The BIO revolution:
biodesorbable stents

Federico Conrotto
Cardiologia 2
Città della Salute e della Scienza di Torino
Strut Material: Poly-L-Lactic acid

Coating Material: Poly-D,L-lactide

Design: out of phase sinusoidal hoops with straight and direct links in cohort A and in-phase hoops with straight links in cohort-B

Absorption products: Lactic acid, CO2 and H2o

Drug: Everolimus
Bioresorbable Scaffolds Polylactide Resorption vs. Radial Support

“In a BRS era, the goal is to provide temporary vessel support and then allow the physiology to evolve naturally”
Meta-Analysis of Everolimus-Eluting Versus Paclitaxel-Eluting Stents in Coronary Artery Disease.
Final 3-Year Results of the SPIRIT Clinical Trials Program (Clinical Evaluation of the Xience V Everolimus Eluting Coronary Stent System in the Treatment of Patients With De Novo Native Coronary Artery Lesions)

A) All-cause Death

- Everolimus DES (n=3350)
- Paclitaxel DES (n=1638)

B) Myocardial Infarction

- Everolimus DES (n=3350)
- Paclitaxel DES (n=1638)

HR [95%CI] = 0.65 [0.49, 0.86] p=0.003

HR [95%CI] = 0.64 [0.48, 0.85] p=0.002
Meta-Analysis of Everolimus-Eluting Versus Paclitaxel-Eluting Stents in Coronary Artery Disease.

Final 3-Year Results of the SPIRIT Clinical Trials Program (Clinical Evaluation of the Xience V Everolimus Eluting Coronary Stent System in the Treatment of Patients With De Novo Native Coronary Artery Lesions)

Figure 1. Three-Year Differences in TLF
Meta-Analysis of Everolimus-Eluting Versus Paclitaxel-Eluting Stents in Coronary Artery Disease.

Final 3-Year Results of the SPIRIT Clinical Trials Program (Clinical Evaluation of the Xience V Everolimus Eluting Coronary Stent System in the Treatment of Patients With De Novo Native Coronary Artery Lesions)
Etiology of DES events beyond 1 year
Very Late Thrombosis and restenosis

1. Uncovered stent struts (thrombosis)
2. Persistent stimulation of SMCs, from adherent fibrin and/or loss of normal vessel curvature
3. Abnormal shear stress form protruding struts and/or loss of cyclic strain relief (compliance mismatch)
4. Chronic inflammation due to late foreign body reactions and polymer hypersensivity
5. Positive remodeling with strut malapposition
6. Strut fracture
7. Neoatherosclerosis
Metallic Stent – A caged lumen doomed to get reduced, or a cage doomed to get malapposed

Compensatory Expansive Remodeling of EEM

Lumen Reduction

Metallic Struts

Lumen Reduction by Intrastent Growth of tissue

Late acquired malapposition

c/o Patrick Serruys
Bioresorbable Scaffold – A new treatment Paradigm for Atherosclerotic Plaque

Compensatory Expansive Remodeling of EEM

Lumen Enlargement by Plaque Regression

Scaffolding

- Lumen Reduction

c/o Patrick Serruys
### Incremental benefit of BRS over Xience

<table>
<thead>
<tr>
<th></th>
<th>One year</th>
<th>Five year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>-</td>
<td>?</td>
</tr>
<tr>
<td>MI</td>
<td>-</td>
<td>?</td>
</tr>
<tr>
<td>TLR</td>
<td>-</td>
<td>?</td>
</tr>
</tbody>
</table>

**Conclusion: No benefit at one year**

<table>
<thead>
<tr>
<th></th>
<th>One year</th>
<th>Five year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scaffold thrombosis</td>
<td>-</td>
<td>+?</td>
</tr>
<tr>
<td>Vasomotion/ Pulsatility</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Pharmaco-access</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

**Acetylcholine positive have better outcomes**

<table>
<thead>
<tr>
<th></th>
<th>One year</th>
<th>Five year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Late lumen enlargement</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Wall thinning</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Adaptive remodelling</td>
<td>-</td>
<td>+</td>
</tr>
</tbody>
</table>

**Late benefit of VRT**
WELCOME
NATIONAL SOCIETY
OF SKEPTICS

I DON'T BELIEVE WE'VE MET...

