General Information							Baseline Patient Demographics				Results												
Study Device(s)	Sample Size	Study Design	MAE Definition	Primary Patency Definition	TLR Definition	Inclusion Criteria	Diabetic	Rutherford 3–5	CTO	Lesion Location	Period	MAE	Primary Patency (Per Protocol)	Primary Patency (Per Kaplan-Meier)	TLR	Stent Fracture Rate	Mean No. of Stents Implanted (± SD)	Range of No. of Stents Implanted	Mean Length of Lesion Stented (± SD)	Range Length of Lesion Stented	Core Lab (Was Echo and/or Fluoroscopy Used in Follow-Up?)	Published In	Presented At
4EVER (Biotronik) Astron Pulsar/ Pulsar-18	120 patients	Multicenter, prospective registry	According to ISO14155	Primary patency at 12 months, defined as freedom from > 50% restenosis at 12 months as indicated by an independently verified DUS PSVR < 2.5 in the target vessel with no reintervention	Clinical success at follow-up is defined as endovascular or surgical TLR in surviving patients with preserved limb	Length of the target lesion is ≤ 20 cm by visual estimation and can be covered with one stent	65%	62.5%	22.8%	Femoropopliteal	12 months	3.3% access site	N/A	81.4	10.7	Data expected September 2013	1.16	N/A	72.42 ± 47.81 mm	10–200	Duplex	Pending publication	CIRSE 2012
Absolute Vienna (Medical University of Vienna [Austria] and Vienna General Hospital [Austria]) Dynalink/ Absolute	104 patients (stent 51; PTA 53)	Single-center, randomized	N/A	Primary endpoint: angiographic restenosis at 6 months; secondary endpoint: binary restenosis rates	N/A	Symptomatic PAD with severe intermittent claudication (Rutherford class 3) or chronic CLI with either rest pain (Rutherford class 4) or ischemic ulcers (Rutherford class 5) and stenosis of > 50% or occlusion of the ipsilateral SFA, a target lesion length of > 30 mm, and at least 1 patent (< 50% stenoses) tibioperoneal runoff vessel	43% (stent); 32% (PTA ± stent)	3: 88%; 4: 2%; 5: 10%	37% (stent); 32% (PTA ± stent)	SFA	12 months	No major complications	Binary restenosis rate: 36.7% (stent); 63.5% (PTA)	N/A	N/A	1.5%	N/A	57% 1 stent; 27% 2 stents; 6% 3 stents; 8% 4 stents; 2% 5 stents	132 ± 71 mm (stent); 127 ± 55 mm (PTA)	N/A	Yes	Schillinger M, et al. N Engl J Med. 2006;354:1879–1888	N/A
											24 months	No major complications	Binary restenosis rate: 49.7% (stent); 69.2% (PTA)	N/A	N/A	No new stent fractures	N/A	54% 1 stent; 28% 2 stents; 3% 3 stents; 4% 4 stents; 2% 1 stent	138 ± 71 mm (stent); 117 ± 56 (PTA)	N/A		Schillinger M, et al. Circ. 2007;115:2745–2749.	MEET 2007
Complete SE SFA Study (Medtronic, Inc.) Complete SE	196 patients	Multicenter, OPC	Defined as device- or procedure-related death, target limb loss, and target lesion or target vessel revascularization	Defined as uninterrupted patency with no procedures performed on or at the margins of the treated segment, with no restenosis ≥ 50% as documented by DUS PSVR ≥ 2	TLR defined as repeat percutaneous intervention of the target lesion or as any bypass surgery of the target vessel to maintain blood flow distal to the treated vessel segment	Rutherford class 2-4, reference diameter ≥ 4 and ≤ 7 mm, total lesion length ≥ 40 and ≤ 140 mm	45%	67%	30%	50%	12 months	11%	72.6%	90.9% at 360 days	8.4%	0	225	85.7% 1 stent; 14.3% 2 stents	60.7 ± 37.6 mm	5 mm, 228 mm (min/max)	Yes	Publication submitted and pending	LINC 2012, LINC 2013, ISET 2012
DURABILITY II (Covidien) EverFlex Self-Expanding Peripheral Stent System	287 patients	Multicenter, nonrandomized study, OPC (by VIVA Physician's, Inc. [VPI])[a]	MAE at 30 days, defined as clinically driven TLR, amputation of treated limb, or all-cause mortality	Primary stent patency rate at 1 year, defined as DUS PSVR < 2 and no clinically driven reintervention within the stented segment	Clinically driven TLR, defined as ≥ 50% diameter stenosis in the presence of recurrent symptoms or a ≥ 70% stenosis associated with decreased ABI ≥ 0.15 in the treated segment	Target lesion total length ≥ 4 cm and ≤ 18 cm	42.5%	60.5%[b]	48.1%	Proximal and distal SFA, and SFA/popliteal	12 months	No MAEs observed (0%) at 30 days,	67.7%	77.2%	13.9%	0.4% (1 type V fracture)	303 stents in 287 patients	95% 1 stent; 5% multiple stents	89.1 ± 44.8 mm (core lab assessed); 109.6 ± 45 mm (site assessed)	7.3–200.9 (core lab assessed); 10–180 (site assessed)	Angiographic, ultrasound, and x-ray core laboratories	Matsumura JS, et al. J Vasc Surg. 2013;58:73–83 e71	VIVA 2011, LINC 2012, ISET 2012, PVSS 2012
