
<tr>
<td>Total Inflation Time (min/lesion)</td>
<td>3.4</td>
<td>3.9</td>
<td>0.002</td>
</tr>
<tr>
<td>Dissection Grade &gt; C</td>
<td>20.4%</td>
<td>19.9%</td>
<td>0.895</td>
</tr>
<tr>
<td>Post-Dilatation</td>
<td>25.0%</td>
<td>23.9%</td>
<td>0.758</td>
</tr>
<tr>
<td>Post-Procedure DS (%)</td>
<td>23.9%</td>
<td>26.4%</td>
<td>0.068</td>
</tr>
<tr>
<td>Bailout Stent (per lesion)</td>
<td>13.3%</td>
<td>12.7%</td>
<td>0.787</td>
</tr>
</tbody>
</table>

### 12-month Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Non-Severely Calcified</th>
<th>Severely Calcified</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from Primary Safety Event(^1)</td>
<td>93.0%</td>
<td>93.0%</td>
<td>0.996</td>
</tr>
<tr>
<td>12 Month Major Adverse Event(^2)</td>
<td>7.3%</td>
<td>7.8%</td>
<td>0.634</td>
</tr>
<tr>
<td>Clinically-Driven TLR</td>
<td>7.0%</td>
<td>7.0%</td>
<td>0.996</td>
</tr>
<tr>
<td>All TLR</td>
<td>8.0%</td>
<td>8.3%</td>
<td>0.893</td>
</tr>
</tbody>
</table>

\(^1\) Defined as the composite of freedom from device and procedure-related death through 30 days post-procedure and freedom from target lesion revascularization through 12 months post-procedure.

\(^2\) Defined as cardiovascular death, target vessel revascularization, or clinically-driven target lesion revascularization (CD-TLR).

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### 12-month Primary Patency

- **Severely Calcified**: 80.0%
- **Non-Severely Calcified**: 82.9%

Per KM estimate at day 365.

### IN.PACT Global (LL&CTO) + Severe Calcium

#### Definition of Calcium\(^1,2\)

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 each 30-day window.

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### Stent in Calcified Lesions

- In very calcified SFA lesions consider primary stenting as a first line therapy.
- Eccentric calcifications can lead to stent deformation, especially with self-expanding stent.
- High risk of stent fracture / stent collapse.

No specific data on DES in calcified lesions.
Correct choice of stent design can minimize struts stress while maintaining a patent lumen.

### Calcified vs. Non-Calcified Lesions
Traditional Laser Cut Nitinol Stent

<table>
<thead>
<tr>
<th></th>
<th>Calcified lesions</th>
<th>Non-calcified lesions</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLDmax (mm)</td>
<td>4.1 ± 0.7</td>
<td>4.0 ± 0.4</td>
<td>0.62</td>
</tr>
<tr>
<td>%DSmax</td>
<td>30 ± 1.8</td>
<td>18 ± 1.4</td>
<td>0.0007</td>
</tr>
<tr>
<td>MLDmin (mm)</td>
<td>3.8 ± 0.7</td>
<td>4.8 ± 0.3</td>
<td>0.01</td>
</tr>
<tr>
<td>%DSmin</td>
<td>32 ± 1.11</td>
<td>17 ± 2.4</td>
<td>0.01</td>
</tr>
<tr>
<td>Procedural Success</td>
<td>80% (33)</td>
<td>0% (0)</td>
<td>0.001</td>
</tr>
<tr>
<td>%Distal Patent Lumen &gt;30</td>
<td>0% (0)</td>
<td>0% (0)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

ESD = diameter stenosis, MLD.ACA = minimal lumen area cross-sectional area, MLD = minimal lumen diameter

### Majestic DES Trial

**Subgroup Analysis – 24 Months**

**Severe Calcification, Occlusion, Diabetes**

24-Month Freedom from TLR

- Low reintervention rates among patients with challenging medical and lesion characteristics at baseline.

66 y, Female
Diabetic, heavy smoker - Lt claudication <50 m

**ABI 0.5**

**Grade 4**

**Advance Enforcer 35**
6 x 40 mm
(Cook)

**Zilver PTX**
6 x 120 mm
(Cook)

**Impact of Calcification on Clinical Outcomes After Endovascular Therapy for Superficial Femoral Artery Disease: Assessment Using the Peripheral Artery Calcification Scoring System**

Shota Okano, MD1, Osamu Ishii, MD1, Tatsumi Shinkai, MD1, Masashi Fujita, PhD1, Masaharu Matsuda, MD1, Shin Osumoto, MD1, Takayuki Ishikura, MD1, Kenjiro Niku, MD1, Takashi Kanda, MD1, Hisayoshi Takahara, PhD1, and Masanori Uematsu, PhD1

- Retrospective analysis
- 394 consecutive patients
- Intermittent claudication
- de novo SFA lesions [length 152.1±96.7 mm; 199 (50%) TASC II class C/D

**TASC II class C/D**

- ABI 0.5
- Grade 4
Conclusions

- Calcium limits optimal dilatation and optimal drug absorption.
- Circumferential distribution and bilateral distribution of calcium represent the main barriers for drug uptake.
- In spite of a still notable DCB biologic effect, calcium represents a barrier to optimal drug absorption.
- No specific data are available to evaluate the efficacy of DES in calcified lesions.
- However, also DES seems to be affected by severely calcified lesions.
- The only comparative study available showed an increased benefit of DES in comparison to DCB in longer SFA lesions.
- In heavy calcified lesions, proper lesion preparation, can increase the patency rate not only of DCB but also of DES.

ABI: 0.9

Zilver PTX 6 x 120 mm Cook

3 y F.U.

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