

Review Article

Peripheral stent technology and current status for endovascular treatment of femoropopliteal artery disease: a clinical review

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ABSTRACT

Over the past decade, the treatment of peripheral artery disease poses a number of technical challenges for the physician. The primary rationale of this article is to review the available literature on the current practices involved in the treatment of peripheral artery disease (PAD), particularly the femoropopliteal lesions. It is evident from the landmark clinical trials that the use of self-expanding drug-eluting stents (DES) has become the most favored clinical strategy for treating peripheral lesions above the knee. It is chiefly due to higher patency rates, and minimal in-stent restenosis and stent fracture rates associated with the use of DES. The technical evolution in the endovascular approach from the use of bare nitinol stents to DES for treating PAD and the factors responsible for this transformation have also been reviewed with their respective justification. Presently there is a need of DES technology for the treatment of femoropopliteal lesions, which can reduce the risk of stent fracture and in-stent restenosis for longer lesions while maintaining patency during long-term follow-up. To conclude, this review establishes that self-expanding DES and drug coated balloons using anti-proliferative drugs like sirolimus and paclitaxel are currently the most effective method of treating the femoropopliteal lesions in PAD.

Keywords: Ankle brachial index, Drug-eluting stents, Endovascular, Femoropopliteal, Nitinol, Peripheral artery disease, Self-expanding, Sirolimus

INTRODUCTION

Globally, peripheral arterial disease (PAD) is estimated to affect more than 200 million people. It is one of the leading cause of morbidity and mortality which predominantly affects the elderly population.¹ PAD usually appears after the age of 50 years, with an exponential increase after the age of 65. This rate reaches around 20% by the age of 80.²

Claudicating in PAD reduces walking distance and impairs quality of life after the blood flow is limited in the area. PAD in superficial femoral arteries (SFA) and popliteal arteries (PPA) share common significant risk factors for atherosclerosis. Quarterly of the total patients with PAD present intermittent claudication (IC) and

progress to critical limb ischemia which leads to significant disability and limb loss. Patients with asymptomatic as well as symptomatic PAD are at an increased risk of cardiovascular morbidity and mortality compared with subjects without PAD.³⁻⁷

Challenges in management of PAD with current technology: focus on device characteristics

As per current standards, personal and family clinical history of the patient should be assessed initially to detect the presence of cardiovascular disease (CVD) as well as LEAD to evaluate risk factors and co-morbidities. Lifestyle habits and physical activities also need to be systematically investigated to provide reasonably accurate outcome measures and determine the

impairment level and selection of appropriate care.^{8,9,10,11} Furthermore, a thorough clinical examination must be done.¹²⁻¹⁴ Laboratory testing should be included from the minimal biological assays to complementary laboratory testing if required.² As Ankle Brachial Index (ABI) has high accuracy, sensitivity and specificity, it should be primarily used as a bedside diagnostic tool to diagnose PAD.¹⁵ An ABI of ≤ 0.90 is associated on an average with 2 to 3 fold increased risk of total and cardiovascular death. Along with general cardiovascular risk, ABI measurement can also identify a patient's risk for lower-extremity events.²

Nowadays, advanced diagnostic modalities to detect PAD such as duplex ultrasound (DUS), digital subtraction

angiography (DSA), computed tomography angiography (CTA), and magnetic resonance imaging (MRI) are increasingly recommended for detailed evaluation of the occluded arteries due to higher resolution.²

Classifying PAD

Classification systems in PAD have been widely used in clinical settings for direct patient management as well as for research purposes.¹⁶

Firstly, Rutherford classified PAD into acute and chronic limb ischemia, emphasizing that each presentation requires different treatment algorithms (Table 1 and Table 2).

Table 1: Rutherford classification for chronic limb ischemia.

