Conclusions: DREAMS shows excellent safety and efficacy data up to 2 years in cohort 1 of the BIOSOLVE-I trial. Multi-modality imaging documented the absorption process and the uncaging aspect of this device already at 6 months.

TCT-39
6-Month Angiographic Follow-up of the Novel DESolveTM Myolimus-Eluting Bioresorbable Coronary Scaffold for the Treatment of Non-Complex Coronary Lesions – Results from the DESolve I First-In-Man Trial
RICARDO COSTA1, Alexandre Abizaid2, Mark Webster3, James Stewart1, Jose Costa Jr.4, Lynn Morrison4, John Ornstein4, Stefan Verheyt4
1INSTITUTO DANTE PAZZANEESE DE CARDIOLOGIA, SAO PAULO, Brazil, 2Antwerp Cardiovascular Center, ZNA Middelheim, Antwerp, Belgium, 3Antwerp Cardiovascular Center, ZNA Middelheim, Antwerp, Belgium, 4Associate Professor, University of Auckland Medical School, Auckland, New Zealand

Background: The DESolveTM Myolimus-Eluting Bioresorbable Coronary Scaffold (Elixir Medical Corporation, Sunnyvale, CA) is a novel bioresorbable vascular scaffold device that combines a PLLA-based scaffold coated with a potent antiproliferative sirolimus analog agent Myolimus (3 mcg per mm of scaffold length).

Methods: A total of 15 patients with single de novo coronary artery lesions ≤14 mm in vessels 2.5-3.75 mm in diameter were enrolled in this prospective, multi-center, single-arm, first-in-man study, and underwent serial angiographic studies at baseline/index and 6 months follow-up. Primary endpoint was angiographic in-scaffold late lumen loss, as determined by quantitative coronary angiography (QCA) analysis performed by an independent angiographic core laboratory.

Results: Overall, 14 patients/lesions were available for paired analysis. The Right coronary artery was the most prevalent lesion location (43%) and lesion class according to the ACC/AHA classification demonstrated type A in 36%, type B1 in 29% and type B2 in 24%. Baseline QCA showed mean lesion length, reference diameter (RD), main lumen diameter (MLD) and % diameter stenosis (DS) of 8.95 ± 2.64 mm, 2.65 ± 0.32 mm, 0.81 ± 0.29 mm and 70.0 ± 10.5%, respectively. During procedure, predilatation was performed in 93%, postdilatation was performed in 29%, and final TIMI flow was achieved in 100%. Final and 6-month follow-up QCA analyses are shown in the Table. Overall, there was only 1 case of in-segment binary restenosis, which involved the proximal edge outside the scaffold.

Variable | In-Scaffold (N=14) | Final
---|---|---
- RD, mm | 2.77 ± 0.25
- MLD, mm | 2.60 ± 0.19
- % DS | 8.1 ± 7.9
- Acute gain, mm | 1.79 ± 0.39
Follow-up at 6 months
- RD, mm | 2.41 ± 0.28
- MLD, mm | 12.6 ± 11.4
- % DS | 11.9 ± 9.19
- Late lumen loss, mm | 0.19 ± 0.19

Conclusions: The DESolve device demonstrated excellent performance in non-complex coronary lesions including high acute gain and optimal expansion at postprocedure as demonstrated by the low final %DS. At 6-month follow-up, there was relatively low in-scaffold late lumen loss (0.19mm), suggesting efficacy of this new technology on inhibiting neointimal hyperplasia.

TCT-40
Incidence and Acute Clinical Outcomes of Small Side Branch Occlusion After Implantation of Everolimus-eluting Bioresorbable Vascular Scaffold in the ABSORB-EXTEND Single-arm Trial
Takashi Muramatsu1, Yoshinobu Onuma1, Hector M. Garcia-Garcia1, Vassil Varoqui1, Marie-Angèle Morel1, Cécile Dorange1, Susan Veldhof1, Alexandre Abizaid2, Patrick W. Serruys1
1Thoraxcenter, Erasmus Medical Center, Rotterdam, Netherlands, 2Cardialysis B.V., Rotterdam, Netherlands

Background: Side branch occlusion (SBO) contributes to the peri-procedural myocardial infarction (MI), which has been associated with unfavorable late clinical outcomes. However, the incidence and acute clinical outcomes of SBO after bioresorbable vascular scaffold (BVS) implantation has been unexplored.

