Current Status of the Bioresorbable Vascular Scaffold
Where the Data Is Leading Us

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Director of Structural & Coronary Interventions
HonorHealth and the Scottsdale-Lincoln Health Network
Are Metallic DES More Forgiving?

Suboptimal Implant Technique

Courtesy Alok Sharma, MD
13 Years Post Metallic DES Implant
2-3% per year late hazard with DES

Spirit III Target Lesion Failure @ 5 Years

Spirit IV Target Lesion Failure @ 3 Years

Stone GW et al JACC 2011
BVS 4-years Post Implant

- 3.0 x 20 NC for pre-dil
- 3.0 x 28 mm BVS
- 3.5 x 20 NC for post-dil
Everolimus-eluting Bioresorbable Vascular Scaffolds in Patients with Coronary Artery Disease: The ABSORB III trial

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NEJM October, 2015
1-Year TLF Components

- TLF: 7.8% (P=0.16)
- Cardiac death: 0.6% (P=0.29)
- TV-MI: 6.0% (P=0.18)
- ID-TLR: 3.0% (P=0.50)
## Device Thrombosis to 1 Year
Definite & Probable ST 1.53% vs 0.74%

<table>
<thead>
<tr>
<th></th>
<th>Absorb (N=1322)</th>
<th>Xience (N=686)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Thrombosis (def*/prob)</td>
<td>1.54%</td>
<td>0.74%</td>
<td>0.13</td>
</tr>
<tr>
<td>- Early (0 to 30 days)</td>
<td>1.06%</td>
<td>0.73%</td>
<td>0.46</td>
</tr>
<tr>
<td>- Late (&gt; 30 to 1 year)</td>
<td>0.46%</td>
<td>0.00%</td>
<td>0.10</td>
</tr>
<tr>
<td>- Definite* (1 year)</td>
<td>1.38%</td>
<td>0.74%</td>
<td>0.21</td>
</tr>
<tr>
<td>- Probable (1 year)</td>
<td>0.15%</td>
<td>0.00%</td>
<td>0.55</td>
</tr>
</tbody>
</table>

*One “definite ST” in the Absorb arm by ITT was in a pt that was treated with Xience*
Outcomes by QCA RVD 2.25 mm
Thicker BVS struts may be of particular concern in small vessels

Eligibility: 2.50-3.75 mm
19% has a RVD < 2.25

<table>
<thead>
<tr>
<th></th>
<th>Absorb</th>
<th>Xience</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLF</td>
<td>12.9%</td>
<td>8.3%</td>
</tr>
<tr>
<td>ST</td>
<td>4.6%</td>
<td>1.5%</td>
</tr>
<tr>
<td>TLF 71</td>
<td>6.7%</td>
<td>5.5%</td>
</tr>
<tr>
<td>ST 30</td>
<td>0.9%</td>
<td>0.6%</td>
</tr>
</tbody>
</table>

# Events: TLF 31, ST 11, TLF 71, ST 30
# Risk: TLF 241, ST 238, TLF 1067, ST 1058
Absorb China Outcomes at 2 years:

All-cause death, MI, or revascularization for BVS vs. Xience: 10.1% vs. 11.4%, p = 0.66

All-cause mortality: 0.4% vs. 2.5%, p = 0.12
MI: 3.0% vs. 2.1%, p = 0.56

Target lesion revascularization: 8.9% vs. 8.4%, p = 0.87

Scaffold thrombosis: 0.8% vs. 0%, p = 0.5 (very late thrombosis: 0.4% vs. 0%)

*** Lowest rate of small vessels of RCTs
Using OCT to Optimize BVS Result
Take Home Message on PSP
A BVS-specific implantation strategy can improve outcomes

PREPARE THE LESION
SIZE APPROPRIATELY
POST-DILATE

Why be meticulous in vessel preparation?
Aids device delivery
Aids device expansion
Makes the PCI procedure easier

Sizing for BRS?
Ameliorates the risk early events
Exclude small vessels (< 2.5 mm vessels)

Post dilation of BRS?
Reduces the incidence of late events
Worldwide Absorb Voluntary Reporting of Thrombosis by Implant Date

1. Data represents exponentially weighted moving average

Data/analysis not submitted or reviewed by FDA
## ABSORB II Trial Results

### Key Clinical Outcomes by 4 Years

<table>
<thead>
<tr>
<th></th>
<th>Absorb BVS (N=335)</th>
<th>XIENCE (N=166)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3-4 Years</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TLF</td>
<td>1.0% (3)</td>
<td>0.7% (1)</td>
<td>1.00</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>0.3% (1)</td>
<td>0.7% (1)</td>
<td>0.54</td>
</tr>
<tr>
<td>TV-MI</td>
<td>0.3% (1)</td>
<td>0.0% (0)</td>
<td>1.00</td>
</tr>
<tr>
<td>ID-TLR</td>
<td>0.3% (1)</td>
<td>0.0% (0)</td>
<td>1.00</td>
</tr>
<tr>
<td>ST (Def/Prob)</td>
<td>0.0% (0)</td>
<td>0.0% (0)</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>0-4 Years</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TLF</td>
<td>11.5% (36)</td>
<td>6.0% (9)</td>
<td>0.06</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>1.3% (4)</td>
<td>2.7% (4)</td>
<td>0.28</td>
</tr>
<tr>
<td>TV-MI</td>
<td>7.3% (23)</td>
<td>1.3% (2)</td>
<td>0.008</td>
</tr>
<tr>
<td>ID-TLR</td>
<td>6.7% (21)</td>
<td>2.0% (3)</td>
<td>0.03</td>
</tr>
<tr>
<td>ST (Def/Prob)</td>
<td>3.0% (9)</td>
<td>0.0% (0)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