Grade	Category	Clinical description	Objective criteria
0	0	Asymptomatic-no hemodynamically significant occlusive disease	Normal treadmill or reactive hyperemia test
	1	Mild claudication	Completes treadmill exercise; AP after exercise > 50 mmHg but at least 20 mmHg lower than resting value
I	2	Moderate claudication	Between categories 1 and 3
	3	Severe claudication	Cannot complete standard treadmill exercise, and AP after exercise < 50 mm Hg
II	4	Ischemic rest pain	Resting AP < 40 mmHg, flat or barely pulsatile ankle or metatarsal PVR; TP < 30 mm Hg
III	5	Minor tissue loss non-healing ulcer, focal gangrene with diffuse pedal ischemia	Resting AP < 60 mm Hg, ankle or metatarsal PVR flat or barely pulsatile; TP < 40 mm Hg
	6	Major tissue loss-extending above TM level, functional foot no longer salvageable	Same as category 5

AP: ankle pressure; PVR: pulse volume recording; TM: transmetatarsal; TP: toe pressure.

Table 2: Rutherford classification for acute limb ischemia.

Category	Description/ prognosis	Findings		Doppler signal	
		Sensory loss	Muscle weakness	Arterial	Venous
Viable	Not immediately threatened	None	None	Audible	Audible
Threatened					
Marginally	Salvageable if promptly treated	Minimal (toes) or none	None	Inaudible	Audible
Immediately	Salvageable with immediate revascularization	More than toes, associated rest pain	Mild, moderate	Inaudible	Audible
Irreversible	Major tissue loss or permanent nerve damage inevitable	Profound, anesthetic	Profound, paralysis	Inaudible	Inaudible

In recent practice, the Trans-Atlantic Inter-Society Consensus Document II (TASC II) has been the most widely accepted and used system for classifying atherosclerotic disease patterns in the lower extremities according to anatomic distribution and the number and

nature of lesions (stenosis, occlusion) as shown in Figure 1.

Type A lesions: Single stenosis ≤ 10 cm in length; single occlusion ≤ 5 cm in length.

Type B lesions: PAD with multiple lesions (stenoses or occlusions) can be included under Type B lesions, each should be $\leq 5\text{cm}$; single stenosis or occlusion $\leq 15\text{cm}$ not involving the infrageniculate popliteal artery; single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass; heavy calcified occlusion $\leq 5\text{cm}$ in length; single popliteal stenosis.

Type C lesions: Multiple stenoses or occlusions totaling $>15\text{cm}$, with or without heavy calcification; recurrent stenoses or occlusions that need treatment after two endovascular interventions can be a part of this lesion class.

Type D lesions: Chronic total occlusions of CFA or SFA ($>20\text{cm}$, involving the popliteal artery); chronic total occlusion of popliteal artery and proximal trifurcation vessels are included in type D.¹⁷

Therapeutic approaches for treating PAD

Supervised exercise programs may benefit in walking. Prescribed home exercise programs may be more convenient and may also improve maximal and pain-free walking. Smoking-cessation interventions and patient counseling should also be offered to all patients with PAD who use tobacco.¹⁸

Pharmacotherapy

Statin therapy improves claudication symptoms in addition to lowering lipid levels. Single or dual anti-platelet therapy with aspirin and/or clopidogrel is also recommended to reduce cardiovascular risk or vascular death in patients with symptomatic PAD. Cilostazol can also be safely used alone or in combination with aspirin or clopidogrel to improve claudication symptoms and increase maximal pain-free walking distances. Pentoxifylline is another anti-platelet agent commonly used for claudication. Angiotensin converting enzyme (ACE) inhibitor ramipril has also been evaluated for treating functional limitations in patients with PAD.¹⁸

Endovascular treatment

Endovascular therapy is a fast expanding option for the treatment of PAD, leading to the development of numerous revascularization strategies.¹⁹ Innumerable clinical studies assessing new technologies in endovascular lower limb arterial revascularization have been recently published (Table 4). As per evidence, revascularization is typically considered in patients who have developed any 1 of 3 distinct clinical presentations:

- Lifestyle-limiting claudication no longer responsive to conservative therapy (IC).
- Critical limb ischemia (CLI).
- Acute limb ischemia (ALI).