I DON'T BELIEVE YOU DON'T BELIEVE WE'VE MET...
A bioabsorbable everolimus-eluting coronary stent system (ABSORB): 2-year outcomes and results from multiple imaging methods

Patrick W Serruys, John A Ormiston, Yoshinobu Onuma, Evelyn Regar, Nieves Gonzalo, Hector M Garcia-Garcia, Koen Nieman, Nico Bruining, Cécile Dorange, Karine Miquel-Hébert, Susan Veldhof, Mark Webster, Leif Thuesen, Dariusz Dudek

Summary
Background Drug-eluting metallic coronary stents predispose to late stent thrombosis, prevent late lumen vessel enlargement, hinder surgical revascularisation, and impair imaging with multislice CT. We assessed the safety of the bioabsorbable everolimus-eluting stent (BVS).

Methods 30 patients with a single de-novo coronary artery lesion were followed up for 2 years clinically and with multiple imaging methods: multislice CT, angiography, intravascular ultrasound, derived morphology parameters (virtual histology, palpography, and echogenicity), and optical coherence tomography (OCT).

Findings Clinical data were obtained from 29 of 30 patients. At 2 years, the device was safe with no cardiac deaths, ischaemia-driven target lesion revascularisations, or stent thromboses recorded, and only one myocardial infarction (non-Q wave). 18-month multislice CT (assessed in 25 patients) showed a mean diameter stenosis of 19% (SD 9). At 2-year angiography, the in-stent late loss of 0.48 mm (SD 0.28) and the diameter stenosis of 27% (11) did not differ from the findings at 6 months. The luminal area enlargement on OCT and intravascular ultrasound between 6 months and 2 years was due to a decrease in plaque size without change in vessel size. At 2 years, 34.5% of strut locations presented no discernible features by OCT, confirming decreases in echogenicity and in radiofrequency backscattering; the remaining apparent struts were fully apposed. Additionally, vasomotion occurred at the stented site and adjacent coronary artery in response to vasoactive agents.

Interpretation At 2 years after implantation the stent was bioabsorbed, had vasomotion restored and restenosis prevented, and was clinically safe, suggesting freedom from late thrombosis. Late luminal enlargement due to plaque reduction without vessel remodelling needs confirmation.
The ABSORB Clinical Trial Program

