Review and description of a clinical case



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# Endovascular revascularization in case of femoropopliteal artery occlusion

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**Abstract.** Effective revascularization for patients with peripheral artery disease is much more than an elementary procedure. The approach to the patient with symptom-limiting intermittent claudication or limb-threatening ischemia begins with understanding the population at risk and variation in clinical presentation. The urgency of revascularization varies significantly by presentation; from patients with intermittent claudication who should undergo structured exercise rehabilitation before revascularization (if needed) to those with acute limb ischemia, a medical emergency, who require revascularization within hours. Recent years have seen the rapid development of new tools including wires, catheters, drug-eluting technology, specialized balloons, and biomimetic stents. Open surgical bypass remains an important option for those with advanced disease. The strategy and techniques employed vary by clinical presentation, lesion location, and lesion severity. There is limited level 1 evidence to guide practice, but factors that determine technical success and anatomic durability are largely understood and incorporated into decision-making. Following revascularization, medical therapy to reduce adverse limb outcomes and a surveillance plan should be put in place. There are many hurdles to overcome to improve the efficacy of lower extremity revascularization, such as restenosis, calcification, microvascular disease, silent embolization, and tools for perfusion assessment. Endovascular revascularization is a critical strategy in managing total occlusions of the femoropopliteal artery, a significant challenge in patients with peripheral artery disease. This review provides a comprehensive analysis of procedural strategies, highlighting the role of drug-coated balloons, atherectomy devices, and advanced crossing techniques like subintimal recanalization and re-entry methods. It discusses the importance of lesion-specific considerations, such as the use of atherectomy devices for un-crossable or un-dilatable lesions and the effectiveness of drug-coated balloons in reducing restenosis. Emerging techniques, including the PIERCE needle-cracking method and intravascular lithotripsy, offer novel approaches for treating heavily calcified plaques. Moreover, the review compares endovascular interventions with surgical bypass, noting that while minimally invasive techniques are preferred for high-risk patients, a hybrid approach may be optimal for selected cases. Despite advances, challenges remain regarding long-term outcomes and the management of complex calcified lesions, emphasizing the need for ongoing research and innovation in this field.

**Keywords:** endovascular surgery, femoropopliteal segment, peripheral artery disease, balloon angioplasty, stenting, bypass



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Обзор и описание клинического случая
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# Эндоваскулярная реваскуляризация при окклюзии бедренно-подколенной артерии

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**Резюме.** Эффективная реваскуляризация пациентов с заболеваниями периферических артерий — это больше, чем просто процедура. Подход к пациентам с симптоматической перемежающейся хромотой или ишемией, угрожающей потерей конечности, начинается с понимания группы риска и различий в клинической картине. Срочность реваскуляризации значительно варьирует в зависимости от клинической картины: от пациентов с перемежающейся хромотой, которым следует пройти структурированную физическую реабилитацию перед реваскуляризацией (при необходимости), до пациентов с острой ишемией конечности, требующей неотложной медицинской помощи, которым реваскуляризация необходима в течение нескольких часов. В последние годы быстро развиваются новые инструменты, включая проводники, катетеры, стенты и баллоны с лекарственным покрытием, специализированные баллоны и биомиметические стенты. Открытое хирургическое шунтирование остается важным вариантом для пациентов с «запущенным» заболеванием. Стратегия и методы варьируют в зависимости от клинической картины, локализации и тяжести поражения. Имеются ограниченные доказательства 1-го уровня для практического применения, но факторы, определяющие технический успех и анатомическую прочность, в значительной степени изучены и учитываются при принятии решений. После реваскуляризации следует проводить медикаментозную терапию для снижения частоты неблагоприятных исходов в отношении конечностей и разрабатывать план наблюдения. Для повышения эффективности реваскуляризации нижних конечностей необходимо преодолеть множество препятствий, таких как рестеноз, кальцификация, микрососудистое заболевание, бессимптомная эмболизация и оценка перфузии. Эндоваскулярная реваскуляризация — критически важная стратегия при тотальных окклюзиях бедренно-подколенного сегмента, представляющих значительную проблему при заболеваниях периферических артерий. В статье выполнен всесторонний анализ стратегий, подчеркивающий роль баллонов с лекарственным покрытием, устройств для атерэктомии и передовых методов пересечения, таких как субинтимальная реканализация и повторный вход. Обсуждаются важность учета особенностей поражения, устройств для атерэктомии при непроходимых или нерасширяемых поражениях, а также эффективность баллонов с лекарственным покрытием для снижения рестеноза. Новые методы, включая PIERCE с применением иглы и внутрисосудистую литотрипсию, предлагают новые подходы к лечению выраженно кальцинированных бляшек. В обзоре сравниваются эндоваскулярные вмешательства с хирургическим шунтированием. Отмечено, что, хотя минимально инвазивные методы предпочтительны для пациентов с высоким риском, гибридный подход может быть оптимальным в отдельных случаях. Несмотря на успехи, сохраняются проблемы, связанные с отдаленными результатами и лечением сложных кальцинированных поражений, что подчеркивает необходимость исследований и инноваций в этой области.