The revascularization strategy for PAD differs from coronary artery disease (CAD). Vessels in the leg are treated by revascularization strategy with the expectation of the patient requiring the same segments revascularized again in the future. PAD restenosis rates are very high with the use of both PTA and stents.²⁰

Stents in the legs are exposed to twist and turn which are not found in the heart.²⁰ The superficial femoral artery (SFA) is uniquely subjected to essential and complex external mechanical stresses, being the longest artery with the fewest side branches. Due to this, it is the most common location of occlusive disease precipitating IC. Consequently, treating IC in this area is significantly influenced by these repetitive mechanical stresses. These are also believed to be responsible for stent fractures, restenosis, and thrombosis.²¹

Thus, stenting which was once used as a bailout option, has evolved from “not indicated” in the TransAtlantic Inter-Society Consensus (TASC) I to “preferred choice” in conditions such as stenoses/occlusions up to 10cm in TASC II. These recommendations have led to development of specialty stents for PAD. Most peripheral stents are self-expanding, flexible and can handle flexing and external crushing pressures better than rigid balloon expanded stents.

Individualization can be the key to endovascular treatment success

Recently, Kobayashi et al, have made a formal comparison of effectiveness of different endovascular approaches to treat PAD. Their suggested flow sheet for approach to SFA disease has been depicted below Figure 2.²² However, there are numerous demerits associated with these existing technologies which also warrant continuous development of new endovascular strategies.

Challenges faced with the use of bare nitinol stents

Nitinol self-expanding stents proved to be effective as they had shown to possess thermal shape memory and were found to be more resilient to mechanical stresses.²¹ The invention of the nitinol stent with the intrinsic super-elastic and high radial force properties, theoretically imparted higher resistance to the extraordinary mechanical forces exerted on these vessels, and thus altered endovascular treatment strategies, then, in femoropopliteal disease.²³

On those lines, significant trials such as the Vienna randomized trial showed that patients receiving self-expanding stents for femoral artery disease had lower rates of restenosis and resulted in better walking capacity than those treated by balloon angioplasty alone.²¹

Initially, the supra peripheral stent system was also introduced as a woven self-expanding stent constructed from nitinol. Scheinert et al, reported the first

retrospective study with the use of supra stents in atherosclerotic femoropopliteal lesions. The 1 year and 2-year primary patency rates were 85% and 76%, respectively for a mean stent length of 111 mm.²⁴ Supera stents in the femoropopliteal segment demonstrated favorable results compared to all other major stent types despite the inclusion of more favorable lesion characteristics (e.g., shorter length, calcification, and less popliteal involvement) in other trials. Later, the resilient trial suggested better outcomes with primary stenting using self-expanding stents compared with balloon angioplasty (12-month primary patency of 87.3% vs. 45.2%) although the crossover rate to stenting in the angioplasty group was high (40%) and was included as an adverse end point.²⁵ However, several concerns

including stent fracture after SFA self-expanding stenting, which may lead to in-stent restenosis (ISR) and occlusion were reported. The incidence of stent fracture seemed to vary depending on the type of stent used, its design, the length of stented segment, and the number of stents implanted.^{26,27}

Boston Scientific had also introduced the Innova self-expanding stent for the SFA or PPA. It was designed specifically for the challenging anatomy of the SFA and PPA. The platform consisted of a nitinol self-expanding bare metal stent available in diameters from 5-8mm and lengths of 20-200mm. This stent platform served as the foundation for the Eluvia drug-eluting vascular stent in future development.²⁰ (Table 3 and Table 4).

Table 3: Evolutionary comparison of the basic features of available stents.

