Treating Femoropopliteal Disease: Established and Emerging Technologies

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Abstract

Keywords

- ▶ angioplasty
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- ▶ restenosis
- ▶ severe leg ischemia
- ▶ interventional radiology

The femoropopliteal artery is the most common site of disease in patients with peripheral arterial disease and presents some of the greatest challenges for interventional radiology. Many patients can be managed with medical treatment combined with supervised exercise alone. However, a significant proportion, especially those suffering from severe intermittent claudication or critical limb ischemia, will require some form of endovascular or surgical revascularization procedure. During the past few years an endovascular-first approach has gained support from all vascular specialties. Today, even complex lesions can be treated successfully with an endovascular approach. Unfortunately, the unique bio-mechanical properties of this vascular segment have limited long-term patency rates and clinical value of the endovascular options. In this review, the authors discuss the methods and techniques for treatment of femoropopliteal lesions and review the current evidence for commercially available devices on patency outcomes following successful recanalization.

Objectives: Upon completion of this article, the reader will be able to discuss the clinical indications, treatment options, and the techniques used to treat femoropopliteal arterial disease.

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Involvement of the femoropopliteal arteries in patients suffering from peripheral arterial disease (PAD) is very common.¹ Patients with obstructive arterial disease of the femoropopliteal arteries typically present with symptoms of

either intermittent claudication (IC) or critical limb ischemia (CLI), depending on the degree and extent of circulatory compromise. Patients with severe claudication and CLI typically exhibit extensive femoropopliteal occlusive disease, often in combination with more proximal (aorto-iliac) and/or more distal (infrapopliteal) lesions.

In recent years, percutaneous endovascular management of obstructive arterial disease of the superficial femoral artery (SFA) and/or popliteal artery has emerged as the first-line treatment option in most of the patients meeting the anatomical criteria set by international intrasociety guidelines.^{2–5} Although new techniques and modern tools have significantly broadened the spectrum of patients who can be treated with endovascular techniques, restenosis and low rates of long-term patency remain the Achilles heel of percutaneous techniques. In the present review, the authors discuss the currently available methods to treat obstructive femoropopliteal lesions and the current evidence of available devices to preserve patency following successful recanalization.

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Exercise, Endovascular Treatment, or Surgery

Supervised exercise training programs have well-documented clinical efficacy and usually precede (mild to moderate IC) or are even combined with the revascularization procedure (severe IC).⁶ Conversely, revascularization is the first-line therapy for patients with more severe ischemia. Prompt revascularization is indicated in at-risk grafts to reduce the risk of occlusion, and in CLI to improve the perfusion of the distal ischemic tissue and assist and/or accelerate the wound and ulcer healing process.

When revascularization is required the optimal method must be decided on an individual patient basis. In many cases the choice of treatment is clear, but where there is uncertainty case review at the multidisciplinary team (MDT) meeting is recommended. The Inter-Society Consensus for the management of peripheral arterial disease (Trans-Atlantic Inter-Society Consensus [TASC] II guideline) recommends which lesions should be treated endovascularly based on morphological criteria.³ However, there may be other considerations including other patient specific issues, patient preference, and local experience. Contraindications to treatment must also be considered, including unstable patients, life-threatening infected gangrene or/and life-threatening osteomyelitis, and uncorrectable coagulopathy. Pregnancy, uncooperative patients, critically ill elderly patients, patients with impaired mobility and limited life-expectancy, impaired renal function or iodinated contrast allergy, and contraindication to antiplatelet or heparin treatment are all relative contraindications; these patients may require additional support if treated.

Ideally, complex cases with severe ischemia and/or multi-level disease should be considered by the MDT to determine the best treatment for each individual patient. Indications and also contraindications to treatment must be taken into account, and the decision should be documented in the patient record. The final decision will take into account many factors, including symptom severity, lesion morphology, run-off disease, comorbidity, life expectancy, overall patient prognosis, anatomical challenges, the presence of renal impairment, history of contrast allergy, and, last but not least, the availability of vein conduits.^{3,7}

The TASC II guidelines classify femoropopliteal lesions into four categories based on lesion morphology (TASC A–D).^{2,3} The guidelines recommend that the majority of patients (TASC A–C) lesions should be treated by endovascular-first methods, while vein bypass surgery is recommended for TASC D lesions, especially in young fit patients.^{2,3,7} This is based on the reasoning that the treatment associated with the least morbidity and mortality is preferred when the two therapies achieve comparable clinical benefits.^{3,7} Improving techniques and tools have increased the ability to treat even the most complex lesions (e.g., complex TASC D cases). Endovascular techniques are not the first choice in these lesions but in patients who are considered poor surgical candidates they offer an alternative despite being considered unsuitable according to the guidelines.

