Paradigm For Optimal Treatment Of Various Types of SFA–Pop Occlusive Disease: Which Treatment for Which Lesion: Role of Multiple Stents and Zilver PTX DESs (Cook) For Long Lesions

Gary M Ansel MD
System Medical Chief: Vascular
OhioHealth/Riverside Methodist Hospital
Columbus, Ohio

Gary M Ansel MD. Conflicts of Interest
- Equity - Embolitech - Primacea

DES vs DEB: Leave nothing behind?

InPact: Primary Patency² Results through 2 Years

Lesion Length Affects Patency Outcomes

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IN.PACT Global Long Lesion Imaging Cohort: Results across IN.PACT Clinical Studies

Consistent clinical outcomes with the IN.PACT® Admiral® DCB across studies and complex femoropopliteal lesions.
**So The DCB Data to Date**
- Is from optimal PTA
- Did not include significant calcification
- Did not demonstrate a class effect
- Does not address problematic lesions such as ostial disease
- Was a DCB BMS paradigm for long lesions

**DES has the Longest Term (5-year data) with Stable results and low fracture rates in Varied Populations including Calcification**

**What Are the Reasons to “Not Stent”?**
- Stent Fracture
- Difficult to treat restenosis
- Leave Surgical option

**DES: 5-year Primary Patency (PSVR < 2.0)**

- **Provisional BMS**
  - 53.0%
- **Provisional Zilver PTX**
  - 72.4%
  - \( p = 0.03 \) log-rank

**5-year Primary Patency (PSVR < 2.0)**

- **Zilver PTX vs. Standard Care**
  - From 1-5 years, the relative separation increases by 35%

**MAJESTIC 24-Month Freedom from TLR**

- **Kaplan-Meier Estimate**
  - **96.4%** (12M)
  - **91.3%** (24M)
Generalizing: 2-yr OUS Registry: Subgroups Freedom from TLR

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>12 Months</th>
<th>24 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>89% (n = 818)</td>
<td>82% (n = 427)</td>
</tr>
<tr>
<td>De novo (all)</td>
<td>91%</td>
<td>88%</td>
</tr>
<tr>
<td>&lt; 7 cm Lesions</td>
<td>94%</td>
<td>91%</td>
</tr>
<tr>
<td>&gt; 7 cm to 15 cm Lesions</td>
<td>92%</td>
<td>86%</td>
</tr>
<tr>
<td>&gt; 15 cm Lesions</td>
<td>84%</td>
<td>80%</td>
</tr>
<tr>
<td>TASC C and D*</td>
<td>87%</td>
<td>78%</td>
</tr>
<tr>
<td>Occlusions</td>
<td>86%</td>
<td>77%</td>
</tr>
<tr>
<td>Stenosis</td>
<td>90%</td>
<td>85%</td>
</tr>
<tr>
<td>Restenosis (all)</td>
<td>81%</td>
<td>70%</td>
</tr>
<tr>
<td>Restenosis (not ISR)</td>
<td>87%</td>
<td>73%</td>
</tr>
<tr>
<td>In-stent Restenosis (ISR)</td>
<td>78%</td>
<td>69%</td>
</tr>
</tbody>
</table>

Japan Post Market Registry

- N: 907 patients (95 institutions)
- Comorbidities:
  - diabetes (58.8%)
  - chronic kidney disease (43.8%)
  - critical limb ischemia (21.5%)
- Lesions complex:
  - average length of 14.7 cm
  - 41.6% total occlusions
  - 18.6% in-stent restenosis
- Excellent Results:
  - 12 month Freedom from TLR = 91.0%
  - Primary patency 86.4%


Symptomatic Instant Restenosis Pattern Results

<table>
<thead>
<tr>
<th></th>
<th>Silver BMS</th>
<th>Zilver PTX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average days to TLR</td>
<td>250</td>
<td>252</td>
</tr>
<tr>
<td>Average stented length (cm)</td>
<td>15.6</td>
<td>19.1</td>
</tr>
<tr>
<td>Plaque burden (% area)*</td>
<td>28%</td>
<td>17%</td>
</tr>
</tbody>
</table>

*P<0.05, statistically significant

39% relative reduction in plaque burden with Zilver PTX compared to BMS

Full Drug Jacket

- N = 89, First year of Zilver PTX use
- Cut off for short vs full length 20 cm
  - Average lesion length in short group = 13.9 cm
  - Average lesion length in long group = 33 cm
- Limitation of stent lengths to 80 cm

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**Summary**

**DES and “Dont Stent” argument?**

- Stent Fracture
- Difficult to treat restenosis
- Leave Surgical option
- High Restenosis in Long lesions
- Very low fracture rates
- Low and Less plaque burden
- Only bad technique takes away surgical options
- Appears to be as good as surgical bypass