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Bioresorbable Vascular Scaffold (BVS) System

Communicating the value of an Innovative Therapy for Coronary Artery Disease

Dr. Aniff YEAROO
• Presentations are intended for educational purposes only and do not replace independent professional judgement.

• I do not have any potential conflict of interest.
C.A.D

A LEADING CAUSE OF MORBIDITY AND MORTALITY
Coronary artery disease is the worldwide leading cause of mortality and a major cause of morbidity

- Coronary artery disease (CAD) is the worldwide leading cause of mortality and a major cause of morbidity
  - With an aging population and increasing prevalence of other risk factors, the health and economic burden of CAD will increase

- Percutaneous coronary intervention (PCI) with drug-eluting stents (DES) is a minimally invasive and highly effective treatment for CAD
  - PCI with stenting is the treatment of choice for key CAD patient groups; it offers benefits over medical and surgical therapies and is cost-effective
The prevalence of CAD is expected to rise with an aging population.

Estimated population aged 60 or over from 1950–2050

- Global
- Developing regions
- Developed regions

Predictions:

2020
- 82 million healthy life years lost globally (up 74% vs. 1990)

2030
- US healthcare spending on CAD >$239 billion (up 100% vs. 2013)

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Current treatment options for CAD can be broadly defined as medical or surgical

- **Medical treatments** are pharmaceutical agents, including anti-ischemic agents, antiplatelet therapy, anticoagulants and statins

- **Surgical treatments** aim to provide coronary revascularization – the primary procedures for this are:

  **Coronary artery bypass grafting (CABG)**
  - Re-establishes blood flow to heart by bypassing blocked regions of artery using graft of alternative artery/vein of patient1

  **Percutaneous coronary intervention (PCI)**
  - Re-establishes blood flow to heart by opening up blocked artery2, using catheter-based procedures3, including:
    - **Stenting** – using either BMS or DES
    - **Balloon angioplasty** (percutaneous transluminal coronary angioplasty – PTCA) which can also include the use of:
      - **Drug-eluting/coated balloons** - local delivery of drug on non-stent based platforms

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BMS=bare-metal stent; CAD=coronary artery disease; DES=drug-eluting stent.
PCI with stenting is the treatment of choice for a wide range of CAD patients

Revascularization procedures per quarter 2001–2008 in the US

1. Epstein AJ et al. JAMA 2011;305(17):1769–78. BMS=Bare metal stent; CAGB=coronary artery bypass graft. CAD=coronary artery disease; DES=drug eluting stent; PCI=percutaneous coronary intervention; PTCA=percutaneous transluminal coronary angioplasty.

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Despite improvements in PCI, there is evidence of unmet need with current treatment options

There is still room for improvement in clinical outcomes for PCI patients

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2. SPIRIT III: Ischemia-driven TLR through 5 years. Stone GW, TCT 2011.

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PCI and DES have revolutionized cardiovascular care; Absorb represents the next major advancement

1977
Andreas Gruentzig performs the first PTCA in Zurich, Switzerland

1988
Julio Palmaz and Richard Schatz develop a stainless steel stent for coronary applications

2001 - 2003
Drug-eluting stents are introduced to the European and U.S. markets

2010*
First Absorb Biodegradable Vascular Scaffold (BVS) approved for use in Europe and Asia-Pacific

- Continuous PCI technology advancements have significantly improved clinical outcomes for CAD and expanded patient access to less invasive treatment options
- Absorb represents a new approach that provides the safety and efficacy of a best-in-class DES while improving long-term benefits with lower revascularization and post-PCI angina rates

*Additional sizes received CE Mark in 2012 and 2014.
‘Caged’ Vessel

Delayed Healing $\rightarrow$ Stent Thrombosis?

Benign Neointima

Late Acquired Malapposition $\rightarrow$ Stent Thrombosis?

Neo-Atheroma $\rightarrow$ Stent Thrombosis?

