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CLINICAL DECISION MAKING

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SCAI consensus guidelines for device selection in femoral-popliteal arterial interventions

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1 | INTRODUCTION

The Society for Cardiovascular Angiography and Interventions (SCAI) has a history of prioritizing quality initiatives in the field of endovascular therapy (EVT) for peripheral artery disease (PAD). In 2017, SCAI updated the 2014 Appropriate Use Criteria (AUC) for EVT in the aorto-iliac, femoral-popliteal (FP), infra-popliteal and renal arterial circulations, promoting data-driven procedural decision making and understanding of relative risks and benefits of EVT in specific clinical and anatomic scenarios [1]. In 2016, the updated AHA/ACC PAD Guidelines document provided

Abbreviations: AUC, appropriate use criteria; BMS, bare metal stent; CBA, cutting balloon angioplasty; CFA, common femoral artery; CLI, critical limb ischemia; COR, class of recommendation; CTO, chronic total occlusion; DA, directional atherectomy; DCB, drug coated balloon; DES, drug eluting stent; DUS, duplex ultrasonography; EPD, embolic protection device; EVT, endovascular therapy; FP, femoral-popliteal; ISR, in stent restenosis; LA, laser atherectomy; LOE, level of evidence; MALE, major adverse limb events; OA, orbital atherectomy; PFA, profunda femoris artery; PTA, percutaneous transluminal angioplasty; RA, rotational atherectomy; RCT, randomized controlled trial; SFA, superficial femoral artery; TLR, target lesion revascularization; TVR, target vessel revascularization; QoL, quality of life.

contemporary recommendations for diagnosis and management of lower extremity PAD [2]. However, these documents did not address the selection of specific devices when EVT is indicated. Device choices for EVT in the FP arterial bed remain challenging due to a wide spectrum of available endovascular device options and a paucity of comparative effectiveness data. The purpose of this first device-focused consensus document is to provide a review of comparative effectiveness data, including safety and efficacy of FP devices, and to provide clinicians with guidance and recommendations for device selection, when these devices are intended as the definitive or adjunctive therapy.

2 | METHODOLOGY

This document provides recommendations applicable to devices used for EVT in FP disease. The goal is to guide clinical judgment with an emphasis on evidence-based and cost-effective utilization. This document is intended as a guide to improve decision making regarding EVT device selection for patients undergoing EVT.

A balanced writing group was nominated and selected based on their EVT expertise, with consideration of relationships with industry and professional specialty or area of focus. The Writing Group Chairman and ≥50% of the members had no relevant relationships with industry (Table 1). The recommendations listed, whenever possible, were based on randomized controlled trials (RCTs) and meta-analyses, but also included registries, nonrandomized comparative studies, case series, cohort studies, and expert opinion. The writing committee chose the studies to highlight in this document; the final summary of the reviewed and most relevant clinical data is included in the Supporting Information Tables S1-S7.

The Class (strength) of Recommendation (COR) represents the anticipated magnitude and certainty of comparative benefit for a group of devices (i.e., symptom improvement, patency, functional status, and/or quality of life) against the risks and cost of the device use based on the SCAI (modified ACC/AHA guideline recommendation) [3] classification (Table 2). The Level of Evidence (LOE) provides evidence supporting the effect of the devices on the basis of the type, quality, quantity, and consistency of data. The COR and LOE are determined independently; any COR may be paired with any LOE.

The committee used a modified Delphi panel methodology, which employed an expert panel of clinicians who rated a series of anatomical scenarios with respect to COR/LOE. The panel participated in three rounds of voting, with communication among the panelists after the first anonymized round. Each panelist had equal weight in determining the final rating. Agreement among panelists was achieved when >80% of the recommendations ratings for the scenarios were concordant (Tables 2 and 3).

2.1 | Definitions and assumptions

1. The scenarios chosen in this document are largely based on the anatomical features of the lesions and presence of hemodynamically significant FP disease rather than clinical presentation and are not intended to be all-inclusive.
2. Lesion length is categorized into focal (<10 cm), intermediate (10–20 cm), and diffuse (>20 cm), which is consistent with the definitions used for the peripheral vascular interventions AUC document [1].
3. For all device scenarios, assume that COR/LOE (Table 1) are provided for groups or categories of devices and not intended to compare individual devices and/or manufacturers.
4. The COR/LOE for a category of the devices were assigned according to the best comparative evidence-based data from the published trials/registries, with conventional uncoated PTA frequently being the comparison group. For instance, *Class III: No Benefit* recommendation implies that there is no benefit relative to the comparison group (e.g., conventional uncoated balloon PTA), rather than no benefit at all from the examined category of the devices.
5. For device scenarios, this document focuses on the devices intended as the definitive therapy (Table 3), and not necessarily the final device therapy. PTA may be chosen as the intended definitive treatment, even if it may be necessary to use atherectomy for preparation of an undilatable lesion. DCB may be chosen as the intended definitive treatment with planned predilation with PTA. DCB or uncoated PTA may be chosen as the intended definitive treatment, even if it may be necessary to use "bail-out" stenting to preserve vessel patency.
6. The use of the adjunctive devices for lesion preparation, such as atherectomy or specialty balloons, is separately addressed in this document including recommendations for both dilatable and undilatable lesions (Table 4). Atherectomy may be chosen as the adjunctive device for lesion preparation, whereas DCB may be selected as the intended definitive treatment.
7. The cost of the devices (Table 5) was considered secondary to examining efficacy and safety data when determining COR/LOE, particularly for devices with limited comparative clinical data that could justify their additional cost.
8. The utilization of a combination of different groups/categories of devices as the intended definitive therapy (e.g., laser atherectomy plus DCB for in stent restenosis) is not addressed and beyond the scope of this document.
9. Occlusion describes complete cessation of flow through the arterial segment.
10. Provisional stenting implies PTA with stent placement intended only for "bail-out" (i.e., for flow-limiting dissection or significant [>50%] residual stenosis).
11. Primary stenting implies the intention to place a stent regardless of the outcome of any predilation or pretreatment.

2.2 | Clinical outcomes and endpoints, assessing the efficacy of revascularization

There has been a lack of consistent definitions and nomenclature across clinical trials of devices, drugs or biologics for the treatment of PAD. In an effort to overcome this barrier, the Peripheral Academic Research Consortium (PARC) developed consensus definitions for clinically

