PCI and follow up intravascular ultrasound (IVUS, mean 9.9±2.4 months) were performed in all patients.

Results: The Post-PCI external elastic membrane (EEM) volume (group I vs group II, 417.3±196.5 vs 409.7±180.1 mm³, p=NS), post-PCI lumen volume (228.6±111.0 vs 223.0±89.5 mm³, p=NS), follow up EEM volume (435.1±168.1 vs 414.9±179.4 mm³, p=NS), and follow up lumen volume (236.6±91.7 vs 222.5±90.1 mm³, p=NS) by IVUS were not different between the two groups. There were three LISAs (2.5%, group I (n=2) vs group II (n=1)) and thirty four PISAs (28.1%, group I (n=23) vs group II (n=11)) that were resolved [14.7%, group I (n=4) vs group II (n=1)]. Post-PCI and follow up volume of PISA was not significantly different in both group I (5.9±5.6 vs 5.1±4.6 mm³, p=NS) and group II (8.9±4.4 vs 8.5±4.2 mm³, p=NS). There was no major adverse cardiac event associated with LISA or PISA during 12-month clinical follow up.

Conclusion: The incidence of LISA was very low in both groups comparing to the previous generation of drug eluting stent. Both LISA and PISA were not associated with cardiac events during 12-month follow up. Future long-term follow up study to clarify the clinical impacts of LISA and PISA would be needed.

TCT-209
Drug Eluting Stents in the Treatment of Isolated Proximal LAD Disease are Associated with Similar Outcomes Compared to Minimally Invasive LIMA Grafts
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Background: We studied the long term outcome of patients with isolated proximal LAD disease revascularised with either DES or ‘off-pump’ left internal mammary artery (LIMA) graft.

Methods: 874 consecutive patients with stable angina undergoing either elective percutaneous coronary intervention with a DES or ‘off-pump’ CABG for significant isolated proximal LAD disease at a London centre between Oct 2003-December 2010 were studied. The primary end point used was major adverse cardiac events (MACE), defined as the composite of death, myocardial infarction (MI), stroke and target vessel revascularisation (TVR).

Results: 752 patients underwent PCI with DES and 122 pts underwent ‘off-pump’ CABG. The baseline demographic and angiographic characteristics were similar between the two groups. The mean duration of hospitalization after CABG was 6.33 ± 1.61 days vs. 1.06 ± 0.20 days after PCI (P < 0.001). Kaplan-Meier estimates of major adverse cardiac events showed no differences between the groups over the follow-up period (11.8% vs 12.0%, p=0.9 at 4 years) (Figure 1a). On MACE breakdown there was a trend towards higher mortality in the LIMA cohort (7.8% vs 11.8%, p=0.9 at 4 years) (Figure 1a). There were three LIMA grafts with a TVR (5.8% vs 2.8%, p=0.19) (Figure 1b). After multivariate adjustment revascularisation technique was not predicative of major-adverse cardiac events.

Conclusion: The study demonstrated that DES have similar long-term results to LIMA grafts in patients with isolated proximal LAD disease.

TCT-210
Low Incidence of Stent Thrombosis in Asian Races: Multicenter Registry in Asia 6 Years Follow-Up Result
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Background: The aim of this study was to evaluate the frequency, predictors and the clinical outcome of stent thrombosis after DES implantation and bare metal stent (BMS) implantation in Asian races.

Methods: A total of 14,577 consecutive patients who underwent successful DES implantation (8,809 patients, 62% of the lesion with Sirolimus-eluting stent: SES, 38% of the lesion with Paclitaxel-eluting stent: PES) and BMS implantation (5,768 patients) were included in this study. We evaluate the frequency, predictor of stent thrombosis.

Results: At a mean follow-up of 78.5±29.9 months in DES and 81.8±26.4 months in BMS. The cumulative incidence of stent thrombosis were subacute stent thrombosis (SAT): 0.5% with DES and 0.6% with BMS, late stent thrombosis (LAST): 0.18% with DES and 0.1% with BMS, very late stent thrombosis (VLAST): 0.18% per year with DES and no BMS. Independent predictors of stent thrombosis are bifurcation lesion (OR=1.90, 95% CI: 1.83 to 24.24, p=0.01) and ejection fraction (OR=0.90, 95% CI: 0.86 to 0.94, p<0.03). Only 0.2 % of the patients were died because of the
**TCT-211**

The SYNTAX Trial at 3 Years: A Global Risk Approach to Identify Patients With 3-Vessel & or Left Main Stem Disease Who Could Safely & Efficaciously Be Treated With Percutaneous Coronary Intervention Part 2: The All-Comers SYNTAX Population

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**Background:** The Global Risk Categorisation (GRC), a combination of the SYNTAX score (SSCORE) & additive EuroSCORE, is superior to the SSCORE alone in predicting clinical outcomes in patients with 3VD &/or LMS coronary disease undergoing PCI. The GRC is investigated in the All-Comers “real-world” SYNTAX population.

