# TCT-610

## Abstract Withdrawn

## TCT-611

### Effect of stent inflation pressure and post-dilation on the outcome of coronary artery intervention. A report of more than 90,000 stent implantations

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**Background:** PCI stent inflation pressure correlates to angiographic lumen improvement and stent expansion but the relation to outcome is not clarified. Using comprehensive registry data our aim was to evaluate how stent inflation pressure influences restenosis and stent thrombosis following PCI.

**Methods:** We evaluated all consecutive coronary stent implantations in Sweden from January 2008, to October 26, 2011 using data from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR). We used logistic regression and Cox proportional hazard modeling to estimate risk of outcomes with different balloon pressures.

**Results:** In total, 93,697 stents were eligible for analysis and divided into five different pressure intervals: ≤15 atm, 16-17 atm, 18-19 atm, 20-21 atm and ≥22 atm. The risks of stent thrombosis (Fig. 1) and restenosis were significantly higher in the ≤15 atm, 18-19 atm and ≥22 atm groups (but not in the 16-17 atm group) compared to the 20-21 atm group. Post-dilation was associated with a higher restenosis risk ratio (RR) of 1.22 (95% confidence interval (CI) 1.14-1.32, P<0.001) but stent thrombosis did not differ statistically between procedures with or without post-dilation.

**Conclusions:** Our retrospective study identified a possible optimal stent inflation pressure of 20-21 atm during PCI which was associated with a lower risk of stent thrombosis and restenosis. Post-dilation might increase restenosis risk.

### TCT-612

## Two-Year Results Following Implantation of 32mm and 38mm Platinum Chromium Everolimus Eluting Element Stents in Long Coronary Lesions

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**Background:** Long coronary lesions are a risk factor for increased restenosis and event rates following coronary stenting. The PLATINUM Long Lesion study evaluates the bio-platinized Element platinum chromium everolimus-eluting stent (Boston Scientific, Natick, MA) for the treatment of long coronary lesions. Two year results have not yet been reported.

**Methods:** The prospective, single-arm PLATINUM Long Lesion (LL) study enrolled 102 patients at 30 clinical sites. Patients had angina pectoris or documented silent ischemia. One de novo target lesion >24 to ≤34mm long with reference diameter ≥2.50 to ≤4.25mm could be treated with a 32 or 38mm stent. A lesion in a different epicardial vessel could be treated with a non-study treatment before the target lesion. Exclusion

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### Table 1: XIENCE Prime Observed Rate vs. LLR (N=1104)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>XIENCE Prime Observed Rate</th>
<th>LLR (N=1104)</th>
</tr>
</thead>
<tbody>
<tr>
<td>One Year</td>
<td>Two Years</td>
<td></td>
</tr>
<tr>
<td>One Year</td>
<td>Two Years</td>
<td></td>
</tr>
<tr>
<td>TLF (per WHO)</td>
<td>4.5% (18/399)</td>
<td>6.4% (25/392)</td>
</tr>
<tr>
<td>TLF (per ARC)</td>
<td>6.5% (26/399)</td>
<td>8.3% (33/392)</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>0.3% (1/399)</td>
<td>0.5% (2/392)</td>
</tr>
<tr>
<td>All MI (per WHO)</td>
<td>1.8% (7/399)</td>
<td>2.0% (8/392)</td>
</tr>
<tr>
<td>All MI (per ARC)</td>
<td>4.5% (18/399)</td>
<td>6.9% (23/392)</td>
</tr>
<tr>
<td>TV-MI (per WHO)</td>
<td>1.8% (7/399)</td>
<td>1.8% (7/392)</td>
</tr>
<tr>
<td>TV-MI (per ARC)</td>
<td>4.0% (16/399)</td>
<td>4.6% (18/392)</td>
</tr>
<tr>
<td>CI-THR (per WHO)</td>
<td>2.9% (10/399)</td>
<td>4.1% (16/392)</td>
</tr>
<tr>
<td>ARC-Defined MI (Probable)</td>
<td>0.5% (2/399)</td>
<td>0.5% (2/386)</td>
</tr>
<tr>
<td>TV-MI (per ARC)</td>
<td>1.8% (7/399)</td>
<td>1.8% (7/392)</td>
</tr>
<tr>
<td>TV-MI (per ARC)</td>
<td>4.0% (16/399)</td>
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<td>2.5% (10/399)</td>
<td>4.1% (16/392)</td>
</tr>
</tbody>
</table>

### Notes:
- N is the total number of subjects.
- Population for SPIRIT PRIME consists of those subjects who were treated with at least one XIENCE PRIME stent and had cardiac enzyme data between 8 hours post index procedure and hospital discharge.
- TLF includes cardiac death, target vessel MI or clinically indicated LTL.
- Time frame includes follow-up window (1-year: 365 ± 28 days, 2-year: 730 ± 28 days).
- TLF from hierarchical counts; other outcomes from non-hierarchical counts.
- WHO: World Health Organization.

