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PERIPHERAL VASCULAR DISEASE (S KINLAY, SECTION EDITOR)

Endovascular Interventions for Peripheral Artery Disease: A Contemporary Review

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Abstract

Purpose of Review Peripheral artery disease (PAD) is an increasingly prevalent but frequently underdiagnosed condition that can be associated with high rates of morbidity and mortality. While an initial noninvasive approach is the cornerstone of management, revascularization is often pursued for patients with treatment-refractory claudication or chronic limb-threatening ischemia (CLTI). In this review, we discuss the current state of endovascular interventions for PAD and explore the many new emerging technologies.

Recent Findings The last decade has resulted in numerous advances in PAD interventions including the ongoing evolution of drug-coated devices, novel approaches to complex lesions, and contemporary evidence from large clinical trials for CLTI.

Summary Advances in endovascular management have allowed for increasingly complex lesions to be tackled percutaneously. Future directions for the field include the continued evolution in device technology, continued development of state-of-the-art techniques to revascularization of complex lesions, and increased collaboration between a largely multidisciplinary field.

Keywords Peripheral artery disease · Endovascular therapy · Claudication · Chronic limb-threatening ischemia

Introduction

Peripheral artery disease (PAD) is a significant global health concern, affecting approximately 237 million patients worldwide and approximately 8–10 million Americans each year [1, 2]. The prevalence of PAD is expected to continue growing over time due to the aging population and rising incidence of cardiovascular risk factors [3, 4, 5•].

Numerous modalities exist for the treatment of PAD, and modern clinical management strategies focus on a multimodal approach, initially emphasizing medical treatment, risk factor modulation, and supervised exercise therapy [6, 7]. These approaches, including smoking cessation programs, dietary and lifestyle modification, and medication therapy targeting cardiovascular risk factors, have been proven to be highly effective for many patients with PAD [8]. Moreover, noninvasive treatments such as supervised exercise therapy have been shown to be able to markedly improve a patient's functional status and clinical symptoms resulting in an improved quality of life [9–11]. However, among patients who experience intermittent claudication and endorse persistent symptoms despite these conservative strategies, revascularization may be indicated [12]. Timely revascularization is also pursued in patients with chronic limb-threatening ischemia (CLTI), the most severe manifestation of lower extremity PAD, which is defined by rest pain, tissue loss, or, at an extreme, gangrene/necrosis [13, 14].

Various revascularization approaches exist for lower extremity PAD and can be broadly categorized as either surgical or

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endovascular. While the decision of which revascularization approach to pursue is complex and involves a careful assessment of individualized surgical risk, anatomic features, availability of venous conduits, and lesion complexity, an endovascular approach is often used in the treatment of complex lesions due to advancements in endovascular technologies and overall complexity of the patient population. Moreover, while the utilization of paclitaxel-coated devices in peripheral interventions has been a subject of controversy for numerous years, this safety concern has recently been disputed by the Food and Drug Administration (FDA) [15]. Concerns regarding an increase in mortality associated with paclitaxel-coated devices were initially based on a meta-analysis of 28 trials [16]. However, numerous publications derived from both real-world samples and randomized controlled trials have subsequently reassured against this association leading to a reversal of the warning issued by the US FDA and allowing drug-coated devices to be back in the landscape of endovascular management [17, 18].

In this review, we provide a brief overview of the current state of endovascular interventions for PAD with a particular focus on contemporary data and the emerging technologies available for the modern peripheral interventionist.

Selection of Patients for Endovascular Intervention

Over the past several decades, it has become well established that endovascular approaches have high rates of technical success and offer many benefits over bypass procedures among patients with PAD [19]. In comparison to surgical intervention, endovascular therapy is associated with a reduction in anesthetic requirements, shorter hospitalization, decreased overall costs, and a lower risk of peri-procedural complications. Additionally, endovascular approaches are often advantageous as patients in need of revascularization are frequently at an elevated surgical risk due to the high rates of comorbid conditions. As a result, for patients undergoing revascularization for intermittent claudication, an endovascular approach can be applied for a majority of patients; however, specific recommendations for procedural interventions also depend on anatomic location, availability of venous conduits, and lesion complexity.

