lesions were ACC/AHA class B2/C. Device success was 100%. At one year, target lesion failure was 5.0% (31/220), and comprised of target lesion revascularization 2.3% (5/220), cardiac death 1.4% (3/220), and target vessel myocardial infarction 2.3% (5/220). ARC definite/probable stent thrombosis was 0.9% (2/220) at one year. Outcomes at 12 months were also similar in patients with and without DM (Figure).

CONCLUSIONS The RESOLUTE INTEGRITY US study included a large number of diabetic patients and patients with complete anatomy. Use of Resolute Integrity ZES was associated with excellent device success and clinical outcomes, including in patients with diabetes mellitus, at one year. Two-year outcomes will be available at the time of TCT 2015.

CONCLUSIONS Use of new-generation DES in women with multiple risk factors for atherothrombosis is associated with a lower risk for long-term adverse ischemic events compared with early-generation DES.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Drug-eluting stent, High risk patient populations, Women

TCT-578
Predictive Factors of Early, Late and Very Late Atherothrombotic Events in Women Undergoing Percutaneous Coronary Intervention with Drug-Eluting Stents: Results from a Patient-Level Pooled Analysis of Randomized Controlled Trials

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BACKGROUND Predictive factors of atherothrombotic events in women after implantation of drug eluting stents (DES) are unclear. Prior studies of this subject were conducted on predominantly male patient populations.

METHODS The objective of the current study was to investigate the predictive factors of atherothrombotic events in female patients with DES relative to the time when these events occurred. We pooled patient-level data from 26 randomized controlled trials of DES. The primary endpoint was the risk of intracoronary thrombotic event (ITE) at 3 years, defined as the composite of stent thrombosis or myocardial infarction. The timing of ITEs was subdivided into early (occurring ≤30 days after DES placement), late (31 days to 1 year), and very late (>1 year). Predictive factors of ITEs were analyzed via multivariable Cox regression models at each time point. Women who received a bare-metal stent were excluded from this analysis.

RESULTS Out of 10,449 women included in the pooled database, 5333 (51%) had high AT risk. A significantly higher crude rates of 3-year MACE was observed in women with versus without high AT risk (15.8% vs. 10.6%; p < 0.0001). Following multivariable adjustment, high AT risk was independently associated with higher 3-year risk of MACE (HR: 1.59; 95% CI: 1.28–1.99; p < 0.0001) and all-cause mortality (HR: 1.76; 95% CI: 1.18–2.63; p = 0.003). Compared with early-generation DES, in women at high AT risk, the use of new-generation DES was associated with significantly lower risk of MACE at 3 years (HR: 0.79; 95% CI: 0.63–0.99; p = 0.04). New-generation DES had no significant effect on all-cause mortality in high AT risk women (HR: 0.69; 95% CI: 0.47–1.02; p = 0.06). The effect of new-generation DES was uniform between high and non-high AT risk women, without evidence of interaction.

CONCLUSIONS Use of new-generation DES in women with multiple risk factors for atherothrombosis is associated with a lower risk for long-term adverse ischemic events compared with early-generation DES.
HR: 1.37; 95% CI: 1.25-1.51; p<0.0001), and ACC/AHA type B2C lesions (HR: 1.47; 95% CI: 1.34-1.90; p=0.003). The influence of these factors varied over time (Table 1).

### Table 1. Predictors of Early, Late and Very Late Intracoronary Thrombotic Events

<table>
<thead>
<tr>
<th>Variables</th>
<th>Early ITE HR (95% CI)</th>
<th>Late ITE HR (95% CI)</th>
<th>Very Late ITE HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Age (per year increase)</td>
<td>-</td>
<td>-</td>
<td>HR: 1.02 (1.00 - 1.04)</td>
</tr>
<tr>
<td>Diabetic Mellitus</td>
<td>-</td>
<td>-</td>
<td>HR: 2.25 [1.46 - 3.47]</td>
</tr>
<tr>
<td>Arterial Hypertension</td>
<td>HR: 1.50 [1.10 - 2.06]</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Previous PCI</td>
<td>-</td>
<td>HR: 2.30 [1.45 - 3.64]</td>
<td></td>
</tr>
<tr>
<td>First-generation DES</td>
<td>-</td>
<td>-</td>
<td>HR: 1.64 (1.07 - 2.51)</td>
</tr>
<tr>
<td>Number of Stents implanted (per additional stent)</td>
<td>HR: 1.44 [1.32 - 1.58]</td>
<td>-</td>
<td>HR: 1.50 [1.24 - 1.82]</td>
</tr>
<tr>
<td>ACC/AHA Type B2C lesions</td>
<td>HR: 1.45 [1.08 - 1.95]</td>
<td>HR: 2.02 [1.20 - 3.39]</td>
<td>-</td>
</tr>
</tbody>
</table>

### CONCLUSIONS
Multiple clinical, anatomical and procedural characteristics were independently associated with the occurrence of ITEs, with variable impact on early, late and very late ITE risk. First-generation DESs were associated with higher risk of very late ITE.