### Conclusions:
The SPIRIT PRIME study demonstrated sustained 2-year safety and efficacy of the new XIENCE PRIME EES with low cardiac death, MI and CI-TLR rates in both core size and long lesion cohorts and no new ARC definite/probable ST events in either arm.

### TCT-609

## Abstract Withdrawn

## TCT-607

### Long-Term Outcomes of Complete Versus Incomplete Revascularization After Drug-Eluting Stent Implantation in Patients with Multivessel Coronary Disease

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**Background:** This study was sought to investigate the impact of complete revascularization (CR) vs. incomplete revascularization (IR) on long-term outcomes in patients with multivessel coronary disease (MVD) in current practice of percutaneous coronary intervention (PCI).

**Methods:** Between April 2004 and November 2010, 7376 consecutive patients with MVD underwent PCI at our center. Patients who underwent prior CABG and those who had an acute myocardial infarction (MI) within 24 hours before revascularization or presented with cardiogenic shock were excluded.

**Results:** Among 7065 patients with MVD undergoing PCI treatment, angiographic CR was performed in 1188 patients (16.8%), and proximal CR in 2053 patients (29.1%). The study found that either angiographic or proximal IR were associated with significantly higher estimated 3-year rate of cardiac death (2.55% vs. 1.13%, log-rank p=0.016; and 2.70% vs. 1.43%, log-rank p=0.024, respectively). After adjustment for differences in baseline characteristics between IR and CR patients, angiographic IR was associated with a significantly higher rate of cardiac death (adjusted hazards ratio [HR]: 2.56, 95% confidence interval [CI]: 1.72 to 3.72; 95% CI: 0.93 to 3.17). For the subgroup of >2-vessel IR with total occlusion, either angiographic or proximal IR patients had significantly higher rate of cardiac death (adjusted HR: 4.25, 95% CI: 1.50 to 12.0; and adjusted HR: 3.02, 95% CI: 1.40 to 6.52, respectively).

**Conclusions:** Compared with IR, patients with CR had better clinical outcomes, especially when only single vessels were treated, supporting CR as first choice for patients with MVD.
criteria included acute or recent myocardial infarction (MI), left ventricular ejection fraction \(<30\%\), left main or ostial location, major bifurcation disease, chronic total occlusion, and target vessel thrombus. Routine angiographic follow-up was not performed. Planned clinical follow-up is at 1, 6, 12, and 18 months, and annually to 5 years.

**Results:** Patients were predominantly male (62.7\%), and 30.0\% presented with medically treated diabetes. At baseline, target lesion length was 24.38 \(\pm\) 8.21mm and reference vessel diameter was 2.56 \(\pm\) 0.40mm. The study met its primary endpoint of 12-month target lesion failure (composite of target vessel related cardiac death/MI and ischemia-driven target lesion revascularization) with a rate of 3.2\%, which was not significantly different (\(p=0.001\)) than a pre-specified performance goal of 19.4\% (based on historical outcomes with 32mm paclitaxel-eluting stents, the only drug-eluting stent approved in the US when PLATINUM II was initiated). At 1-year follow-up, there were three instances of target lesion revascularization (3.1\%), 1 non-cardiac death, and no cardiac deaths, MIs, or stent thromboses. Two-year clinical follow-up will be reported.

**Conclusions:** The 1-year results of the PLATINUM II study support the use of the PROMUS Element 32mm and 38mm stents in the treatment of long coronary lesions. Two-year results will be available for presentation for the first time at TCT in October 2012.

**TCT-613**
A Prospective Randomized Multi-Center Trial to Assess the Everolimus-Eluting Stent System (Promus Element) for Coronary Revascularization in a Population of Unrestricted Patients

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**Background:** A drug-eluting stent consists of 3 components of equal importance: a metallic platform, a polymer and a drug, all influencing acute and long term results both in safety and efficacy. The Platinum plus trial was designed to compare the Promus element stent to the Xience Prime. These stents have the same polymer poly (n butyl methacrylate) (PBMA) and poly vinylidene fluoride co hexafluoropropylene (PVDF-HFP) and drug (Everolimus) but different platforms (platinum-chromium for the Promus element, cobalt chromium for the Xience Prime) and distinct stent designs.

**Methods:** The design was a non-inferiority single blind randomized 2:1 trial (Promus G1/XienceG2 that recruited 2985 consecutive, all-comer patients in 48 European centers. The primary endpoint was TVF at 1 year.