For CLTI, the initial choice of revascularization approach remains controversial [20]. To date, three randomized controlled trials have investigated the choice of revascularization method for CLTI, which are summarized in Table 1. Many operators initially adopted an endovascular-first approach for CLTI based on the results of the Bypass versus Angioplasty in Severe Ischemia of the Leg (BASIL) trial [21]. BASIL randomized 452 patients with infrainguinal PAD to receive either a surgery-first or an angioplasty-first approach to management. At 3 years following the index procedures, rates of amputation-free survival were similar between those who underwent angioplasty versus surgery (52% versus 57%, respectively; HR 0.89, 95% CI, 0.68–1.17) [21, 22]. However, in subsequent analyses, it was shown that balloon angioplasty was associated with a high rate of reinterventions, and importantly, those who underwent surgical bypass following angioplasty had worse outcomes [23]. Importantly, this finding suggested that both approaches were highly effective, although the careful selection of patients may be warranted.

The recent publication of the Best Endovascular versus Best Surgical Therapy in Patients with CLTI (BEST-CLI) both complemented and challenged the findings initially established by BASIL [24••]. In BEST-CLI, 1830 patients were enrolled and subsequently divided into 2 cohorts. Cohort 1 included patients who had a viable segment of their great saphenous vein for surgical bypass, and cohort 2 included patients who did not have a viable conduit. Differing from BASIL, the primary endpoint for this study was a composite outcome comprised of both major adverse limb events and all-cause mortality. In cohort 1, the composite endpoint was achieved at a higher rate among patients who underwent endovascular intervention (42.6% versus 57.4%; HR: 0.68, 95% CI, 0.59–0.79), which was largely driven by the increased rate of early reintervention and surgical crossover in the endovascular group. Technical success remained low in the endovascular group (85%), mirroring the BASIL trial performed > 15 years earlier, whereas the surgical technical success rate was 98%. Notably, among cohort 2, the rates of the primary endpoint were similar (42.8% versus 47.7%; HR: 0.79, 95% CI, 0.58–1.06). Most importantly, this study confirmed that both approaches are highly effective for patients, although those with a viable great saphenous vein may have the potential to benefit from a bypass-first approach [24••].

The most recent publication investigating this clinical decision was Bypass versus Angioplasty for Severe Ischemia of the Leg-2 (BASIL-2) trial [25••]. This study specifically enrolled patients with CLTI due to lesions located within the infrapopliteal arterial system with or without concomitant proximal disease. A total of 345 patients were randomized to either a vein bypass-first approach or a best endovascular approach and followed for a minimum of 2 years. BASIL-2 demonstrated that an endovascular-first approach was associated with an improved amputation-free survival when compared to surgery (53% versus 63%; HR 1.35, 95% CI, 1.02–1.80), driven most significantly by a reduction in early mortality. Based on these findings, patients with infrainguinal disease, regardless of the presence of concomitant proximal lesions, likely will benefit from an endovascular-first management strategy [25••].

Aortoiliac Disease

Aortoiliac disease, or aortoiliac occlusive disease, is defined as an atherosclerotic stenosis or occlusion located within the suprainguinal vessels [26]. Isolated revascularization targeting the aortoiliac system is most frequently performed in

Table 1 Summary of major randomized controlled trials comparing endovascular- versus surgery-first approach to CLTI