Bare metal stents (BMS)	Drug - eluting stents (DES)	Covered Stents	Bioabsorbable Stents (BAS)
Uncoated stents composed of bare metal that are permanently placed inside the affected artery	DES that are coated with a polymeric material and release drugs locally	Metal stent structures with coverings composed of fabric or graft material such as polytetrafluoroethylene (PTFE)	Composed of bio-degradable materials that can be absorbed or resorbed by the body
Constructed from a range of metals, including nitinol, stainless steel, cobalt chromium, platinum chromium	Stent releases the anti-proliferative or immunosuppressive drug over time, leaving behind the metallic stent in the artery	Graft material covering provides a direct barrier to tissue ingrowth and reduces the risk of chronic inflammation and restenosis	Bioabsorbable DES deliver antiproliferative agents to prevent restenosis and degrade over time, eliminating concerns regarding late stent thrombosis, chronic inflammation, acute vessel closure, and biocompatibility
Classic stent type			Represent the future of stent technology
Either self-expanding or balloon-expandable	Either self-expanding or balloon-expandable	Either self-expanding or balloon-expandable	-

Thus, RCT (randomized controlled trials) of bare metal/nitinol stents compared with PTA showed that target lesion length is responsible for producing advantageous results with primary stenting. There was no advantage for primary stent placement for a mean lesion length of 45 mm in case of discrete lesions.

However, a couple of trials demonstrated significant patency and functional benefit for primary femoral-popliteal BMS with longer lesions. The procedural success rate of endovascular therapy for femoropopliteal lesions is very high, but it remains a barrier in stable ischemia.²⁸

Development of drug-eluting stents

The above drawbacks stimulated the development of DES. Although, the initial results with DES as per SIROCCO trials were promising, the later results showed

no clinical advantage with this particular stent platform. It was associated with a high rate of stent fracture.^{29,30}

In due course, the strides trial tested new platforms of self-expanding DES using anti-proliferative agents. Although stent fracture rates were low, the restenosis rates at 6 and 12 months were 6% and 32%, respectively.³¹

Critical evaluation of paclitaxel-eluting stents for SFA lesions

The first approved drug-eluting, self-expanding stent, was the Cook Medical Zilver PTX. Five-year data from the Zilver PTX showed primary patency of 66.4% in the SFA. This compares to 43.4% patency for patients with PTA or provisional bare metal stent placement.²⁰ Zilver PTX trial also demonstrated higher primary patency with the primary DES group compared with the angioplasty only, (74.8% vs. 26.5%) at 2 years. The provisional DES

group also showed superior primary patency compared with the provisional BMS group (83.4% vs. 64.1%). Subgroup analysis showed superior outcomes for complex disease, including total occlusions and longer

lesions (>70mm), as well as high-risk patient cohorts such as those with diabetes mellitus or CLI with DES use.³²

Table 4: Clinical registry studies of nitinol stents.

Stent	Stent technical aspects	Problem addressed	Study	Patients (n)	Lesion length (mm)	CTO (%)	Primary patency, 1 year (%)	TLR, 1 year (%)	Stent Fracture, 1 year (%)
EverFlex	Nitinol Stent, Spiral connections between nitinol-linking segments, Stent length-max 150mm	Increase conformability vs. earlier stents	Durability I	151	96	40	72	21	8
EverFlex	Nitinol Stent, Spiral connections between nitinol-linking segments, Stent length 200mm		Durability II	287	89	38	67	14	0.4
Supera	Nitinol Stent, interwoven nitinol wires in a closed cell design, Stent length-80-90mm	Increased stent radial strength relative to other nitinol stents, with associated crush resistance	Supera Trial		79	NR	86	10	0
Supera			Supera SFA Registry	107	90	30	85	NR	NR
Supera			Popliteal Registry	101	58	48	88	7	0
Supera			Supera 500	470	126	53	84	NR	NR
Epic	Nitinol SE stent, Laser-cut with radiopaque tantalum Markers	Increased visibility and aid with accurate deployment	SUMMIT	100	69	30	84	8	0
SMART	Nitinol stent with smaller cell size	Longitudinal stability	Stroll	-	77	24	82	12	2
Complete SE	Nitinol stent with an offset crown design	Minimize crown interaction during flexion	Complete SE trial	196	61	30	73	8	0
Misago	Nitinol stent with zigzag cell design and a rapid exchange delivery platform	Improved stent conformity and minimize fractures	Misago 2	744	64	38	88	10	3

Note: CTO, chronic total occlusion; TLR, target lesion revascularization; SFA, superficial femoral artery

