Drug-coated balloons: Also the primary solution for long lesions? Contra position

LINC 2016
Room 1 – Main Arena
Tuesday, January 26, 2016

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Department of Cardiothoracic Surgery
Stanford University School of Medicine
Falk Cardiovascular Research Center
Michael Dake, MD

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

- **Research/Research Grants, Clinical Trial Support**
  - W. L. Gore (major)
  - Cook Medical (major)

- **Consulting Fees/Honoraria**
  - W. L. Gore
  - Cook Medical
  - Abbott Vascular (minor)
  - Medtronic (minor)
  - Cardinal Health (minor)

- **Equity Interests/Stock Option**
  - TriVascular (minor)
  - Intact Vascular (minor)
  - Arsenal (minor)
  - 480 Medical (minor)
  - PQ Bypass (minor)
  - AneuMed (minor)

- **Officer, Director, Board Member or other Fiduciary Role**
  - VIVA Physicians Group

- **Speaker’s Bureau**
  - None
Are we talking about relatively simple TASC II A and B lesions?
Local Delivery of Paclitaxel to Inhibit Restenosis during Angioplasty of the Leg

Gunnar Tepe, M.D., Thomas Zeller, M.D., Thomas Albrecht, M.D., Stephan Heller, M.D., Uwe Schwarzwälder, M.D., Jean-Paul Beregi, M.D., Claus D. Claussen, M.D., Anja Oldenburg, M.D., Bruno Scheller, M.D., and Ulrich Speck, Ph.D.
K-M plots of %TLR in THUNDER
K-M plots of %TLR in THUNDER

Logrank p=0.0003

Survival Probability

Time free of TLR (years)

1: Paccocath Balloon
2: Uncoated Balloon

Department of Cardiothoracic Surgery, Stanford University School of Medicine
Vascular Medicine

Inhibition of Restenosis in Femoropopliteal Arteries
Paclitaxel-Coated Versus Uncoated Balloon: Femoral Paclitaxel
Randomized Pilot Trial

Michael Werk, MD; Soenke Langner, MD; Bianka Reinkensmeier, MS; Hans-Frank Boettcher, MD;
Gunnar Tepe, MD; Ulrich Dietz, MD; Norbert Hosten, MD; Bernd Hamm, MD;
Ulrich Speck, PhD; Jens Ricke, MD
Time [months] from intervention until 1st TLR or 1st major amputation (death = censored)

Pac balloon vs Control

Follow up 18 and/or 24 months

Survival Distribution Function

- Control
- Pac balloon

Censored Control
Censored Pac balloon

\( p = 0.013^{* * } \)
Time [months] from intervention until 1st TLR or 1st major amputation (death = censored)

Pac balloon vs Control

Follow up 18 and/or 24 months

Survival Distribution Function

- Control
- Pac balloon
- Censored Control
- Censored Pac balloon

p = 0.013**
5-year Primary Patency (PSVR < 2.0)
Zilver PTX vs. Standard Care

At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to standard care.

66.4% Zilver PTX
43.4% Optimal PTA + BMS

p < 0.01 log-rank
5-year Primary Patency (PSVR < 2.0)
Zilver PTX vs. Standard Care

From 1-5 years, the relative separation increases by 35%
At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to BMS.

Provisional Patency (PSVR < 2.0)
Primary Patency (PSVR < 2.0) Provisional Zilver PTX vs. BMS

Provisional Zilver PTX
72.4%

Provisional BMS
53.0%

$p = 0.03$ log-rank
## Lesion/Procedural Characteristics (ITT)