**Ключевые слова:** эндоваскулярная хирургия, бедренно-подколенный сегмент, заболевание периферических артерий, баллонная ангиопластика, стентирование, шунтирование

**Источник финансирования**. Авторы заявляют об отсутствии внешнего финансирования при проведении исследования.

## INTRODUCTION

Over the past few decades, endovascular revascularization has become a key treatment method, offering a minimally invasive alternative to traditional surgical bypass in patients with peripheral artery disease (PAD). This approach has gained recognition for its ability to restore perfusion while reducing morbidity and hospital stay duration, especially in high-risk groups such as elderly patients and those with multiple comorbidities [1, 2].

The treatment of femoropopliteal segment occlusions includes various advanced techniques tailored to the characteristics of the lesion, such as drug-coated balloons (DCBs), atherectomy devices, and innovative crossing strategies [3–5]. Despite these advances, achieving stable long-term outcomes remains a significant challenge, particularly in the presence of complex or calcified lesions [6]. Moreover, ongoing debates about the comparative efficacy of DCBs versus stents, as well as the optimal use of atherectomy devices, underscore the need for further research and clinical refinements in this field.

Technological innovations have expanded the scope of endovascular interventions, incorporating strategies such as subintimal recanalization, catheter re-entry devices, and hybrid techniques combining antegrade and retrograde approaches. These developments aim to improve intervention efficacy, reduce restenosis, and address complications associated with complex lesion morphology. The emergence of new tools, including balloons, intravascular lithotripsy, and atherectomy devices, has further enhanced treatment options, providing clinicians with a broader arsenal for managing various types of lesions. Recent evidence suggests that combining multiple endovascular techniques may optimize outcomes. For example, drug-coated balloons in conjunction with atherectomy or intravascular lithotripsy have been used to treat calcified lesions [7–9].

This review provides a comprehensive analysis of endovascular revascularization strategies for femoropopliteal segment occlusions, detailing procedural aspects, comparative outcomes, and emerging innovations. The review also addresses challenges and controversies in this field, such as the management of patients with heavily calcified plaques and the role of revascularization techniques. By integrating recent data with clinical practice, this review aims to support decision-making and stimulate further advancements in PAD treatment.

## ENDOVASCULAR INTERVENTIONS

### Vascular access

Most interventions on the femoropopliteal arteries are typically performed via contralateral femoral access (Fig. 1), which provides excellent angiographic visualization of the iliac, superficial femoral, and deep femoral arteries, as well as comprehensive visualization of total femoropopliteal artery occlusions and associated collateral vessels.

**Fig. 1.** **Contralateral access is used to perform interventions on the iliac segment, femoropopliteal and tibiofemoral segment of the contralateral limb when antegrade femoral access is impossible. For example, scars, abdominal obesity, lesions of the common femoral artery, ostial lesions of the superficial femoral artery (photos by Arshed A. Kuchay and Nikita N. Gruzdev)**