**2011  2012  2013  2014  2015  2016**

**ABSORB RCT**
- Enrollment & Follow-Up
- $n = \sim 2,200$

**ABSORB Japan**
- Enrollment & Follow-Up
- $n = \sim 375$

**ABSORB China**
- Enrollment & Follow-Up
- $n = \sim 500$

**ABSORB II**
- Enrollment & Follow-Up
- $n = \sim 330$

**ABSORB PHYSIOLOGY**
- Enrollment & Follow-Up
- $n = \sim 35$

**ABSORB Extend**
- Enrollment & Follow-Up
- $n = \text{up to } 1,000$

**ABSORB FIRST**
- Enrollment & Follow-Up
- $n = 10,000$

**ABSORB Cohort A**
- 5 Y
- Enrollment & Follow-Up
- $n = 30; \text{ FIM}$

**ABSORB Cohort B**
- 1 Y 2 Y 3 Y 4 Y 5 Y
- Enrollment & Follow-Up
- $n = 101; \text{ FIM}$

**ABSORB Extend**
- 1 Y 2 Y 3 Y
- Enrollment & Follow-Up
- $n = \text{up to } 1,000$

**ABSORB II**
- 1 Y 2 Y 3 Y
- Enrollment & Follow-Up
- $n = \sim 330$

**ABSORB PHYSIOLOGY**
- 1 Y 2 Y
- Enrollment & Follow-Up
- $n = \sim 35$

**ABSORB FIRST**
- 1 Y 2 Y
- Enrollment & Follow-Up
- $n = 10,000$

**ABSORB RCT**
- 1 Y 2 Y 3 Y
- Enrollment & Follow-Up
- $n = \sim 2,200$

**ABSORB Japan**
- 1 Y 2 Y 3 Y
- Enrollment & Follow-Up
- $n = \sim 375$

**ABSORB China**
- 1 Y 2 Y
- Enrollment & Follow-Up
- $n = \sim 500$

**ABSORB Cohort B**
- 5 Y 2 Y 1 Y
- Enrollment & Follow-Up
- $n = 101; \text{ FIM}$

**ABSORB Cohort A**
- 5 Y 4 Y 3 Y 2 Y 1 Y
- Enrollment & Follow-Up
- $n = 30; \text{ FIM}$

**ABSORB Extend**
- 1 Y 2 Y 3 Y
- Enrollment & Follow-Up
- $n = \text{up to } 1,000$

**ABSORB II**
- 1 Y 2 Y 3 Y
- Enrollment & Follow-Up
- $n = \sim 330$

**ABSORB PHYSIOLOGY**
- 1 Y 2 Y
- Enrollment & Follow-Up
- $n = \sim 35$

**ABSORB FIRST**
- 1 Y 2 Y
- Enrollment & Follow-Up
- $n = 10,000$

**ABSORB RCT**
- 1 Y 2 Y 3 Y
- Enrollment & Follow-Up
- $n = \sim 2,200$

**ABSORB Japan**
- 1 Y 2 Y 3 Y
- Enrollment & Follow-Up
- $n = \sim 375$

**ABSORB China**
- 1 Y 2 Y
- Enrollment & Follow-Up
- $n = \sim 500$

**Total Pts Studied**
- $n = 131$
- $n = \sim 931$
- $n = \sim 8,400$
- $n = \sim 13,334$
- $n = \sim 15,590$
- $n = \sim 15,590$
Five Year Angiographic Results of the ABSORB Everolimus Eluting Bioresorbable Vascular Scaffold

B De Bruyne1, MD, PhD; G.G Toth1, MD; Y Onuma2,3, MD, PhD; HM Garcia Garcia3, MD, PhD; PW Serruys2, MD, PhD

1OLV Hospital, Aalst, Belgium; 2Thorax Centre, Erasmus MC, Rotterdam, The Netherlands; 3CardialysisBV, Rotterdam, The Netherlands

• The ABSORB Cohort A trial results demonstrated the safety of Absorb BVS in 30 patients with single de novo native coronary artery lesions.

• The ABSORB Cohort B trial, a continuation of that assessment, enrolled 101 patients at 12 sites in Europe and Asia Pacific
Methods

• The patients of the ABSORB Cohort B Trial were divided into 2 groups, Cohort B1 (n=45) with imaging follow-up at 180 days & 2 years and Cohort B2 (n=56) with imaging follow-up at 1& 3 years.
• A protocol amendment was implemented for a 5 year imaging follow up in all 101 patients.
• The results of the 24/45 patients in B1 who agreed to return for 5 year imaging are presented
Results 1

- Summary of Late Loss at 5-years

![Graph showing late loss at 5 years with data points and labels for 6 months, 2 years, and 5 years.](image)

<table>
<thead>
<tr>
<th>Time</th>
<th>Late Loss (mm)</th>
<th>P-values</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
<td>0.15 ± 0.19</td>
<td>0.0133</td>
</tr>
<tr>
<td>2 years</td>
<td>0.24 ± 0.17</td>
<td>0.8368</td>
</tr>
<tr>
<td>5 years</td>
<td>0.16 ± 0.32</td>
<td>0.0035</td>
</tr>
</tbody>
</table>

Absorb Cohort B1 5 Year Results; B de Bruyne, TCT 2014
Results 2

- Results of nitrate induced vasomotor function at 5-years, n=23. The in-scaffold segment shows either vasodilation (in 83% of the patients) or vasoconstriction, unlike metallic DES in a previous report.\(^1\)

Relative change = 100 x (mean LD post Nit-mean LD pre Nit) / mean LD pre Nit

\(^{1}\)DES implantation associated with long term coronary endothelial dysfunction. Shin et al. Int Heart J 2007;48:553-567

Absorb Cohort B1 5 Year Results; B de Bruyne, TCT 2014
Results 3

OCT Images Over Time Showing Complete Resorbtion of the Scaffold Struts

Baseline  |  6 Months
---------|----------
2 Years  |  5 Years

Courtesy of Dr RJ v Geuns, Rotterdam, The Netherlands

Absorb Cohort B1 5 Year Results; B de Bruyne, TCT 2014
Which factors drive implementation in my clinical practice?