Trial name	Year	Centers	Patients	Inclusion criteria	Disease location	Arms	Primary endpoint	Follow-up	Major findings
BASIL [21, 22]	2005	27 hospitals in UK	452	Severe leg ischemia defined as rest pain or tissue loss of presumed arterial origin for > 2 weeks	Infrainguinal	Surgery-first ($n = 228$) versus angioplasty-first ($n = 224$)	Amputation-free survival	Minimum of 3 years	Amputation-free survival was similar between angioplasty and surgery (52% versus 57%; HR 0.89, 95% CI, 0.68–.17). Angioplasty had high rates of reinterventions, and those who subsequently underwent bypass had worse outcomes
BEST-CLI [24••]	2022	150 hospitals in USA, Canada, Finland, Italy, and New Zealand	1830	Patients > 18 year, with ischemic foot pain at rest, non-healing ulcer or gangrene. Cohort 1: patients had a viable great saphenous vein for surgery. Cohort 2: patients without viable vein graft	Infrainguinal	Surgery-first (any bypass method currently in practice) versus endovascular-first (any available endovascular approach)	Major adverse limb event (composite of above ankle amputation, major reintervention) or all-cause death	Cohort 1: median 2.7 yrs Cohort 2: median 1.6 yrs	Cohort 1: Those who had an adequate graft for bypass had a lower risk of death or MALE (42.6% versus 57.4%). Difference largely driven by reinterventions Cohort 2: Among those who lacked an adequate graft, there were similar rates of death/MALE (42.8% versus 47.7%)
BASIL II [25••]	2023	41 sites in UK, Denmark, Sweden	345	Life expectancy > 6 months, no interventions within previous 12 months	Infrapopliteal with or without concomitant proximal disease	Surgical bypass versus best endovascular treatment	Amputation-free survival	Median: 3.33 years	A best endovascular approach was associated with improved amputation-free survival (53% versus 63%; HR 1.35) (95% CI 1.02–1.80). This endpoint was largely due to a decrease in mortality with a best endovascular approach (45% versus 53%)

patients suffering from intermittent claudication, whereas aortoiliac revascularization is usually performed in conjunction with infrainguinal intervention among those with CLTI. These lesions are frequently approached from an ipsilateral femoral access in a retrograde fashion to allow for more precise delivery of equipment; however, complex occlusions can be engaged from the contralateral approach or via an upper extremity access site. Lesions within the aortoiliac vessels are graded utilizing the Trans-Atlantic Inter-Society Consensus-II (TASC-II) classification system. Although, historically, only patients with TASC A lesions were considered appropriate for endovascular intervention, more recent studies have demonstrated that increasingly advanced lesions including TASC C/D disease can be performed percutaneously with high rates of both safety and efficacy. For example, in a recent meta-analysis including 9319 patients with TASC C/D lesions derived from a total of 66 studies, endovascular techniques were associated with improved 30-day mortality when compared to open surgery (endovascular: 0.79% (95% CI 0.3–1.3%); surgical: 3% (95% CI 2–3%)) [27].

Utilizing an endovascular approach, modern treatment options for aortoiliac disease include balloon angioplasty, stenting, or other novel techniques. For focal aortoiliac disease, early studies suggested that balloon angioplasty alone provides adequate outcomes in patients; however, the primary approach remains stent implantation. The percutaneous transluminal angioplasty (PTA) data were initially based on the Dutch Iliac trial which included a total of 279 patients with > 50% iliac stenosis randomized to receive either primary stent placement or angioplasty with selective stent placement [28]. The primary finding of this analysis was that there were no substantial differences in treatment success or quality of life outcomes between groups, suggesting the benefit of a selective stent placement strategy [28, 29]. However, this trial has often been criticized as the population was overwhelmingly represented by patients with less severe disease burden (i.e., TASC A/B lesions). The Stents versus Angioplasty (STAG) trial further investigated primary stenting versus percutaneous transluminal angioplasty among patients with total iliac artery occlusions. Similar to the Dutch iliac study, STAG demonstrated no difference in primary or secondary patency at one and two years of follow-up, however, technical success was higher with primary stent placement [30]. More recent, larger analyses have further demonstrated the role of primary stent placement for aortoiliac PAD, primarily in complex lesions. For instance, in a large meta-analysis consisting of nearly 1000 patients with TASC C/D aortoiliac disease, improvements in long-term patency were observed with primary stenting as compared to selective stenting [31]. As a result, primary stenting is still the preferred approach for many endovascular operators.

Outside of PTA and stenting, novel devices have been developed to facilitate aortoiliac intervention and allow for safe treatment of complex disease, in particular highly calcified lesions. As discussed below, intravascular lithotripsy (IVL) has a unique role in the aortoiliac space, as it allows for the treatment of highly calcified lesions with low-pressure balloons facilitated by ultrasound energy [32, 33].

