Drug Eluting Stents (Zilver® and Eluvia®) Are Changing The Paradigm For Treating Long Complex SFA/Pop Lesions: The Trials And Registries Show Why

Prof. I. Baumgartner, Head Clinical & Interventional Angiology

Conflict of Interest
Educational and Research Grants: Cook, Boston Scientific, Amgen, Terumo, Abbott, Medtronic

Endovascular Treatment for Femoropopliteal PAD

DES & DCB technology improved patency and reintervention rate vs older endovascular therapy

Calcium associated with DCB efficacy

- 60 patients with SFA stenosis or occlusion treated with DCB
- CTA, DSA, and IVUS used to quantify the calcium burden
- At 1 year, greater calcification was associated with:
  - lower patency
  - lower ABI
  - greater LLL and TLR rate

Stents used in DCB studies

- Stents are utilized in DCB studies
- Longer mean lesion length correlated with higher provisional BMS stenting rate

Grants used in DCB studies


Future Studies are needed to further confirm these findings.

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IN.PACT Global (SFA DCB) Long Lesion Imaging Cohort: Lesion/Procedural Characteristics

Device Success

Procedure Success

Clinical Success

Pre-dilatation

Post-dilatation

Lesion Type: de novo restenotic (no ISR)

ISR

0.0% (0/161)

83.2% (134/161)

16.8% (27/161)

0.0% (0/161)

Lesion Length: 26.40 ± 8.61 cm

Total Occlusions: 60.4% (99/164)

Calcification: Severe: 71.8% (117/163)

RVD (mm): 4.59 ± 0.81

Diameter Stenosis (pre-treatment): 90.9% ± 14.2

Dissections: 0 37.9% (61/161) A-C 47.2% (76/161) D-F 14.9% (24/161)

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Calcification: High: 71.8% (117/163)

Calcification: Low: 28.2% (46/163)

1. Device success: successful delivery, inflation, deflation and retrieval of the intact study balloon without burst below the RBP
2. Procedure success: residual stenosis of ≤ 50% (non-stented subjects) or ≤ 30% (stented subjects) by core lab (if core lab was not available then the site reported estimate was used)
3. Clinical success: procedural success without procedural complications (death, major target lesion occlusion, TVR prior to discharge)

Given the provisional BMS use in complex SFA lesion morphologies, should primary DES deployment be considered the primary ‘de facto’ strategy?
5-year Primary Patency: Provisional Zilver PTX vs. BMS

- **Zilver PTX (Provisional)**: 72.4%
- **BMS (Zilver Flex)**: 53.0%

\[ p = 0.03 \] (log-rank)

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Real PTX RCT: 3 year data from a randomized comparison of DCB vs. DES in femoropopliteal lesions

- **Zilver PTX vs. BMS**
- **Loss of Primary Patency in Lesions >20 cm**

<table>
<thead>
<tr>
<th>Stratified (n)</th>
<th>PP @ 24 month (%)</th>
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<tbody>
<tr>
<td>1 ≤ 10 cm (25)</td>
<td>78.4</td>
</tr>
<tr>
<td>2 &gt; 10 cm ≤ 20 cm (24)</td>
<td>56.7</td>
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<tr>
<td>3 &gt; 20 cm ≤ 30 cm (26)</td>
<td>43.3</td>
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Zilverpass RCT: Zilver PTX vs. Surgical Bypass (1:1 random., n=220, 13 sites)

- **Results of new endovascular devices (ZILVER PTX stent) can challenge the bypass results**

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Imperial RCT: Eluvia vs. Zilver PTX for Femoropopliteal Interventions
Conclusions

- Increased patency and better durability of DES vs. DCB in long lesions @ 3-year follow-up (REAL PTX, RCT)
- DES superior performance as compared to their BMS platform (ZILVER PTX, RCT)
- Preliminary results show non-inferiority of DES vs. prosthetic bypass surgery (AK), with similar patency and less complications in TASC C/D lesions (ZILVERPASS, RCT)
- Primary non-inferiority effectiveness & safety endpoints met between Zilver PTX® and Eluvia™ DES (Imperial Trial RCT)
- IMPERIAL long lesion sub-study, and independent registry with consistent performance in long lesions