											24 months	16.8% at 12 months	N/A	66%	24.9%	0.9% (in addition to the single fracture at 12 months, 1 type III identified at 24 months)	N/A	N/A				Proceedings of the 14th Annual New Cardiovascular Horizons Abstracts	NCVH 2013
											36 months	Patients in follow-up											
ETAP (Prof. Thomas Zeller) LifeStent Vascular Stent	246 patients (LifeStent 119; PTA 127)	Multicenter, randomized	N/A	Freedom from target lesion restenosis (luminal narrowing ≥ 50%) detected with DUS (PSVR > 2.4)	Clinically driven repeat intervention (surgical or endovascular) of the target lesion	The goal was to cover the lesion with one stent; more than one stent was allowed only in the case of geographic miss of the first stent; stent lengths were available up to 170 mm	37.8% (PTA); 36.1% (LifeStent)	83.4% (PTA); 73.9% (LifeStent)	33.1% (PTA); 32.8% (LifeStent)[c]	P1 (29.1%), P2 (42.5%), P3 (4.7%), multiple popliteal segments (23.7%) (PTA); P1 (29.4%), P2 (40.3%), P3 (5.9%), multiple popliteal segments (24.4%) (LifeStent)	12-month PTA	N/A	44.9%	N/A	44.1%	N/A	N/A	N/A	LifeStent (41.3 ± 31.3 mm); PTA (43.2 ± 28.1 mm); these were isolated popliteal lesions	N/A	DUS; angiography; x-ray for fracture analysis	Rastan A, et al. Circulation. 2013; 127:2535–2541	TCT 2012
											12-month LifeStent	N/A	67.4%	N/A	14.7%	3.4%: type I (n = 1); type II (n = 1); the fracture rate was calculated: No. fractures/No. stents evaluated by the core lab	1.05 stents/ patient	1–2 stents		N/A			
RESILIENT (Bard Peripheral Vascular) LifeStent Vascular Stent	206 patients (LifeStent 134; PTA 72)	Multicenter, randomized	Death, stroke, myocardial infarction, emergent surgical revascularization, significant distal embolization in target limb, thrombosis of target vessel, and worsening of Rutherford-Becker category[d]	Continuous blood flow through the treatment area (without repeat intervention) as evidenced by DUS; loss of primary patency was defined as reduction in luminal diameter of > 50% (measured by DUS) or a TLR; PSVR 2.5	Clinically driven repeat intervention (surgical or endovascular) of the target lesion following the return of ischemic symptoms and/or reduced blood flow confirmed by DUS or angiography	The total allowable lesion length was 150 mm; multiple lesions could be treated in the target vessel as long as the total length of the lesions did not exceed 150 mm; multiple stents were allowed	38.9% (PTA); 38.1% (LifeStent)	51.4% (PTA); 61.2% (LifeStent)	18.5% (PTA); 17% (LifeStent)[c]	Proximal SFA (14.8%), middle SFA (38.3%), distal SFA (45.7%), proximal popliteal (1.2%) (PTA); proximal SFA (13.1%), middle SFA (32.0%), distal SFA (50.3%), proximal popliteal (4.6%) (LifeStent)	12-month PTA	14.9%	N/A	36.7%	54.8%	N/A	1.6 stents/ patient	1–3 stents	LifeStent (70.5 ± 44.3 mm); PTA (64.4 ± 40.7 mm)	N/A	DUS; angiography; x-ray for fracture analysis	Laird JR, et al. Circ Cardiovasc Interv. 2010; 3:267–276	N/A
											12-month LifeStent	13.4%	N/A	81.5%	12.7%	3.1%; type I (n = 6); type IV (n = 6); no fractures were associated with restenosis or MACE; the fracture rate was calculated: No. fractures/ No. stents evaluated by the core lab							
											24-month PTA	20.3%	N/A	N/A	58.2%	N/A						N/A	
											24-month LifeStent	19.5%	N/A	N/A	22.2%	18-month: 4.1%							
											36-month PTA	24.8%	N/A	N/A	58.2%	N/A						Laird JR, et al. J Endovasc Ther. 2012; 19:1–9	