Femoropopliteal Disease

The femoropopliteal segment is the most commonly revascularized segment in patients with refractory claudication and CLTI. Similar to aortoiliac interventions, femoropopliteal lesions in classes TASC C and D are often deemed feasible for an endovascular first approach. This segment imposes several technical challenges including mechanical stress secondary to complex tension, compression, and torsion forces associated with leg movement, as well as increased lesion complexity including a high burden of calcification and chronic total occlusions [34•]. A variety of interventions including angioplasty, stenting, and plaque modification devices are employed in the treatment of femoropopliteal disease.

With respect to short (< 100 mm), low-complexity lesions, plain balloon angioplasty (PBA) may be a reasonable option. However, drug-coated balloons (DCBs) extend the lifetime of angioplasty, in particular for longer, more complex lesions, while minimizing the need for stents and attendant risk of stent fracture and restenosis. Drug-coated balloons have been supported by robust randomized data, as highlighted by a meta-analysis of 13 randomized trials and 9 global registries which demonstrated that drug-coated balloons (paclitaxel based) decrease the risk of target lesion restenosis (OR 0.29, 95% CI, 0.20–0.40) and late lumen loss (MLD − 0.80 mm, 95% CI, − 1.44 to − 0.16), while improving primary patency (OR 0.38, 95% CI 0.27–0.54) [35]. Unfortunately, the increased late mortality signal with paclitaxel in the Katsanos meta-analysis caused the use of DCBs to decline precipitously, but with the recent reversal by the FDA, this is expected to rebound [16].

Longer (> 100 mm) and more complex lesions (calcified, chronic total occlusions (CTOs)) often require plaque modification with and without stent implantation. A major limitation of stents in the femoropopliteal segment is the risk of stent fracture and restenosis related to repeated mechanical stress. Nonetheless, data support their use in this segment. For instance, the Balloon Angioplasty Versus Stenting with Nitinol Stents in the Superficial Femoral Artery (VIENNA) trial established the superiority of bare metal stents over PBA in terms of rates of restenosis at 12 months [36]. However, in-stent restenosis remained the Achilles heel of early stent technology. This led to the development and evolution of paclitaxel-coated stents, with Zilver PTX (Cook Medical, Bloomington, IN) being the first to emerge. Zilver gained approval based on the Zilver PTX trial and demonstrated

improved patency and event-free survival extending out to 5 years when compared to PBA. The newer generation Eluvia stent (Boston Scientific, Marlborough, MA), which has more sustained release paclitaxel kinetics, had improved patency at 12 months (86.8% vs 81.5%; difference, 5.3%; $P < 0.0001$) and greater freedom from major adverse events (93.9% vs 91%; difference, 3.9%; $P < 0.0001$) compared to Zilver PTX in a head-to-head trial [37, 38]. With regards to the risk of stent fracture, improving biomimetic design has also shown promise with nitinol woven stents like Supera and purpose-built vascular scaffolds such as the Biomimics 3-dimensional stent demonstrating improved patency in complex lesion subsets.

Given the high burden of calcium and CTOs in this segment, plaque modification remains an important yet controversial topic. Namely, while a multitude of atherectomy devices are available on the market and provide a plausible benefit of improving vascular diameter, compliance, and drug transfer, their efficacy has not yet been robustly studied in head-to-head trials. Further, another limitation is the lack of widespread consensus and individual device requirements with the need for distal embolic protection devices. In addition to atherectomy devices, a number of plaque modification devices are used to address fibro-calcific disease in the femoropopliteal segment (e.g., cutting, scoring, Chocolate and Serranator balloons). As mentioned previously, IVL is a novel device that is gaining traction in this particular segment, as it has a favorable complication profile with a lower risk of dissection and distal embolization compared to atherectomy yet is efficacious at yielding non-compliant lesions.

