DRUG-ELUTING STENT UPDATE In every issue, a report on today's drug-eluting stent studies

New items are in **bold**.

STUDY	SAMPLE SIZE	SPONSOR	STUDY DESIGN		LOCATION	RESULTS	STATUS
Paclitaxel, Taxol (antineoplastic)							
DESTINY	**n=60; 10 US centers**	**Cook**	**Zilver PTX paclitaxel-eluting stent vs balloon angioplasty without stenting**		***De novo* or restenotic above-the-knee femoro-popliteal lesions**	**No results available.**	**Enrollment to start in 9/04.**
ELUTES (dose-finding study)	n=192; 9 clinical centers	Cook	V-Flex Plus PTX vs bare stent		*De novo* lesions in native coronaries	6-month binary restenosis: 3.1% highest-dose, 20% lowest-dose, 20.6% control. 12-month TLR: 5% highest dose vs 16% in control. No late thrombosis, death, or MI (presented at AHA 11/02).	CE Mark approval 9/02 for V-Flex Plus PTX stent. This stent will not be introduced in the US.
In-stent ELUTES	n=600 (planned); 22 European centers	Cook	Three treatment groups using low-dose and high-dose V-Flex Plus PTX stent vs bare stent		In-stent restenosis	No results available.	Results to be used in request for additional indications for V-Flex Plus PTX stent.
ATLAS	**n=822; 60 sites**	**Boston Scientific**	**Taxus Liberté stent system vs bare Liberté stent**		***De novo* lesions in native coronaries**	**No results available.**	**Enrollment started 8/04.**
TAXUS II (safety and efficacy)	n=536; 38 centers in 15 countries	Boston Scientific	1.0 µg/mm^2 slow-release and moderate-release drug-eluting NIR stent vs bare NIR stent		*De novo* lesions in native coronaries	12-month MACE: 10.9% SR, 9.9% MR (vs 21.7% in combined controls; 1 stent thrombosis in SR, 1 in MR, 0 in controls.	Results published in *Circulation* (2003;108:788-794).
TAXUS III (single-arm registry)	n=30; 2 European centers	Boston Scientific	NIR drug-eluting stent		In-stent restenosis	6-month binary restenosis: 16%; MACE: 28.6%.	Results published in *Circulation* (2003;107:559-564).
TAXUS IV (pivotal study)	n=1,326; 74 US centers	Boston Scientific	Taxus stent vs bare Express^2 stent		*De novo* lesions in native coronaries	TLR at 9 and 12 mos: 3% and 4.2% for Taxus vs 11.3% and 14.7% for controls. 9-mo TVR: 4.7% for Taxus vs 12% for controls (61% relative RR). 9- and 12-mo MACE: 8.5% and 10.6% for Taxus vs 15% and 19.8% for controls. Stent thrombosis: 0.6% vs 0.8%.	Taxus Express^2 stent received FDA approval 3/04. Results published in the *New England Journal of Medicine* (2004;350:221-231). **One-year results published in *Circulation* (2004;109:1942-1947).**
TAXUS V	n=1,172; up to 70 clinical centers	Boston Scientific	Taxus stent vs bare Express^2 stent		High-risk patients with long *de novo* lesions (<4.0 mm) in native coronaries	No results available.	Enrollment completed. Final 9-month results expected in early 2005.
TAXUS VI	n=448; 44 sites	Boston Scientific	Moderate-release drug-eluting Taxus stent vs bare Express^2 stent		High-risk patients with long *de novo* lesions (18 mm-40 mm) in native coronaries	9-mo TVR : 9.1% Taxus MR vs 19.4% controls (53% decrease). 9-mo TLR decreased 64% from 18.9% to 6.8%. MACE: 22.5% controls and 16.1% Taxus. No difference in incidence of stent thrombosis between groups.	9-month results presented at EuroPCR 5/04.
Rapamycin, sirolimus, Rapamune (macrocyclic lactone, immunosuppressant)							
SIRIUS	n=1,101; 53 US sites	Cordis (J&J)	Cypher stent vs Bx Velocity bare stent		*De novo* lesions in native coronaries; lesions 2.5 mm-3.5 mm in length	8-mo restenosis: 32% for Cypher vs 35.4% for controls. 2-year TLR and TVF: 6.3% and 13% for Cypher vs 21% and 26.6% in control. 2-yr MACE: 10.9% vs 24.2%, respectively. Stent thrombosis: 0.6% Cypher, 0.8% controls.	Cypher received FDA approval 4/03. SIRIUS results published in *New England Journal of Medicine* (2003;349:1315-1323). 2-yr results presented at AHA 11/03.
E-SIRIUS	n=353 in Europe	Cordis (J&J)	Cypher stent vs. Bx Velocity stent. Direct stenting (DS) option left to investigator's discretion.		*De novo* lesions in native coronaries	DS done on 26%. 9-mo MACE reduced 79% compared to DS control vs 60% in predilat group (results maintained at 1-year). In-lesion restenosis: Cypher+DS=2.4% and Cypher+predilat=7%.	Results presented at ESC 9/03; published in *Lancet*. 2003;362(9390):1093-1099. Results updated at AHA 11/03.
C-SIRIUS	n=102 in Canada	Cordis (J&J)	Cypher stent vs Bx Velocity bare stent		*De novo* lesions in native coronaries	100% reduction in in-stent restenosis at 8 months; 91% reduction in late loss; 64% improvement in minimum lumen diameter.	Results presented at ACC 3/03.