In-Stent Restenosis (NIH)

* uncovered struts

1Virmani, R. CIT 2010
# The clinical need for a Bioresorbable Vascular Scaffold

<table>
<thead>
<tr>
<th>Rationale</th>
<th>Vessel scaffolding is only needed transiently*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vision</td>
<td>As Safe and Effective as a Best in Class DES with Unique Benefits</td>
</tr>
<tr>
<td>Potential Benefits</td>
<td></td>
</tr>
<tr>
<td>- Reduction in post-PCI angina leading to fewer revascularizations</td>
<td></td>
</tr>
<tr>
<td>- Restoration of the vessel to a more natural state, capable of natural vascular function</td>
<td></td>
</tr>
<tr>
<td>- Vessels remain free for future treatment options**</td>
<td></td>
</tr>
<tr>
<td>- Allows for use of non-invasive imaging techniques (CCTA/MSCT)</td>
<td></td>
</tr>
<tr>
<td>- Improve patient quality of life</td>
<td></td>
</tr>
</tbody>
</table>

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*Seruys PW, et al., Circulation 1988; 77: 361. Serial study suggesting vessels stabilize 3-4 months following PTCA.
**Small platinum markers at scaffold edges remain for fluoroscopic landmarking.
CCTA: Absorb vs. permanent implant
Vascular Reparative Therapy: Potential for Improved Long-Term Outcomes

Could Absence of an Implant Reduce Long-Term Events?

Cumulative Rates of Target Lesion Revascularization

- The goal of bioresorbable vascular scaffolds is to achieve the early benefits seen with DES, but improve on long-term outcomes by eliminating the implant

2Adapted from Stone, GW, TCT 2011 (dotted line represents projection)
3Data on file at Abbott Vascular; adapted from ABSORB Cohort B and EXTEND data (dotted line represents projection)
Bioresorbable Vascular Scaffold (BRS): The ideal of leaving nothing behind*

Data and images on file at Abbott Vascular. Illustrations are artist renditions; not drawn to scale. Cohort B OCT images - courtesy of RJ van Geuns, Erasmus Medical Center, Netherlands. Image after implantation is with Cohort B device. Small platinum markers at scaffold edges remain for fluoroscopic landmarking.

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Absorb Bioresorbable Vascular Scaffold (BVS) System Design Elements

**Bioresorbable Scaffold**
- Poly(L-lactide) (PLLA)
- Based on proven MULTI-LINK pattern
- Naturally resorbed, fully metabolized*

**Bioresorbable Coating**
- Poly(D,L-lactide) (PDLLA)
- Naturally resorbed, fully metabolized

**Everolimus**
- Similar dose density and release rate profile to XIENCE V

**XIENCE V Delivery System**
- World-class deliverability

*Small platinum markers at scaffold edges remain for fluoroscopic landmarking.

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Absorb is designed to work in three phases to deliver Vascular Reparative Therapy

- **Revascularize**
  - Restores blood flow like a best-in-class DES, XIENCE

- **Restore**
  - Preliminary evidence of natural vessel function may improve long-term outcomes

- **Resorb**
  - Resorbs leaving no scaffold behind *

*Small platinum markers at scaffold edges remain for fluoroscopic landmarking. Porcine coronary artery model images. For Revascularize and Restore, the images are with Cohort B device. For Resorb, the image is with Cohort A device.

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CASES FROM FORTIS CLINIQUE DARNE
**TABLE I.** – Baseline characteristics of patients treated with BVS.

BVS: bioresorbable vascular scaffold; CABG: coronary artery bypass graft; MI: myocardial infarction; LVEF: left ventricular ejection fraction; PCI: percutaneous coronary intervention.