1. Evidence from controlled randomized trials
2. Hard endpoints
3. Generalizability
4. Ease of use
5. Costs (positive cost-effectiveness ratio)
6. Soft endpoints
A bioresorbable everolimus-eluting scaffold versus a metallic everolimus-eluting stent for ischaemic heart disease caused by de-novo native coronary artery lesions (ABSORB II): an interim 1-year analysis of clinical and procedural secondary outcomes from a randomised controlled trial

Patrick W Serruyts, Bernard Chevalier, Dariusz Dudek, Angel Cequier, Didier Carrié, Andres Iniguez, Marcello Dominici, René J van der Schaar, Michael Haude, Luc Wasungu, Susan Veldhof, Lei Peng, Peter Staehr, Maik J Grudeken, Yuki Ishibashi, Hector M Garcia-Garcia, Yoshinobu Onuma

Single-blind, multicentre, randomised trial, 2:1 ratio: everolimus-eluting bioresorbable scaffold (Absorb) or everolimus-eluting metallic stent (Xience)

501 patients
The co-primary endpoints

1) Vasomotion (change in mean lumen diameter before and after nitrate administration at 3 years)
2) Difference between minimum lumen diameter (after nitrate administration) after the index procedure and at 3 years.

....but recognizing the scaffold's widespread use – 70,000-100,000 implants in use - the ABSORB II investigators decided to "report the secondary clinical endpoints at 1 year in order to provide the medical community with the first randomized data on the device."
1) Despite a larger profile (ABSORB: 1.4mm, vs. Xience 1.1mm), device success was similar

<table>
<thead>
<tr>
<th>Procedural details</th>
<th>Bioresorbable scaffold group</th>
<th>Metallic stent group</th>
<th>Difference (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of lesions</td>
<td>364</td>
<td>182</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Balloon dilatation prior to device implantation</td>
<td>364 (100%)</td>
<td>180 (99%)</td>
<td>1.10% (-0.21, 3.42)</td>
<td>0.11</td>
</tr>
<tr>
<td>Planned overlap with the same type of device</td>
<td>56 (15%)</td>
<td>20 (11%)</td>
<td>4.40% (-1.93, 9.94)</td>
<td>0.16</td>
</tr>
<tr>
<td>Unforeseen additional implantation with the same device</td>
<td>14 (4%)</td>
<td>11 (6.0)</td>
<td>-2.20% (-6.91, 1.44)</td>
<td>0.25</td>
</tr>
<tr>
<td>More than one study device implanted</td>
<td>70 (19%)</td>
<td>27 (15%)</td>
<td>4.40% (-2.57, 10.62)</td>
<td>0.21</td>
</tr>
<tr>
<td>Nominal size of study device (mm)</td>
<td>3.01 (0.31)</td>
<td>3.05 (0.28)</td>
<td>-0.04 (-0.10, 0.01)</td>
<td>0.10</td>
</tr>
<tr>
<td>Balloon dilatation after device implantation</td>
<td>221 (61%)</td>
<td>107 (59%)</td>
<td>1.92% (-6.66, 10.67)</td>
<td>0.67</td>
</tr>
<tr>
<td>Nominal diameter of balloon used (implantation or post-dilatation; mm)</td>
<td>3.08 (0.34)</td>
<td>3.16 (0.36)</td>
<td>-0.08 (-0.14, 0.01)</td>
<td>0.02</td>
</tr>
<tr>
<td>Maximum balloon pressure used (implantation or post-dilatation; atm)</td>
<td>14.23 (3.43)</td>
<td>15.03 (3.33)</td>
<td>-0.80 (-1.4, -0.2)</td>
<td>0.01</td>
</tr>
<tr>
<td>Expected diameter of balloon used (implantation or post-dilatation; mm)</td>
<td>3.29 (0.35)</td>
<td>3.35 (0.37)</td>
<td>-0.06 (-0.14, 0.02)</td>
<td>0.15</td>
</tr>
<tr>
<td>Angiographic acute recoil of device following implantation per device (mm)</td>
<td>0.19 (0.19)</td>
<td>0.19 (0.18)</td>
<td>-0.00 (-0.04, 0.03)</td>
<td>0.85</td>
</tr>
</tbody>
</table>