Methods: Amongst consecutive 469 patients who were enrolled in the ABSORB-EXTEND single-arm trial from January 2010 to January 2012, a total of 1127 side branches in 435 patients were evaluated. Although major side branches ≥ 2 mm in diameter was excluded per protocol, any visible side branches originating within to-be-scaffolded segment or its 5 mm-proximal and -distal margins were included in the angiographic assessment. SBO was defined as a reduction in thrombolysis in myocardial infarction (TIMI) flow to grade 0 or 1.

Results: Pre-procedure reference vessel diameter (RVD) and percent diameter stenosis were 2.62 mm and 58.6 % in the main vessel, and 1.18 mm and 20.0 % in the side branch, respectively. Post-procedure SBO was observed in 67 out of 1127 side branches (5.9 %), while it was 9 out of 537 side branches with a RVD of > 1.0 mm (1.7 %). Amongst 67 occluded side branches, 60 (89.6 %) were originated within the obstruction segment in the main vessel, which was automatically delineated by quantitative coronary angiography. Periprocedural Non-Q-wave MI (NQMI) according to the protocol definition was adjudicated in 5 patients (mean ratio of peak CK and CKMB to upper limit of normal were 2.82 and 4.61, respectively) amongst 61 patients with the angiographic evidence of SBO post-procedure (8.2 %).

<table>
<thead>
<tr>
<th>Clinical events</th>
<th>SBO (N=1)</th>
<th>Non-SBO (N=374)</th>
<th>Relative Risk (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac death</td>
<td>0.0 (0/61)</td>
<td>0.0 (0/374)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>8.2 (5/61)</td>
<td>0.5 (2/374)</td>
<td>15.3 (3.0, 77.3)</td>
<td>0.001</td>
</tr>
<tr>
<td>Q-wave</td>
<td>0.0 (0/61)</td>
<td>0.0 (0/374)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Non-Q-wave</td>
<td>8.2 (5/61)</td>
<td>0.5 (2/374)</td>
<td>15.3 (3.0, 77.3)</td>
<td>0.001</td>
</tr>
<tr>
<td>Ischemia driven target lesion revascularization</td>
<td>0.0 (0/61)</td>
<td>0.0 (0/374)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Major adverse cardiac events</td>
<td>8.2 (5/61)</td>
<td>0.5 (2/374)</td>
<td>15.3 (3.0, 77.3)</td>
<td>0.001</td>
</tr>
<tr>
<td>30-days events (%)</td>
<td>0.0 (0/61)</td>
<td>0.0 (0/374)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Conclusions: Although 5.9 % of small side branches occluded after BVS implantation, the incidence of periprocedural MI was quite limited.

DES: Long Term Results
C227-228
Tuesday, October 23, 2012, 10:30 AM–12:30 PM
Abstract nos: 41-48

TCT-41
The Impact of Left Main Disease on Long-term Clinical Outcomes Among Patients Treated With The Unrestricted Use of Everolimus-Eluting, Sirolimus-Eluting, and Paclitaxel-Eluting Stents: A Substudy of the Bern-Rotterdam Cohort
Aris Moschovitis1, Giulio Stefani1, Michael Magro1, Lorenz Raber1, Bindu Kalean2, Masanori Taniwaki2, Joost Daemert3, Peter Wenaeser4, Ron Van Domburg5, Bernhard Meier5, Peter Juni1, Patrick Serruys5, Stephan Windecker1
1Bern University Hospital, Bern, Switzerland, 2Thoraxcenter, Erasmus MC, Rotterdam, The Netherlands, 3University Hospital Bern, Bern, Switzerland