**Results:** Population consisted of 79% of males, mean age: 65 yrs \(\pm\) 9 yrs. Indications were 42 \% stable angina 31.2\% ACS and 10.2 \% silent ischemia. Risk factors were well balanced between the 2 populations as follows: hypertension (65.8\% vs. 68.1\%), hypercholesterolemia (66.08\% vs. 65.5\%), diabetes I (3.5\% vs. 4.07\%), diabetes II (24.8 \% vs. 22.4\%), insulin-treated diabetes (7.4\% vs. 6.8\%), family history (32.4\% vs. 23.3\%), current smoker (20.4\% vs. 19.9\%). Procedural success was 98.4\% in recipients of Promus stents and 97.8\% for Xience Prime. Mean number of stents implanted per patient was 1.7 \(\pm\) 0.8. In-hospital complications included death N=3 and N=1 (0.13 \% and 0.10 \%) for Promus and Xience, respectively. MI N=7 (0.36\%) and N=2 (0.19\%) emergency CABG N=1 and N=0 (0.05\% and 0 \%), repeat PCI (N=4 N=1). The observed differences were statistically not significant.

**Conclusions:** No differences in acute results were observed between the 2 stents; the 30-day outcome will be available for the meeting.

**TCT-614**
Remote ischemic preconditioning improves outcome in 6 years following elective percutaneous coronary intervention: the CRISP-Stent trial.

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**Background:** Remote ischemic preconditioning (rIPC) attenuates MI4a in humans undergoing elective percutaneous coronary intervention (PCI). However the long-term impact of rIPC on clinical outcomes after PCI is unknown. We hypothesized that rIPC attenuation of MI4a would improve clinical outcome at 6-years.

**Methods:** We randomized 215 patients with normal cardiac troponin-I (Troponin-I < 0.04ng/ml) undergoing elective PCI to either rIPC (n = 110) - three 5-minute blood pressure cuff inflations to 200mmHg around the upper arm with 5-minutes of cuff deflation between, or control (n = 105): a deflated cuff throughout. Before PCI. Patients taking nitrates or glibenclamide were excluded and randomization was stratified for diabetes mellitus (DM). Post-PCI serum cardiac troponin-I (CrTnI) levels were recorded at 24-hours and major adverse cardiac and cerebral event (MACCE) rate determined at 6-years (90% follow-up, mean time to event or last follow-up: 1579.7 +/- 603.6 days).

**Results:** The two groups were matched demographically. Median 24-hour CrTnI was significantly lower in the rIPC group (0.06 vs. 0.16ng/ml, p = 0.04). Mean CrTnI was higher in those with MACCE (0.91 vs. 2.07ng/ml, p = 0.05). MACCE rate at 6-years was significantly lower in the rIPC group (23 vs. 36, p = 0.039, Figure). The non-DM subgroup (n = 166) MACCE rate at 6-years was significantly lower following rIPC (17 vs. 29, p = 0.045) but those with DM (n = 49) did not derive benefit from rIPC (6 vs. 7, p = 0.541).

**Conclusions:** Fewer patients receiving rIPC have post-PCI CrTnI release and rIPC has a superior MACCE-free survival compared to control out to 6-years.

**TCT-615**
Coating Damage of Drug-Eluting Stent Occurs in Front Edge Strut: a Scanning Electron Microscopy Study

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**Background:** Although the use of drug-eluting stents (DES) appears to markedly reduce restenosis in patients undergoing percutaneous coronary interventions (PCI), there are ongoing discussions with regards to late and very late strut thrombosis (LST and VLST). Some reports have indicated that coarse irregularities of DES coating could play a role in promoting strut thrombosis. The aim of this study was to investigate whether and where damage to surface of DES occurs when the DES was delivered through a newly deployed strut.

**Methods:** Fifteen coronary artery phantom models were constructed with a tube of approximately 3 mm inner diameter. Fifteen Paclitaxel-eluting stents (PES) were implanted in each curved tube (r = 20 mm). Then, the other 15 PES were delivered to pass through the implanted stents with guide wire, and moved back and forth completely through them three times. The entire accessible surface area of these unexpanded and expanded stents was examined with a scanning electron microscope. Each PES was divided into 4 equivalent parts for qualitative assessment with/without damage of polymer. We named the most distal part as part 1 (P1) and the most proximal part as part 4 (P4), respectively.

**Results:** Damage was observed more frequently in distal part than in proximal part of both expanded and unexpanded stents (as shown in figures).

**Conclusions:** Placement of DES through an expanded strut could cause damage to polymer of DES. In such cases, the distal site of DES might be easy to fail to prevent restenosis and easy to occur LST and VLST.