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
Paclitaxel, Taxol (antineoplastic)			
ELUTES (dose-finding study)	n=192; 9 clinical centers	Cook	V-Flex Plus PTX vs bare stent
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
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
TAXUS III (single-arm registry)	n=30; 2 European centers	Boston Scientific	NIR drug-eluting stent
TAXUS IV (pivotal study)	n=1,326; 74 US centers	Boston Scientific	Taxus stent vs Express^2 uncoated stent
TAXUS V	n=1,100 planned; up to 70 clinical centers	Boston Scientific	Taxus stent vs bare Express stent
TAXUS VI	n=448	Boston Scientific	Moderate-release drug-eluting Express stent vs bare Express stent
DELIVER	n=1,043	Guidant	3.0 µg/mm^2 drug-eluting Achieve stent vs bare Penta stent
DELIVER II	n=1,533; 76 non-US clinical sites	Guidant	Achieve stent system
Rapamycin, sirolimus, Rapamune (macrocyclic lactone, immunosuppressant)			
SIRIUS	n=1,101; 53 US sites	Cordis (J&J)	Cypher stent vs Bx Velocity bare stent
E-SIRIUS	n=353 in Europe	Cordis (J&J)	Cypher stent vs. Bx Velocity stent. Direct stenting (DS) option left to investigator's discretion.
C-SIRIUS	n=102 in Canada	Cordis (J&J)	Cypher stent vs Bx Velocity bare stent
RAVEL	n=238; 19 centers in Europe and Latin America	Cordis (J&J)	Cypher stent vs Bx Velocity bare stent
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
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
FIM (feasibility study)	n=45; Sao Paulo, Brazil, and Rotterdam, The Netherlands	Cordis (J&J)	Slow-release and fast-release Cypher stent
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
Tacrolimus (immunosuppressive macrolide)			
PRESENT I (safety study)	n=22	Abbott Vascular	FlexMaster nanopourous ceramic coated stent
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
Everolimus (immunosuppressive, antiproliferative)			
FUTURE I (safety study)	n=42, 1 site	Guidant	Champion everolimus-eluting stent with bioabsorbable polymer matrix vs bare-metal stent.
FUTURE II	n=64; 3 sites	Guidant	Champion everolimus-eluting stent with bioabsorbable polymer matrix vs bare metal stent
SPIRIT FIRST	n=60; multiple European sites	Guidant	Multi-Link Vision with durable polymer vs uncoated stent
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)
ENDEAVOR II (pivotal study)	n=approx. 1,200; 96 centers in 21 non-US countries	Medtronic	Endeavor drug-eluting stent vs Driver standard stent

	LOCATION	RESULTS	STATUS
	De novo lesions in native coronaries	6-month binary restenosis: 3.1% highest-dose, 20.0% 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 restenosis	No results available.	Results to be used in request for additional indications for V-Flex Plus PTX 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;108:788-94).
	In-stent restenosis	6-month binary restenosis: 16%; MACE: 28.6%.	Results published in *Circulation* (2003;107:559-564).
	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 12.0% 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).
	High-risk patients with long *de novo* lesions (<4.0 mm) in native coronaries	No results available.	Enrollment anticipated to begin in early 2003.
	High-risk patients with long *de novo* lesions (18 mm-40 mm) in native coronaries	No differences in postprocedure QCA between groups. 30-day in-hosp MACE: 4.8% group A, 6.8% group B; out-of-hosp MACE: 0.9% and 0.5%, respectively. Stent thrombosis: A=1, B=2 at 30 days.	Long-term and 9-month IVUS and angiographic results to be presented at EuroPCR 2004.
	De novo lesions in native coronaries	9-mo MACE: 10.3% in study vs 13.3% in control (P=.147). Target vessel failure (TVF) at 9 mo was 11.9% and 14.5%, respectively (P=.128).	Enrollment and follow-up completed.
	High-risk patients with *de novo* lesions and ISR coronaries	6-month TLR: 10.5%; 6-month MACE: 15.7%.	Results presented at ESC 9/03.
	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 13.0% for Cypher vs 21.0% 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.
	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=7.0%.	Results presented at ESC 9/03; published in *Lancet*. 2003;362(9390):1093-1099. Results updated at AHA 11/03.
	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.
	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 85.0% 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 stent rec'd CE mark approval, 4/02.
	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.
	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.
	De novo lesions in native coronaries, 3.0 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.**
	Renal artery stenosis	No results available.	Trial announced 2/03.
	De novo lesions in native coronaries	30-day MACE: 0%. 6-mo MACE 13.6% (all from TLR). In-stent restenosis 19%.	PRESENT III trial currently underway.
	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.
	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.	**Updated FUTURE II and pooled FUTURE I and II results presented at ACC 3/04.**
	De novo lesions in native coronaries ≤18 mm in length, diabetics included	6-mo MACE: 4.8% for DES and 17.5% for BMS; TLR: 4.8% vs 15.0%. MLD at 6 months: 2.74 mm vs 2.02 mm; late loss: 0.12 mm vs. 0.85 mm. 94% reduction in neointimal volume by IVUS with DES.	**Updated FUTURE II and pooled FUTURE I and II results presented at ACC 3/04.**
	De novo lesions ≤12 mm; diabetics included	No results available.	First human implant 12/03.
	De novo lesions in native coronaries; lesions up to 15 mm in length, vessels 3.0 mm-3.5 mm in length	30-day MACE: 1% for study group, 4-month MACE: 2% and in-stent late loss: 0.33 mm. Percent DS reduced from 70.3% preprocedure to 5.4% postprocedure and 14.4% at 4 months.	**9-month results to be presented at EuroPCR 5/04.**
	De novo lesions in native coronaries; lesions 14.0 mm-27.0 mm in length	No results available.	**Enrollment completed 1/04. Early results to be presented at EuroPCR 5/04.**