TABLE 1 Author relevant relationships with industry and other entities

Committee member	Employment	Relevant relationships with industry
Dmitriy N. Feldman, MD	Weill Cornell Medical College, New York, NY	None
Ehrin J. Armstrong, MD	University of Colorado School of Medicine	Abbott Vascular—advisory board Boston Scientific—advisory board Cardiovascular Systems—advisory board Cook—advisory board Gore—consultant Spectranetics—consultant, advisory board
Herbert D. Aronow, MD	The Warren Alpert Medical School of Brown University	None
Osvaldo S. Gigliotti, MD	Seton Heart Institute	None
Michael R. Jaff, DO	Newton-Wellesley Hospital	Non-Compensated Advisor: Abbott Vascular; Boston Scientific; Cordis, a Cardinal Health Company; Medtronic Compensated Advisor: Philips/Volcano; Micell; Vactronix; Venarum; American Orthotics and Prosthetics Association Equity Investment: PQ Bypass; Primacea; Gemini; eFemoral; Embolitech; Vascular Therapies; Sano V
Andrew J. Klein, MD	Piedmont Heart Institute	None
Sahil A. Parikh, MD	NY Presbyterian Hospital/Columbia University Medical Center	Abbott Vascular—advisory board Boston Scientific—advisory board Medtronic—advisory board Philips/Spectranetics—advisory board
Anand Prasad, MD	UT Health Science Center at San Antonio	Abiomed—Speaker ACIST Medical—Grants/Research Support AstraZeneca—Speaker General Electric—Consultant Medtronic—Grants/Research Support Osprey Medical - Consultant
Kenneth Rosenfield, MD	Massachusetts General Hospital	Abbott Vascular—advisory board, consultant Atrium—grants/research support (national PI) Bard—grants/research support (national PI) Capture Vascular—advisory board, consultant Cardinal Health—advisory board, consultant Contego—advisory board, consultant Cook—advisory board Cruzar—advisory board, consultant, Ownership/Stock Owner/Shareholder Endospan—advisory board, consultant, Ownership/Stock Owner/Shareholder Eximo—advisory board, consultant, Ownership/Stock Owner/Shareholder
Mehdi H. Shishehbor, DO	University Hospitals Cleveland Medical Center	Medtronic—advisory board, consultant Abbott - advisory board, consultant Boston Scientific - advisory board, consultant Phillips - advisory board, consultant
Rajesh V. Swaminathan, MD	Duke University Medical Center	ACIST Medical—Grants/Research Support Boston Scientific—Ownership/Stock Owner/Shareholder
Christopher J. White, MD	Ochsner Medical Center	None

meaningful outcomes and endpoints [4]. The current consensus document recommends adopting the PARC definitions for acute procedural and technical success of EVT, short- and long-term surrogate endpoints of procedural success (using imaging and physiologic measures), and functional/clinical outcome definitions [4]. In patients with claudication, functional assessments using standardized validated treadmill protocols or 6-min hall walk testing should be used. In CLI patients, limb outcomes with respect to major and minor lower extremity amputation, wound healing, ischemic rest pain, and major adverse limb events (MALE) should be examined. In this document, when evaluating comparative effectiveness, clinical and functional outcomes (e.g., clinically driven TLR) were given greater emphasis than surrogate endpoints (e.g., DUS-derived restenosis), which in turn were weighted more heavily than procedural success endpoints. When available, cost effectiveness studies were also taken into consideration in the recommendations.

2.3 | Anatomic, clinical, and technical definitions

Lower extremity PAD has classically been defined by the anatomic segments affected as aorto-iliac, femoral-popliteal (FP) segment, and below

TABLE 2 Applying COR and LOE to device strategies

Class (strength) of recommendation	Level (quality) of evidence
Class I (Strong) Benefit ⋙ Risk (&Cost) • Device is recommended • Device is indicated/useful/beneficial/cost-effective	**Level A** • High-quality evidence from >1 RCT • Meta-analyses of high-quality RCTs • One or more RCTs corroborated by high-quality registry studies
Class IIa (Moderate) Benefit ≫ Risk (&Cost) • Device is reasonable • Device can be useful/beneficial/cost-effective	**Level B-R (Randomized)** • Moderate-quality evidence from 1 or more RCTs • Meta-analyses of moderate-quality RCTs
Class IIb (Weak) Benefit ≥ Risk (&Cost) • Device may/might be useful • Device may/might be considered • Device usefulness/cost-effectiveness is unknown/unclear/uncertain or not well established	**Level B-NR (Nonrandomized)** • Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized, observational or registry studies • Meta-analyses of such studies
Class III: No Benefit (Moderate) Benefit = Risk (&Cost) • Device is not recommended • Device is not indicated/useful/beneficial/cost-effective	**Level C-LD (Limited Data)** • Randomized or nonrandomized observational or registry studies with limitations of design or execution • Meta-analyses of such studies • Physiological or mechanistic studies in human subjects
Class III: Harm (Strong) Risk > Benefit (&Cost) • Device is potentially harmful • Device can cause harm • Device is associated with excess morbidity/mortality	**Level C-EO (Expert Opinion)** • Consensus of expert opinion based on clinical experience

knee infra-popliteal (IP) or infrageniculate arteries. The FP segments represent the common femoral artery (CFA), profunda femoris artery (PFA), superficial femoral artery (SFA) and popliteal artery, the longest nonbranched vessel. In this document, we discuss devices specific to the above-knee FP segment, while separately addressing CFA disease. The CFA bifurcation lesions refer to lesions that involve the common femoral bifurcation and ostial SFA/PFA; however, the recommendations also apply to isolated CFA disease. The above-knee popliteal artery segment includes the P1 (from intercondylar fossa to proximal edge of patella) and P2 (from proximal part of patella to center of knee joint space) popliteal segments. In addition to anatomical location, the lesions are classified according to length, stenosis versus occlusion, degree of calcification, and whether they represent de novo or in-stent restenosis (ISR). The TASC classification has previously placed FP lesions into 4 categories according to lesion length and whether disease is stenotic or occlusive [5]. However, in this document and relevant to existing data for devices in RCTs, we have defined lesion length as focal (<10 cm), intermediate (10–20 cm), and diffuse (>20 cm), which is consistent with the AUC document [1]. Given that definitions for degree of calcification varied between trials, we have provided recommendations for a general category of moderate-severely calcified lesions (≥180° degree of calcification involving both sides of vessel at same location). The lesion is considered undilatable if it could not be fully expanded during a balloon predilation. In stent restenosis (ISR) is defined as a stenosis or occlusion within a previously placed stent, regardless of whether the original stent was bare metal, drug eluting, or a covered stent.

When EVT is considered, there are technical considerations such as choice of access site, the use of embolic protection and the use of re-entry devices. In this document, the choice of access site is left to the discretion of the operator. In some chronic total occlusions (CTOs), antegrade crossing results in subintimal wire passage and the need for re-entry into the true lumen. A number of re-entry devices and techniques have been described [6]. Occasionally during FP treatment, an embolic protection device (EPD) may be appropriate, and several are commercially available. The utilization of re-entry or EPDs is beyond the scope of this document.

2.4 | Common femoral artery EVT

Surgical endarterectomy has historically been the treatment of choice for CFA disease [7,8]. However, recent reports of EVT (DCB, atherectomy, stenting) [9,10] and a randomized trial of stenting versus surgery [11] have demonstrated high technical success, improved safety and comparable patency for EVT compared to open surgery for CFA lesions. Data derived from a large pooled analysis ($n = 1{,}014$) from the Vascular Quality Initiative, demonstrate low procedural morbidity with CFA EVT (77% cases were PTA) [12]. The TECCO (The Endovascular Versus Open Repair of the Common Femoral Artery) trial randomized 117 patients with de novo disease to CFA endarterectomy or stent placement [11]. Of note, in the stenting group, 1/3 were treated with balloon-expandable stents, particularly in lesions that involved the common femoral bifurcation. There were more early complications in the surgical group (26% vs. 12.5%, $P = 0.05$) and longer duration of

TABLE 3 COR[a] and LOE for device selection as the *Intended Definitive Therapy* in the femoral-popliteal arterial interventions

