SFA STENTING STUDIES

Study	Sponsor	Sample Size	Device	Study Design	Lesions	Results	Core Lab	Status
ABSOLUTE	Medical University of Vienna	N=104	Dynalink and/or Absolute	Prospective, single-center, randomized study of 6-mm stents in SFA lesions.	Approx. 13 cm	Freedom from restenosis in the stent arm (54.3%) statistically significantly better than PTA (30.8%) at 24 months. Stent fracture rate: 2% at 1 year.	No	2-year results published in *Circulation.*
DURABILITY I (OUS)	ev3	N=150	Protégé EverFlex	Prospective, multicenter, nonrandomized registry of single stents in SFA and proximal popliteal lesions.	<14 cm	Not available.	Yes	Currently enrolling.
DURABILITY II (US)	ev3	Confidential	Protégé EverFlex	Prospective, multicenter, single-arm study of single stents in long SFA/proximal popliteal lesions.	7 cm to 16 cm	Not available.	Yes	Not yet begun enrolling.
FAST	Bard Peripheral Vascular	N=244	Luminexx	Randomized, prospective, multicenter study of PTA vs stenting in proximal SFA lesions. Primary endpoint of ultrasound-assessed binary restenosis at 12-month with fracture follow-up.	≤10 cm	No statistically significant difference between treatment groups at 12 months. Properly powered trials in individual subgroups appears warranted.	Yes	Results presented; paper accepted for publication.
RESILIENT	Edwards Lifesciences	N=246	LifeStent	Randomized, prospective, multicenter trial of PTA vs PTA plus stenting in SFA and proximal popliteal.	≤15 cm	6-month primary patency: 94.6% (stent) vs 50.1% (PTA). Freedom from reintervention: 95.3% (stent) vs 54.1% (PTA). Stent fracture rate: 1.2%.	Yes	Enrollment complete; PMA submitted to FDA.
SIROCCO I	Cordis Endovascular (Division of Cordis Corporation)	N=36; 6 sites in Europe and Canada	Smart	Randomized, prospective, multicenter study of slower-eluting Smart nitinol self-expanding DES and fast-eluting model vs bare Smart stent control.	7 cm to 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.	Yes	Results presented at TCT 9/03.
SIROCCO II	Cordis Endovascular (Division of Cordis Corporation)	N=57; 6 sites in Europe and Canada	Smart	Randomized, prospective, multicenter study of slower-eluting Smart nitinol self-expanding DES vs bare Smart stent control.	7 cm to 14.5 cm	6-month in-stent angiography: 0% restenosis in study group; 7.7% control. Late loss: .38±.64 vs .68±.97. TVR: 3.4% vs 10.7%. 0 TLRs. 0 thromboses. 6% fracture rate.	Yes	Results presented at TCT 9/03.
VIABAHN	Gore & Associates	N=244	Viabahn	Randomized, prospective multicenter trial of PTA vs Viabahn. Efficacy endpoint: primary patency of the target vessel at 1 year, treatment success, technical success, clinical success.	≤13 cm	When compared to PTA, Viabahn resulted in higher rates of treatment success, technical success, and 12-month patency as defined by current clinical standards.	Yes	PMA approved 6/05.
VIBRANT	Gore & Associates	N=150	Viabahn	Randomized, prospective, multicenter trial of Viabahn vs nitinol stent of choice. Efficacy endpoint: primary patency at 3 years defined by CDUS PSVR <2 for target lesion.	≥8 cm	Initial 63 randomized subjects enrolled (mean lesion length, 19 cm). MAE at 30 days: 0% thrombosis, 0% amputation, 1.6% TLR.	Yes	Currently enrolling. Interim results presented at ISET 2007.
ZILVER PTX (US phase 1)	Cook Medical	N=60	Zilver with PTX	Randomized, prospective multicenter trial of PTA with provisional stenting vs DES stenting in SFA and proximal popliteal. Efficacy endpoint: 12-month TLR/TVR determined by duplex.	≤7 cm	Primary patency at 9 months: PTA=52%, DES=90%. 0% fracture rate for 41 lesions at 6 months and 18 lesions at 1 year. Event-free survival: PTA=91%, DES=89%.	Yes	Enrolling completed. Interim 9-month trial data presented at ISET 2007.
ZILVER PTX (US phase 2)	Cook Medical	Confidential	Zilver with PTX	Randomized, prospective multicenter trial of PTA with provisional stenting vs DES stenting in SFA and proximal popliteal. Efficacy endpoint: 12-month TLR/TVR determined by duplex.	≤14 cm	Not available.	Yes	Currently enrolling.
ZILVER PTX (OUS)	Cook Medical	Confidential; 50 sites OUS	Zilver with PTX	Prospective, multicenter registry. Primary DES stenting in SFA and proximal popliteal. Efficacy endpoint: 12-month TLR/TVR determined by duplex.	≤28 cm	Not available.	Yes	Trial began 5/05.

All data provided by industry with the exception of ABSOLUTE and ZILVER PTX.