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>Standard PTA</th>
<th>P-value</th>
<th>Pooled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two lesions treated</td>
<td>1.9% (6/316)</td>
<td>3.1% (5/160)</td>
<td>0.400</td>
<td>2.3% (11/476)</td>
</tr>
<tr>
<td><strong>Total Lesion Length (mm)</strong></td>
<td><strong>62.9 ± 41.5 (315)</strong></td>
<td><strong>63.6 ± 40.3 (160)</strong></td>
<td><strong>0.866</strong></td>
<td><strong>63.2 ± 41.1 (475)</strong></td>
</tr>
<tr>
<td>Treated Length (mm)</td>
<td>107.7 ± 47.0 (316)</td>
<td>107.3 ± 49.3 (160)</td>
<td>0.933</td>
<td>107.6 ± 47.7 (476)</td>
</tr>
<tr>
<td>Calcification</td>
<td>59.2% (187/316)</td>
<td>57.5% (92/160)</td>
<td>0.726</td>
<td>58.6% (279/476)</td>
</tr>
<tr>
<td>Severe</td>
<td>17.6% (33/187)</td>
<td>13.0% (12/92)</td>
<td>0.326</td>
<td>16.1% (45/279)</td>
</tr>
<tr>
<td>Total Occlusion</td>
<td>20.6% (65/316)</td>
<td>21.9% (35/160)</td>
<td>0.741</td>
<td>21.0% (100/476)</td>
</tr>
<tr>
<td>%DS post-treatment</td>
<td>23.4 ± 12.3 (316)</td>
<td>23.8 ± 12.3 (158)</td>
<td>0.703</td>
<td>23.5 ± 12.3 (474)</td>
</tr>
<tr>
<td>Bail-out Stenting</td>
<td>2.5% (8/316)</td>
<td>6.9% (11/160)</td>
<td>0.022</td>
<td>4.0% (19/476)</td>
</tr>
<tr>
<td>Dissection</td>
<td>63.7% (200/314)</td>
<td>72.3% (115/159)</td>
<td>0.060</td>
<td>66.6% (315/473)</td>
</tr>
<tr>
<td><strong>Final Procedural Dissection</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Grade</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.075</td>
</tr>
<tr>
<td>Grade A</td>
<td>59.5% (119/200)</td>
<td>53.9% (62/115)</td>
<td></td>
<td>57.5% (181/315)</td>
</tr>
<tr>
<td>Grade B</td>
<td>36.5% (73/200)</td>
<td>35.7% (41/115)</td>
<td></td>
<td>36.2% (114/315)</td>
</tr>
<tr>
<td>Grade C</td>
<td>4.0% (8/200)</td>
<td>10.4% (12/115)</td>
<td></td>
<td>6.3% (20/315)</td>
</tr>
<tr>
<td><strong>Procedural success (core lab)</strong></td>
<td>88.9% (281/316)</td>
<td>86.8% (138/159)</td>
<td>0.497</td>
<td>88.2% (419/475)</td>
</tr>
<tr>
<td><strong>Geographic Miss (core lab)</strong></td>
<td>7.9% (24/316)</td>
<td>21.9% (35/160)</td>
<td>&lt;0.001</td>
<td>12.6% (60/476)</td>
</tr>
<tr>
<td>Measure</td>
<td>Test DCB (%(n/N) [95% CI])</td>
<td>Control PTA (%(n/N) [95% CI])</td>
<td>Difference % [95% CI]</td>
<td>P-value¹</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-----------------------------</td>
<td>-------------------------------</td>
<td>------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Total TLR at 12 Months</td>
<td>12.3% (35/285) [8.5, 16.1]</td>
<td>16.8% (24/143) [10.7, 22.9]</td>
<td>-4.5% [-11.7, 2.7]</td>
<td>0.208</td>
</tr>
</tbody>
</table>

¹ Based on asymptotic Likelihood Ratio test. CIs for groups and difference are asymptotic.
Table 22. TLR rate at 12 Months

<table>
<thead>
<tr>
<th>Measure</th>
<th>Test DCB % (n/N) [95% CI]</th>
<th>Control PTA % (n/N) [95% CI]</th>
<th>Difference % [95% CI]</th>
<th>P-value$^1$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total TLR at 12 Months</td>
<td>12.3% (35/285) [8.5, 16.1]</td>
<td>16.8% (24/143) [10.7, 22.9]</td>
<td>-4.5% [-11.7, 2.7]</td>
<td>0.208</td>
</tr>
</tbody>
</table>

$^1$ Based on asymptotic Likelihood Ratio test. CIs for groups and difference are asymptotic.