											36-month LifeStent	24.8%	N/A	N/A	24.5%	N/A							
SuperNOVA (Boston Scientific Corporation) Innova Self-Expanding Stent System	299 patients	Multicenter, OPC	All causes of death through 1 month, target limb major amputation through 12 months, and/or TLR through 12 months	Freedom from more than 50% stenosis based on DUS PSVR comparing data within the treated segment to the proximal normal arterial segment; a systolic velocity ratio > 2.4 suggests > 50% stenosis	Not clinically driven	Lesion length 30–190 mm; 1 stent	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Enrollment completed June 2013	

General Information							Baseline Patient Demographics					Results												
Study Device(s)	Sample Size	Study Design	MAE Definition	Primary Patency Definition	TLR Definition	Inclusion Criteria	Diabetic	Rutherford 3-5	CTO	Lesion Location		Period	MAE	Primary Patency (Per Protocol)	Primary Patency (Per Kaplan-Meier)	TLR	Stent Fracture Rate	Mean No. of Stents Implanted (± SD)	Range of No. of Stents Implanted	Mean Length of Lesion Stented (± SD)	Range Length of Lesion Stented	Core Lab (Was echo and/or fluoro used in follow up?)	Published In	Presented At
SUPERB (Idev Technologies, Inc.) Supera Peripheral Stent System	264 patients	Multicenter, prospective, nonrandomized, single-arm trial, OPG	Not defined	Defined as freedom from restenosis (defined as diameter stenosis > 50% with a PSVR > 2 as measured by DUS) and TLR	Any repeat percutaneous intervention or bypass surgery performed in the target lesion	Stenotic lesion(s) or occluded length within the same vessel (one long or multiple serial lesions) 4–140 mm	43.5%	62.5%	24.7%	SFA, popliteal, and distal SFA/popliteal		12 months	N/A	N/A	86.1%	10%	0%	N/A	N/A	83.2 mm	N/A	Yes	N/A	VIVA 2012, TCT 2012, LINC 2013
Gore VIPER Clinical Study (W. L. Gore & Associates) Gore Viabahn Endoprosthesis With Heparin Bioactive Surface	119 limbs	11 centers, controlled, single-arm	Require therapy, minor hospitalization (< 48 hours), require major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 hours), permanent adverse sequelae, and death	Defined as no evidence of restenosis or occlusion in the treated SFA segment on color-coded DUS (PSVR < 2.5), as determined at the participating center, no angiographic evidence of restenosis of > 50% if color-coded DUS was unavailable or uninterpretable, or no reintervention in the target lesion	The protocol defined TLR as repeat intervention to maintain or reestablish patency in the stented region	Lesions ≥ 5 cm with no upper limit and lesions beginning 1 cm below SFA origin and ending at least 1 cm proximal to the proximal margin of the intracondylar fossa of femur	33%	74%	56%	SFA		12 months	1 (0.8%)	73%	73%	N/A	N/A	1.92	1–4	190 mm	50–370 mm	No core lab review	Saxon RR, et al. J Vasc Interv Radiol. 2013;24:165–173	VIVA 2011 (first presentation)
VIASTAR Clinical Trial (Medical University of Vienna [Austria] and Vienna General Hospital [Austria]) Gore Viabahn Endoprosthesis With Propaten Bioactive Surface Versus BNS (Bard LifeStent; Covidien Protégé Everflex; Cordis SMART Control)	Intent-to-treat: 141 (72 in Gore Viabahn device arm, 69 in BNS arm); per protocol: 129 (66 in Gore Viabahn device arm, 63 in BNS arm)	7 centers, randomized	Death, myocardial infarction, study limb amputation, access site and treatment site complications requiring surgery, blood transfusion or prolonged hospital stay within 30 days of the index procedure	No evidence of restenosis ≥ 50% or occlusion within the study lesion based on color-coded DUS with PSVR ≥ 2.5 and no TLR	Clinically driven	Included lesions 10–35 cm in length; no limit on total number of stents used	35% (Viabahn); 36% (BNS)	81% (Viabahn); 81% (BNS)	79% (Viabahn); 70% (BNS)	SFA (Viabahn and BNS)		12-month Gore Viabahn Endoprosthesis	1 (1.4%)	78%	78%	9 (14%)	N/A	N/A	N/A	190 ± 63 mm	N/A	Color Doppler ultrasound examinations were anonymized and blinded before review by the CorLab Bad Krozingen in Bad Krozingen, Germany	Lammer J, et al. J Am Coll Cardiol. Published online July 10, 2013	CIRSE 2012, VEITH 2012, ISET 2013, LINC 2013
