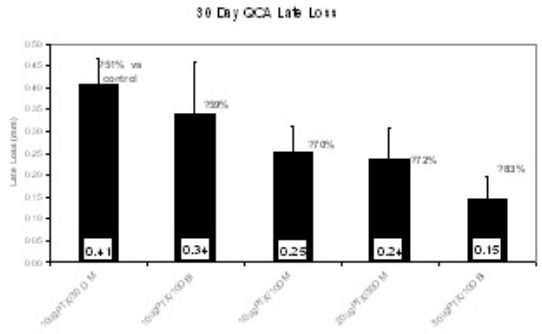

1139-52 **Biolimus A9: A New Generation Rapamycin Analogue Inhibits Intimal Hyperplasia in a Porcine Model**

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Background: Biolimus A9 is a novel, rapamycin analogue especially designed for drug eluting stent application . Biolimus A9 is developed with the intent of optimizing release kinetics and tissue partitioning while maintaining the inhibitory properties of Sirolimus on smooth muscle cells.
Methods: Nine Bare metal(B) and 9 BiolimusA9(B9) coated stents were evaluated in 28 day ovestretch porcine model. The drug delivery polymer was thin layer bio-resorbable Poly-lactic-acid. The average balloon artery ratio was 1.18±0.3. At sacrifice coronary angiography and histologic analysis was performed for each stented vessel.
Results: The results are tabulated in Table 1. There was no difference of injury in both groups. There was 50% reduction of area stenosis by the B9 coated stent(p=0.001). Histology, showed near complete endotheliazation in both control and A9 groups with a only a slight increase in fibrin content in the B9 group.**Conclusions;** BiolimusA9 delivered via bioresorbable polymer coated stent inhibits intimal hyperplasia in a porcine model. There is normal healing of treated arteries at 28days and no inflammation as compared to controls.A first-in man clinical trial has been intiated

Histomorphometric Analysis of the Bare and Biolimus A9 stents

	Bare Stent(9)	Biolimus A9(9)	p value
Injury Score	0.30± 0.10	0.30± 0.12	NS
Intimal Hyperplasia(Um)	238 ± 24	152 ± 14	0.004
Area Stenosis(%)	38	20	0.001

1139-53 **The Long-Term Clinical Results of a Platelet Glycoprotein IIb/IIIa Receptor Blocker (Abciximab: ReoPro®) Coated Stent in Patients With Coronary Artery Disease**

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Background : Previously we reported the inhibition of coronary restenosis with Abciximab(ReoPro®)-coated stent in a porcine model. ReoPro® inhibits platelet aggregation, the proliferation of vascular smooth muscle cells and inflammatory reaction.
Methods : We performed a prospective randomized trial to compare two types of stents for the revascularization in native coronary artery. The primary effective end points were major adverse coronary events (MACE): cardiac death, acute myocardial infarction, target vessel revascularization (TVR), restenosis at 6-month clinical and angiographic follow-up.
Results : One hundred fifty-five patients were enrolled between Aug, 2001 and Jun, 2003. Mean ages (56.0±10.0 vs. 56.9±10.8 years), baseline diameter stenosis and minimal luminal diameter were not different between the two groups. There was one myocardial infarction and revascularization during hospital stay in control stent group. During clinical follow-up, there were two myocardial infarctions in control group. Follow-up coronary angiogram was done 62.3% (48/77) in coated and 65.4% (51/78) in control groups. Diameter stenosis and late loss were significantly less in the ReoPro®-coated stent group compared with controls (16.4±5.8% vs. 34.3±6.1%, p=0.009; and 0.33±0.28 mm vs. 0.88±0.41 mm; p=0.002). The restenosis and TVR rates of ReoPro®-coated stent were relatively lower compared with control stent [14.6%(7/48) vs. 29.4%(15/51), p=0.062; and 9.2%(7/76) vs. 14.7%(11/75); p=0.327].
Conclusion : A ReoPro®-coated stent is safe and may be effective in the prevention of coronary restenosis.