**Methods:** The study population (n=3075) consisted of pre-specified powered randomised LMS & 3VD cohorts (n=1800) & non-randomisable nested CABG (n=1275) patients with the 857 patients in the BES arm of LEADERS together with different MI definitions. A 25% rate of protocol mandated angiographic FU may also contributed to higher rates of peri-procedural MI and TVR. However, the near identical event rates beyond 30 days for all components of MACE, suggest that under-reporting of events is unlikely to have played a major role.

**TCT-212**

Are Results from an All-Comers Registry Comparable with the Results from an All-Comers Randomized Clinical Trial? Insights from 12-Month Results of the e-BioMatrix PMS Registry

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**Background:** The safety and effectiveness of BioMatrix A9™-eluting stents (BES) has been evaluated relative to sirolimus-eluting stents in the LEADERS all-comers RCT and in several observational registries. We compared the 1-year results for the first 1102 patients in the e-BioMatrix registry with the 857 patients in the BES arm of LEADERS and analysed how the different study designs impacted the results.

**Methods:** Both the e-BioMatrix PMS registry and the LEADERS RCT are all-comers, “real world” studies, not limited by lesion length, number of treated lesions/vessels or clinical indication (chronic stable angina vs. ACS). The baseline characteristics were similar (mean age: 64.1 vs. 63.5; DM: 24% vs. 26% (p=0.35); ACC/AHA criteria for high vs. low risk: 55% (p=0.41). LEADERS had higher proportions of patients with prior PCI and prior MI (36% vs. 25% (p=0.001) and 32% vs 21% (p=0.001)). We compared the rates of cardiac death, MI, clinically-indicated TVR and ARC-defined stent thrombosis at 12 months.

**Results:** The patients enrolled in the e-BioMatrix registry had similar rates of cardiac death (1.7% vs 2.1%) and QW MI (0.5% vs 0.5%) compared to those in LEADERS, although lower rates of all MI (2.5% vs. 5.8%, p=0.001) and a trend toward lower clinically indicated TVR (4.3% vs. 5.8%, HR 0.75, p=0.08) at 1 year. The 1-year MACE rates were 7% and 10.6% for e-BioMatrix and LEADERS respectively (p=0.10). Although e-BioMatrix showed a lower rate of early definite ST vs LEADERS (0.5% vs 1.6%, p=0.05), the rates of late ST were similar (0.4% vs 0.4%).

**Conclusion:** The e-BioMatrix PMS registry confirms the good safety profile of BES at 12 months. Even though LEADERS was an “all-comers” study, some of the adverse event rates were lower in the e-BioMatrix registry, especially during the first 30 days, consistent with a patient selection process and a per protocol analysis (vs. ITT in LEADERS). This could be related to mandatory ECG and biomarker determinations required post-procedure in LEADERS together with different MI definitions. A 25% rate of protocol mandated angiographic FU may also contributed to higher rates of peri-procedural MI and TVR. However, the near identical event rates beyond 30 days for all components of MACE, suggest that under-reporting of events is unlikely to have played a major role.

**TCT-213**

Increased Tissue Stress Leads to Increased Neointima Evaluated by Histology and Computational Modeling

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**Background:** The biomechanical performance of stenting can be best understood through a coupling of computational modeling with in vivo pathology evaluations. To this end, finite element analysis (FEA) of stent-artery interaction can be used to characterize vessel-specific stresses and their correlation to biologic response.

**Methods:** Two bare-metal stent designs differing in strut thickness were compared for differences in vessel wall stress. FEA was used to simulate the deployment of both stent models in a mock artery model. Acute and chronic stresses induced in the vessel wall were determined and compared between stent models. Stents (n=4) were implanted in a normal rabbit iliac artery at a 1.3:1 stent:artery ratio. Twenty-eight days following stenting, histomorphometric analysis was performed.

**Results:** Stresses were ~70% lower for thin versus thick stents. Overall, there was increased neointimal area in the thick versus thin stents (0.68 ± 0.07 vs 0.66 ± 0.10, p < 0.02). Though neointimal thickness above struts trended lower in thick struts (0.02 ± 0.00 vs 0.03 ± 0.01, p = 0.08), the change in neointimal thickness immediately adjacent to struts was greater in thick struts (0.18 ± 0.00 vs 0.11 ± 0.01, p = 0.01). Neointimal thickness was similar between the two groups between struts (0.07 ± 0.02 vs 0.03 ± 0.01, p = 0.67).

**Table 1:** FEA predicted principal stress (PS) and Von Mises stress (VM) at stent strut locations.

**Conclusion:** Stent design impacts the stress induced in the vessel wall during and after stent deployment. Von Mises and principal stresses are focused at stent strut contact

**POSTERS**

**TUESDAY, NOVEMBER 8, 2011, 8:00 AM - 10:00 AM**