The most recent MAJESTIC trial has showed that patients whose femoropopliteal arteries which were treated with the Eluvia™ DES sustained high patency and low major adverse event (MAE) rates through 12 months. This prospective, single-arm, multicenter trial enrolled 57 patients with chronic lower limb ischemia referable to de novo or restenotic lesions in the native superficial femoral and/or proximal popliteal arteries. Mean lesion length was 70.8±28.1mm, and diameter stenosis was 86.3%±16.2%; 46% lesions were occluded. All 57 patients enrolled in this trial had a single Eluvia™ stent

implanted, employing pre- and post-dilation in 93% and 95% of cases, respectively. Technical success was 97%. At 12 months, primary patency was 96% and the MAE rate was 4%; both MAEs were target lesion revascularization (TLRs). No stent fractures or major amputations were identified. Improvements in the Rutherford category were sustained through 1 year, with 81% exhibiting no symptoms (category 0) and 13% presenting with mild claudication (category 1). Mean ABI improved from 0.73±0.22 at baseline to 1.02±0.20 at 12 months.³³

One-year clinical trial outcomes assessing the Eluvia DES reflected a primary patency rate of more than 96%. These results represented the highest 12-month primary patency reported for an endovascular treatment of femoropopliteal artery lesions among comparable trials.²⁰ Thus, recent RCT showing benefit for DES in femoropopliteal lesions will likely change

recommendations for them. But, to date, there has been no direct comparison of primary DES to either BMS or drug coated balloons (DCB) in femoral and popliteal arteries. However, a propensity score-based comparison of DES and DCB in consecutive patients with TASC C and D long (>10cm) lesions has been published by Zeller.²⁸ (Table 5).

Table 5: Comparison of effectiveness of drug-eluting stents.

Stent	Study	Patients (n)	Lesion length (mm)	CTO (%)	Primary patency, 1 yrs	TLR, 1 year	Stent fracture (%)
Sirolimus-SMART	SIROCCO I and SIROCCO II	47 DES	85mm DES	69% DES	77% DES	6% DES	NR
		46 BMS	81mm BMS	57% BMS	79% BMS	13% BMS	
Everolimus-Dynalink	STRIDES	104 DES	90mm	45%	68%	20%	0
Zilver PTX	Zilver PTX Trial	236 DES	54mm DES	30% DES	83% DES	9.5% DES	0.9%
		238 PTA	53mm PTA	25% PTA	32% PTA	18% PTA	
Zilver PTX	Zilver PTX Registry	787 DES	99mm	38%	83%	10%	1.2%

Note: DES, drug eluting stent; BMS, bare metal stent; NR, not reported; PTA, percutaneous transluminal angioplasty

Clinical success with drug-coated balloons

Lutonix and INPACT Admiral DCB have both been indicated to treat PAD of SFA. DCBs offer the ability to treat a vessel segment without stenting and deliver the anti-proliferative drug to the vessel wall. Long-term DCB clinical data continues to increase, demonstrating superiority of DCBs over conventional PTA.²⁰

The prospective, multicenter, single-blinded INPACT SFA trial enrolled 331 patients in a 2:1 randomization to a DCB group or standard PTA. The primary efficacy endpoint was primary patency, defined as freedom from TLR and duplex-derived restenosis. At two years, patients treated with DCB showed higher primary patency compared to PTA (78.9 vs. 50.1%). Freedom from TLR was 91% for DCB compared to 72.2% for PTA.²⁰

DCB have the likelihood to become the first-line treatment strategy for at least TASC II A and B lesions (even for TASC II C) supported by the evidence from recent trials. As primary DES strategy is limited by the costs, DES might remain more expensive than DCB in the future and the feature of being a permanent implant. As long as DES do not show better outcomes technical and clinical as compared to DCB without or with stenting they might remain the second choice.³⁴

Highlights of covered stents

Stent grafts such as a polytetrafluoroethylene covered nitinol stent (Viabahn) offers the advantage of excluding the neo-intima from the vessel lumen. A small series of 22 patients with femoropopliteal in-stent restenosis

(femoropopliteal-ISR) (mean lesion length, 214mm) treated with a Viabahn stent graft demonstrated 85.1% primary patency rate at 1 year.