Appropriate patient selection for femoropopliteal bypass for patients with CLTI is crucial and is based on several key principles including assessment of surgical risk, presence of venous conduits, anatomy favorable for potential bypass, and patient-centered shared decision-making. The findings of the recently published BEST-CLI trial are particularly relevant in that a majority of treated lesions were in the femoropopliteal segment in both the surgical and endovascular arms [24••]. Several limitations of this study include that many of the re-interventions in the cohort with adequate saphenous vein group occurred in the first 6 months due to early technical failure and a substantial rate of cross-over, although the reasons why have yet to be further specified. Further, the enrollment period coincided with the 2018 Katsanos meta-analysis which drove down the use of paclitaxel-coated devices [16]. In a recent pooled analysis of five randomized controlled trials comparing endovascular therapy versus surgical bypass, there was no significant difference in MALE (40.1% vs 36.4%; adjusted HR: 1.04; 95% CI: 0.80–1.36) and amputation-free survival (88.1% vs 90.0%; adjusted HR: 1.04, 95% CI: 0.63–1.71). Furthermore, these findings have not been replicated in older patients undergoing CLTI treatment. Additionally, endovascular therapy had other notable benefits including lower rates of early complications (6.8% vs 22.6%; $P < 0.001$) and shorter hospital stay (3.1 ± 4.2 days vs 7.4 ± 4.9 days; $P < 0.001$) [39, 40]. These data in sum emphasize the need to tailor patient selection to optimize outcomes. Furthermore, with a growing interest in limus-based drug-coated technology and bioabsorbable scaffolds, the contemporary patency outcomes with endovascular therapy may not yet be fully characterized.

Infrapopliteal Disease

Revascularization within the infrapopliteal segment is almost exclusively performed for patients with CLTI. Similar to interventions within other lower-extremity segments, endovascular approaches are frequently the first modality considered for revascularization as numerous studies have demonstrated equivalent rates of patency as compared to surgery [41]. This approach was further supported by the findings of the recently published BASIL-2 trial, which demonstrated improved amputation-free survival as compared with surgical approaches (Table 1) [25••].

Balloon angioplasty is the most common intervention performed within this segment and historically has been the mainstay of treatment [42]. Numerous studies have demonstrated that PTA alone is associated with favorable limb salvage rates in below-the-knee revascularization procedures, with the goal to drive in-line flow to the wound or corresponding angiosome [43, 44]. However, patency rates with PTA alone can be poor, often due to recoil or dissection, and coronary stents remain the bailout option of choice due to the lack of approved infrapopliteal stents. As such, recent technological developments have focused on the use of purpose-built scaffolds for below-the-knee application as well as the role of drug technology. Table 2 summarizes the select trials investigating drug-coated devices for below-the-knee revascularization.

For drug-eluting stents (DES), several studies have investigated the benefit of coronary stents to improve vessel patency when compared to PTA. The ACHILLES randomized controlled trial was an early study which compared a sirolimus-eluting stent to PTA alone and found improved rates of binary restenosis with DES devices (22.4% versus 41.9%, $p = 0.019$) [45]. Similarly, in trials investigating paclitaxel-eluting stents, rates of vessel patency were improved compared to PTA with or without BMS placement [46]. Favorable vessel and clinical outcomes were also demonstrated in a large meta-analysis which included five RCTs comparing DES to controls (either PTA or bare metal stents). In this study, DES were associated with a reduction in TLR (OR 0.31, 95% CI, 0.18–0.54, $p < 0.001$), restenosis (OR: 0.25, 95% CI, 0.15–0.43, $p < 0.001$), and amputation rates (OR: 0.50, 95% CI, 0.26–0.97, $p = 0.04$) at a median follow-up of 12 months [47].

Table 2 Selected RCTs investigating drug-coated devices for below-the-knee revascularization

