Tried & True: Evaluating the Momentary Hype

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DISCLOSURES

Consultant/Medical Advisory Board

- Abbott
- BSCI
- Cardinal Health/Cordis
- Cook Medical
- CR BARD/Becton Dickinson
- CSI
- Endologix
- Inari
- Medtronic
- Micro Medical Solutions
- Philips/Volcano/Spectranetics
- Penumbra
- Terumo/Bolton
- WL Gore
Practice Patterns

• Several new drug-eluting technologies have emerged recently
  – DCB, additional DES
  – Focus of this talk will be on DES

• How do we choose?
  – Let’s look at the numbers
Global Clinical Program for Zilver PTX

Pre-Market Studies

- RCT
  - Moderate lesions
  - PTA
    - Optimal
      - Zilver Flex n=56
    - Sub-optimal
      - Zilver PTX n=63
      - Zilver PTX n=787
      - Zilver PTX n=178

Post-Market Studies

- SAS
  - More complex lesions
  - Zilver PTX n=242

- China
  - Similar lesions to RCT
  - Zilver PTX n=63
  - Zilver PTX n=178

- Japan PMS
  - All-comers
  - Zilver PTX n=904

- US PAS
  - Similar lesions to RCT
  - Zilver PTX n=200

- EU
  - Longer Lesions
  - Zilver PTX n=45

More than 2400 patients included in current Zilver PTX clinical program

- 2-year follow-up COMPLETE
- 1-year follow-up COMPLETE
- 5-year follow-up COMPLETE
- 3-year follow-up COMPLETE
- 1-year follow-up COMPLETE

1-year follow-up COMPLETE
5-year follow-up COMPLETE
3-year follow-up COMPLETE
### RCT, SAS, and Japan PMS

<table>
<thead>
<tr>
<th>Key Study Criteria</th>
<th>Zilver PTX RCT</th>
<th>Zilver PTX SAS</th>
<th>Zilver PTX Japan PMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>No significant untreated inflow tract stenosis</td>
<td>At least one patent runoff vessel</td>
<td>Maximum 2 Zilver PTX stents per lesion</td>
<td>Maximum 4 Zilver PTX stents per patient</td>
</tr>
<tr>
<td>Lesion length ≤ 14 cm</td>
<td>One lesion per limb</td>
<td>No exclusions</td>
<td>ISR included</td>
</tr>
<tr>
<td>No prior stent in SFA</td>
<td>Excluded if serum creatinine &gt; 2.0, renal failure, or dialysis</td>
<td>No exclusions</td>
<td></td>
</tr>
</tbody>
</table>

**Antiplatelets**
- Clopidogrel or ticlopidine recommended for 60 days, aspirin indefinitely

**Follow-up**
- 5 years
- 2 years
- 5 years

**Patency**
- DUS core laboratory analysis
- DUS site analysis

**Stent Integrity**
- X-ray core laboratory analysis

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**Increasingly complex patients and lesions**
Freedom from TLR

<table>
<thead>
<tr>
<th>Years</th>
<th>RCT (n=305)</th>
<th>SAS (n=787)</th>
<th>Japan PMS (n=903)</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>91.6%</td>
<td>89.8%</td>
<td>90.8%</td>
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<td>2</td>
<td>85.7%</td>
<td>83.3%</td>
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<td>78.8%</td>
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<td>4</td>
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<tr>
<td>5</td>
<td>82.8%</td>
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<td>74.2%</td>
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</table>

Consistently good results in challenging patient population including diabetics, renal failure, long lesions, ISR, no runoff, CLI
Clinical Benefit

<table>
<thead>
<tr>
<th>Years</th>
<th>RCT (n=301)</th>
<th>SAS (n=787)</th>
<th>Japan PMS (n=903)</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>87.1%</td>
<td>86.7%</td>
<td>88.6%</td>
</tr>
<tr>
<td>2</td>
<td>82.0%</td>
<td>78.6%</td>
<td>79.6%</td>
</tr>
<tr>
<td>3</td>
<td>80.3%</td>
<td>n/a</td>
<td>74.7%</td>
</tr>
<tr>
<td>4</td>
<td>79.8%</td>
<td>n/a</td>
<td>71.6%</td>
</tr>
<tr>
<td>5</td>
<td>79.8%</td>
<td></td>
<td>68.2%</td>
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</table>