**Device success**

<table>
<thead>
<tr>
<th></th>
<th>Bioresorbable scaffold group</th>
<th>Metallic stent group</th>
<th>Difference (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical device success</td>
<td>361 (99%)</td>
<td>182 (100%)</td>
<td>-0.82% (-2.39, 1.31)</td>
<td>0.55</td>
</tr>
<tr>
<td>Clinical procedural success</td>
<td>322 (96%)*</td>
<td>164 (99%)*</td>
<td>-2.68% (-5.46, 0.80)</td>
<td>0.16</td>
</tr>
</tbody>
</table>

**99% Vs 100%**
2) Acute gain was reduced 
QCA (ABSORB: 1.15mm vs. Xience: 1.46mm) 
Q-IVUS (ABSORB 2.9mm² vs. Xience: 3.6mm²).

**Operator’s behavior**
- Limited expansion of device
- Fear of scaffold disruption
- Use of a smaller postdilatation balloon at a lower pressure

**Preparation strategy**
- Protocol did not allow use of adjunctive device

**Reduced acute gain**

**Acute recoil**
- Not an issue
3) The definite scaffold/stent thrombosis 0.6% (1 acute and 1 subsacute) in the ABSORB arm vs. 0% in the Xience arm.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Bioresorbable scaffold group (n=335)</th>
<th>Metallic stent group (n=166)</th>
<th>Difference (95% CI)†</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All deaths</td>
<td>0</td>
<td>1 (1%)</td>
<td>-0.61% (−3.35 to 0.65)</td>
<td>0.33</td>
</tr>
<tr>
<td>Cardiac deaths</td>
<td>0</td>
<td>0</td>
<td>0.00% (NA)</td>
<td>1.00</td>
</tr>
<tr>
<td>Myocardial infarction per protocol</td>
<td>15 (4%)</td>
<td>2 (1%)</td>
<td>3.32% (−0.25 to 6.26)</td>
<td>0.06</td>
</tr>
<tr>
<td>Q-wave</td>
<td>2 (1%)</td>
<td>0</td>
<td>0.60% (−1.71 to 2.18)</td>
<td>1.00</td>
</tr>
<tr>
<td>Non-Q-wave</td>
<td>13 (4%)</td>
<td>2 (1%)</td>
<td>2.72% (−0.78 to 5.53)</td>
<td>0.16</td>
</tr>
<tr>
<td>All target-lesion revascularisation</td>
<td>4 (1%)</td>
<td>3 (2%)</td>
<td>-0.61% (−4.08 to 1.60)</td>
<td>0.69</td>
</tr>
<tr>
<td>Clinically indicated target-lesion revascularisation</td>
<td>4 (1%)</td>
<td>3 (2%)</td>
<td>-0.61% (−4.08 to 1.60)</td>
<td>0.69</td>
</tr>
<tr>
<td>All target-vessel revascularisation</td>
<td>8 (2%)</td>
<td>8 (5%)</td>
<td>-2.43% (−7.01 to 0.86)</td>
<td>0.15</td>
</tr>
<tr>
<td>Clinically indicated target-vessel revascularisation</td>
<td>6 (2%)</td>
<td>6 (4%)</td>
<td>-1.82% (−6.01 to 1.04)</td>
<td>0.23</td>
</tr>
<tr>
<td>Non-clinically indicated target-vessel revascularisation</td>
<td>3 (1%)</td>
<td>3 (2%)</td>
<td>-0.91% (−4.35 to 1.19)</td>
<td>0.40</td>
</tr>
<tr>
<td>Non-target-vessel revascularisation</td>
<td>6 (2%)</td>
<td>6 (4%)</td>
<td>-1.82% (−6.01 to 1.04)</td>
<td>0.23</td>
</tr>
<tr>
<td>Clinically indicated non-target-vessel revascularisation</td>
<td>5 (1%)</td>
<td>4 (2%)</td>
<td>-0.91% (−4.66 to 1.55)</td>
<td>0.49</td>
</tr>
<tr>
<td>Non-clinically indicated non-target-vessel revascularisation</td>
<td>3 (1%)</td>
<td>2 (1%)</td>
<td>-0.31% (−3.46 to 1.63)</td>
<td>1.00</td>
</tr>
<tr>
<td>All revascularisation</td>
<td>12 (4%)</td>
<td>12 (7%)</td>
<td>-3.65% (−8.89 to 0.37)</td>
<td>0.08</td>
</tr>
<tr>
<td>Clinically indicated revascularisation</td>
<td>9 (3%)</td>
<td>9 (5%)</td>
<td>-2.74% (−7.50 to 0.75)</td>
<td>0.12</td>
</tr>
<tr>
<td>Non-clinically indicated revascularisation</td>
<td>6 (2%)</td>
<td>5 (3%)</td>
<td>-1.22% (−5.21 to 1.49)</td>
<td>0.52</td>
</tr>
</tbody>
</table>
4) Cardiac biomarker rise < 48 hours after the index procedure and per-protocol peri-procedural MI did not differ between the two arms.
5) Exercise performance and angina status as assessed by SAQ were comparable, however a difference in nitrate use was observed at 6 months (17.8% vs 26.7%, p=0.02) and 12 months (19.5% vs 26.2%, p=0.09) in favor of the Absorb arm.
# Clinical Outcomes