The RELINE trial (multicenter trial with 100 patients) randomized to Viabahn stent grafting or PTA, demonstrated a primary patency rate of 28% in the PTA group vs. 74.8% in the Viabahn group (P<0.001) at 1 year. There were no stent fractures at 1 year in the Viabahn group.³⁵

Relevance of bioresorbable scaffolds

Despite the initial encouraging results, long-term findings particularly for SFA are scarce with bioresorbable scaffolds (stents). Results from multicenter RCT are required to make any strong claims regarding the use of these devices for PAD. Additionally, the mechanical properties of the polymers used in these devices also cannot be trusted.³⁶

Relevance of novel approaches including surgery to treat PAD

Novel approaches such as atherectomy have not been widely tested and their use is also minimal.³⁵ However, recent clinical studies have shown that atherectomy can be safe and effective as a frontline PAD therapy. Results from the DEFINITIVE LE study using the Turbo Hawk and/or Silver Hawk systems demonstrated 95% limb salvage in patients with CLI, and 78% overall patency in patients with claudication at 12 months. The definitive LE study is the largest atherectomy study conducted to date with independent, core lab analysis of the clinical outcomes.

Table 6: Comparison of technical specifications and clinical endpoints of different stent platforms as per popular trials.

Trial	Trial Design	Stent Specifications	No. of Patients /Limbs	Follow-up criteria	CLI, % (% wounds)	CT O (n or %)	Lesion Length (cm)	Primary patency or end-point change	TLR, 1 year	Stent Fracture, 1 year
INPERI A I, 2006 ⁴⁰	MC: BA vs. BMS (carbofilm)	PTA - 5 Fr conventional BA catheter and guidewire Stent - Carbostents, diameter range - 2.0-4 mm diameter length – 15-25 mm.	51 patients	6 months, 43 patients and 57 lesions	100 (76.5)	6/95 (6.3 %)	2.4 (.5 - 3.0)	BMS, 83.7%, BA, 61.1%	NA	NA
AMS INSIGHT, 2009 ⁴¹	MC: BA vs BMS (magnesium)	AMS, BMS, tubular, slotted, balloon-expandable stent, 3 mm diameter, 15 mm long stent, Both stent ends are protected by sleeves.	117 patients	6 months, 77 patients and 94 lesions	100 (72.6)	149 (n)	1.2±0.5 [<1.5]	AMS, 31.8%, PTA, 58% at 6 months	NA	NA
Randon, 2010 ⁴² , SC: BA vs. spot BMS	SC: BA vs spot BMS	BA-4-6-Fr introducer, 0.014 or 0.035 hydrophilic guidewire, with Support catheter Mean balloon diameter-3 mm, Mean length-39 mm ²) Stent-Astron pulsar and Xpert, 3 mm, mean length-21.5 mm	38 limbs	12 months, 38 limbs	87	64%	2.2 vs. 3.9	PTA, 66% Primary Stenting, 56% at 12 months	NA	NA
INPERI A II, 2011 ⁴³	MC: BA vs BMS (carbofilm)	InPeria Carbostent., PTA-Pegaso balloon (lesion length ≤ 30 mm)	88 patients	9 months, 43 patients and 47 lesions	NA	NA	NA	MLD (9 months)- 1.19±0.92 mm vs. 1.02±1.02 mm; DS- 38.68% ± 25.47 vs. 43.31% ± 28.37 for stent group vs. PTA	NA	NA
ACHILLES, 2012 ⁴⁴	MC: BA vs DES (sirolimus)	CYPHER SELECT sirolimus-eluting stents (lengths 8 to 33 mm; diameters 2.5, 3.0, and 3.5 mm)	200 patients	12 months, 154 patients and 141 lesions	39 (% wounds)	78.3 %	2.7±2.1 cm	75.0% vs. 57.1% for SES vs. PTA	10.0% for SES, 16.5% for PTA	0.9% for SES
IN.PACT DEEP, 2014 ⁴⁵	MC: BA vs PCB	Paclitaxel eluting over-the-wire Amphirion Deep™ balloon catheter, 014"-wire platform. 120-150 cm usable shaft length, Nominal balloon diameter-2-4 mm, Length range-4-120 cm, balloon crossing and tip crossing profile - 0.017", loaded paclitaxel dosage - 3 µg/mm ²	358 patients	12 month, 256 patients and 167 lesions	84.6	41.1 %	11.1±9.0	NA	ITT populationally driven TLR, 11.9% for IA DEB vs. 13.5 % for PTA	NA

