SFA STUDY CHART

STUDY	SPONSOR	SAMPLE SIZE	DEVICE	STUDY DESIGN	LESION LENGTH	RESULTS	STATUS
ev3 IntraCoil study	ev3	n=266; 23 US sites	IntraCoil	Randomized prospective, multicenter trial of PTA (alone) vs PTA plus stenting in SFA and popliteal arteries; primary endpoints MACE and TLR at 9 months	Stenotic lesions (length ≤15 cm) or occlusive lesions (length ≤12 cm) in femoropopliteal arteries, to the bifurcation of the tibial artery, with a reference vessel diameter of 3.0 cm to 7.8 cm	Data show IntraCoil stent is comparable to PTA in the treatment of symptomatic atherosclerotic disease in femoropoliteal arteries. MACE-free at 9 months 81.2% (PTA) vs 80.5% (stent) (*P*=.8766) and TLR-free 83.9% (PTA) vs 85.7% (stent) (*P*=.7335). PTA group had significantly more major complications at 30 days (8.4%) than the stent group (1.5%) (*P*=.0100)	Study completed 2001
FAST	C.R. Bard, Inc.	n=244	Luminexx	Randomized PTA vs stenting in SFA; proximal SFA lesions; primary endpoint is patency; also performing 12-month follow-up for fractures	<10 cm	Showed equivalency bewteen PTA and stenting	30 day results released at EuroPCR, May 2005; 6 month to be released at TCT in October 2005
Mewissen Trial	N/A	122 patients; 137 limbs	Smart	Single center, retrospective. Primary stenting. Hemodynamic endpoint: >50% stenosis within the stent, measured by duplex	12.2 cm (4 - 28 cm)	98% technical success. 92%, 76%, 66%, and 60% at 6, 12, 18, and 24 months, respectively	Ongoing single center
PELA	Spectranetics	n=251 patients with claudication (Rutherford 2-4) at 16 sites in the US and Europe	N/A	Multicenter, prospective randomized trial comparing excimer laser-assisted PTA vs PTA alone to treat long total SFA occlusions	Total occlusions >10 cm	Fewer stents places in the laser arm (42%) vs the balloon-only arm (59%) No statistically significant difference in acute procedural outcomes or in complications between the two groups. Twelve-month patency rates and functional status were also similar in both groups	Completed
REAL SFA	Vascular Architects	n=125; 11 US sites	aSpire	Prospective, multicenter registry of aSpire in SFA and popliteal artery after failed/suboptimal balloon angioplasty; clinical patency and stent integrity endpoints at 9 months	≤40 cm (average lesion = 10.2 cm)	9 month overall TLR = 20%	Complete results presented at MEET 2005 and TCT 2005
RESILIENT	Edwards Lifesciences LLL	n>200; up to 25 sites	LifeStent NT	Randomized, prospective multicenter trial of PTA (alone) vs. PTA plus stenting in SFA and proximal popliteal; efficicacy endpoints are TLR/TVR	≤150 mm	Not available	Enrolling
SIROCCO I	Cordis Endovascular	n=36; 6 sites in Europe and Canada	Smart	Randomized, prospective, multicenter study of slower-eluting Smart nitinol self-expanding drug-eluting stent and fast-eluting model vs bare Smart stent control	7 cm - 20 cm	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	Cordis Endovascular	n=57; 6 sites in Europe and Canada	Smart	Randomized, prospective, multicenter study of slower-eluting Smart nitinol self-expanding drug-eluting stent vs bare Smart stent control	7 cm - 14.5 cm	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
VIABAHN	W.L. Gore & Associates	n=244	Viabahn	Randomized between PTA and Viabahn, prospective, multicenter	≤13cm	Not available	Pending approval by FDA
ZILVER PTX,US	Cook Incorporated	Confidential	ZILVER with PTX	Randomized, prospective multicenter trial of PTA (alone) vs DES stenting in SFA and proximal popliteal; efficicacy endpoints are TLR/TVR	≤70 mm	Not available	Enrolling
ZILVER PTX, OUS	Cook Incorporated	50 sites OUS	ZILVER with PTX	Prospective multicenter trial DES stenting (alone) in SFA and proximal popliteal; efficicacy endpoints are TLR/TVR	≤200 mm	Not available	Trial began May 2005