**September 2013 – October 2014**

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>Treated with BVS (N = 40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>55</td>
</tr>
<tr>
<td>Male</td>
<td>92%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>15/40 – 37.5%</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>10/40 – 25%</td>
</tr>
<tr>
<td>Insulin</td>
<td>0</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>15/40 – 37.5%</td>
</tr>
<tr>
<td>Current smoker</td>
<td>12/40 – 30%</td>
</tr>
<tr>
<td>Family history</td>
<td>10/40 – 25%</td>
</tr>
<tr>
<td>Previous M.I</td>
<td>7/40 – 17.5%</td>
</tr>
<tr>
<td>Previous PCI</td>
<td>5/40 – 12.5%</td>
</tr>
<tr>
<td>Previous CABG surgery</td>
<td>3/40 – 7.5%</td>
</tr>
<tr>
<td>LVEF, %</td>
<td>55%</td>
</tr>
<tr>
<td>Stable angina</td>
<td>22/40 – 55%</td>
</tr>
<tr>
<td>Triple vessel disease</td>
<td>9/40 – 22.5%</td>
</tr>
</tbody>
</table>
Lesion characteristics  | Lesions treated with BVS (N = 46)
---|---
**Vessels treated**
LMS | 0
LAD | 18/46 – 39.1%
Cx | 9/46 – 19.5%
RCA | 13/46 – 28.2%
**Lesion type**
A | 40%
B1 | 20%
B2 | 20%
C | 20%
Bifurcations | 3/46 – 6.5%
Calcified lesions | 8/46 – 17.3%
CTO | 0
In-stent restenosis | 3/46 – 6.5%

TABLE II. – Baseline characteristics of lesions treated with BVS.
BVS: bioresorbable vascular scaffold; CTO: chronic total occlusion; LAD: left anterior descending; LMS: left main stem; Cx: circumflex; RCA: right coronary artery.
<table>
<thead>
<tr>
<th>Procedural characteristics</th>
<th>Lesions treated with BVS (N = 46)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predilatation</td>
<td>46/46 - 100%</td>
</tr>
<tr>
<td>Access Radial</td>
<td>36/40 – 90%</td>
</tr>
<tr>
<td>Post dilatation</td>
<td>39/46 – 84.7%</td>
</tr>
<tr>
<td>Max balloon size, mm</td>
<td>0.25mm above stent size</td>
</tr>
<tr>
<td>Max inflation pressure, atm</td>
<td>18 ATM</td>
</tr>
<tr>
<td>IVUS</td>
<td>0</td>
</tr>
<tr>
<td>OCT</td>
<td>0</td>
</tr>
<tr>
<td>Number of BVS per patient</td>
<td>48/40 – 1.2%</td>
</tr>
<tr>
<td>Number of BVS per lesion</td>
<td>48/46 – 1.04%</td>
</tr>
<tr>
<td>BVS diameter, mm</td>
<td>2.5 - 10</td>
</tr>
<tr>
<td></td>
<td>3 - 26</td>
</tr>
<tr>
<td></td>
<td>3.5 - 12</td>
</tr>
<tr>
<td>Total BVS length, mm</td>
<td>18 - 16</td>
</tr>
<tr>
<td></td>
<td>28 - 32</td>
</tr>
</tbody>
</table>

BVS: bioresorbable vascular scaffold; FKBI: final kissing balloon inflation; IVUS: intravascular ultrasound; OCT: optical coherence tomography.
<table>
<thead>
<tr>
<th>Clinical Event</th>
<th>1 Year Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angina</td>
<td>2/40 – 5%</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>0%</td>
</tr>
<tr>
<td>Scaffold Thrombosis</td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>0%</td>
</tr>
<tr>
<td>Sub-Acute (6 weeks)</td>
<td>1/40 – 2.5%</td>
</tr>
<tr>
<td>Late</td>
<td>0%</td>
</tr>
<tr>
<td>Target Lesion Revascularization</td>
<td>0%</td>
</tr>
<tr>
<td>Target Vessel Revascularization</td>
<td>2/40 – 5%</td>
</tr>
<tr>
<td>Death</td>
<td>0%</td>
</tr>
</tbody>
</table>
Absorb
Bioresorbable Vascular Scaffold System

Clinical Overview

Conclusion:

Dr. E. Christiansen
Aarhus University Hospital,
Denmark

- No additional MACE between 3-4 years
- 0% scaffold thrombosis

44% B2/C Type Lesions

1488-day HR
0.76 [0.37, 1.55]
p=0.4447

Δ=3.4%

<table>
<thead>
<tr>
<th>Time After Index Procedure (days)</th>
<th>Absorb</th>
<th>XIENCE (3.0x18, subgroup, SPIRIT I/II/III RCT) Patients at Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>101</td>
<td>227</td>
</tr>
<tr>
<td>37</td>
<td>99</td>
<td>224</td>
</tr>
<tr>
<td>194</td>
<td>96</td>
<td>219</td>
</tr>
<tr>
<td>284</td>
<td>96</td>
<td>211</td>
</tr>
<tr>
<td>303</td>
<td>96</td>
<td>204</td>
</tr>
<tr>
<td>573</td>
<td>94</td>
<td>202</td>
</tr>
<tr>
<td>758</td>
<td>92</td>
<td>191</td>
</tr>
<tr>
<td>1123</td>
<td>91</td>
<td>182</td>
</tr>
<tr>
<td>1488</td>
<td>88</td>
<td>174</td>
</tr>
</tbody>
</table>