Table 6: Continue..

Trial	Trial Design	Stent Specifications	No. of Patients /Limbs	Follow-up criteria	CLI, % (% wounds)	CTO (n or %)	Lesion Length (cm)	Primary patency or end-point change	TLR, 1 year	Stent Fracture, 1 year
IDEAS, 2014 ⁴⁶	SC: DES vs PCB	Paclitaxel eluting over-the-wire Amphirion Deep™ balloon catheter, loaded paclitaxel dosage - 3 µg/mm ²	52 limbs	6 months, 44 limbs	46.2	18.2%	13.8±4.0	NA	7.7% for DES vs. 13.6% for PCB group at 6 months	NA
EXPAND, 2015 ⁴⁷	MC: BA vs SE BMS	Astron Pulsar, Pulsar-18 self-expanding bare nitinol stents, loaded on an over-the-wire system. Sizes of range 4.0 and 5.0 mm and 100 to 200 mm.	92 patients	12 months, 92 patients	59.8	92 (n)	3.4 vs. 4.0	SCI at 12 months: 74.3% for primary stenting vs. 68.6% for PTA with bail-out stenting	Freedom from TLR: 76.6% and 77.6% for primary and PTA with bail-out stenting respectively	NA
MAJESTIC, 2016 ³³	SE DES (Paclitaxel)	Self-expanding, Nitinol, Eluvia™ stent, Closed cells at ends, open cells in middle, Dual-coating- PVDF-HFP and paclitaxel at concentration of 0.167 µg/mm ² , Stent diameter-6-7 mm, Stent Length-40, 80, or 120mm	57 patients	57 patients for 12 months	NA	46%	70.8±28.1 mm	96% at 12 months	4%	None

Note: PTA, percutaneous transluminal angioplasty; BA, balloon angioplasty; AMS, absorbable metal stent; BMS, bare metal stent; MC, multicenter; NA, not available; n/N, count/sample; PCB, paclitaxel coated balloon; PES, paclitaxel-eluting stent; pts, patients; SC, single center; SE, self-expanding; CLI, Chronic limb ischemia; CTO; Chronic total occlusion; TLR, target lesion revascularization; PVDF – HFP, [poly(vinylidene fluoride-co-hexafluoropropylene)]; SCI, sustained clinical improvement

Surgical revascularization can be performed by open surgery techniques and/or a hybrid procedure combining open and endovascular strategies. They range from a local procedure for limited femoral lesions to long full-leg bypasses. Beyond clinical presentation and lesion distribution, one key element to discuss in indications for open surgery is the availability of venous material for bypass grafting. The optimal bypass material varies depending on the location of the lesion, outflow conditions, availability of material and the absence or presence of infection.³⁷

It can be concluded from the above Table 6 and the review, in general, that there still remains substantial room for improvement both in de novo and ISR lesions particularly for longer lesion length.

CONCLUSION

Endovascular therapy has become increasingly common in the treatment of PAD, particularly for the SFA and popliteal arteries. The introduction of self-expanding nitinol stents and DES has resulted in improved clinical success for intermediate and longer length SFA lesions. Despite all the potential limitations, currently, paclitaxel-eluting stents and DCB offer the best long-term favorable results in the femoropopliteal artery. To conclude the review, we give a bird’s eye view of all the major clinical trials involving comparison of different endovascular strategies for treating PAD.

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