Baseline Assessment

Baseline assessment includes both clinical evaluation and imaging investigations, which are discussed in detail elsewhere in this *Seminars* issue (see Russell et al). When patients are reviewed prior to intervention, there is an opportunity to ensure that they are receiving the best medical therapy for risk modification (smoking cessation, antiplatelets, and statins).^{2,3}

The importance of the interventional radiologist performing a preoperative assessment of the patient is emphasized elsewhere to recognize complications when they occur. In particular, the level and degree of ischemia and presence and quality of pulses must be noted. Care should also be taken to reduce procedural risk.

A key element in preoperative planning is review of the imaging of the infra-renal peripheral arteries to plan the intervention. Noninvasive methods such as duplex ultrasound, magnetic resonance angiography (MRA), and computed tomography angiography (CTA) are preferred as they carry less risk for the patients compared with digital subtraction angiography (DSA).^{7,8} CTA and MRA also have the advantage of providing details about the lesion morphology and extra-vascular anatomy.⁸ The latest guidelines for PAD by the National Institute for Health and Care Excellence (NICE) in England favors MRA over CT due to its better safety profile.⁹

Endovascular Techniques

The site of arterial access treatment method, the need for mechanical scaffolding (stents), and the application of therapies aimed at preventing restenosis (drug-coated balloons [DCBs] and drug-eluting stents [DES]) are important considerations when deciding endovascular treatment strategy. Recent developments in the field of medical devices combined with accumulated experience of interventional radiologists allows for treatment of lesions with morphological characteristics that until recently were considered unfavorable for endovascular repair.

Arterial Access

The arterial access site is usually either the ipsilateral or the contralateral common femoral artery. The authors suggest the use of ultrasound (US) guidance for all arterial punctures as it considerably increases the success rate and at the same time reduces the risk of arterial injury and access time.

The authors approach is to use antegrade ipsilateral access in the majority of infrainguinal cases, especially if they require treatment of the infrapopliteal outflow arteries. The retrograde contralateral approach is used if there is a need for assessment of the inflow or when treatment of coexisting iliac lesions is required. The contralateral approach also allows for treatment of the common femoral artery and may simplify treatment of proximal lesions. The contralateral approach may be difficult or even impossible in patients with acute aortic bifurcation, tortuous iliac arteries, or a history of previous bifurcated endovascular stent graft. Other approaches may occasionally be required but usually only after the antegrade approach has failed.

Lesion Crossing

Before any treatment, the target lesion has to be crossed. Most stenotic lesions can be traversed intraluminally. When this is not possible, especially in cases of chronic total occlusions (CTO), alternative techniques may be used including subintimal crossing, retrograde access, use of CTO wires (specifically designed wires with weighted tips), or dedicated occlusion-crossing devices. Baseline angiograms are necessary to identify where the distal vessel reconstitutes and to identify important collaterals. In some cases longer angiographic runs are required to allow the distal artery to opacify via collaterals.

Instructions for successful lesion crossing can be broken down to a few simple rules. First, use of an angled catheter to steer and navigate the guidewires is necessary. Second, a stiff straight hydrophilic wire will easily cross most of long-segment stenoses and short focal occlusions, and, third, a soft hydrophilic wire (angled or half-stiff) may be employed for subintimal crossing of long-segment total occlusions. For crossing of chronic total occlusions, a myriad of different techniques have been described, but to the authors' view, plain subintimal tracking is the most straightforward and cheapest approach.

The subintimal technique has been well described in the literature.^{10,11} A hydrophilic angled-tip wire or a dedicated J-shaped tip half-stiff (Terumo, Japan) wire is used to cross the lesion through the space created between the intimal and medial arterial wall with the wire in a looped configuration (intentional dissection). Re-entry in the healthy patent distal segment is usually achieved spontaneously. In practice, care should be taken to avoid extending the subintimal track too far distally as this may damage existing collateral vessels and

compromise surgical options. When spontaneous distal re-entry is not possible or whenever a targeted distal re-entry is preferred, there are commercially available devices that can achieve assisted targeted re-entry with a > 90% success rate. These include the following: Outback (Cordis, Bridgewater, NJ), Pioneer (Medtronic, Minneapolis, MN), Enteer catheter (Covidien, Mansfield, MA), and Offroad catheter (Boston Scientific, Natick, MA). In the authors' practice, these devices are necessary in less than 5% of the chronic total occlusions treated; calcification seems to predispose to unsuccessful spontaneous re-entry. The authors have found re-entry devices particularly useful in achieving a targeted re-entry, avoiding extension of the subintimal dissection plane more distally than initially intended. Both intraluminal and extraluminal techniques are useful in crossing the lesion, and long-term patency results seem to be comparable between these techniques.¹² However, in the authors' view intraluminal crossing must always be attempted first, as it reduces the risk of unintended compromise of the distal vessels by extension of the subintimal tract. In addition, the intraluminal approach theoretically carries less risk of vessel perforation and is associated with less angioplasty-related vessel barotrauma compared with subintimal angioplasty (►Figs. 1 and 2).