<table>
<thead>
<tr>
<th>Cumulative incidence in percentage</th>
<th>Absorb 335 pts</th>
<th>Xience 166 pts</th>
<th>(p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite of cardiac death, target vessel MI</td>
<td>4.8 %</td>
<td>3.0 %</td>
<td>0.35</td>
</tr>
<tr>
<td>and clinically indicated target lesion revascularization (TLF, DoCE)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac death</td>
<td>0 %</td>
<td>0 %</td>
<td>1.00</td>
</tr>
<tr>
<td>Target vessel MI</td>
<td>4.2 %</td>
<td>1.2 %</td>
<td>0.07</td>
</tr>
<tr>
<td>Clinically indicated TLR</td>
<td>1.2 %</td>
<td>1.8 %</td>
<td>0.69</td>
</tr>
<tr>
<td>All TLR</td>
<td>1.2 %</td>
<td>1.8 %</td>
<td>0.69</td>
</tr>
</tbody>
</table>
Registry data

1) Absorb EXPAND Real-World Registry (TCT 2014)
2) EXTEND Real World Registry (Eurointervention 2014)
3) ASSURE Registry (TCT 2014)
4) Ghost-EU Registry (Eurointervention 2014)
5) AMC Single Centre Real World PCI Registry (Eurointervention 2014)

Results from 5 studies and 2206 Patients

<table>
<thead>
<tr>
<th>Study (n)</th>
<th>Expand (187)</th>
<th>GHOST (1189)</th>
<th>AMC (135)</th>
<th>Extend (512)</th>
<th>Assure (183)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FU Lenght months</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Multicenter</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
### Patient characteristics

<table>
<thead>
<tr>
<th>Study (n)</th>
<th>Expand (187)</th>
<th>GHOST (1189)</th>
<th>AMC (135)</th>
<th>Extend (512)</th>
<th>Assure (183)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>60.2±11.1</td>
<td>62±11</td>
<td>59±11</td>
<td>62±11</td>
<td>63.5</td>
</tr>
<tr>
<td>Female</td>
<td>24.5%</td>
<td>21%</td>
<td>27%</td>
<td>26%</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>17.9%</td>
<td>25%</td>
<td>20%</td>
<td>25%</td>
<td>25.7</td>
</tr>
<tr>
<td>Hypertension</td>
<td>60.8%</td>
<td>74%</td>
<td>50%</td>
<td>65%</td>
<td>82%</td>
</tr>
<tr>
<td>Renal impairment</td>
<td>5.4%</td>
<td>14.9%</td>
<td>8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous MI</td>
<td>18.8%</td>
<td></td>
<td>25%</td>
<td>29%</td>
<td>27%</td>
</tr>
<tr>
<td>Previous PCI</td>
<td>9.9%</td>
<td>34%</td>
<td>26%</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Previous CABG</td>
<td>0</td>
<td>4.6%</td>
<td>2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACS</td>
<td>59.1%</td>
<td>47.4%</td>
<td>53%</td>
<td>35% (UA)</td>
<td></td>
</tr>
</tbody>
</table>
# Procedural characteristics