### CATEGORIES CORONARY: Stents: Drug-Eluting

### KEYWORDS
Drug-eluting stent, Women

## TCT-579
Stent Strut Coverage and Stent Apposition After Implantation of a Novel Drug-Filled Coronary Stent: Optical Coherence Tomography Results from ReVolution Trial

Stephen G. Worthley,1 Alexandre Abizaid,2 Ajay J. Kirtane,3 Daniel Simon,4 Stephan Windecker,5 Gregg W. Stone6

### BACKGROUND
The novel drug-filled coronary stent (DFS; Medtronic, Inc., Santa Rosa, CA) is formed from a continuous tri-layered wire with the innermost layer removed to create a hollow strut lumen that functions as an internal drug reservoir. Small holes (~20 μm) are laser drilled into the abluminal side of the stent, and the inner channel is loaded with sirolimus. The DFS provides controlled drug elution from an internally loaded drug platform without utilization of a polymeric matrix, and thus may avoid chronic inflammation and adverse vascular responses associated with a polymer. The stent is formed from a continuous tri-layered wire with the innermost layer removed to function as a reservoir that elutes sirolimus from small holes (~20 μm) in the abluminal side of the stent. The impact of the reservoir and holes on mechanical properties of the stent and its radiopacity has not been previously reported.

### METHODS
Stent integrity and mechanical strength with the DFS were compared to the current generation Resolute Onyx™ drug-eluting stent (DES, Medtronic, Inc.). Radial strength was tested by measuring the force required to radially compress the stent (diameter 3.0 mm) in a standard iris test. Longitudinal stent deformation was tested by measuring the peak force required to compress the stent by 1 cm after deployment in a 1.5 cm radius curved mock vessel (3.0 x 18 mm). Results are reported as average ± standard deviation. Radiopacity was tested under fluoroscopy in a porcine coronary artery model.

### RESULTS
The DFS had greater radial strength as Resolute Onyx DES (Figure upper right panel), and comparable resistance to longitudinal deformation (Figure upper right panel). Under fluoroscopy, the DFS had greater radiopacity than the Integrity stent™ (Figure lower left panel), and similar radiopacity as the Resolute Onyx and Omega™ stents (Figure lower right panel).

### CONCLUSIONS
The DFS utilizes an internally loaded drug platform to provide controlled release of sirolimus without using a polymeric matrix. Mechanical strength, as well as radiopacity, are at least comparable to current-generation DES. These in-house tests are being independently validated and will be available for presentation at TCT 2015.

## TCT-580
Novel Drug-Filled Coronary Stent and Its Impact on Mechanical Attributes

Nicolas Foin,1 Justin Goshgarian,2 Alexandre Abizaid,3 Ajay J. Kirtane,4 Daniel Simon,5 Stephen Windecker,7 Gregg W. Stone6

### BACKGROUND
A novel drug-filled coronary stent (DFS; Medtronic, Inc., Santa Rosa, CA) provides controlled drug elution from an internally-loaded drug platform without using a polymeric matrix, and thus may avoid chronic inflammation and adverse vascular responses associated with a polymer. The stent is formed from a continuous tri-layered wire with the innermost layer removed to function as a reservoir that elutes sirolimus from small holes (~20 μm) in the abluminal side of the stent. The impact of the reservoir and holes on mechanical properties of the stent and its radiopacity has not been previously reported.

### METHODS
Stent integrity and mechanical strength with the DFS were compared to the current generation Resolute Onyx™ drug-eluting stent (DES, Medtronic, Inc.). Radial strength was tested by measuring the force required to radially compress the stent (diameter 3.0 mm) in a standard iris test. Longitudinal stent deformation was tested by measuring the peak force required to compress the stent by 1 cm after deployment in a 1.5 cm radius curved mock vessel (3.0 x 18 mm). Results are reported as average ± standard deviation. Radiopacity was tested under fluoroscopy in a porcine coronary artery model.

### RESULTS
The DFS had greater radial strength as Resolute Onyx DES (Figure upper left panel), and comparable resistance to longitudinal deformation (Figure upper right panel). Under fluoroscopy, the DFS had greater radiopacity than the Integrity stent™ (Figure lower left panel), and similar radiopacity as the Resolute Onyx and Omega™ stents (Figure lower right panel).

### CONCLUSIONS
The DFS utilizes an internally loaded drug platform to provide controlled release of sirolimus without using a polymeric matrix. Mechanical strength, as well as radiopacity, are at least comparable to current-generation DES. These in-house tests are being independently validated and will be available for presentation at TCT 2015.