Angioplasty or Stent

The ideal endovascular treatment for the femoropopliteal segment continues to be debated. It is essential to have an understanding of the likely outcomes of therapy in terms of technical success, symptom improvement, complications, and recurrence to make appropriate decisions on treatment strategy, and to be able to explain the options to the patient.

Figure 1 Complex femoropopliteal artery recanalization. (A, B) Baseline antegrade angiogram in a 67-year-old man with short distance claudication and occasional rest pain during the night shows a long-segment TASC D flush total chronic occlusion of the superficial femoral and proximal popliteal artery (arrow). The procedure was performed with carbon-dioxide imaging because of impaired renal function. (C, D) Subintimal recanalization with the Bolia loop wire technique and targeted re-entry at the level of P2 segment with the OUTBACK catheter (Cordis) (arrow).

Figure 2 Final result. Completion angiogram (right panel) shows a widely patent femoropopliteal artery after long 6-mm balloon angioplasty and placement of a new generation interwoven nitinol metal stent (SUPERA, Abbott, Abbott Vascular, Illinois; left panel) (arrow). The whole procedure was completed with the use of a total volume of 400 mL CO₂.

The unique biomechanical properties of the superficial femoral and popliteal arteries, which are subject to flexion torsion and compression forces, may lead to high early and late restenosis.¹³ The modern interventional toolkit combines a variety of available solutions, including conventional balloons, DCBs, cryoplasty balloons, bare nitinol self-expanding stents, DES, and covered stents (e.g., VIABAHN), as well as other not yet commercially available solutions such as bio-absorbable stents.^{13–15} Of those, cryoplasty balloons have been recently abandoned due to lack of convincing data regarding their effectiveness and long-term results.^{16,17}

A recent summary of the results of different technologies was published in a recent Cardiovascular and Interventional Radiological Society of Europe (CIRSE) Standards of Practice

document on superficial femoral and popliteal artery (►Table 1).⁷ Technical success of endovascular treatment of stenotic disease of the superficial femoral and/or popliteal artery ranges between 98 and 100%, while the respective range for occlusions is between 81 and 94%.^{7,18} Despite the relatively high technical success, patency rates vary considerably, depending on baseline symptoms (IC vs. SLI), associated co-morbidities such as renal disease and diabetes, compliance with medication, and the lesions characteristics such as baseline length, degree of lesion (stenosis vs. occlusion), and presence of calcification. Calcium is one of the primary determinants of immediate technical success and long-term vessel patency. The 1-year reported data for primary patency following percutaneous angioplasty of the femoropopliteal artery range roughly between 70 and 80%, declining to 50% at 5-years postprocedure.^{7,18} In reality, however, observed results vary significantly and may depend on the baseline lesion characteristics, technique applied, and treatment technology, as well as on the experience of the interventionalist performing the procedure.

Poor patency is associated with immediate elastic recoil of the treated segment, intimal dissection, and late development of neointimal hyperplasia (NIH) or progression of the atheromatous disease. The first two are causes of acute post-angioplasty failure and should be managed by either prolonged balloon dilatation or mechanical scaffolding with placement of a stent. Metal stents have significantly improved the immediate technical success of endovascular procedures; however, they are associated with high rates of late in-stent restenosis and/or re-occlusion because of development of NIH. NIH remains a significant drawback of all endovascular methods, but especially for stents.¹⁹

A recent meta-analysis of RCTs showed a statistically significant difference with regard to restenosis rates at 12 months for long lesions favoring primary stenting compared with primary balloon angioplasty (OR: 3.02, 95% CI: 1.3–6.71, $p < 0.001$); however, this difference had no significant impact in the pooled re-intervention rates.²⁰ Despite that, available data from a series of meta-analyses and systematic reviews have not provided solid proof that there

Table 1 Systematic review of femoropopliteal outcomes

Recanalization technology	Lesion length (range, cm)	Technical success (%; 95% CI)	Primary patency at 1 y [%; 95% CI]
Balloon angioplasty	5–12	69 (59–78)	57 (42–71)
Drug-coated balloons	5–8		81 (67–91) ^a
Nitinol stents	5–18	94 (91–97)	66 (60–72)
Drug-eluting stents	5–10		83 (77–90)
Covered stents	11–26		68 (60–75)