Trial name	Year	Patients	Type of drug-coated device	Arms	Follow-up	Binary restenosis	CD-TLR	Major amputation	Death
Drug-eluting stents									
PARADISE [81]	2010	106	83% sirolimus, 17% paclitaxel	DES	3 years	12%	15%	6%	29%
ACHILLES [45]	2012	200	Sirolimus	DES versus PTA	1 year	22.4% (DES) versus 41.9% (PTA)	10% (DES) versus 16.5% (PTA)	13.8% (DES) versus 20.0% (PTA)	10.1% (DES) versus 11.9% (PTA)
DESTINY [82]	2012	140	Everolimus	DES versus BMS	1 year	15% (DES) versus 46% (BMS)	9% (DES) versus 34% (BMS)	1.4% (DES) versus 3.0% (BMS)	NR
YUKON-BTX [83]	2012	161	Sirolimus	DES versus BMS	Median 2.78 years	NR	NR	5.3% (DES) versus 22.6% (BMS)	32.3% (DES) vs 26.6% (BMS)
PADI [46]	2016	137	Paclitaxel	DES versus PTA +/− BMS	6 months	9.9% (DES) versus 29.9% (PTA)	NR	9.8% (DES) versus 20.5% (PTA)	13.7% (DES) versus 14.1% (PTA)
Drug-coated balloons									
SINGA-PACLI [84]	2021	70	Paclitaxel-coated balloon	Paclitaxel-coated balloon versus PTA	6 months	NR	20% (DEB) versus 18% (PTA)	22% (DEB) versus 15% (PTA)	10% (DEB) versus 10% (PTA)
Biolux P-II [85]	2015	72	Passeo-18 LUX paclitaxel eluting balloon	DEB versus PTA	1 year	14.6% (DEB) versus 20.1% (PTA)	31.3% (DEB) versus 26.9% (PTA)	3.3% (DEB) versus 5.6% (PTA)	9.4% (DEB) versus 6% (PTA)
DEBATE-BTK [49]	2013	132	IN.PACT Amphirion drug eluting balloon	DEB versus PTA	1 year	27% (DEB) versus 74% (PTA)	18% (DEB) versus 43% (PTA)	0.0% (DEB) versus 1.5% (PTA)	7.7% (DEB) versus 4.5% (PTA)
ACOART-BTK [48]	2020	105	ACOART Litos paclitaxel-coated balloon	DEB versus PTA	1 year	37.9% (DEB) versus 87.1% (PTA)	10% (DES) versus 41% (PTA)	0% (DEB) versus 0% (PTA)	7.7% (DEB) versus 13.2% (PTA)
IN-PACT DEEP [86]	2014	358	IN.PACT Amphirion drug eluting balloon	DEB versus PTA	1 year	41% (DEB) versus 35.5% (PTA)	11.9% (DEB) versus 13.5% (PTA)	8.8% (DEB) versus 3.6% (PTA)	10.1% (DEB) versus 8.1% (PTA)
IDEAS [87]	2014	50	Paclitaxel-coated balloon	PCB versus DES	6 months	57.9% (PCB) versus 28% (DES)	13.6% (PCB) versus 7.7% (DES)	4% (PCB) versus 8% (DES)	8% (PCB) versus 12% (DES)
Lutonix BTK	2019	442	Paclitaxel-coated balloon	PCB versus PTA	6 months	NR	6.2% (PCB) versus 14.4% (PTA)	1.1% (PCB) versus 2.0% (PTA)	5.0% (PCB) versus 4.0% (PTA)

Drug-coated balloons (DCB) have also been designed for application within longer lower extremity lesions which otherwise would require placement of several overlapping stents. The ACOART-BTK trial compared the efficacy of the Litos paclitaxel-coated balloon to PTA and found that the DCB significantly reduced the risk of late lumen loss, vessel reocclusion, and CD-TLR in patients requiring below-the-knee revascularization [48]. Similar findings of vessel patency were also seen with another paclitaxel-coated balloon in a diabetic population in the DEBATE-BTK study [49]. Although infrapopliteal DCBs are available outside the USA, two trials performed in the USA, IN.PACT Deep and Lutonix BTK, failed to demonstrate sufficient benefit to gain FDA approval. Furthermore, in a meta-analysis investigating ten studies compared DCBs to standard PTA, there was no significant difference in the rates of limb salvage, restenosis, or survival between groups [50]. While some studies investigating DCBs in particular with newer devices involving limus-based antiproliferative agents have been encouraging, larger RCTs further investigating outcomes associated with these devices are needed.

Emerging Therapies

Percutaneous Deep Venous Arterialization (pDVA) and Endovascular Bypass Systems

Among patients with CLTI, up to 20% have no options for revascularization due to various factors, including poor surgical candidacy, lack of an adequate bypass graft, or inadequate distal target vessels, the so-called "desert foot." Previously, surgical arterialization of the deep veins was developed as a last resort procedure for these patients with no-option CLTI but failed to find a role in routine use due to variable outcomes. More recently, percutaneous approaches to deep vein arterialization have entered the treatment landscape with more promising limb salvage data [51, 52].

