inclusion were Mehran Class I, II, or III lesions less than 30 mm in length, 50-99% diameter, covered in their entirety by no more than 2 contiguously placed stents inserted a minimum of90 days prior to enrollment. After pre-dilation,15 mm NIRx™ Conformer Coronary Stent(s) with 1.0 µg/mm2 (loaded drug/stent surface area) Paclitaxel in a slow-release formulation were implanted. Pre- and post- stent intra-vascular ultrasound (IVUS) was performed. The primary endpoint was the 30-day incidence of major cardiac events (MACE) defined as death, myocardial infarction, or target vessel revascularization.

Results: The study has completed enrollment. All 29 patients had successful stent implantation. Fourteen patients received 2 stents; the rest received 1. Two peri-procedural MACE events have been reported at this time. Planned follow-up will be at 1, 6, 12 months and then annually. Repeat IVUS and angiography will be performed 6 months after the baseline procedure.

Conclusions: Early feasibility data show promise for the use of polymer-controlled Paclitaxel-eluting stents to treat ISR. Six month clinical and angiographic data will be reported in March 2002.

1174-16 Sirolimus Coated Stent Versus Bare Stent: Angiographic and IVUS Analysis at Four-Month and One-Year Follow-Up

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Background: Sirolimus (Rapamycin) coated stent has been shown to decrease intimal hyperplasia (IH) compared to bare stent.

Objective: To assess the difference of IH between 4 and 12 months of sirolimus-coated compared to non-coated (bare) Bx Velocity coronary stents in patients with CAD.

Methods: Forty-five patients underwent elective, single vessel stenting in our institution. Sirolimus-coated stents were implanted in 30 patients (15 fast [15 days] release formulation and 15 slow [28 days] release of sirolimus) and non-coated stents were implanted in 15 pts. All stents were 18mm long and 3.0-3.5 mm in diameter. Angiographic and volumetric IVUS analyses were performed by two experience analysts, after the procedure, at 4 and 12 month follow-up.

Results: All stents were successfully deployed after balloon pre-dilatation and pts were discharged without complications. Baseline characteristics were similar between groups and 23% of the pts had diabetes. Reference vessel diameter was 2.96 ± 0.3 mm (FR), 2.98 ± 0.4 (SR) and 2.9± 0.4 mm (noncoated stent group), p=NS.

	FR 4m	FR12m	SR 4m	SR 12m	Bare 4m	Bare12m
Late loss (mm)	0.11±0.11	0.2±0.3	0.05±0.1	0.08±0.3	0.84±0.37	0.91±0.4
Intimal hyperplasia (mm3)	2.04±3.8	2.5±4.3	0.23±0.89	0.3±1.3	39.01±21.5	42.3±23.5

FR vs SR: p = NS; FR vs Bare: p< 0.0001; SR vs Bare: p < 0.0001; 4 m vs 12 m: p = NS

Conclusion: Late lumen loss and intimal hyperplasia was virtually absent after implantation of sirolimus-coated stents and significantly less than non-coated stents, regardless the formulation used (FR versus SR) and the time of follow-up (4 versus 12 months).

1174-17 Effect on Restenosis With a Paclitaxel Eluting Stent: Factors Associated With Inhibition in the Elutes Clinical Study

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Background: In-stent restenosis remains a clinical problem and the efficacy of drug-coated stents is unproven. Paclitaxel inhibits microtubule formation rendering cells cytostatic and has been shown to inhibit restenosis in animal models.

Methods: To evaluate the safety and efficacy of the paclitaxel-eluting V-Flex Plus™ coronary stent (without polymer coating), a multicenter, randomized, triple-blinded, dose-ranging study (ELUTES) with 4 progressive dose treatment groups and one control group (uncoated stent) was conducted. In-hospital and 6 month clinical and angiographic data were collected. Patients with severe calcification, left main lesion and multiple lesions in the target vessel were excluded. Study endpoints were percent diameter stenosis and late loss at 6 months measured by QCA, and MACE at 1 and 6 months. The study had independent core lab QCA analysis, clinical events adjudication, and data safety monitoring.

Results: 190 pts received stents (37% LAD, 37% RCA, 21% LCX, 5% RAM). Patients were 81% male. Mean age was 60 years. Patients had 56% one- and 27% two-vessel disease, 11% unstable angina, 34% prior MI, 2% prior CABG. Lesions were 27% A, 63% B1, and 9% B2. There was 1 death, no Q Wave MI's, no emergent CABG, one re-PTCA (0.5%) and 5 (2.6%) non Q MI. MACE rate at 30 days was 1.1%. Procedural QCA on 183 patients and follow-up QCA on 110 patients revealed a reference vessel diameter of 2.96 ± 0.41mm, a minimum lumen diameter of 0.55 ± 0.27mm prestent, 2.68 ± 0.39 mm post stent, and 2.16 ± 0.78 mm at 6 months. Overall residual stenosis at follow-up was 27.1 ± 24.5% and late loss was 0.49 ±0.68 mm including the control group and the four progressively active groups . Follow-up will be completed in November 2001 after which unblinding and analysis of clinical, angiographic and procedural factors associated with restenosis inhibition will be completed.