												12-month BNS	1 (1.4%)	54%	54%	13 (21%)	N/A	N/A	N/A	173 ± 66 mm	N/A			
The Zilver PTX Randomized Clinical Study (Cook Medical) Zilver PTX Drug-Eluting Peripheral Stent	479 (236 stent arm)	Multicenter, randomized	CEC-adjudicated death, amputation, clinically driven TLR, target limb ischemia requiring surgical intervention, or surgical repair of the target vessel; worsening of Rutherford score by 2 classes or to class 5 or 6	Duplex ultrasound-derived PSVR < 2 from core lab analysis or < 50% diameter stenosis from arteriographic core lab analysis, when available	Reintervention performed for ≥ 50% diameter stenosis confirmed by angiography within ± 5 mm of the target lesion after documentation of recurrent clinical symptoms of PAD	Maximum of 2 stents/lesion or 4 stents/patient; lesion length ≤ 14 cm	42% (PTA [control] group); 49.2% (PTX [treatment] group)	Rutherford 2–3: 90.7%, Rutherford 4–6: 8.5% (PTA [control] group); Rutherford 2–3: 90.2%, Rutherford 4–6: 8.9% (PTX [treatment] group)	24.7% (PTA [control] group); 29.6% (PTX [treatment] group)	SFA: 92.4%, SFA/popliteal: 2.4%, popliteal: 5.2% (PTA [control] group); SFA: 92.7%, SFA/popliteal: 3.6%, popliteal: 5.5% (PTX [treatment] group)		12-month PTA (control)	17.4%	N/A	32.8%	17.5%	N/A	N/A	N/A	63.1 ± 40.7 mm	N/A	Yes; core lab for angio, x-ray, and ultrasound	Dake MD et al. Circ Cardiovasc Interv. 2011;4:495–504	N/A
												12-month PTX (treatment)	9.6%	N/A	83.1%	9.5%	0.9% (type I, 2; type II, 0; type III, 2; type IV, 0)	1.5 stents/patient	1–4 stents/patient	66.4 ± 38.9 mm	≤ 14 cm			
												24-month PTA (control)	22.1%	N/A	26.5%	N/A	N/A	N/A	N/A	N/A	N/A	Yes; core lab for angio, x-ray, and ultrasound	Dake MD et al. J Am Coll Cardiol. 2013;61:2417–2427	N/A
												24-month PTX (treatment)	13.4%	N/A	74.8%	13.4%	N/A	N/A	N/A	N/A	N/A			
												36-month standard care (optimal PTA + BMS)	N/A	N/A	49.1%	29.8%	N/A	N/A	N/A	N/A	N/A	Yes; core lab for angio, x-ray, and ultrasound	N/A	VIVA 2012
												36-month (Zilver PTX)	N/A	N/A	70.7%	16.3%	2.1% (type I, 4; type II, 0; type III, 3; type IV, 0)	N/A	N/A	N/A	N/A			
The Zilver PTX Single-Arm Study (Cook Medical) Zilver PTX Drug-Eluting Peripheral Stent	787	Multicenter, OPC	CEC-adjudicated procedure- or device-related death, clinically driven TLR, target limb ischemia requiring surgical intervention, or surgical repair of the target vessel; worsening of Rutherford classification by 2 classes or to class 5 or 6	PSVR < 2.5	Reintervention for >50% diameter stenosis within 5 mm of the study segment after documentation of recurrent clinical symptoms of PAD	Maximum of 4 DES/patient; no lesion length limit	36.2%	N/A	38.3%	SFA/popliteal		12 months	11.0%	N/A	86.2%	9.5%	1.5% (type I, 1; type II, 5; type III, 2; type IV, 14)	1.9 stents/lesion; 2.2 stents/patient	1–4 DES	99.5 ± 82.1 mm	3–400 mm	Core lab for x-ray	Dake MD, et al. J Endovasc Ther. 2011;18:613–623	N/A
												24 months	20.7%	N/A	N/A	19.5%	N/A	N/A	N/A	N/A	N/A	N/A	Dake MD, et al. J Am Coll Cardiol. 2013;61:2417–2427	

ABI, ankle-brachial index; BMS, bare-metal stent; BNS, bare-nitinol stent; DES, drug-eluting stent; DUS, duplex ultrasound; PSVR, peak systolic velocity ratio; TLR, target lesion revascularization.

[a]*Study safety and effectiveness outcomes were compared with performance goals developed by VPI; the objective of the study was to evaluate the safety and efficacy of a single self-expanding stent up to 20 cm.*
[b]*Per the DURABILITY II protocol, patients were included if they had Rutherford Clinical Category Score of 2, 3, or 4. One patient was enrolled with RCC 5, a protocol deviation.*
[c]*Presented % occlusion, not necessarily chronic total occlusions.*
[d]*Defined as MACE in RESILIENT (major adverse clinical event).*