The LimFlow pDVA system (LimFlow Inc, San Jose, CA) is one such platform that has been developed to facilitate pDVA application. PROMISE I was a multicenter, prospective study which enrolled 32 patients with no option CLTI and was treated with the LimFlow pDVA system. In this study, an overall high rate of technical success was observed as well as a high rate of amputation-free survival (74% and 70% at 6 and 12 months, respectively) [53•]. Furthermore, the initial results of the PROMISE II study were recently published [54]. PROMISE II was a single-cohort, multicenter study which sought to investigate amputation-free survival at 6 months compared to a performance goal of 54%. Among the 105 patients enrolled, procedural success was attained in 99% of patients, and 6-month amputation-free survival was 66.1%, supporting both the feasibility and efficacy of this platform [54].

Different from pDVA, percutaneous bypass has been explored as a treatment option for long-occluded femoropopliteal segments. The PQ Bypass DETOUR system (PQ Bypass, Milpitas, CA) involves the percutaneous diversion of flow through covered stent grafts into the parallel femoral vein to bypass such complex lesions, with arterial re-anastomosis in the distal healthy femoropopliteal segment. In a study investigating patients with long segment (> 100 mm) femoropopliteal disease, adequate safety and efficacy endpoints were met at 1 year of follow-up, and this platform has since achieved FDA approval [55•]. Future studies further investigating the long-term outcomes associated with these novel revascularization strategies remain needed.

TACK Endovascular System

An unwanted but frequent complication of angioplasty is an uncontrolled dissection, which involves an extension of the expected post-angioplasty injury beyond the initial site of treatment. Prior work has suggested that the incidence of arterial dissections can range from nearly 7.4 to 84% in peripheral interventions [56, 57]. Operators have several options to manage these complications, including a prolonged balloon inflation strategy, the placement of a longer stent at the location of the injury, or simply leaving it untreated [58, 59]. The TACK endovascular system (Philips, San Diego, CA) was developed in an effort to limit the extent of stent placement following these focal complications [60]. TACK is composed of a delivery catheter which carries and deploys up to six short self-expanding nitinol implants at the site of the lesion. TACK has been designed with open cell geometry and short longitudinal length to specifically limit the amount of metal left behind in the patient and reduce future complications [56].

To date, several studies have investigated the safety and efficacy of TACK [61]. The TOBA II trial was a prospective, multicenter study which enrolled 213 patients with a post-angioplasty dissection located in the SFA or the proximal popliteal artery and was treated with TACK [62]. After 1 year, 79.3% of patients had primary patency, and 86.4% of patients did not require subsequent revascularization proving its efficacy for these complications [62]. TACK implants have also been demonstrated to be effective in the management of below-the-knee dissections as well. In a recent trial including over 200 patients, a total of 341 dissections located in the infrapopliteal arteries were treated with TACK implants, and after 6 months, similar rates of safety and efficacy were demonstrated [63].

Intravascular Ultrasound

Intravascular ultrasound (IVUS) is an emerging technique which utilizes ultrasound waveforms to provide cross-sectional

images of a vessel's lumen beyond what can be visualized on traditional angiography. The efficacy of IVUS-guidance was initially established for coronary interventions, with multiple randomized and observational studies demonstrating a reduction in major adverse cardiac events and death [64, 65]. Evidence for the application of IVUS in peripheral interventions is growing, and recent studies have suggested that its utilization is rising within the USA [66]. IVUS-guidance as compared to angiography alone has numerous advantages for endovascular operators including an enhanced ability to size vessels, characterize lesions, identify eccentric remodeling, and recognize procedural complications including vascular damage and dissections. For instance, in the iDissection study, the utilization of IVUS significantly improved the detection of post-atherectomy dissections when compared to angiography alone [67].

A recently published randomized controlled trial investigated the application of IVUS in femoropopliteal interventions and assessed rates of binary restenosis. In this single center trial including 150 patients, freedom from binary restenosis after 1 year was higher with IVUS compared to angiography alone (72.4% versus 55.4%, $p < 0.01$). Interestingly, the benefit with IVUS was most predominately seen among patients who were treated with drug-coated balloons. Moreover, this study demonstrated that IVUS use altered operators' treatment plan in 79% of patients, indicating its value when used in addition to angiography [68].