Source: Adapted from Katsanos et al.⁷

Notes: Pooled analysis of control and treatment arms of major randomized trials, major single-arm prospective studies and large ($n > 50$ limbs) cohort studies (ABSOLUTE, FAST, RESILIENT, ASTRON, SIROCCO, STRIDES, ZILVER-PTX, THUNDER, FEMPAC, LEVANT I, PACIFIER, VIABAHN, and VIBRANT trials). Pooled proportional outcomes were calculated with a random effects (DerSimonian–Laird) meta-analytic model.

^aReported primary patency rates are at 1 year with the exception of drug-coated balloons (6-month outcomes) and are based on the 50 or 70% restenosis threshold evaluable with either Duplex ultrasound or quantitative vascular angiography.

Figure 3 Popliteal stenting case. (A) Baseline antegrade angiography in a 70-year-old woman with relatively recent deterioration (6 weeks ago) of her symptoms of lifestyle limiting claudication at the level of the calf. Angiogram shows an 8-cm long total occlusion of the distal SFA and P1 segment of the popliteal artery (occlusion between open arrows) (B) The lesion was treated with primary stenting with a hybrid heparin-bonded nitinol ring stent (TIGRIS, Gore Medical; white arrows), as it was felt that there was a high risk of distal embolization because the wire crossed the lesion very easily. (C) Balloon post-dilation of the stent, and (D) completion angiogram shows a widely patent artery.

is superiority of clinical outcomes following primary stenting and thus their use in the femoropopliteal segment as a first-line treatment is not currently recommended.^{1,7,15,20,21} On the other hand, metal stents have an unequivocal utility in improving the initial technical success as they achieve significant higher immediate success rates by scaffolding the vessel and maximizing acute luminal gain¹³ (→Figs. 3 and 4).

Development of NIH and vascular restenosis remains the Achilles heel of all endovascular treatments of the femoropopliteal segment. Pharmacological and mechanical means of inhibiting NIH is an area of intense ongoing investigation. Several alternative treatments have been proposed to im-

prove outcomes by inhibiting the process of NIH development, including DCBs, DESs, and covered stents.¹⁹ DCBs and DESs potentially minimize the development of NIH by delivering drugs that inhibit restenosis (such as paclitaxel or sirolimus) directly to the vessel wall. Covered stents provide a mechanical barrier between the vessel wall and the lumen, thereby constraining NIH in-growth and protecting against vessel re-narrowing.^{7,19}

Available high quality data on outcomes with DESs in the femoropopliteal segment are limited to three major clinical studies: the SIROCCO, the STRIDES, and the ZILVER-PTX studies.²²⁻²⁴ The early 6-month results from the SIROCCO trial

Figure 4 Dynamic stent imaging Lateral knee-flexion angiogram (right panel) of the TIGRIS stent (white arrows; left panel) shows good stent conformability with the demanding biomechanical environment of the popliteal anatomy without any kinks or functional stenosis.

Figure 5 Network meta-analysis. Horizontal bars denote the cumulative rank probabilities of being the best treatment for the various different devices analyzed in a recently published mixed treatment comparison meta-analysis.¹³ Paclitaxel balloons and stents ranked as the top treatments, as they were both associated with the least vascular restenosis and the lowest need for repeat procedures.

spread enthusiasm by reporting superior patency rates for sirolimus-eluting self-expanding DES in the superficial femoral artery (SFA).²² Unfortunately, that benefit is not maintained at 2 years follow-up.²³ The ZILVER-PTX study was designed to assess a paclitaxel self-expanding DES in the femoropopliteal segment. At 12-months, on an as-treated analysis, the DES group showed significantly better primary patency rates and event-free survival compared with the control group.²⁴ This was maintained at 2 years follow-up, where the DES group exhibited significantly higher rates of primary patency when compared with the overall control group, as well as in comparison with the bare metal stent group.^{19,25}

Covered stents have also been applied in the femoropopliteal segment. Compared with conventional balloon angioplasty in the superficial femoral artery, PTFE-covered nitinol stents (VIABAHN stents) were associated with higher primary patency at 12 months.^{7,26} A recently published RCT, the VIASTAR study, compared the heparin-bonded VIABAHN covered stent (VIABAHN, W. L. Gore & Associates, Inc., Newark, DE) with bare metal stents. On an intention to treat basis, the trial showed significantly higher primary patency rates for TASC D lesions that were treated with the VIABAHN at 1 year compared with controls (71.3 vs. 36.8%, $p = 0.01$). This was associated with a nonsignificant trend toward a reduction in repeat revascularizations.^{19,27}

