eliminate in-stent restenosis in selected simple lesions (FIM, RAVEL trials). The aim of this study is to investigate the efficacy of SES in the treatment of bifurcation lesions.

**Methods:** Since 1st April 2002 it is the policy of our institution to utilize the SES as a device of choice for all percutaneous interventions, with no carotid or anastomotic exclusion criteria. The patients with bifurcation lesions are being included in this study. The follow-up angiography will be performed at 6 months after procedure. **Results:** Up to 16th August 2002, 44 bifurcation lesions have been treated with SES. The mean age was 61 years old and 13 patients (29.5%) were diabetic. All patients underwent SES deployment in both vessels. The baseline QCA results are present in the table. So far, there had been one late loss lesion revascularization 5 weeks after procedure, however it is noteworthy that the restenosis occurred at the ostium of a side branch that was not covered with SES. The clinical outcomes and follow-up QCA results will be available at the time of presentation. Conclusions: In this study, the impact of sirolimus-eluting stents on the outcome of patients with bifurcation lesions in the "real world" experience will be reported.

**Parent vessel side branch**

<table>
<thead>
<tr>
<th>Pre reference diameter (mm)</th>
<th>2.54 - 0.56</th>
<th>2.31 - 0.54</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre minimum lumen diameter (mm)</td>
<td>0.75 - 0.59</td>
<td>0.65 - 0.59</td>
</tr>
<tr>
<td>Post reference diameter (mm)</td>
<td>2.56 - 0.56</td>
<td>2.33 - 0.54</td>
</tr>
<tr>
<td>Post minimum lumen diameter(mm)</td>
<td>2.30 - 0.94</td>
<td>1.98 - 0.94</td>
</tr>
</tbody>
</table>

**1030-181**
The Frequency and Consequences of Angiographic Aneurysms after Sirolimus-eluting Stents: Results from SIRIUS

Marco A. Costa, Jeffrey W. Moses, Bruce W. Reiner, Paul R. Teirstein, Steven Yakubov, Andrew J. Carter, Tim A. Fischell, Paul Gilmore, Theodore A. Bass, University of Florida, Jacksonville, FL

**Background:** Angiographic aneurysms are observed after control bare metal stents (CBS) in < 1% of pts and thus far, have not been associated with detrimental clinical outcomes. The marked anti-proliferative effects of sirolimus-eluting stents (SES) raise concerns regarding potential vessel wall thinning and an increase in aneurysm formation.

**Methods:** In the randomized double-blind SIRIUS trial (1058 pts), 8-month angiographic follow-up (FU) was obtained in 66% (702 pts). Angiographic aneurysms were defined as treatment site vessel diameter > 1.5x the normal reference diameter (either at baseline or at FU) and all patients were assessed for clinical events (up to 9 months).

**Results:** Aneurysms were found at FU in 6 pts (0.9%); 4 pts with CBS (1.1%) and 2 pts with SES (0.6%). In the 4 CBS aneurysms @ FU, 2 were present at baseline and morphology was fusiform in 2 (both multiple stents), and eccentric focal (≤ 10 mm length) outlining in 2 (1 proximal to RCA stent). In the 2 SES aneurysms @ FU, none were present at baseline and morphology was fusiform ectasia in 1 (3 SES after long RCA dissection) and eccentric focal protruding in 1 (within RCA SES). In the 1 case of SES focal protrusion, IVUS exam revealed clear incomplete apposition at FU (flush apposition at baseline) with positive remodeling. Although 2 pts with angiographic aneurysms in CBS pts had Res at FU, no pt in either group had adverse clinical events (death, MI, or stent thrombosis) during FU.

**Conclusions:** Results from the SIRIUS angiographic analysis indicate that aneurysms at FU are (1) extremely infrequent (< 1%) with both CS and SES; (2) commonly were present at baseline and were often not distinct from fusiform ectasia; (3) are not associated with important clinical events (or morr Fus). Thus, there are no objective data to suggest that SES confer added risk of aneurysm formation and subsequent clinical events.

**1030-182**
Platelet Activation After Stenting With Heparin-Coated Versus Noncoated Stents

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**Objectives:** The purpose of the study was to investigate the effect of heparin coating on platelet activation following coronary artery stenting.Background: Animal models of heparin coating reduces platelet aggregation induced by coronary injury. However, reduced platelet activation has never been demonstrated in humans. **Methods:** In a prospective randomized study of 50 consecutive elective patients, platelet activation was analyzed by measuring aggregation and surface receptor expression at baseline and at 2 hours, 24 hours, 5 and 30 days following implantation of either heparin-coated or noncoated (fix velocity stent(s). **Results:** Platelet activation as measured by 24 hour expression of mean fluorescence intensity of active glycoprotein (GP) IIb/IIIa, and total GP IIb/IIIa, was decreased following implantation of a heparin coated stent as compared to bare stent. A P = 0.01 for active GPIIb/IIIa and 328±10 vs 303 ± 98 (P=0.01 for total GP IIb/IIIa). A trend at 20 days post stenting of lower total (293±140 vs 293±60, P=0.07) and active GP IIb/IIIa expression (10.3±6.9 vs 7.5±2.9, P=0.15) was also observed with the heparin-coated stent. Aggregation and stimulated p-selectin did not differ between groups.