<table>
<thead>
<tr>
<th>Study (n)</th>
<th>Expand (187)</th>
<th>GHOST (1189)</th>
<th>AMC (135)</th>
<th>Extend (512)</th>
<th>Assure (183)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHA/ACC A/B1/B2/C type</td>
<td>100 (B2 + C)</td>
<td>22/26.8/23.6/27.6</td>
<td>17/16/42/25</td>
<td>41 (B2+C)</td>
<td>13.1/22.2/43.4/25.2</td>
</tr>
<tr>
<td>Number of stents</td>
<td>2.16±1.32</td>
<td>1.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stent diameter</td>
<td>3.00±0.44</td>
<td>3.0±0.5</td>
<td></td>
<td></td>
<td>2.7±0.4</td>
</tr>
<tr>
<td>Total stent length, mm</td>
<td>42.8±30.0</td>
<td>32.6±23.0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study  (n)</td>
<td>Expand (187)</td>
<td>GHOST (1189)</td>
<td>AMC (135)</td>
<td>Extend (512)</td>
<td>Assure (183)</td>
</tr>
<tr>
<td>-----------</td>
<td>--------------</td>
<td>--------------</td>
<td>-----------</td>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Death</td>
<td>4 (2.2%)</td>
<td>15 (1.3%)</td>
<td>1 (0.8%)</td>
<td>2 (0.4%)</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>MI</td>
<td>3 (1.7%)</td>
<td>32 (2.7%)</td>
<td>4 (3%)</td>
<td>15 (2.9%)</td>
<td>3 (1.6%)</td>
</tr>
<tr>
<td>MACE</td>
<td>8 (4.3%)</td>
<td></td>
<td></td>
<td>22 (4.3%)</td>
<td>9 (5%)</td>
</tr>
<tr>
<td>TVF</td>
<td></td>
<td>58 (4.9%)</td>
<td>11 (8.5%)</td>
<td>25 (4.9%)</td>
<td></td>
</tr>
<tr>
<td>ST</td>
<td>2 (2.2%)</td>
<td>25 (2.1%)</td>
<td>4 (3%)</td>
<td>4 (0.8%)</td>
<td>0</td>
</tr>
</tbody>
</table>
Random-effect pooled estimates of clinical outcomes

Death: 1.2 ± 0.5
MI: 2.6 ± 0.6
MACE: 4.4 ± 0.7
TVF: 5.3 ± 0.8
ST: 1.5 ± 0.2
Meta regression analysis

ACS

Regression of acs on Logit event rate

Logit event rate

ACS

p=0.21

Age

Regression of AGE on Logit event rate

Logit event rate

AGE

p=0.38

Diabetes

Regression of Diabetes on Logit event rate

Logit event rate

Diabetes

p=0.81
Def/ProbST Ghost-EU registry (1.189 patients)

Capodanno et al.
Possible causes of BVS thrombosis

• Underexpansion
• Multiple Overlap
• Possible scaffold disruption
• Malapposition
• Microenvironmental flow turbulence potentially caused by the BVS thick struts (~150 μm)
Update: The Absorb EXPAND Real-World Registry

A propensity matched comparison of complete 6 months FU

Diameter up to 4.0 mm, length: > 32 mm, Bifurcations, Calcified lesions, ACS patients (non-STEMI), No previous CABG or metallic stent in target vessel