In 2022, the first consensus statement outlining the appropriate use of IVUS within both arterial and venous peripheral interventions was published. In this consensus paper, over forty vascular experts concluded that IVUS usage was appropriate for the majority of phases during lower extremity arterial interventions and provides a framework for incorporating IVUS into routine peripheral practice [69•].

Intravascular Lithotripsy (IVL)

During revascularization procedures, the management of calcified lesions is often challenging [70, 71]. Calcified lesions have been associated with higher rates of restenosis and procedural complications including dissection, perforations, and distal embolization [72, 73]. IVL has emerged as a novel endovascular device which utilizes acoustic waves to penetrate soft tissues to interact with calcium deposits and induce fractures. These sonic waves can penetrate both intimal and medial calcium deposits, thus allowing for safe vessel dilation irrespective of calcium location. This ability to effect medial calcium is an advantage relative to contemporary modalities such as atherectomy that primarily target intimal calcification.

The DISRUPT PAD II trial demonstrated the safety and effectiveness of IVL in the management of calcified disease within the femoropopliteal segment. A total of 60 patients with moderate or severe calcified femoropopliteal disease were treated with IVL, and there was a low rate of major adverse events at 30 days (1.7%). Additionally, the rate of patency was 54.5%, and the rate of CD-TLR was 20.7% at 1 year of follow-up [74]. The highly anticipated DISRUPT PAD III trial compared IVL with a drug-coated balloon to a drug-coated balloon alone for calcified PAD. In this randomized controlled trial, higher rates of procedural success (defined as residual stenosis < 30% without a flow-limiting dissection measured at 30 days) were found in the IVL group (65.8% vs 50.4%, $p = 0.0065$) [75•]. Moreover, longer-term follow-up extending to 2 years demonstrated improved freedom from CD-TLR with this modality [76].

Bioresorbable Vascular Scaffolds

Bioresorbable vascular scaffolds (BVS) are another technical advance with potential application for peripheral interventions [77]. BVS are biopolymer-based stents that function in two stages. In the initial acute healing phase, the stent provides radial support and allows for the elution of an antiproliferative drug. Following vascular healing and restoration of vasomotor properties, the stent is able to be resorbed into the intimal tissue [34•, 78]. The temporary nature of this device has the potential to be highly favorable for long-term outcomes and mitigates late complications such as in-stent restenosis or occlusion. One such device currently under investigation is the Abbott Vascular ESPRIT BVS system (Abbott, Abbott Park, IL). The ESPIRIT 1 study evaluated this scaffold in 35 patients with symptomatic claudication due to disease within the SFA or external iliac arteries. At 2 years, there was a low rate of binary restenosis (16.1%), and CD-TLR was performed in only 11.8% of patients [79]. Moreover, the esprit scaffold is also being investigated for below-the-knee applications. The LIFE-BTK trial investigating this indication has already completed enrollment with results expected later this year [80]. A similar platform is being investigated in the EFEMORAL I study and is currently enrolling patients (ClinicalTrial.gov ID: NCT04584632).

Conclusions

The past several decades have introduced numerous technological advances for the endovascular treatment of PAD, allowing for increasingly complex lesions to be tackled percutaneously. Contemporary evidence from BEST-CLI and the BASIL trials have re-introduced the merits of initial surgical approaches after carefully weighted patient selection, particularly among those with viable saphenous conduits. Nevertheless, these large-scale RCTs have inherent limitations including the underutilization of modern endovascular techniques including paclitaxel-coated devices and outstanding questions regarding the generalizability of these findings

to real-world practice. It is yet to be determined how the durability of endovascular interventions may improve with modern best practices as well as with new emerging devices. Finally, as the management for PAD is becoming increasingly multidisciplinary and spans the expertise of numerous subspecialties (including primary care, vascular medicine, cardiology, vascular surgery, and interventional radiology, among others), multidisciplinary collaboration at the hospital level and a focus on inter-society partnership to further guide treatment decisions is of critical importance.

Compliance with Ethical Standards

Conflict of Interest Eric A. Secemsky reports personal fees from Abbott, BD, Boston Scientific, Cook, Cordis, InfraRedx, Medtronic, Philips, RapidAI, Shockwave, and VentureMed, outside the submitted work. The other authors declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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- • Of importance
- •• Of major importance

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