Table 20. Primary Patency of Target Lesion (ITT Population)

<table>
<thead>
<tr>
<th>Measure$^1$</th>
<th>Test DCB % (n/N) [95% CI]</th>
<th>Control PTA % (n/N) [95% CI]</th>
<th>Difference % [95% CI]</th>
<th>P-value$^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Patency</td>
<td>65.2% (172/264) [59.4, 70.9]</td>
<td>52.6% (71/135) [44.2, 61.0]</td>
<td>12.6% [2.4, 22.8]</td>
<td>0.015</td>
</tr>
</tbody>
</table>

$^1$ Primary Patency is defined freedom from target lesion restenosis (defined by DUS core lab adjudication) and target lesion revascularization (TLR).

$^2$ Based on asymptotic likelihood ratio test. CIs for groups and difference are asymptotic.
Table 16: Primary Patency Rate at 12 Months based on Alternative PSVR Thresholds (ITT Population)

<table>
<thead>
<tr>
<th>Threshold for Binary Restenosis&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Lutonix DCB % (n/N) [95% CI]</th>
<th>Control PTA % (n/N) [95% CI]</th>
<th>Difference % [95% CI]</th>
<th>P-value&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Core Lab Adjudications (primary analysis)</td>
<td>65.2% (172/264) [59.4, 70.9]</td>
<td>52.6% (71/135) [44.2, 61.0]</td>
<td>12.6% [2.4, 22.8]</td>
<td>0.015</td>
</tr>
<tr>
<td>DUS PSVR ≥ 3.0 (&lt; = ~60% stenosis)</td>
<td>68.3% (164/240) [62.4, 74.2]</td>
<td>56.1% (69/123) [47.3, 64.9]</td>
<td>12.2% [1.7, 22.8]</td>
<td>0.022</td>
</tr>
<tr>
<td>DUS PSVR ≥ 2.5 (per original protocol) (&lt; = ~50% stenosis)</td>
<td>64.0% (155/242) [58.0, 70.1]</td>
<td>51.2% (65/127) [42.5, 59.9]</td>
<td>12.9% [2.3, 23.5]</td>
<td>0.017</td>
</tr>
<tr>
<td>DUS PSVR ≥ 2.0 (&lt; = ~40% stenosis)</td>
<td>53.2% (133/250) [47.0, 59.4]</td>
<td>45.0% (59/131) [36.5, 53.6]</td>
<td>8.2% [-2.4, 18.7]</td>
<td>0.130</td>
</tr>
</tbody>
</table>

<sup>1</sup> Primary Patency is defined as the absence of target lesion restenosis (totally occluded or application of the strict stated PSVR threshold) and target lesion revascularization (TLR).

<sup>2</sup> Nominal P-values based on asymptotic Likelihood Ratio test and CI for difference are provided without adjustment for multiplicity; hypothesis testing at alternative thresholds was not prespecified.
<table>
<thead>
<tr>
<th>Measure</th>
<th>Test DCB % (n/N) [95% CI]</th>
<th>Control PTA % (n/N) [95% CI]</th>
<th>Difference % [95% CI]</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITT: Primary Patency</td>
<td>65.2% (172/264) [59.4, 70.9]</td>
<td>52.6% (71/135) [44.2, 61.0]</td>
<td>12.6% [2.4, 22.8]</td>
<td>0.015</td>
</tr>
<tr>
<td>PP: Primary Patency</td>
<td>65.3% (160/245) [59.3, 71.3]</td>
<td>56.0% (56/100) [46.3, 65.7]</td>
<td>9.3% [-2.1, 20.7]</td>
<td>0.11</td>
</tr>
</tbody>
</table>

At 24 months, the rate of primary patency among patients treated with the Lutonix DCB was superior to standard PTA [58.6% vs 53%; \( P = .05 \)]. Rate of freedom from target lesion revascularization (TLR) was 82% for the Lutonix arm. Composite safety at 24 months demonstrated noninferiority and a trend toward superiority over standard PTA [78.7% vs 70.9%; \( P = .08 \)].