Loss of clinical benefit includes TLR, claudication, rest pain, change in Rutherford by 2 or more categories, gangrene, ischemic ulcers, and amputation.
MAJESTIC

- European Eluvia Trial (Müller-Hülsbeck CIRSE 2017)
- n = 57
- First in Man Study
- Mean lesion length 70.8 ± 28.1 mm
- 46% CTO’s
IMPERIAL

- USA Eluvia Trial
- n = 465
- Randomized to Eluvia or Zilver PTX
  - Showed to be non-inferior
- Top enroller
  - Well-acquainted with DES technology and platform
• Long lesions subgroup
• n=50
• Mean lesion length 162.8 mm
• 32% CTO’s
For the Sake of Argument

• I am in a “real-world” practice
  – Demands of balancing evidence with throughput

• Remainder of the talk will focus on our plan for institutional outcomes in treating FP disease
  – Starting with long lesions $\geq 15$ cm
  – All comers: *de novo* stenting of SFA to within 3 cm of tibial plateau involving P1/2 popliteal
Zilver PTX at MSMC (2014-18)

- 1018 DES implanted for femoropopliteal disease (primarily)
- One of highest volume centers in US

<table>
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<tr>
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<tr>
<td>Mount Sinai Medical Center</td>
<td>6-100-PTX</td>
<td>41</td>
<td>62</td>
<td>88</td>
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<td>26</td>
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<td>5</td>
<td>1</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>7-80-PTX</td>
<td>19</td>
<td>14</td>
<td>15</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
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<td>8-40-PTX</td>
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<td>5</td>
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<tr>
<td>Total</td>
<td></td>
<td>160</td>
<td>157</td>
<td>250</td>
<td>199</td>
<td>252</td>
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</table>
5-year Institutional Experience

- n = 1018
- Most commonly used stents (cm) – 6x100, 6x80, 7x100 & 6x40
- Higher use from 2016-2018 corresponding to growth from 1 -> 3 partner practice
MSMC Institutional Experience

- We evaluated patients with long-segment FP disease (>15 cm) from 2014-2018
  - Claudicants (RC3)
  - CLI (RC4-6)
- *de novo* stenosis
  - In-stent stenosis or prior stent patients excluded

<table>
<thead>
<tr>
<th>Age (Mean)</th>
<th>72.5 Years</th>
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<tbody>
<tr>
<td>Gender</td>
<td>Male 65%</td>
</tr>
<tr>
<td></td>
<td>Female 35%</td>
</tr>
<tr>
<td>DM</td>
<td>39%</td>
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<tr>
<td>Hypertension</td>
<td>50%</td>
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<tr>
<td>Dyslipidemia</td>
<td>26%</td>
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<tr>
<td>Chronic Kidney Disease ( &gt; Stage III )</td>
<td>13%</td>
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<tr>
<td>Myocardial Infarction</td>
<td>7%</td>
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</tbody>
</table>
570 Patients
2014 – 2018
1018 Zilver PTX placed

- ≤ 14 cm
- ≥ 15 cm

Goal to present findings at NCVH in May 2019

Early interim data: ≥ 15 cm reporting 1 year primary patency at ≈ 90%
(Ultrasound or Angiographic Evaluation)
Not all that glitters is ZILVER

• Our initial institutional review of complex, long lesions is in line with current literature
• It is also comparable to recent Eluvia long lesion 1-year patency data
• Longer-term data will be needed to change our practice patterns- if it’s not broke, don’t fix it!
• “The enemy of good is better”
MSMC Multi-Disciplinary Peripheral Team

Have questions, contact us (305) 674-2071

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Students are welcome to rotate with us.

@SOBE_Vascular #CLIFighters
THANK YOU!
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