RAVEL	n=238; 19 centers in Europe and Latin America	Cordis (J&J)	Cypher stent vs Bx Velocity bare stent		*De novo* lesions in native coronaries; lesions 2.5 mm-3.5 mm in length	MACE (death, MI, CABG, re-PTCA) free survival at 3 years was 85% study vs 77.1% control. MACE-free survival at 1 year was 94.2% study vs 81.4% control.	Results presented at ACC 3/04. Cypher receives regulatory approval in Japan 3/04.
SIROCCO I	n=36; 6 sites in Europe and Canada	Cordis (J&J)	Slower-eluting Smart nitinol self-expanding drug-eluting stent and fast-eluting model vs bare Smart stent control		Superficial femoral artery; 7 mm-20 mm in length; max of 3 stents allowed	24-month total restenosis: 40% (slower-eluting) vs 44.4% (fast-eluting) vs 47.1% control. TLR: 0% vs 11.1% vs 5.8%, respectively; 24% overall fracture rate.	Results presented at TCT 9/03.
SIROCCO II	n=57; 6 sites in Europe and Canada	Cordis (J&J)	Slower-eluting Smart nitinol self-expanding drug-eluting stent vs bare Smart stent control		Superficial femoral artery; 7 mm-14.5 mm in length; max of 2 stents allowed	6-month in-stent angio: 0% restenosis in study group; 7.7% control; late loss: 0.38±0.64 vs 0.68±0.97; TVR: 3.4% vs 10.7%; 0 TLRs; 0 thromboses; 6% fracture rate.	Results presented at TCT 9/03.
FIM (feasibility study)	n=45; Sao Paulo, Brazil, and Rotterdam, The Netherlands	Cordis (J&J)	Slow-release and fast-release Cypher stent		*De novo* lesions in native coronaries, 3 mm-3.5 mm in length	4-year event-free survival: 87.2%. Late loss at 4 years: 0.3 mm for fast release, 0.1 mm for slow release.	4-year results presented at ACC 3/04.
GREAT (safety and efficacy)	n=100; multiple centers in Europe	Cordis (J&J)	Drug-eluting stainless steel balloon-expandable stent vs bare stainless steel balloon-expandable stent		Renal artery stenosis	No results available.	Trial announced 2/03.
Dexamethasone (corticosteroid)							
STRIDE (safety and feasibility study)	n=71; 8 Belgian sites	Abbott Vascular	BiodivYsio phosphorylcholine (PC) drug-eluting 0.5 µg/mm^2 dexamethasone Matrix Lo stent		*De novo* lesions in native coronaries	6-month MACE: 3.3%. Six-month restenosis: 13.3%. Promising results in patients with UA (presented at ACC 3/02).	Dexamet DES launched in Europe 2/03.
Everolimus (immunosuppressive, antiproliferative)							
FUTURE I (safety study)	n=42, 1 site	Guidant	Champion everolimus-eluting stent with bioabsorbable polymer matrix vs bare-metal stent.		*De novo* lesions in native coronaries ≤18 mm long; diabetics excluded	6-month angiographic late loss and restenosis: .11 mm and 0% for DES vs .85 mm and 9.1% for control. No new MACE from 6 to 12 mos, no in-stent binary restenosis at 12 mos, no aneurysms or malapposition.	**Six- and 12-month results published in *Circulation* (2004;109:2168-2171).**
FUTURE II	n=64; 3 sites	Guidant	Champion everolimus-eluting stent with bioabsorbable polymer matrix vs bare metal stent		*De novo* lesions in native coronaries ≤18 mm in length, diabetics included	6-month MACE: 4.8% for DES and 17.5% for BMS; TLR 4.8% and 15%; MLD: 2.74 mm vs. 2.02 mm; late loss, 0.12 mm vs 0.85 mm. No new MACE occurred in the everolimus arm between 6 and 12 months.	12-month results presented during a company mid-quarter conference call 5/04.
SPIRIT FIRST	n=60; multiple European sites	Guidant	Multi-Link Vision DES with durable polymer vs. bare-metal stent		*De novo* lesions ≤12 mm; diabetics included	30-day MACE: 7.1% in one arm and 0% in the other arm (blinded).	30-day results presented at EuroPCR 5/04.
ABT-578 (immunosuppressive, rapamycin analogue)							
ENDEAVOR	n=100 planned; 8 clinical centers in Australia and New Zealand	Medtronic	Endeavor drug-eluting stent (no control group)		*De novo* lesions in native coronaries; lesions up to 15 mm in length, vessels 3 mm-3.5 mm in length	MACE at 9 and 12 mos: 2.0%; TVF at 9 and 12 mos: 2.0%; TLR at 9 and 12 mos: 1.0%. In-stent late lumen loss at 12 mos, 0.58 mm; in-segment late lumen loss was 0.40 mm.	1-year results presented at EuroPCR 5/04.
ENDEAVOR II (pivotal study)	n=1,500 planned; 96 centers in 21 non-US countries	Medtronic	Endeavor drug-eluting stent vs Driver standard stent		*De novo* lesions in native coronaries; lesions 14 mm-27 mm in length	30-day results were presented blinded. 30-day MACE was 2.9% for Group Y and 3.5% for Group Z. TLR at 30 days was 0.2% and 0.3%; 30-day TVR was 0.3% and 0%, respectively.	30-day (blinded) results presented at EuroPCR 5/04.
ENDEAVOR III	n=436 (327 to receive Endeavor stent)	Medtronic	Endeavor drug-eluting stent or Cypher sirolimus-eluting stent		*De novo* lesions in native coronaries	No results available.	Enrollment began in February 2004.