The primary patency at two years in the complete data dropped from 65.2% at one year to 58.6% at two years in the Lutonix group, which DeFord said is still positive. He said the re-intervention rate was also positive, although not statistically significant, with 12% re-intervention at one year and 18% at two years. As for safety, he said the Lutonix was "almost superior" over the standard device at two years, even though the study was never powered to evaluate that.
ALL ITT, 12-month Primary Patency [1]

1. Primary patency is defined as freedom from clinically-driven TLR and freedom from restenosis as determined by duplex ultrasound (DUS) Peak Systolic Velocity Ratio (PSVR) ≤ 2.4
Primary Patency Results through 2 Years

Log-rank $P < 0.001$

<table>
<thead>
<tr>
<th>Number at risk</th>
<th>Time after Index Procedure (Months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DCB 220</td>
<td>209  185  153  143</td>
</tr>
<tr>
<td>PTA 111</td>
<td>103  66   51   50</td>
</tr>
</tbody>
</table>

1. Freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR $\leq 2.4$) or clinically-driven target lesion revascularization through 24 months (adjudicated by a Clinical Events Committee blinded to the assigned treatment)
Primary Patency\(^1\) Results through 2 Years

Log-rank \(p < 0.001\)

78.9% (DCB)

50.1% (PTA)

Number at risk\(^2\)

<table>
<thead>
<tr>
<th></th>
<th>Time after Index Procedure (Months)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td><strong>DCB</strong></td>
<td>220</td>
</tr>
<tr>
<td><strong>PTA</strong></td>
<td>111</td>
</tr>
</tbody>
</table>

1. Freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR ≤2.4) or clinically-driven target lesion revascularization through 24 months (adjudicated by a Clinical Events Committee blinded to the assigned treatment)
RCT: Paclitaxel Coating Effect
Primary Patency **Provisional Zilver PTX vs. Bare Zilver**

GEE Model

<table>
<thead>
<tr>
<th>Months</th>
<th>0</th>
<th>6</th>
<th>12</th>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Provisional Zilver PTX</strong></td>
<td>63</td>
<td>60</td>
<td>54</td>
<td>46</td>
</tr>
<tr>
<td><strong>Provisional Bare Zilver</strong></td>
<td>62</td>
<td>53</td>
<td>41</td>
<td>35</td>
</tr>
</tbody>
</table>

**Provisional Zilver PTX** vs. **Bare Zilver**

- **Primary Patency**
  - **Provisional Zilver PTX**: 90.2%
  - **Provisional Bare Zilver**: 83.4%

- **Log rank**
  - **p-value**: < 0.01

- **Primary Patency at Risk**
  - **Provisional Zilver PTX**: 72.9%
  - **Provisional Bare Zilver**: 64.1%

- **GEE Model**
  - **Time**: 12 mo
  - **p-value**: 0.02
At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to BMS.
5-year Primary Patency (PSVR < 2.0)
Zilver PTX vs. Standard Care

From 1-5 years, the relative separation increases by 35%
Zilver PTX Study Design

Primary Randomization

Enrollment

PTA

Zilver PTX

Suboptimal PTA

Optimal PTA

Secondary Randomization

Provisional BMS

Provisional Zilver PTX

n=124

n=62

n=125

n=252
5-year Primary Patency (PSVR < 2.0)
Zilver PTX vs. Standard Care

From 1-5 years, the relative separation increases by 35%
TASC A and B lesions

Stent
1. FAST
2. FACT
3. RESILIENT
4. 4EVER
5. DURABILITY
6. ASTRON
7. VIENNA

PTA
A. FAST
B. ZILVER PTX
C. RESILIENT
D. SAXON
E. ASTRON
F. VIENNA
G. VIENNA-3
But what about the effect when treating longer, more complicated, real world lesions?
Such as extensive complex SFA disease?
Or diffuse in-stent restenosis?
## Global Clinical Program