	PTA	Specialty balloons	BMS (Self-expanding)	DES	DCB	Covered stents	Laser atherectomy	Directional atherectomy	Orbital/ Rotational atherectomy	Excisional/ aspiration atherectomy
1. CFA bifurcation lesion	IIB C-LD	IIB C-EO	IIA B-R	IIA C-EO	IIA C-EO	III H C-EO	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO
2. Above knee popliteal lesion	III NB B-R	III NB C-EO	IIA A	I B-R	I A	IIB B-R	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO
3. Ostial SFA lesion	IIB B-R	IIB C-EO	IIA A	I B-R	I A	IIB C-EO	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO
4. Focal SFA lesion	IIB A	III NB C-LD	IIA A	I B-R	I A	IIB B-R	III NB C-LD	III NB C-LD	III NB C-LD	III NB C-LD
5. Intermediate SFA lesion	III NB B-R	III NB C-LD	IIA A	I B-R	I A	IIB B-R	III NB C-LD	III NB C-LD	III NB C-LD	III NB C-LD
6. Diffuse SFA lesion	III NB B-NR	III NB C-EO	IIA B-NR	I B-NR	I B-R	IIA B-R	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO
7. Moderate to severe calcified, focal lesion	IIB B-NR	IIB C-LD	IIA C-LD	I C-LD	I C-LD	IIB C-EO	III NB C-LD	III NB C-LD	III NB C-LD	III NB C-LD
8. Moderate to severe calcified, intermediate lesion	III NB B-NR	III NB C-LD	IIA C-LD	I C-LD	I C-LD	IIB C-EO	III NB C-LD	III NB C-LD	III NB C-LD	III NB C-LD
9. Moderate to severe calcified, diffuse lesion	III NB B-NR	III NB C-LD	IIA C-EO	I C-EO	I C-LD	IIA C-EO	III NB C-EO	III NB C-EO	III NB C-EO	III NB/ C-EO
10. Chronic total occlusion, focal lesion	IIB B-R	III NB C-EO	IIA B-R	I B-R	I B-R	IIB C-LD	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO
11. Chronic total occlusion, intermediate lesion	III NB B-R	III NB C-EO	IIA B-R	I B-R	I B-R	IIB B-R	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO
12. Chronic total occlusion, diffuse lesion	III NB B-NR	III NB C-EO	IIA C-LD	I B-NR	I B-NR	IIA B-R	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO
13. ISR, focal lesion	IIB B-R	III NB C-LD	III NB C-EO	IIB C-LD	I B-R	IIB C-LD	IIA B-R	III NB C-EO	III H C-EO	III NB C-EO
14. ISR, intermediate lesion	III NB B-R	III NB C-LD	III NB C-EO	IIA C-LD	I B-R	IIB B-R	IIA B-R	III NB C-EO	III H C-EO	III NB C-EO
15. ISR, diffuse lesion	III NB B-NR	III NB C-EO	III NB C-EO	IIA C-LD	I B-R	IIA B-R	IIA B-R	III NB C-EO	III H C-EO	III NB C-EO

Abbreviations: BMS, bare metal stent; CFA, common femoral artery; COR, class of recommendation; DCB, drug coated balloon; DES, drug eluting stent; ISR, in-stent restenosis; LOE, level of evidence; PTA, percutaneous transluminal angioplasty; SFA = superficial femoral artery.
[a]Colors were assigned based on COR.

hospitalization with surgery (6.3 vs. 3.2 days, $P < 0.0001$); however, at 2 years there were no significant differences in freedom from TLR, patency or the sustained clinical improvement between the 2 groups. Based on the single randomized trial and expert consensus, recommendations for EVT in CFA disease are listed in Table 3.

2.5 | Uncoated balloons for percutaneous transluminal angioplasty

PTA therapy includes the use of conventional uncoated balloons. An "uncoated PTA-first" strategy that reserves stent placement for "bail-out"

TABLE 4 COR[a] and LOE for device selection as the *Adjunctive Therapy* in the femoral-popliteal arterial interventions

	Specialty balloons	Laser atherectomy	Directional atherectomy	Orbital/ Rotational atherectomy	Excisional/ aspiration atherectomy
1. CFA bifurcation lesion	IIB C-EO	III NB C-EO	IIB C-EO	IIB C-EO	III NB C-EO
2. Above knee popliteal lesion	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO
3. Ostial SFA lesion	IIB C-EO	III NB C-EO	IIB C-EO	IIB C-EO	III NB C-EO
4. Focal SFA lesion	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO
5. Intermediate SFA lesion	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO
6. Diffuse SFA lesion	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO
7. Moderate to severe calcified, undilatable, focal lesion	IIA C-EO	IIB C-LD	III NB C-EO	IIA C-EO	IIB C-EO
8. Moderate to severe calcified, undilatable, intermediate lesion	IIA C-EO	IIB C-LD	III NB C-EO	IIA C-EO	IIB C-EO
9. Moderate to severe calcified, undilatable, diffuse lesion	IIA C-EO	IIB C-LD	III NB C-EO	IIA C-EO	IIB C-EO
10. Moderate to severe calcified, dilatable, focal lesion	IIB C-EO	III NB C-EO	III NB C-EO	IIB C-EO	III NB C-EO
11. Moderate to severe calcified, dilatable, intermediate lesion	IIB C-EO	III NB C-EO	III NB C-EO	IIB C-EO	III NB C-EO
12. Moderate to severe calcified, dilatable, diffuse lesion	IIB C-EO	III NB C-EO	III NB C-EO	IIB C-EO	III NB C-EO
13. Chronic total occlusion, focal lesion	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO
14. Chronic total occlusion, intermediate lesion	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO
15. Chronic total occlusion, diffuse lesion	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO	III NB C-EO
16. ISR, focal lesion	III NB C-EO	IIA B-R	III NB C-EO	III H C-EO	III NB C-EO
17. ISR, intermediate lesion	III NB C-EO	IIA B-R	III NB C-EO	III H C-EO	III NB C-EO
18. ISR, diffuse lesion	III NB C-EO	IIA B-R	III NB C-EO	III H C-EO	III NB C-EO

Abbreviations: CFA, common femoral artery; ISR, in-stent restenosis; SFA, superficial femoral artery.
[a]Colors were assigned based on COR.

has historically been the common initial treatment approach. However, this approach is no longer the standard of care given the overwhelming evidence from RCTs in favor of DCB and DES therapy over stand-alone PTA with uncoated balloons. Uncoated PTA still remains an important adjunctive treatment modality for lesion preparation in primary stenting or DCB drug delivery and in conjunction with atherectomy devices. Based on comparative data for PTA with uncoated balloons versus other devices (see future sections), recommendations for stand-alone uncoated PTA as the intended definitive therapy in FP disease have been derived (Table 3).

Recent meta-analyses of RCTs comparing treatment modalities in FP disease demonstrated that PTA with uncoated balloons alone was inferior to bare metal stents, covered stents, DCB, and DES with respect to technical success, restenosis and TLR rates [13,14]. For relatively short lesions (<5 cm), registry data suggested the primary patency rates approached 90% at 1 year, 80% at 2 years, and ~70% at 3 years [15]. Comparative data from multiple RCTs of bare metal stents failed to demonstrate a benefit of stents over uncoated balloons PTA alone in lesions of <10 cm lengths [16,17]. However, as lesion length increases (i.e., lesions >10 cm), data suggest superiority of bare metal stents over PTA with uncoated balloons alone [18,19].