<table>
<thead>
<tr>
<th>Event</th>
<th>Absorb (n=187)</th>
<th>Drug-eluting metallic stents (n=365)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>2.2%</td>
<td>1.9%</td>
<td>0.76</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1.7%</td>
<td>0.0%</td>
<td>0.04</td>
</tr>
<tr>
<td>Target-lesion revascularization</td>
<td>2.2%</td>
<td>1.1%</td>
<td>0.26</td>
</tr>
<tr>
<td>Composite of death, MI and TLR</td>
<td>4.3%</td>
<td>3.0%</td>
<td>0.44</td>
</tr>
<tr>
<td>Definite stent/scaffold thrombosis</td>
<td>2.2%</td>
<td>0.0%</td>
<td>0.01</td>
</tr>
<tr>
<td><strong>Acute/subacute</strong></td>
<td><strong>0.0%/0.0%</strong></td>
<td><strong>0.0%/0.0%</strong></td>
<td><strong>-</strong></td>
</tr>
<tr>
<td><strong>Late</strong></td>
<td><strong>2.2%</strong></td>
<td><strong>0.0%</strong></td>
<td><strong>0.01</strong></td>
</tr>
</tbody>
</table>
no differences in the incidence of definite or probable scaffold/stent thrombosis
ABSORB Biodegradable Stents Versus Second-Generation Metal Stents: A Comparison Study of 100 Complex Lesions Treated Under OCT Guidance

A. Mean Lumen Area
   - BVS: p = NS
   - DES: p = NS

B. % Residual Area Stenosis
   - BVS: p = NS
   - DES: p = NS

C. % of malapposed struts
   - BVS: p = NS
   - DES: p = NS

D. % of stents with proximal edge malapposition
   - BVS: p = 0.05
   - DES: p = 0.05

Early outcome after implantation of Absorb bioresorbable drug-eluting scaffolds in patients with acute coronary syndromes

150 patients with ACS treated with BVS
Vs
103 consecutive patients treated with everolimus drug-eluting stent
Bioresorbable vascular scaffolds in acute ST-segment elevation myocardial infarction: a prospective multicentre study ‘Prague 19’

40 patients with STEMI
Everolimus-eluting bioresorbable vascular scaffolds for treatment of patients presenting with ST-segment elevation myocardial infarction: BVS STEMI first study

Roberto Diletti, Antonios Karanasos, Takashi Muramatsu, Shimpei Nakatani, Nicolas M. Van Mieghem, Yoshinobu Onuma, Sjoerd T. Nauta, Yuki Ishibashi, Mattie J. Lenzen, Jurgen Ligthart, Carl Schultz, Evelyn Regar, Peter P. de Jaegere, Patrick W. Serruys, Felix Zijlstra, and Robert Jan van Geuns

Table 6  Clinical outcomes at the 30-day follow-up intent-to-treat population

<table>
<thead>
<tr>
<th>Clinical events</th>
<th>N = 49</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target-lesion failure</td>
<td>(0/49) 0%</td>
<td>(0–7.41)</td>
</tr>
<tr>
<td>TVF</td>
<td>(0/49) 0%</td>
<td>(0–7.41)</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>(0/49) 0%</td>
<td>(0–7.41)</td>
</tr>
<tr>
<td>Target-vessel MI</td>
<td>(0/49) 0%</td>
<td>(0–7.41)</td>
</tr>
<tr>
<td>Q-wave MI</td>
<td>(0/49) 0%</td>
<td>(0–7.41)</td>
</tr>
<tr>
<td>Non Q-wave MI</td>
<td>(0/49) 0%</td>
<td>(0–7.41)</td>
</tr>
<tr>
<td>Clinically driven target-vessel revascularization</td>
<td>(0/49) 0%</td>
<td>(0–7.41)</td>
</tr>
<tr>
<td>Any MI</td>
<td>(1/49) 2.6%</td>
<td>(0–10.69)</td>
</tr>
<tr>
<td>Q-wave MI</td>
<td>(0/49) 0%</td>
<td>(0–7.41)</td>
</tr>
<tr>
<td>Non Q-wave MI</td>
<td>(1/49) 2.6%</td>
<td>(0–10.69)</td>
</tr>
<tr>
<td>Major adverse cardiac events</td>
<td>(1/49) 2.6%</td>
<td>(0–10.69)</td>
</tr>
<tr>
<td>Non-target-vessel revascularization</td>
<td>(1/49) 2.6%</td>
<td>(0–10.69)</td>
</tr>
<tr>
<td>Definite or probable scaffold thrombosis</td>
<td>(0/49) 0%</td>
<td>(0–7.41)</td>
</tr>
</tbody>
</table>

Data are expressed number and proportion, n (%). 95% CI, 95% confidence interval.
Conclusions

1. Solid physiopathological bases
2. Limited outcome data (long term?)
3. ST: an issue?
4. Safe in ACS
5. Optimal deployment