<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></td>
<td>No significant untreated inflow tract stenosis</td>
<td></td>
<td>ALL patients treated with Zilver PTX enrolled (up to enrollment limit), NO exclusion criteria</td>
</tr>
<tr>
<td>At least one patent runoff vessel</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maximum 2 Zilver PTX stents per lesion</td>
<td>Maximum 4 Zilver PTX stents per patient</td>
<td></td>
</tr>
<tr>
<td>Lesion length ≤ 14 cm</td>
<td></td>
<td>No exclusions</td>
<td></td>
</tr>
<tr>
<td>One lesion per limb</td>
<td></td>
<td>No exclusions</td>
<td></td>
</tr>
<tr>
<td>No prior stent in SFA</td>
<td></td>
<td>ISR included</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Excluded if serum creatinine &gt; 2.0, renal failure, or dialysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antiplatelets</td>
<td>Clopidogrel or ticlopidine recommended for 60 days, aspirin indefinitely</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td>5 years</td>
<td>2 years</td>
<td>5 years</td>
</tr>
<tr>
<td>Patency</td>
<td>DUS core laboratory analysis</td>
<td>DUS site analysis</td>
<td></td>
</tr>
<tr>
<td>Stent Integrity</td>
<td></td>
<td></td>
<td>X-ray core laboratory analysis</td>
</tr>
</tbody>
</table>

Increasingly complex patients and lesions
# Patient Demographics and Comorbidities

<table>
<thead>
<tr>
<th></th>
<th>RCT</th>
<th>SAS</th>
<th>Japan PMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>236</td>
<td>787</td>
<td>907</td>
</tr>
<tr>
<td>Age (years)</td>
<td>68 ± 10</td>
<td>67 ± 10</td>
<td>74 ± 9</td>
</tr>
<tr>
<td>Diabetes</td>
<td>50%</td>
<td>36%</td>
<td>59%</td>
</tr>
<tr>
<td>High cholesterol</td>
<td>76%</td>
<td>58%</td>
<td>61%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>89%</td>
<td>80%</td>
<td>85%</td>
</tr>
<tr>
<td>Renal disease(^1)</td>
<td>10%</td>
<td>11%</td>
<td>44%</td>
</tr>
<tr>
<td>Lesion length (cm)</td>
<td>6.6 ± 3.9</td>
<td>10.0 ± 8.2</td>
<td>14.7 ± 9.7</td>
</tr>
<tr>
<td>Total occlusions</td>
<td>33%</td>
<td>38%</td>
<td>42%</td>
</tr>
<tr>
<td>In-stent restenosis (ISR)</td>
<td>0%</td>
<td>15%</td>
<td>19%</td>
</tr>
<tr>
<td>Rutherford 4-6 (CLI)</td>
<td>9%</td>
<td>11%</td>
<td>20%</td>
</tr>
</tbody>
</table>

\(^1\) Of patients with renal disease in the Japan PMS, 82% were in renal failure (eGFR < 60 and/or dialysis)