Increasing amounts of FP lesion calcification increase the risk of PTA failure. Among 394 patients undergoing EVT for FP disease

TABLE 5 The cost of the devices (average retail cost) and medicare reimbursement for femoral-popliteal arterial interventions

			2018 medicare base payment rate			
Femoral-popliteal endovascular therapy devices	**Cost of devices ($)**	**2018 work RVUs**	**Physician Nonfacility[a]**	**Physician Facility[a]**	**Ambulatory Surgery Center[b]**	**Outpatient Facility[c]**
PTA	$80–400	8.75 (CPT® Code 37224)	$3,790	$467	$3,581	$5085 (APC 5192)
Specialty balloons	$500-1,700					
DCB	$1,000–2,000					
Self-expanding BMS	$700-1,400	10.24 (CPT® Code 37226)	$9,100	$549	$6,603	$10,510 (APC 5193)
Wire-intervowen nitinol stents	$1,400-2,000					
DES	$1,000–2,000					
Covered stents	$2,700-3,500					
Laser atherectomy	$2,600-3,000	11.75 (CPT® Code 37225)	$11,130	$637	$6835	$10,510 (APC 5193)
Directional atherectomy	$2,800-3,200					
Orbital atherectomy	$3,200-3,600					
Excisional/aspiration atherectomy	$2,800-3,200					

Abbreviations: BMS, bare metal stent; DCB, drug coated balloon; DES, drug eluting stent; PTA, percutaneous transluminal angioplasty.
[a]The MPFS payment amounts are based on data elements published by the Centers for Medicare and Medicaid Services (CMS) in the 2018 National Physician Fee Schedule Relative Value File January Release (RELEASED 12/18/2017) reflecting a conversion factor of $35.9996.
[b]Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs: 2018 NFRM OPPS Addenda published by the Centers for Medicare and Medicaid Services (CMS) in the Final Rule [CMS-1678-FC] published in the Federal Register on December 14, 2017. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1678-FC.html.
[c]Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Correction: Correction Notice ASC Addendum AA, BB, DD1, DD2, EE published by the Centers for Medicare and Medicaid Services (CMS) - correcting technical errors that appeared in the final rule with comment period published in the Federal Register on December 14, 2017 entitled "Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs." https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1678-CN.html.

uncoated balloon PTA alone was successful in only ~20% of cases, largely confined to noncalcified lesions [20]. In lesions with more severe calcification, the uncoated balloon PTA-only success rate was low, 8.3%. These data highlight the limitations of uncoated balloon PTA alone in severely calcified lesions.

Late patency rates following uncoated balloon PTA in CTOs at 12–36 months remain disappointing, with rates after a subintimal PTA approach declining from ~70–80% at 6 months to ~40–50% at 36 months [21,22]. Restenosis rates with uncoated balloon PTA alone, particularly for long segments of ISR or occluded stents, have also been disappointing with restenosis and TLR rates approaching 50% [23,24]. Uncoated balloon PTA has demonstrated inferior outcomes when compared to DCB and laser atherectomy in ISR lesions [23,25,26]. Based on comparative clinical data, DCB or DES as the definitive device therapy for most lesions in the FP segment, with or without adjunctive PTA, would be preferred (Table 6).

2.6 | Specialty balloons for PTA

Specialty balloons (i.e., the Angiosculpt scoring balloon [Royal Philips, Amsterdam, The Netherlands], the peripheral cutting balloon [Boston Scientific, Inc., Marlborough, MA], the Chocolate PTA balloon [TriReme Medical, LLC, Pleasanton, CA], and the VascuTrak [Bard Peripheral Vascular, Inc., Tempe, AZ]) emerged to address the limitations of conventional uncoated balloon PTA - the ability to treat severely calcified and undilatable lesions. In general, specialty balloon studies are small, observational and the main comparator (when performed) is conventional stand-alone PTA (Supporting Information Table S1). There are no head-to-head comparisons between different specialty balloons or newer technologies (e.g., DCB). All of the devices have demonstrated their safety, but have a substantially higher cost (Table 4). In clinical practice, specialty balloons are rarely used as the intended definitive therapy but rather as the adjunctive, lesion preparation devices. Based on limited published data [27–33], consensus recommendations for stand-alone specialty balloons utilization as the intended definitive therapy (Table 7) as well as the adjunctive (lesion preparation) therapy (Table 8) in FP disease have been derived.

2.7 | Bare metal stents: Self-expanding stents

BMS were developed to address the short-term (e.g., dissection, acute closure, >50% residual stenosis) and long-term (e.g., restenosis)

TABLE 6 Recommendations for percutaneous transluminal angioplasty with uncoated balloons as the *Intended Definitive Therapy* in the femoral-popliteal arterial interventions

Recommendations for percutaneous transluminal angioplasty with uncoated balloons as the Intended Definitive Therapy in the femoral-popliteal arterial interventions		
Uncoated PTA	**COR**	**LOE**
1. CFA bifurcation lesion	IIB	C-LD
2. Above knee popliteal lesion	III NB	B-R
3. Ostial SFA lesion	IIB	B-R
4. Focal SFA lesion	IIB	A
5. Intermediate SFA lesion	III NB	B-R
6. Diffuse SFA lesion	III NB	B-NR
7. Moderate to severe calcified, focal lesion	IIB	B-NR
8. Moderate to severe calcified, intermediate lesion	III NB	B-NR
9. Moderate to severe calcified, diffuse lesion	III NB	B-NR
10. Chronic total occlusion, focal lesion	IIB	B-R
11. Chronic total occlusion, intermediate lesion	III NB	B-R
12. Chronic total occlusion, diffuse lesion	III NB	B-NR
13. ISR, focal lesion	IIB	B-R
14. ISR, intermediate lesion	III NB	B-R
15. ISR, diffuse lesion	III NB	B-NR

TABLE 7 Recommendations for percutaneous transluminal angioplasty with specialty balloons as the *Intended Definitive Therapy* in the femoral-popliteal arterial interventions

Recommendations for percutaneous transluminal angioplasty with specialty balloons as the Intended Definitive Therapy in the femoral-popliteal arterial interventions		
Specialty balloons	**COR**	**LOE**
1. CFA bifurcation lesion	IIB	C-EO
2. Above knee popliteal lesion	III NB	C-EO
3. Ostial SFA lesion	IIB	C-EO
4. Focal SFA lesion	III NB	C-LD
5. Intermediate SFA lesion	III NB	C-LD
6. Diffuse SFA lesion	III NB	C-EO
7. Moderate to severe calcified, focal lesion	IIB	C-LD
8. Moderate to severe calcified, intermediate lesion	III NB	C-LD
9. Moderate to severe calcified, diffuse lesion	III NB	C-LD
10. Chronic total occlusion, focal lesion	III NB	C-EO
11. Chronic total occlusion, intermediate lesion	III NB	C-EO
12. Chronic total occlusion, diffuse lesion	III NB	C-EO
13. ISR, focal lesion	III NB	C-LD
14. ISR, intermediate lesion	III NB	C-LD
15. ISR, diffuse lesion	III NB	C-EO

TABLE 8 Recommendations for percutaneous transluminal angioplasty with specialty balloons as the *Adjunctive Therapy* in the femoral-popliteal arterial interventions