Background: The impact of left main (LM) revascularization with the unrestricted use of drug-eluting stents (DES) on long-term clinical outcomes is still a matter of debate.
Moreover, everolimus-eluting stents (EES) have not been compared with early generation sirolimus-eluting (SES) and paclitaxel-eluting stents (PES) in LM disease. **Methods:** Out of 12,339 consecutive patients, 11,941 completed last follow-up. 410 (3.4%) patients that underwent LM treatment (177 treated with EES and 233 with SES/PES) were compared with 11,531 (96.6%) patients that underwent non-LM treatment (3,924 treated with EES and 7,607 with SES/PES). In addition, clinical outcomes were stratified by stent type among LM and non-LM patients, respectively. Adjustment was performed with inverse probability of treatment weighting. Primary endpoint was a composite of cardiac death, myocardial infarction (MI), and target-vasel revascularization (TVR).**Results:** At baseline, LM patients were older, had more frequently renal failure, LVEF<30%, cardiacogenic shock, and smoking habits, and less frequently ACS compared with non-LM patients. At 4 years, LM patients had a higher risk of the primary endpoint compared with non-LM patients (34.7% vs 21.5%; HR 1.83, 95% CI 1.52-2.11). This was mainly driven by a higher risk of cardiac death (18.9% vs 7.3%; HR 2.36, 95% CI 2.13-2.64), whereas no significant differences were observed for MI (4.7% vs 5.4%; HR 0.93, 95% CI 0.52-1.65) and TVR (17.5% vs 14.0%; HR 1.31, 95% CI 0.99-1.73). Stratification of the primary endpoint by stent type showed a risk reduction with the use of EES compared with early generation SES/PES. This risk reduction was numerical among LM patients (30.2% vs 36.8%; HR 0.85, 95% CI 0.62-1.13) and met statistical significance among non-LM patients (18.5% vs 23.2%; HR 0.73, 95% CI 0.66-0.81), with no interaction between EES use and LM treatment (p-interaction=0.74).**Conclusions:** LM patients have impaired clinical outcomes compared with non-LM patients during long-term follow-up, mainly due to a higher risk of cardiac death. Absence of significant interaction between EES use and LM treatment suggests that EES use has comparable impact on clinical outcomes in LM and non-LM patients.

**TCT-42**

Long-term Safety and Efficacy of Percutaneous Coronary Intervention With Stenting and Coronary Artery Bypass Surgery for Left Main Disease: Final Five-year Follow-up of the SYNTAX Trial

Patrick Serruys1, Gregorz Religa2, Witold Ruzyllo2, Elisabeth Ståhle3, Antonio Colombo4, Michael Mack5, A. Pieter Kappetein6, Marie-Claude Morice7, David Holmes Jr8, Roberto Corti9, William Wijns10, Marie-Claude Morice11, Carlo Di Mario12, Corrado Virdis13, Roberto Corti9, Peter Kolh14, Patrick Serruys12, Roberto Corti9, Peter Kolh14, Patrick Serruys12