Increasingly complex patients and lesions
Baseline Lesion Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Zilver PTX RCT</th>
<th>Ziver PTX SAS</th>
<th>Zilver PTX Japan PMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesions</td>
<td>247</td>
<td>900</td>
<td>1081</td>
</tr>
<tr>
<td>Lesion length (cm)</td>
<td>6.6 ± 3.9 *</td>
<td>10.0 ± 8.2 *</td>
<td>14.7 ± 9.7</td>
</tr>
<tr>
<td>Diameter stenosis (%)</td>
<td>80 ± 17 *</td>
<td>85 ± 16 *</td>
<td>92 ± 11</td>
</tr>
<tr>
<td>Total occlusions</td>
<td>30% *</td>
<td>38%</td>
<td>42%</td>
</tr>
<tr>
<td>In-stent restenosis (ISR)</td>
<td>0% *</td>
<td>15%*</td>
<td>19%</td>
</tr>
<tr>
<td>Patent runoff vessels</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>0%</td>
<td>0%</td>
<td>7%</td>
</tr>
<tr>
<td>1</td>
<td>22%</td>
<td>*</td>
<td>19%</td>
</tr>
<tr>
<td>2</td>
<td>35%</td>
<td>*</td>
<td>32%</td>
</tr>
<tr>
<td>3</td>
<td>42%</td>
<td>45%</td>
<td>29%</td>
</tr>
</tbody>
</table>

* p < 0.05 compared to Japan PMS

Japan PMS lesions are more complex (e.g., longer, more ISR, fewer patent runoff vessels)
Freedom from TLR Across Studies

*Graph showing freedom from TLR across studies.*

### Freedom from TLR across studies (n=patients)

<table>
<thead>
<tr>
<th>Months</th>
<th>RCT (n = 305)</th>
<th>SAS (n = 787)</th>
<th>Japan PMS (n = 907)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>91.6%</td>
<td>89.5%</td>
<td>91.0%</td>
</tr>
<tr>
<td>24</td>
<td>85.7%</td>
<td>83.3%</td>
<td>85.0%</td>
</tr>
</tbody>
</table>

*Freedom from TLR consistent across studies*
Primary Patency by DUS

Primary patency rate is consistent across studies
The Leipzig experience with DCB, conventional, and interwoven nitinol stents for complex SFA disease

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DCB – BMS - Supera

1:1 match for each comparison

- **BMS cohort (N=432)**
  - 368 pairs, 736 patients
  - 254 pairs, 508 patients

- **Supera cohort (N=470)**
  - 736 patients

- **DCB cohort (N=390)**
  - 568 patients

- **368 pairs, 736 patients**
  - 284 pairs, 568 patients
  - 254 pairs, 508 patients
Comparison: DCB - BMS

- **Supera cohort (N=470)**: 368 pairs, 736 patients
- **BMS cohort (N=432)**: 254 pairs, 508 patients
- **DCB cohort (N=390)**: 284 pairs, 568 patients
## DCB - BMS

**Matched Cohort:**

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>BMS</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion length, mm</td>
<td>171 ± 108</td>
<td>159 ± 114</td>
<td>0.2</td>
</tr>
<tr>
<td>Instent restenosis, %</td>
<td>18</td>
<td>19</td>
<td>0.8</td>
</tr>
</tbody>
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**K-M curve with 95% Confidence Interval**

Hazard ratio (95%CI): 0.87 (0.68-1.1)
Choice between DCB and DES

• NOT CLEAR
  – Lack of data currently - no direct comparisons of effectiveness
  – Different metrics utilized
  – Variable populations/lesion sets
  – Unknown costs and unknown
  – Unknown MD and patient preferences and sensitivities re: permanent implant vs. DCB
Conclusions: When and Why I Use DES

• As the first randomized controlled SFA device trial with 5-year follow-up, these results with the Zilver PTX stent provide important insights regarding long-term outcomes for endovascular treatment

• Abundant Zilver PTX data for more complex anatomy (TASC C and D lesions) in patients at high risk of re-stenosis (DM, CRF, ISR, etc.)
  – Promising >1 year outcomes (TLR, patency)
  – These benefits increase with time – results with Zilver PTX continue to diverge from standard care over 5 years with no late catch-up
  – Await similar long-term analyses for DEB, atherectomy + DEB, biomimetic stents, etc.
Drug-coated balloons: Also the primary solution for long lesions? Contra position

LINC 2016
Room 1 – Main Arena
Tuesday, January 26, 2016

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