Recommendations for percutaneous transluminal angioplasty with specialty balloons as the Adjunctive Therapy in the femoral-popliteal arterial interventions		
Specialty balloons	**COR**	**LOE**
1. CFA bifurcation lesion	IIB	C-EO
2. Above knee popliteal lesion	III NB	C-EO
3. Ostial SFA lesion	IIB	C-EO
4. Focal SFA lesion	III NB	C-EO
5. Intermediate SFA lesion	III NB	C-EO
6. Diffuse SFA lesion	III NB	C-EO
7. Moderate to severe calcified, undilatable, focal lesion	IIA	C-EO
8. Moderate to severe calcified, undilatable, intermediate lesion	IIA	C-EO
9. Moderate to severe calcified, undilatable, diffuse lesion	IIA	C-EO
10. Moderate to severe calcified, dilatable, focal lesion	IIB	C-EO
11. Moderate to severe calcified, dilatable, intermediate lesion	IIB	C-EO
12. Moderate to severe calcified, dilatable, diffuse lesion	IIB	C-EO
13. Chronic total occlusion, focal lesion	III NB	C-EO
14. Chronic total occlusion, intermediate lesion	III NB	C-EO
15. Chronic total occlusion, diffuse lesion	III NB	C-EO
16. ISR, focal lesion	III NB	C-EO
17. ISR, intermediate lesion	III NB	C-EO
18. ISR, diffuse lesion	III NB	C-EO

limitations of PTA, where a strong relationship between PTA, lesion length and restenosis has been demonstrated [34]. Early RCTs in primarily short-segment FP stenosis or occlusion failed to demonstrate incremental reductions in restenosis, improvements in primary patency or reductions in TVR with planned versus provisional BMS following PTA. Three RCTs subsequently demonstrated an incremental benefit of self-expanding BMS, including the Vienna Absolute [18,35], ASTRON (The Balloon Angioplasty Versus Stenting with Nitinol Stents in Intermediate Length Superficial Femoral Artery Lesions) [36], and RESILIENT (Randomized Study Comparing the Edwards Self-ExpandIng Lifestent versus Angioplasty Alone In LEsions INvolving The SFA and/or Proximal Popliteal Artery) [17] studies, all of which enrolled patients with moderate length FP disease (Supporting Information Table S2). These studies were pooled in a 2014 Cochrane meta-analysis of 11 RCTs, enrolling 1,387 patients with claudication or CLI and TASC A or B lesions [37]. Collectively, these trials demonstrated superior 6-month patency by DUS and angiography, and superior 12-month patency by DUS (OR 1.78 [95% CI 1.02–3.10]) with primary versus provisional

TABLE 9 Recommendations for bare metal self-expanding stents as the *Intended Definitive Therapy* in the femoral-popliteal arterial interventions.

Recommendations for bare metal self-expanding stents as the Intended Definitive Therapy in the femoral-popliteal arterial interventions		
Bare metal self-expanding stents	**COR**	**LOE**
1. CFA bifurcation lesion	IIA	B-R
2. Above knee popliteal lesion	IIA	A
3. Ostial SFA lesion	IIA	A
4. Focal SFA lesion	IIA	A
5. Intermediate SFA lesion	IIA	A
6. Diffuse SFA lesion	IIA	B-NR
7. Moderate to severe calcified, focal lesion	IIA	C-LD
8. Moderate to severe calcified, intermediate lesion	IIA	C-LD
9. Moderate to severe calcified, diffuse lesion	IIA	C-EO
10. Chronic total occlusion, focal lesion	IIA	B-R
11. Chronic total occlusion, intermediate lesion	IIA	B-R
12. Chronic total occlusion, diffuse lesion	IIA	C-LD
13. ISR, focal lesion	III NB	C-EO
14. ISR, intermediate lesion	III NB	C-EO
15. ISR, diffuse lesion	III NB	C-EO

BMS. However, at 24 months patency by DUS and angiography were equivalent between primary versus provisional BMS.

A number of recent noncomparative studies have examined newer generation interwoven design BMS stents for treatment of FP disease, including in longer lesions, significant calcification, higher prevalence of CTOs, but not ISR lesions [38–43]. Unfortunately, these studies have not included any comparative devices, so that limited conclusions about the relative effectiveness or comparative safety of the newer devices can be made. (Supporting Information Table S3) Comparative RCTs of interwoven BMS to older BMS scaffolds, DES and DCB therapies are needed to determine their relative value. (Table 9)

2.8 | Drug-eluting stents

The Zilver PTX (Cook Medical, Bloomington, IN) DES is a polymer-free paclitaxel coated nitinol stent, which was developed for treatment of the FP segment to provide both a stent scaffold and paclitaxel drug elution to limit neointimal hyperplasia. The Zilver PTX randomized trial enrolled 474 patients with claudication and SFA or proximal popliteal disease to DES or PTA [44]. At 12 months, the primary DES group had significantly higher primary patency (83.1%) than the primary PTA group (32.8%). Among patients who underwent a secondary randomization for failed PTA, provisional DES use was also associated with superior primary patency (89.9%) compared to provisional BMS (73.0%). Five-year follow-up of this study demonstrated sustained freedom from reintervention (83.1% vs. 67.6%) [45]. There was also a trend toward improved freedom from re-intervention among patients treated with a provisional DES strategy (84.9%) versus provisional BMS (71.6%).

Three single arm multicenter studies with predefined endpoints have further investigated the outcomes of Zilver PTX in real-world lesions: the Zilver PTX single arm study [46–48], a Japanese postmarket surveillance study [49], and the Japanese ZEPHYR registry [50] (Supporting Information Table S4). The Zilver PTX single arm study was a multinational registry of patients with symptomatic PAD treated with Zilver PTX [46]. The 12-month primary patency was 86.2%, and the 12-month freedom from TLR was 90.5%. The TASC C/D lesion subgroup of this registry included 135 lesions with a mean lesion length of 226 mm [47]. Twelve month primary patency was 77.6%, and 85.4% freedom from TLR, with a stent fracture rate of only 2.1%. In the subgroup of 119 ISR lesions, primary patency was 78.8% at 1 year and freedom from TLR was 81% [48] (Table 10).

2.9 | Drug coated balloons

To date, three DCBs have been developed, rigorously studied in preclinical models and human RCTs, and have been granted FDA approval for the treatment of FP disease: Lutonix (Bard Lutonix, New Hope, Minnesota), IN.PACT (Medtronic Vascular, Santa Rosa, California), and Stellarex (Royal Philips, Amsterdam, The Netherlands) with paclitaxel coating densities from 2 to 3.5 ug/mm^2 and in combination with diverse excipients: polysorbate and sorbitol, urea and polyethylene glycol, respectively (Supporting Information Table S5). A systematic analysis of DCB trials suggests that there may not be a class effect and that

TABLE 10 Recommendations for drug-eluting stents as the *Intended Definitive Therapy* in the femoral-popliteal arterial interventions

Recommendations for drug-eluting stents as the Intended Definitive Therapy in the femoral-popliteal arterial interventions		
Drug-eluting stents	**COR**	**LOE**
1. CFA bifurcation lesion	IIA	C-EO
2. Above knee popliteal lesion	I	B-R
3. Ostial SFA lesion	I	B-R
4. Focal SFA lesion	I	B-R
5. Intermediate SFA lesion	I	B-R
6. Diffuse SFA lesion	I	B-NR
7. Moderate to severe calcified, focal lesion	I	C-LD
8. Moderate to severe calcified, intermediate lesion	I	C-LD
9. Moderate to severe calcified, diffuse lesion	I	C-EO
10. Chronic total occlusion, focal lesion	I	B-R
11. Chronic total occlusion, intermediate lesion	I	B-R
12. Chronic total occlusion, diffuse lesion	I	B-NR
13. ISR, focal lesion	IIB	C-LD
14. ISR, intermediate lesion	IIA	C-LD
15. ISR, diffuse lesion	IIA	C-LD