**Background:** Current guidelines recommend coronary artery bypass graft surgery (CABG) when treating significant de novo LM stenosis; however, percutaneous coronary intervention (PCI) has a Class IIb indication for unifted left main coronary artery (ULMCA). This analysis will compare the 5-year clinical outcomes in PCI- and CABG-treated LM patients in the SYNTAX trial.**Methods:** In the SYNTAX trial, patients (N=1800) with left main and/or 3-vessel coronary artery stenoses were randomized to receive either PCI with TAXUS Express paclitaxel-eluting stents (PES) or CABG. The unprotected LM cohort (N=705) was a predefined subset.**Results:** Four-year MACCE and the composite of death/stroke/MI were similar in ULMCA-PCI and CABG-treated patients (Table). Stroke was significantly increased in the CABG group and repeat revascularization was increased in the PCI arm at 4 years (Table). MACCE was similar between groups in patients with low or intermediate SYNTAX Scores (0-23: 11.7% vs 17.0%, p=0.048) and/or LM disease. After informed consent, the patient was randomized if suitable for equivalent revascularization with either treatment; otherwise, they were enrolled in a nested registry. Analysis of the 3VD patient cohort was postregistered.**Results:** In the 3VD subgroup at 4 years, MACCE was significantly higher in patients with percutaneous coronary revascularization (PCI) compared with CABG patients. The rates of composite death/stroke/MI, death, MI, and repeat revascularization were increased in PCI patients; however, stroke was similar between groups at 4 years (Table). Partitioning 3VD subgroup patients by SYNTAX Score tertile demonstrated similar MACCE in patients with low scores (0-22: CABG 24.7% vs PCI 30.4%, p=0.027); whereas both MACCE and mortality were increased in PCI patients with intermediate scores (23-32: 17.9% vs 33.3%, p<0.001 and 6.8% vs 12.7%, p=0.048), and with scores ≥33 (21.2% vs 37.9%, p<0.001 and 6.3% vs 14.5%, p=0.002). Five-year outcomes will be available at the time of the presentation.

<table>
<thead>
<tr>
<th>Adverse Event Rates at 4 years in the 3VD cohort</th>
<th>CABG (n=549)</th>
<th>PCI (n=546)</th>
<th>CABG (n=549)</th>
<th>PCI (n=546)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACCE</td>
<td>21.0%</td>
<td>33.7%</td>
<td>Stroke</td>
<td>3.4%</td>
</tr>
<tr>
<td>Death/Stroke/MI</td>
<td>12.6%</td>
<td>18.6%</td>
<td>MI</td>
<td>3.3%</td>
</tr>
<tr>
<td>Death</td>
<td>7.3%</td>
<td>11.9%</td>
<td>Repeat Revascularization</td>
<td>10.2%</td>
</tr>
</tbody>
</table>

**Conclusions:** This will be the first presentation of the final 5-year outcomes in the 3VD patient population of SYNTAX. Four-year results suggest that CABG remains the standard of care for patients with complex lesions (intermediate or high SYNTAX Score). With less complex disease (low SYNTAX Scores), PCI is an acceptable revascularization alternative.

**TCT-44**

LEADERS: 5-Year Follow-Up From a Prospective, Randomized Trial of BioResorbable Eluting Stents with a Biodegradable Polymer vs. Sirolimus-Eluting Stents with a Durable Polymer—Final Report of the LEADERS study

Patrick Serruys1, Pavel Bazun2, Axel Linke3, Thomas Ischinger4, Dietmar Anton5, Volker Klauss6, Hue-Young Sohn7, Franz Eberli8, Roberto Corti9, William Wijns10, Marie-Claude Morice11, Carlo Di Mario12, Peter Junt11, Stephan Windecker12

**Background:** 2,694 patients with isolated de novo coronary artery disease were randomized to receive either BioResorbable Eluting Stents with a Durable Polymer (Bioresorb) or Sirolimus-Eluting Stents with a Biodegradable Polymer (Sirolimus).**Methods:** At 5 years, an additional 33 patients were lost to follow-up, of whom 11 were in the Sirolimus group and 22 in the Bioresorb group.**Results:** At 5 years, the composite of death, MI, or repeat revascularization was not different in the Bioresorb (24.3%) and Sirolimus (23.1%) groups (HR 1.02, 95% CI 0.82-1.25). No difference was observed for any of the individual components of the primary outcome. No new safety or side effects were reported.

**Conclusions:** At 5 years, no difference in overall MACCE was found between treatment groups. There was an advantage of PCI in stroke and a reduced need for repeat revascularization with CABG. SYNTAX and other recent studies of LM disease suggest that CABG may be preferred in patients with more complex anatomical disease (high SYNTAX Scores). Five-year data will be available at the time of presentation.