DCBs have also been proposed as a promising alternative to DESs. Theoretically, they encompass the benefits of avoiding a permanent metallic scaffold and at the same time delivering an agent that inhibits development of NIH. The use of balloons coated with the cytotoxic agent paclitaxel has been reported.¹⁹ Published data demonstrated significant inhibition of NIH following treatment with DCBs compared with standard balloon angioplasty in the femoropopliteal segment. A meta-analysis of randomized controlled trials (RCTs) that included the 6-month results of the THUNDER, the FEMPAC, the LEVANT I, and the PACIFIER studies has concluded that DCB compared with control were associated with significantly lower restenosis rates (18.7 vs. 45.5%, $OR = 0.26$), which led to significantly lower repeat revascularization rates (12.2

vs. 27.7%, $OR = 0.22$).¹⁴ Hence, it could be argued that in the short-term DCBs outperform plain balloon angioplasty. However, long-term data of both safety and efficacy are missing, and there have been recent case reports addressing safety issues, such as aneurysmal dilatation of treated segments following application of a DCB.²⁸

Novel Devices

In spite of the aforementioned encouraging results, DCBs cannot replace the need for stent in case of suboptimal initial angioplasty result related to flow-limiting dissection and/or elastic recoil of the vessel. Bioabsorbable scaffolds that may or may not have properties of drug-elution could be the solution in the future. These scaffolds are made either of bio-absorbable polymers (poly-L-lactic acid) or metal alloys (magnesium). Today, the outcomes of two nonrandomized studies (the REMEDY and the GAIA study) investigating the performance of bio-absorbable stents in the SFA have been published with acceptable early primary patency and restenosis rates.^{29,30} Specifically, the GAIA study showed binary restenosis of 67.9% and reinterventions rates of 57.1% at a 1-year follow-up.³⁰ However, long-term data as well as results from properly designed randomized controlled trials (RCTs) are necessary to assess any potential benefit from this promising new technology. Finally, other technologies that have been tested but failed to prove more effective or popular between researchers include cryoplasty (Boston Scientific), cutting (Boston Scientific), and scoring balloons (Angiosculpt; Angioscore Inc., Fremont, CA).^{1,16}

Several RCTs have shown better results in terms of higher patency rates and/or reduced rates of reintervention of some the aforementioned new technologies over balloon angioplasty, but direct comparisons between these treatment options are lacking. Network meta-analysis (NMA) is capable of inferring conclusions about the comparative efficacy of treatments that have or have not been compared head-to-head against each other, provided that all therapies under investigation may be linked in a common chain or network of evidence. Recently a Bayesian NMA attempted to compare

bare nitinol stents, covered nitinol stents, paclitaxel- or sirolimus-eluting stents (PES or SES), and paclitaxel-coated balloons (PCBs) with conventional balloon angioplasty or with each other in the femoropopliteal artery to identify the most effective treatment option.¹³ The authors analyzed 16 RCTs comprising 2,532 patients with 4,227 person-years of follow-up in total, and came to the conclusion that immediate technical success is better with the use of covered stents, whereas PES and PCBs offer the best long-term results in the femoropopliteal artery in terms of reduced rates of vascular restenosis and target lesion revascularization¹³ (► Fig. 5).

Conclusion

In conclusion, current evidence and expert opinion consensus recommend endovascular approach as the first-line treatment in the majority of lesions of the superficial femoral and/or popliteal arteries. Recanalization can be achieved using either intraluminal or subintimal techniques. In more challenging cases, more complex techniques (i.e., SAFARI technique) and advanced devices (re-entry devices, atherectomy catheters) may be required to achieve crossing of the occluded segment. However, preservation of long-term patency remains a challenge, mainly due to progressive neointimal hyperplasia and vascular restenosis. The main factor adversely affecting patency outcomes seems to be the unique biomechanical properties of the femoropopliteal vascular segment. During the past few years several new technologies have emerged claiming a leading role in the treatment of this high demanding area. Nitinol self-expanding stents, DESs, DCBs, and covered stents have shown proof of concept and promising results in early randomized trials. PCBs and PESs seem to be the most promising options so far, but long-term evidence is still lacking. Bioabsorbable vascular scaffolds combined with drug-elution is another intriguing concept that remains to be validated. At present, a policy of conventional balloon angioplasty appears to be a reasonable initial treatment with other adjunctive techniques, such as stenting and local drug delivery reserved for suboptimal results of angioplasty or restenosis.

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