**Conclusion:** Elective stenting with a heparin-coated stent is associated with less early expression of GP IIb/IIIa on circulating platelets as compared to revascularization with a bare stent with the same design. These findings have direct implications on the risk of subacute thrombosis and deserve further investigation.

**1030-183**
Sirolimus-Eluting Stent for the Treatment of Bypass Graft Disease: The Initial U.S. Experience

Marco A. Costa, Jeffrey W. Moses, Martin B. Leon, Paul S. Teirstein, Steven Yakubov, Andrew J. Carter, Tim A. Fischell, Paul Gilmore, Theodore A. Bass, University of Florida, Jacksonville, FL

**Background:** Stenting has provided limited success in the treatment of saphenous vein graft (SVG) as in-stent restenosis (ISR) and adverse clinical events remain a challenge. While brachytherapy has offered clear benefit in this high-risk population, outcomes remain suboptimal. The efficacy of sirolimus-eluting stents in native coronary arteries is proven, however its application in bypass grafts remains to be determined. We report the first series of patients in the United States with graft disease treated with sirolimus-eluting stents as part of the compassionate use SECURE trial.

**Methods:** Compassionate use of sirolimus-eluting stenting was indicated for patients with a serious disease or condition for which there was no acceptable alternative treatment available. To date, 80 patients have been enrolled in the SECURE study. Follow-up angiography will be repeated in all patients with prior brachytherapy failure.

**Results:** Nineteen patients with bypass graft disease have been enrolled so far. Patient characteristics include: 12 (63%) were diabetic, 16 (84%) had Type II diabetes, 11 (57%) had prior myocardial infarction, 55%, diabetes 9%, hypertension 29% and hyperlipidemia 91%. Twenty-four percent present with unstable angina. All patients had previous angioplasty. Seventeen lesions were treated in 15 grafts analyzed to date. Nine target vessels underwent prior revascularization with: atherectomy therapy 2, focal cutting balloon, cryoplasty, stent, and drug-eluting stent. The outcomes of patients are presented in Table 1.

**Conclusions:** Implantation of sirolimus-eluting stents in high-risk patients is feasible. This may represent an important treatment option for patients with bypass graft disease.

**1030-184** Use of the Sirolimus Drug-Eluting Stent for Real World Coronary Lesions The Milan Experience: Results of the First 400 Lesions

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**Background:** Positive results from the use of the sirolimus drug-eluting stent (CYSHERTM, Cordis) in clinical trials and subsequent published lesions have been published. We report our experience with the use of the Cypher stent in everyday clinical practice.

**Methods:** We included all lesions treated with the Cypher stent in Milan between 15 April and 30 of August 2002. Major adverse cardiac events (MACE) were defined as death, Q-wave myocardial infarction or target lesion revascularization.

**Results:** A total of 400 lesions in 296 patients were treated. The baseline characteristics of these lesions included: 212 (54.5%) were acute lesions, 176 (47.8%) were chronic lesions, 15 (3.7%) were restenosis, 11 (2.8%) were treated with atherectomy, 29 (7.5%) were treated with both atherectomy and stent, 14 (3.6%) were treated with a focal cutting balloon, and 9 (2.3%) were treated with both atherectomy and focal cutting balloon. The lesions were distributed as follows: 29% RCA, 36% LAD, and 29% Cx. The reference vessel size was 2.8*0.5mm, the minimal lumen diameter (MLD) 0.79*0.40mm and the mean lesion length 16.5*5.6mm.

**Conclusions:** Implantation of Cypher stents in "real world" lesions is associated with low clinical events and excellent MACE-free survival rates. Thirty day complications are low with an increase in thrombosis, despite usage of long and multiple stents. We will see if follow-up results are in accordance with prior findings in less complex lesions.

**1030-185** Is There Any Arterial Toxic Effect After Overlapping Sirolimus-Eluting Stents?

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**Background:** Drug-eluting stents reduce first-time in-stent restenosis (ISR) and are being investigated as a treatment for ISR after bare-metal stenting. However, it remains unclear whether overlapping drug-eluting stents (and effectively doubling the drug dose) has a toxic effect on the vessel wall.

**Objectives:** The purpose of this study was to analyze the one-year IVUS findings after 2 overlapping Sirolimus-eluting stents were implanted in patients with native artery ISR lesions.

**Methods:** Of 25 patients in the ISR Sirolimus registry, 8 had a lesion length requiring 2 overlapping stents (and effectively doubling the drug dose) at the time of presentation. Conclusions: The implantation of Cypher stents in "real world" lesions, aiming to completely cover the diseased segment, results in high stented vessel lengths. Thirty days complications are low without an increase in thrombosis, despite usage of long and multiple stents.