TABLE 11 Recommendations for Drug Coated Balloons as the *Intended Definitive Therapy* in the Femoral-Popliteal Arterial Interventions

Recommendations for drug coated balloons as the Intended Definitive Therapy in the femoral-popliteal arterial interventions		
Drug coated balloons	**COR**	**LOE**
1. CFA bifurcation lesion	IIA	C-EO
2. Above knee popliteal lesion	I	A
3. Ostial SFA lesion	I	A
4. Focal SFA lesion	I	A
5. Intermediate SFA lesion	I	A
6. Diffuse SFA lesion	I	B-R
7. Moderate to severe calcified, focal lesion	I	C-LD
8. Moderate to severe calcified, intermediate lesion	I	C-LD
9. Moderate to severe calcified, diffuse lesion	I	C-LD
10. Chronic total occlusion, focal lesion	I	B-R
11. Chronic total occlusion, intermediate lesion	I	B-R
12. Chronic total occlusion, diffuse lesion	I	B-NR
13. ISR, focal lesion	I	B-R
14. ISR, intermediate lesion	I	B-R
15. ISR, diffuse lesion	I	B-R

the treatment effects of individual DCB devices may depend on their different characteristics including drug dose and excipient [49–51]. Head to head clinical trials between the DCBs are needed to better understand their value relative to each other. Economic data have suggested DCB to be cost effective in the FP segment [52–54]. Among the current therapeutic options for FP disease, DCB receive strong recommendations based on the LOE from several RCTs. (Table 11)

The LEVANT (Lutonix Paclitaxel-Coated Balloon for the Prevention of Femoropopliteal Restenosis) 1 and 2 multicenter RCTs evaluated the Lutonix DCB with a dose of paclitaxel of 2 μg/mm^2, with a proprietary coating and polysorbate and sorbitol excipient [55,56]. The initial LEVANT 1 feasibility trial enrolled 101 patients randomized to DCB versus PTA, but TLR differences were not significant at 2-year follow-up ($P = 0.23$) [55]. Technical and procedural challenges were refined and the LEVANT 2 multicenter trial further evaluated the use of the Lutonix DCB in FP arteries in 476 patients [56]. A significantly higher rate of primary patency measured by DUS was seen at 12 months with DCB versus PTA arm (65% vs. 53%, $P = 0.02$). A large number of those patients treated with the DCB were free from primary safety events (83.9% vs. 79.0%, $P = 0.005$), including low rates of thrombotic and distal embolic events. While secondary efficacy endpoints compared similarly between PTA and DCB groups, walking-distance scores were significantly higher in those treated with DCB.

A pooled analysis of 331 patients of the European and US cohorts from the IN.PACT SFA (IN.PACT Admiral Drug-Coated Balloon versus Standard Balloon Angioplasty for the Treatment of Superficial Femoral Artery and Proximal Popliteal Artery) trial revealed that primary patency at 12 months was significantly improved in the DCB versus uncoated PTA, and maintained at 24 months (DCB vs. PTA, 82.2% vs. 52.4%, 12 months, $P < 0.001$; 78.9% vs. 50.1%, 24 months, $P < 0.001$) [57,58]. Likewise, DCB use was superior to uncoated PTA in terms of clinically driven TLR at 12 months, which also maintained at 24 months (DCB vs. PTA, 2.4% vs. 20.6%, 12 months, $P < 0.001$; 9.1% vs. 28.3%, 24 months, $P < 0.001$) [57,58].

The third DCB to achieve FDA approval for use in de novo and restenotic FP lesions was the Stellarex DCB resulting from the ILLUMENATE trial series [59–61]. The Stellarex DCB utilizes a paclitaxel dose of 2 ug/mm^2 and is designed with a proprietary polyethylene glycol excipient. The preclinical and first-in-man work resulted in the design and execution of the ILLUMENATE EU RCT [60] and ILLUMENATE PIVOTAL (US) [61] trials. Among 294 patients of the European trial, primary patency (83.9% vs. 60.6%, $P < 0.001$) and clinically driven TLR (5.9% vs. 16.7%, $P = 0.014$) were superior in the DCB versus uncoated PTA at 12 months [59]. Likewise, among 300 patients of the US-based trial, restenosis rates (23.7% vs. 42.2%, $P = 0.003$) and clinically driven TLR were lower (7.9% vs. 16.8%, $P = 0.023$) in the DCB group at 12 months [61].

The use of DCB alone in FP ISR, long lesions and CTOs has been investigated in several trials/registries. The ISAR-PEBIS (Paclitaxel-Eluting Balloon Versus Conventional Balloon Angioplasty for In-Stent Restenosis of Superficial Femoral Artery) 2-center German trial randomized 70 patients with symptomatic SFA ISR to DCB versus PTA (mean lesion length 139 mm, ~1/3 CTOs) [62]. At 24-months, DCB was associated with a significant reduction of TLR in comparison to uncoated PTA (19% vs. 50%, $P = 0.007$). In the IN.PACT Global study, a single-arm registry of the IN.PACT Admiral DCB in real world patients, the clinical cohort included those with long lesions ≥15 cm ($n = 157$), de novo ISR lesions ($n = 131$), and CTO ≥5 cm ($n = 126$) [63]. Primary patency at 12 months was 91.1%, 88.7%, and 85.3%, respectively. Additionally, clinically driven TLR at 12 months was 6.0%, 7.3%, and 11.3%, respectively. These data supported the FDA approval of the IN.PACT Admiral DCB in ISR lesions. Further evaluations of DCB in ISR include the DEBATE-ISR (Drug Eluting Balloon in Peripheral Intervention for In-Stent Restenosis) study, a single-center registry comparing DCB ($n = 44$) versus historical controls ($n = 42$) for FP ISR in diabetic patients with CLI [64,65]. At 1 year, both recurrent restenosis and clinically driven TLR were favorable for DCB [64]. However, at 3 years, TLR rates were similar in DCB (40%) and PTA (43%) groups [65]. Similarly, the FAIR (Femoral Artery In-Stent Restenosis) trial was a small, randomized, multicenter, German study evaluating DCB ($n = 62$) versus uncoated PTA ($n = 57$) in patients with SFA ISR and CLI [23]. Freedom from TLR was significantly better in the DCB cohort at 12 months (90.8% vs. 52.6%, $P < 0.0001$), though long-term results are not yet available.