Conclusions: Even without unblinding, a paclitaxel-coated coronary stent with no polymer appears to be associated with reasonable short-term safety and seems compatible with mid-term restenosis inhibition. Unblinding will permit further description of factors associated with efficacy at the time of the presentation.

1174-18 Are Sirolimus-Eluting Stents Inducing Vascular Remodeling? A Subgroup Analysis of 3D-Intravascular Ultrasound in the RAVEL Trial

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Background: Abolition of intra-stent neointimal hyperplasia after Sirolimus-eluting stent (SES) implantation has been demonstrated in a pilot study (FIM: First In Men) and confirmed in the double-blind, randomized, controlled RAVEL trial. However, the influence of SES on plaque burden behind the struts and on the vessel wall (expansion or retraction of the external elastic membrane area; EEM) has not been documented. **Aim:** To compare vessel remodeling at 6-month follow-up (FU) after SES and uncoated stent (US) implantation in a subset of patients randomized in the RAVEL trial at 6 of 19 participating centers. **Methods:** Patients with single de-novo lesions were randomized to receive either an 18 mm SES Bx-VELOCITY™ stent (Cordis) or an US Bx-VELOCITY™ stent. Motorized IVUS pullback (0.5 mm/sec) was performed at 6-month FU and analyzed by an independent core lab (Cardialysis, Rotterdam, NL). Total vessel volume (TVV), stent volume (SV), and lumen volume (LV) were measured. Total plaque volume (TPV), plaque volume behind the stent (PBS) and neointimal hyperplasia (NIH) were calculated as "TVV-LV", "TVV-SV"; "SV-LV", respectively. Data were compared using an unpaired t-test. **Results:**

Volume (mm^3)	SES (n=36)	US (n=27)	p-value
TVV	275.7± 69.1	283.7±71.9	ns
SV	127.7± 30.7	138.1± 36.1	ns
LV	125.5± 32	96.9± 40.6	0.003
TPV	150.2± 44.4	186.8± 52.8	0.004
PBS	148.0± 45.5	145.6± 0.41	ns
NIH	2.18 ± 7.2	41.2 ± 32.3	0.000

Conclusion: PBS and TVV had similar volumes at FU suggesting that no significant plaque shrinking or positive/negative remodeling occurred as result of Sirolimus elution. In other words, SES is effective in preventing NIH without influencing the vessel wall structure when compared with US.

1174-19 SCORE Six-Month Angiographic Results: Improved Restenosis in Patients Receiving the QUADDS-QP2 Drug-Eluting Stent Compared With the Control, Bare Stents

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Background: The QUADDS-QP2 stent is a 316L stainless steel stent that delivers 4000 ug QP2 (an antiproliferative taxane derivative) from high capacity polymer sleeves. The SCORE trial was stopped early due to higher thrombosis with the QP2 Stent after randomizing 267 of 400 pts with de novo native lesions to a bare metal control stent or the QP2 Stent (available sizes: 3.0 or 3.5mm; 13 or 17 mm long). Methods: We report the quantitative angiographic (QCA) results of the first 260 pts enrolled, with follow-up available in 77% (N=202). Restenosis rates (RS) include thrombosis cases (9.4% QP2 vs 0% Quest). Results: The stent was deployed successfully in all cases. Lesion characteristics were similar at baseline with ACC/AHA class >B1 in 30.9% QP2 vs 33.6% bare stent, p=NS (see table). Follow-up restenosis was reduced by 57%. Conclusion: Despite the safety concerns of high dose QP2 delivered via a high capacity polymer on the QUEST stent, striking reductions in RS are observed within the targeted stent zone, which remains overestimated due to the inclusion of thrombosis cases. Complete adjudicated 6 month data will be presented.

	QUADDS-QP2 N=134	QUEST N=126	p value
Reference, mm	2.92±0.43	3.00±0.48	0.163
Lesion length, mm	11.67±4.62	11.96±4.36	0.603
Final MLD, mm	2.28±0.46	2.28±0.53	0.988
Follow-up Stent MLD, mm	2.31±0.71	1.75±0.79	<0.001
Stent Late Loss, mm	0.35±0.73	0.65±0.71	0.004
Restenosis Stent %	10.1%	36.9%	<0.001

1174-20 Treatment of In-Stent Restenosis Using Paclitaxel Eluting Stents: Results From the Leuven Pilot Trial

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Coronary stents are still hampered by an increased neointimal hyperplasia caused by vessel injury due to stent inplantation and due to a foreign body response induced by the stent itself.

Paclitaxel, extracted from the Pacific Yew Tree, Taxus Brevifolia, possess potent immunosuppressive effects, inhibiting cellular activities such as mitosis , migration, endocytosis and secretion.

Pre-clinical investigation with the Cook Paclitaxel-coated coronary stent showed a slow in-vivo release of the drug. Fourteen days after stent inplantation in a pig coronary artery, 69% of the drug was locally released. This resulted in a significant decrease of late loss,