1139-54 **Nitric Oxide Through Biodegradable Layer Elective Study for Safety and Efficacy (NOBLESSE): Final Results From the South American Study Arm**

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Background: Oxygen free radical scavengers may play a significant role in preventing neointimal hyperplasia after stent implantation. The Blue Medical TEMPO coronary stent is characterized by its particular biodegradable PEA coating conjugated with tempamine, a potent antioxidant substance. Pre-clinical work showed a similar tissue response and reduced intimal hyperplasia in a porcine coronary stent model using this stent. The aim of this study was to evaluate the acute safety and efficacy of the TEMPO loaded Blue Medical stent implanted in patients with de-novo single vessel disease.
Methods: This is a multinational, multicenter, 2 armed phase III trial. 45 patients treated with an intermediate dose (50%) of tempamine loaded on the Blue Medical stent from 2 South American study sites are presented: 64% were male, average age 61 (range 37 - 86) 38% had lesion type B2 or C. One 14 mm or 18mm long stent was used. Minimal lumen diameter (MLD) and % diameter stenosis (DS) were measured. The primary endpoints are 4m in-stent %DS and late loss determined by QCA. The secondary endpoints are binary restenosis rate at 4m follow-up and 30 days, 60 days and one year major adverse cardiac events (MACE) defined as death, MI, CABG & target vessel revascularization.
Results: All the stent implantations were successful except one that resulted in a distal dissection, treated by an additional coated stent implantation. Two patients were excluded because of violation of the inclusion and/or exclusion criteria. There was no MACE at 30 days and 60 days f-up. TLR occurred in 2 patients during the 4m f-up. 4m angiographic f-up rate was obtained in 98%. QCA: mean reference diameter: 3.01±0.29 mm, % Ds was 64.01±12.20% before, 8.40±4.01% after stent implantation and 30.37±17.03 % at 4m f-up. Late loss was 0.69±0.52. Four patients developed an in-stent restenosis at 4m resulted in a binary restenosis rate of 9.52%. Final 12m clinical f-up will be presented
Conclusion: This short term and 4 month results show that implantation of a tempamine loaded Blue Medical stent is feasible and safe. QCA data showed a low late loss and binary restenosis rate, therefore suggesting a beneficial effect on neointimal hyperplasia and in-stent restenosis.

1139-55 **Optimal Geometry Is Still Important With Sirolimus-Eluting Stents: Incomplete Stent Expansion as a Risk for Target Lesion Revascularization**

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Background: Despite the striking reduction in neointimal hyperplasia seen with sirolimus eluting stents (SES), target lesion revascularization (TLR) has not been completely eliminated. The aim of this IVUS substudy was to clarify procedure-related risk factors for TLR in sirolimus-eluting stents.
Methods and Results: Angiographic and IVUS data were obtained from SIRIUS, a prospective, randomized, multicenter clinical trial comparing SES (sirolimus-eluting Bx VELOCITY, Cordis) and bare metal stent (BMS). Post-procedure IVUS measurements in SES were available in 108 cases. Stent expansion was defined as minimum stent area (MSA) divided by reference LA. There were 6 TLR cases in SES in this patient cohort. Table summarizes comparisons between TLR and non-TLR cases. Angiographic lesion length was longer in TLR cases. With respect to procedure-related factors, TLR cases had lower maximal pressure, smaller % expansion, and a trend toward smaller MSA.
Conclusions: Incomplete stent expansion may be a risk factor for TLR in sirolimus-eluting stents. Proper mechanical stent deployment to achieve adequate lumen geometry may further improve the clinical success of this technology.

	No-TLR	TLR	P
B/A ratio	1.0±0.1	0.9±0.2	NS
Nominal balloon diameter, mm	3.1±0.5	2.8±0.3	NS
Maximum Pressure, atm	17.0±2.7	14.7±1.0	0.03
Lesion Length, mm	14.2±5.2	18.8±5.0	0.04
MLD, mm	2.7±0.4	2.6±0.2	NS
% diameter stenosis	3.5±8.0	6.4±7.5	NS
Reference lumen area, mm^2	6.6±2.3	6.5±0.8	NS
MSA, mm^2	6.0±1.8	4.6±0.6	0.07
% Stent Expansion	94±22	71±15	0.03

1139-56 **Impact of Stent Implantation Techniques on Stent Edge Neointimal Hyperplasia Following Sirolimus-Eluting Stenting**

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Background: IVUS substudy of the SIRIUS trial showed a tendency for neointimal hyperplasia (NI) to develop at stent edges after sirolimus-eluting Bx VELOCITY stent (SES) implantation. However, predictors for this phenomenon have not been clarified. In this study, we examined the potential risk factors including procedural demographics for stent