2.10 | Covered (endovascular grafts) stents

The use of covered stents (Viabahn, W.L. Gore & Associates, Flagstaff, AZ) is FDA approved for treatment of FP disease. These stent grafts, covered with expanded polytetrafluoroethylene and a self-expanding

TABLE 12 Recommendations for covered (endovascular grafts) stents as the *Intended Definitive Therapy* in the femoral-popliteal arterial interventions

Recommendations for covered (endovascular grafts) stents as the Intended Definitive Therapy in the femoral-popliteal arterial interventions		
Covered (endovascular grafts) stents	**COR**	**LOE**
1. CFA bifurcation lesion	III H	C-EO
2. Above knee popliteal lesion	IIB	B-R
3. Ostial SFA lesion	IIB	C-EO
4. Focal SFA lesion	IIB	B-R
5. Intermediate SFA lesion	IIB	B-R
6. Diffuse SFA lesion	IIA	B-R
7. Moderate to severe calcified, focal lesion	IIB	C-EO
8. Moderate to severe calcified, intermediate lesion	IIB	C-EO
9. Moderate to severe calcified, diffuse lesion	IIA	C-EO
10. Chronic total occlusion, focal lesion	IIB	C-LD
11. Chronic total occlusion, intermediate lesion	IIB	B-R
12. Chronic total occlusion, diffuse lesion	IIA	B-R
13. ISR, focal lesion	IIB	C-LD
14. ISR, intermediate lesion	IIB	B-R
15. ISR, diffuse lesion	IIA	B-R

helical nitinol stent mounted to the outside surface, are generally not recommended for ostial lesions, lesions involving a major side branch/collateral or in the presence of poor infrapopliteal runoff. Based on current efficacy data and risks of device thrombosis, consensus recommendations for covered stents in FP disease have been derived (Supporting Information Tables S6).

In the randomized VIASTAR (Viabahn endoprosthesis with PROPATEN bioactive surface [VIA] versus bare nitinol stent in the treatment of long lesions in superficial femoral artery occlusive disease) trial, Viabahn grafts trended toward better primary patency rates at 12 months versus BMS (71% vs. 55%, $P = 0.11$) in complex FP lesions [66]. In long ($\geq$20 cm) lesions, covered grafts had a significantly higher patency at 12 months (71% vs. 37%, $P = 0.01$) [66]. At 24 months, Viabahn grafts had greater primary patency compared to BMS, however, without a significant impact on TLR rate [67]. In the VIBRANT trial, at 3 years, primary patency rates were not significantly different between patients treated with the VIABAHN graft and those who received BMS (24.2% vs. 25.9%) [68]. In the single-arm VIPER (Viabahn Endoprosthesis with Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease) study, primary patency at 12 months was 73%, which was not affected by device diameter (5 vs. 6 vs. 7 mm) or lesion length ($\leq$20 cm vs. $>$20 cm) [69]. Similar findings were noted in a Japanese cohort, with 12-month primary patency not being affected by lesion length (93% in $\leq$20cm lesions versus 85% in $>$20 cm lesions, $P = 0.22$) [70].

The RELINE trial randomized patients with FP ISR to either PTA or PTA with Viabahn placement [71]. At 12 months the primary patency

TABLE 13 Recommendations for atherectomy as the *Intended Definitive Therapy* in the femoral-popliteal arterial interventions

Recommendations for atherectomy as the Intended Definitive Therapy in the femoral-popliteal arterial interventions								
	Laser atherectomy		Directional atherectomy		Orbital/rotational atherectomy		Excisional/aspiration atherectomy	
Atherectomy	**COR**	**LOE**	**COR**	**LOE**	**COR**	**LOE**	**COR**	**LOE**
1. CFA bifurcation lesion	III NB	C-EO	III NB	C-EO	III NB	C-EO	III NB	C-EO
2. Above knee popliteal lesion	III NB	C-EO	III NB	C-EO	III NB	C-EO	III NB	C-EO
3. Ostial SFA lesion	III NB	C-EO	III NB	C-EO	III NB	C-EO	III NB	C-EO
4. Focal SFA lesion	III NB	C-LD	III NB	C-LD	III NB	C-LD	III NB	C-LD
5. Intermediate SFA lesion	III NB	C-LD	III NB	C-LD	III NB	C-LD	III NB	C-LD
6. Diffuse SFA lesion	III NB	C-EO	III NB	C-EO	III NB	C-EO	III NB	C-EO
7. Moderate to severe calcified, focal lesion	III NB	C-LD	III NB	C-LD	III NB	C-LD	III NB	C-LD
8. Moderate to severe calcified, intermediate lesion	III NB	C-LD	III NB	C-LD	III NB	C-LD	III NB	C-LD
9. Moderate to severe calcified, diffuse lesion	III NB	C-EO	III NB	C-EO	III NB	C-EO	III NB	C-EO
10. Chronic total occlusion, focal lesion	III NB	C-EO	III NB	C-EO	III NB	C-EO	III NB	C-EO
11. Chronic total occlusion, intermediate lesion	III NB	C-EO	III NB	C-EO	III NB	C-EO	III NB	C-EO
12. Chronic total occlusion, diffuse lesion	III NB	C-EO	III NB	C-EO	III NB	C-EO	III NB	C-EO
13. ISR, focal lesion	IIA	B-R	III NB	C-EO	III H	C-EO	III NB	C-EO
14. ISR, intermediate lesion	IIA	B-R	III NB	C-EO	III H	C-EO	III NB	C-EO
15. ISR, diffuse lesion	IIA	B-R	III NB	C-EO	III H	C-EO	III NB	C-EO

TABLE 14 Recommendations for atherectomy as the *Adjunctive Therapy* in the femoral-popliteal arterial interventions

Recommendations for atherectomy as the Adjunctive Therapy in the femoral-popliteal arterial interventions								
	Laser atherectomy		Directional atherectomy		Orbital/rotational atherectomy		Excisional/aspiration atherectomy	
Atherectomy	COR	LOE	COR	LOE	COR	LOE	COR	LOE
1. CFA bifurcation lesion	III NB	C-EO	IIB	C-EO	IIB	C-EO	III NB	C-EO
2. Above knee popliteal lesion	III NB	C-EO	III NB	C-EO	III NB	C-EO	III NB	C-EO
3. Ostial SFA lesion	III NB	C-EO	IIB	C-EO	IIB	C-EO	III NB	C-EO
4. Focal SFA lesion	III NB	C-EO	III NB	C-EO	III NB	C-EO	III NB	C-EO
5. Intermediate SFA lesion	III NB	C-EO	III NB	C-EO	III NB	C-EO	III NB	C-EO
6. Diffuse SFA lesion	III NB	C-EO	III NB	C-EO	III NB	C-EO	III NB	C-EO
7. Moderate to severe calcified, undilatable, focal lesion	IIB	C-LD	III NB	C-EO	IIA	C-EO	IIB	C-EO
8. Moderate to severe calcified, undilatable, intermediate lesion	IIB	C-LD	III NB	C-EO	IIA	C-EO	IIB	C-EO
9. Moderate to severe calcified, undilatable, diffuse lesion	IIB	C-LD	III NB	C-EO	IIA	C-EO	IIB	C-EO
10. Moderate to severe calcified, dilatable, focal lesion	III NB	C-EO	III NB	C-EO	IIB	C-EO	III NB	C-EO
11. Moderate to severe calcified, dilatable, intermediate lesion	III NB	C-EO	III NB	C-EO	IIB	C-EO	III NB	C-EO
12. Moderate to severe calcified, dilatable, diffuse lesion	III NB	C-EO	III NB	C-EO	IIB	C-EO	III NB	C-EO
13. Chronic total occlusion, focal lesion	III NB	C-EO	III NB	C-EO	III NB	C-EO	III NB	C-EO
14. Chronic total occlusion, intermediate lesion	III NB	C-EO	III NB	C-EO	III NB	C-EO	III NB	C-EO
15. Chronic total occlusion, diffuse lesion	III NB	C-EO	III NB	C-EO	III NB	C-EO	III NB	C-EO
16. ISR, focal lesion	IIA	B-R	III NB	C-EO	III H	C-EO	III NB	C-EO
17. ISR, intermediate lesion	IIA	B-R	III NB	C-EO	III H	C-EO	III NB	C-EO
18. ISR, diffuse lesion	IIA	B-R	III NB	C-EO	III H	C-EO	III NB	C-EO

rate was 37% with PTA (excluding bail-out stenting) versus 75% with stent grafts. In a retrospective registry, 27 limbs were treated for ISR (average length 215 mm, 78% TASC D), with 63% of limbs remaining free of restenosis (mean follow-up of 22 months) [72]. Stent thrombosis resulting in acute limb ischemia occurs more frequently following covered stent-grafts compared to BMS; covered stent oversizing, loss of collaterals and edge restenosis have been implicated as the contributing factors to stent graft failure [73]. The concerns regarding stent thrombosis and acute limb ischemia as the failure mode for covered stents have resulted in limited utilization of these devices as first-line definitive therapy for most de novo FP lesions (Table 12).