*Note: non-hierarchical summary of the components of TLF*
ABSORB II 4-Year Results

Between 3 and 4 Years, (Once the Scaffold Disappears), TLF Rate Was Comparable Between Absorb and XIENCE

**Proprietary and confidential — do not distribute**

**DoCE/TLF**: Cardiac death, target-vessel myocardial infarction, and clinically indicated target-lesion revascularisation (TLR)
**ABSORB II 4-Year Results**

Take home: Proposed a 30-50% (safe) reduction in resorption time.

Caveat: Don’t simply shift the time-to-event curves to the left (i.e. earlier time frame).

Proprietary and confidential — do not distribute
**ABSORB III Trial**

**Landmark Analysis 1 to 3 Years**

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**Target Lesion Failure**

**Landmark Analysis**

![Graph showing Target Lesion Failure](image)

<table>
<thead>
<tr>
<th>Time Post Procedure (Months)</th>
<th>Absorb</th>
<th>XIENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 1 Year</td>
<td>7.5%</td>
<td>5.7%</td>
</tr>
<tr>
<td>1 – 3 Years</td>
<td>4.1%</td>
<td>3.2%</td>
</tr>
</tbody>
</table>

**No. at Risk:**

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<tr>
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<tr>
<td>0 – 1 Year</td>
<td>1322</td>
<td>686</td>
</tr>
<tr>
<td>1 – 3 Years</td>
<td>1200</td>
<td>636</td>
</tr>
<tr>
<td></td>
<td>1215</td>
<td>635</td>
</tr>
<tr>
<td></td>
<td>1145</td>
<td>603</td>
</tr>
</tbody>
</table>

**HR [95% CI]**

- 0 – 1 Year: $1.33 [0.92, 1.92]$, $p=0.13$
- 1 – 3 Years: $1.18 [0.81, 1.72]$, $p=0.39$

Proprietary and confidential — do not distribute
Device Thrombosis
Landmark Analysis

**0 – 1 Year**
HR [95% CI] = 2.08 [0.78, 5.55]
p=0.13

**1 – 3 Years**
p=0.02

Absorb
XIENCE

![Graph](image-url)
Several analyses have shown that these contemporary implant techniques are associated with improved outcomes.

### Clinical Outcomes between 2-3 Years

<table>
<thead>
<tr>
<th></th>
<th>ABSORB II (N=335)</th>
<th>ABSORB Japan (N=166)</th>
<th>ABSORB China (N=239)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLF</td>
<td>3.5% (11)</td>
<td>2.0% (3)</td>
<td>1.6% (4)</td>
</tr>
<tr>
<td>ST (Def/Prob)</td>
<td>1.3% (4)</td>
<td>0% (0)</td>
<td>0.4% (1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>ABSORB III</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLF</td>
<td>3.3% (41)</td>
</tr>
<tr>
<td>ST (Def/Prob)</td>
<td>0.5% (6)</td>
</tr>
</tbody>
</table>

*Defined as patients with pre-dilatation, and QCA RVD ≥2.25mm–≤3.5mm, and post-dilatation performed at ≥18 atm, with post-dilatation balloon diameter > nominal scaffold diameter but ≤ nominal scaffold diameter + 0.5mm
HonorHealth Single Center Experience
169 Consecutive BVS Implants

- 169 BVS implants.
- > 90% underwent full P-S-P technique.
- > 90% guided by high resolution imaging.
- Over 2/3 now have at least one year follow up.
- At present, there’s a single S.T.
- That patient was NOT loaded with DAPT until after the implant (acute ST less than an hour after implant).
1. 73 y.o with high grade mid LAD disease.
2. Eccentric lesion.
3. Moderate calcium.
4. Diagonal side branch at lesion site
1. Preservation of S.B.
2. Excellent apposition by OCT

Pre and Post Comparison
50 year old patient with unstable angina. Turned down for CABG and declined previous PCI. Consented to complex PCI specifically for BVS.

Antegrade Wire Escalation Technique
3.0 x 20 NC Balloon for Pre-dilation
7 French Guideliner for Distal BVS Deployment
3.0 x 28 BVS, 4.0 NC Balloon

3.5 x 28 BVS
4.0 NC Balloon

3.5 x 28 BVS
4.0 NC Balloon

4.0 x 15 Xience, 4.5 NC Balloon (based on OCT)
Pre and post compare
Plaque modification with R.A.
Excellent apposition by OCT
Parting Shots...

• ABSORB II, 4 year is the first RCT with data after the scaffold has been resorbed (full resorption is approximately 3 years).

• ABSORB II showed 0% ST between 3-4 years and TLF rate was comparable between Absorb to XIENCE, providing encouraging safety & efficacy results (the promise of BVS).

• No doubt the current device(s) need iteration.

• No doubt, adherence to technique is essential (i.e. P-S-P really works).

• Coronary intervention is a “skill game.”