Source: E. Christiansen, ACC 2014

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# Outcomes in Real World Patient Populations

**Conclusion:**

"Emerging data from real-world expanded use registries suggest that Absorb BVS use is feasible and safe in a wide variety of patients (from low to high risk) and lesions (from simple to complex)."

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Study</th>
<th>Clinical Events</th>
<th>Scaffold Thrombosis</th>
<th>Study Demographics</th>
<th>Follow-Up Time</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All Comers</strong></td>
<td>ASSURE Pt: D. Mathey</td>
<td>5% MACE, 2.8% TLR</td>
<td>0%</td>
<td>27% MI; 25.7% diabetics; 64.6% B2/C type lesions</td>
<td>12 months</td>
<td>183</td>
</tr>
<tr>
<td></td>
<td>BVS EXPAND (excluding STEMI) Pt: R. van Geuns</td>
<td>3.3% MACE, 2.2% TLR</td>
<td>2.2% def ST (4) (due to high complexity of lesions and patients with co-morbidities)</td>
<td>41.1% B2 type lesions or higher; 38.5% MVD; 29.1% bifurcation; 25.41 mm lesion length</td>
<td>6 months</td>
<td>180</td>
</tr>
<tr>
<td></td>
<td>GHOST Registry Pt: C. Tumburino</td>
<td>1.8% MACE, 1.8% TVF</td>
<td>1.07% (3 events in a 280 patient 30 day follow-up population)</td>
<td>50% ACS (33% NSTEMI/STEMI); 21.2 mm lesion length; 49.6% B2/C lesions; 15.8% bifurcations; 9% CTO; 5.7% ISR</td>
<td>6 months</td>
<td>173</td>
</tr>
<tr>
<td></td>
<td>ABSORB FIRST Pt: A. Seth &amp; E. Eckhart</td>
<td>0% Death</td>
<td>0.3% sub-acute ST</td>
<td>38% MI (25.8% acute MI); 11.9% bifurcation; 10.5% total occlusion; 46.7% B2/C type lesions; 46.1% MVD</td>
<td>1 month</td>
<td>800</td>
</tr>
<tr>
<td><strong>ACS</strong></td>
<td>POLAR ACS Pt: D. Dudek</td>
<td>3.2% MI, 0% TLR, 1.1% TVR</td>
<td>1.1% def ST (due to DAPT discontinuation)</td>
<td>16% STEM; 38% NSTEMI; 46% unstable angina</td>
<td>12 months</td>
<td>100</td>
</tr>
<tr>
<td><strong>STEMI</strong></td>
<td>PRAGUE-19 Pt: P. Widimsky</td>
<td>1 Death</td>
<td>1 ST (due to DAPT discontinuation)</td>
<td>100% STEM, all Killip I-II</td>
<td>To date</td>
<td>76</td>
</tr>
<tr>
<td><strong>CTO</strong></td>
<td>CTO Pilot Study Pt: A. Serra</td>
<td>0% MACE</td>
<td>0%</td>
<td>100% CTO; 85.7% stable angina; 26% 3-vessel disease; 25.8% J-CTO score difficult/very difficult; 18.6 mm occlusion length</td>
<td>6 months</td>
<td>33</td>
</tr>
</tbody>
</table>

Goal of Vascular Reparative Therapy (VRT): Improved long-term outcomes

Goals for Vascular Reparative Therapy (VRT)

- Best-in-class DES
- VRT: Improved long-term outcomes
- Delayed disease progression
- Late lumen gain
- Vasomotion
- Functional endothelium
- Mechanical conditioning
- Scaffold degradation

Natural Vessel Function

- Revascularizes
- PCI
- Native CAD

Time
THANK YOU