2.11 | Atherectomy

Atherectomy, the debulking by excision or ablation of atherosclerotic plaque, has been used in the FP segment, despite the lack of comparative outcomes data to justify the additional cost of these devices. Numerous atherectomy devices have been developed over the last decade, including excisional and ablative devices (Supporting Information Table S7). There are no RCTs comparing atherectomy to stents (BMS or DES). It should be recognized that these devices are costly (Table 4) and are rarely used as a stand-alone definitive therapy, but rather as the adjunctive therapy for lesion preparation. Importantly, this document provides separate recommendations for atherectomy devices intended as the definitive therapy (Table 13) and recommendations for devices to be used for "adjunctive," lesion preparation purposes (Table 14). Further data regarding adjunctive use of atherectomy devices, particularly in CFA, ostial SFA, and popliteal locations, are needed.

2.11.1 | Directional atherectomy

The feasibility of DA in the treatment of de novo FP disease was evaluated in the single arm registry, Determination of EFfectiveness of the SilverHawk PerIpheral Plaque ExcisioN System (SIlver-Hawk Device) for the Treatment of InfrainguinalVEssels/LowerExtremities (DEFINITIVE LE) study [74]. This registry reported a 12-month primary patency of 78% in claudicants, with no difference between diabetics and non-diabetics. The use of DA was associated with a low use of stents (3.2%). However, DA was associated with a 3.8% risk of distal embolization and 5.3% risk of arterial perforation. However, without comparative evidence to support the use of this device as a definitive treatment strategy in FP lesions, it is difficult to justify the use of DA based on its increased cost.

Recently, the DEFINITIVE AR trial (Determination of EFfectiveness of the SilverHawk_ PerIpheral Plaque ExcisioN System (SIlver-Hawk-Device) for the Treatment of Infrainguinal VEssels Antirestenosis) evaluated the use of DA + DCB (Bayer Healthcare's Paccocath®) or DCB

alone in 100 patients with lesions between 7 and 15 cm. The trial showed no difference between the two groups with respect to 1-year CD-TLR (7.3% for DA + DCB vs. 8.0% for DCB alone) and patency as assessed by DUS (84.6% for DA + DCB vs. 81.3% for DCB alone) [75].

2.11.2 | Orbital atherectomy and rotational atherectomy

Both orbital and rotational atherectomy devices lack comparative evidence to support their use as a definitive strategy. Early single-center studies of RA [76] and a number of recent noncomparative trials of OA in FP disease (Supporting Information Table S7) have been published. The single comparative trial performed, the Compliance 360° trial (Prospective, Randomized, Multi-Center Trial to Study Clinical Benefit of Alteration in Vessel Compliance by Comparing Balloon Angioplasty to Diamondback 360® Orbital Atherectomy System in Calcified Femoropopliteal Disease) randomized 50 patients to OA + PTA or PTA alone [77]. In this small trial, freedom from TLR or restenosis was not different at 12 months (81.2% with OA + PTA vs. 78.3% with PTA).

2.11.3 | Excisional/aspiration atherectomy

There is no comparative evidence to support the use of the excisional/aspiration atherectomy devices as a definitive treatment strategy. The largest peer-reviewed publication of the Pathway Atherectomy System (Boston Scientific, Inc., Marlborough, MA) included 172 patients at 9 European sites [78]. Lesions <10 cm in the FP and <3 cm in the infrapopliteal vessels with >70% stenosis were included. These lesions were rated to have moderate to high calcium scores in ~50%. Major adverse events occurred in 1% of patients. Clinically driven TLR occurred at 6 months in 15% (25/172) and at 12 months in 26% (42/162). One-year restenosis as assessed by DUS occurred in 38.2% of lesions.

2.11.4 | Laser atherectomy

LASER (Light Amplification by Stimulated Emission of Radiation) debulking therapy was first used in an occluded SFA in 1983 [79]. The randomized multicenter Peripheral Excimer Laser Angioplasty (PELA) Trial, compared the laser to PTA and failed to demonstrate any patency advantage for the device in long SFA occlusions [80]. The EXCImer Laser Randomized Controlled Study for Treatment of FemoropopliTEal In-Stent Restenosis (EXCITE-ISR) trial randomized 250 patients with FP ISR to excimer LA plus PTA versus PTA [81]. At six months of follow-up the excimer LA + PTA in lesions of average 19 cm (1/3 were CTOs) showed superior TLR, but later follow up was compromised by significant losses to follow up. Longer follow will be needed to support the use of this technology in ISR lesions. Another small trial ($n = 48$) compared DCB + excimer LA to DCB alone in CLI patients with occlusion of the FP segment secondary to ISR. The patency rates at 12 months were significantly higher in the excimer LA + DCB group (66.7%) versus DCB alone (37.5%) [26].

2.12 | Adjunctive therapies

A number of adjunctive therapies other than specialty balloons (discussed previously), such as brachytherapy, external beam radiation and cryoplasty have been tested in FP revascularization, which either lacked supportive data or failed to demonstrate significant advantages over currently available PTA and/or stents with respect to improving procedural success or future restenosis [82–84]. Novel therapies such as lithoplasty for calcified undilatable FP disease are currently being investigated [85].

2.13 | Evidence gaps and future research directions

In developing these guidelines, the committee identified the following evidence gaps:

1. Consistent application and validation of definitions and classification systems (i.e., symptoms, anatomic features, plaque characteristics [e.g., extent of calcification], surrogate imaging endpoints, clinical outcomes) in EVT device trials is needed. The committee recommends adoption of the PARC definitions in future EVT trials.
2. Clinical trial processes should incorporate independent adjudication, and core laboratories for major endpoints and safety monitoring.
3. Randomized, prospective, comparative, protocol-driven device trials are needed to determine the value (clinical outcomes, patient safety, durability of treatment effect, and quality of life) and cost-effectiveness of these devices in specific clinical circumstances and lesion subsets.

3 | CONCLUSION

The SCAI writing committee conducted a systematic review and analysis of the scientific evidence and developed concise, focused, unbiased device-specific recommendations for FP EVT. These recommendations are a first step to provide clinicians with relevant anatomical scenarios to guide device selection based on strength and quality of evidence for comparative effectiveness, durability and expert opinion.

CONFLICT OF INTEREST

RWI disclosed in the manuscript.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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