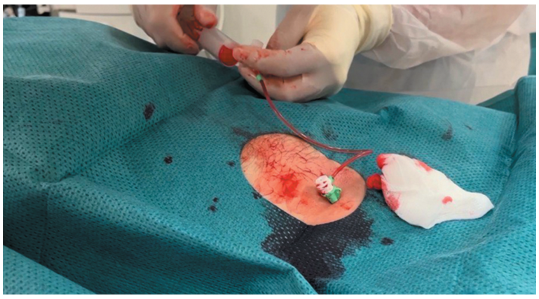

**Fig. 2.** **The antegrade femoral access is the primary approach for interventions on lower extremity arteries. It is the most convenient and common tactic. It provides good support and coaxial instrumentation, improving control compared to other methods. It is performed for lesions of the femoropopliteal segment (if both can be punctured) and the tibial segment of the foot (photos by Arshed A. Kuchay and Nikita N. Gruzdev)**

Usually, a braided introducer sheath of 6 F (45 or 55 cm) is used for these procedures, although a 7 F introducer is preferred when using atherectomy systems. After angiography, which visualizes the anatomy of the aorto-iliac region, a diagnostic catheter (JR or IM, 5 or 6 F) is advanced into the contralateral iliac or femoral artery as deeply as possible using a 0.035-inch glide wire. The introducer can then be advanced over the diagnostic catheter to position it proximally at the target sites.

In cases of severe iliac tortuosity or calcification, either a stiff supportive guidewire (0.035 inch) or a balloon anchor technique can be used to facilitate introducer passage. In some cases, ipsilateral access (Fig. 2) is preferred, as it provides improved guidewire control and greater flexibility for device advancement. Despite technical challenges, particularly with proximal segment stenosis or superficial femoral artery occlusion, this method may not increase vascular complications compared to contralateral access when performed by experienced surgeons [10, 11].

Alternative vascular access sites, such as the radial or brachial arteries, may be considered when femoral access is not feasible. However, several factors must be evaluated, including the distance from access to target (with or without sufficiently long devices), radial artery vessel size, abdominal aortic tortuosity, and the angle between the subclavian artery and aortic arch.

### Crossing strategy

In cases of total occlusion, advancing a guidewire through the affected area can be challenging. Currently, guidewires with diameters of 0.035 or 0.018 inches (0.035 or 0.045 mm) are commonly used. To enhance guidewire maneuverability, it is necessary to facilitate guidewire exchange, perform fixation with a hinge, or enable catheter tip insertion for angiography. The use of a support catheter (microcatheter or balloon catheter advanced over the guidewire) is mandatory.

Compared to microcatheters, balloon catheters have the advantage of dilating the occluded vessel, facilitating catheter advancement and improving guidewire efficacy. For extensive and long total occlusions, a balloon catheter is recommended as a support catheter rather than a microcatheter. To enhance the balloon catheter's ability to penetrate segments of total occlusion over the guidewire, a smaller-diameter balloon catheter (0.018 inch preferred over 0.035 inch) is recommended.

For total occlusion, various crossing strategies may be applied depending on the situation, such as antegrade or retrograde dissection with or without re-entry. Subintimal recanalization often requires subsequent stenting; however, current evidence does not favor one approach (intraluminal or subintimal recanalization) over another, nor the use of bare metal stents versus drug-coated stents [12, 13]. In most cases, antegrade advancement is recommended as the first step.

In the absence of severe calcification, guidewires with a hydrophilic polymer coating and low tip load are recommended for soft tissue trajectories, while guidewires with medium tip load are preferred for traversing fibrotic or calcified plaques to cross the total occlusion zone. Guidewires with high tip load, suitable for penetrating heavily calcified occlusions over distances of several millimeters to centimeters, should be advanced cautiously over long distances due to the risk of wire exit.

If traditional wire manipulation fails, the wire hinge technique may be considered, involving the creation of a loop with a hydrophilic wire supported by a catheter. This technique is particularly useful for subintimal tracking in total occlusions, with the catheter advancing behind the guidewire loop to maintain its small size. It is crucial to monitor re-entry into the distal true lumen to prevent excessive advancement of guidewires or catheters.

If re-entry into the distal true lumen fails with the wire hinge technique or conventional high-tip-load guidewire advancement, antegrade dissection using re-entry devices such as the Outback catheter (Cordis) may be applied. Alternatively, a retrograde approach may be attempted for recanalization, involving puncture of distal arteries such as the superficial femoral, popliteal, or below-knee arteries, followed by advancement of a guidewire and microcatheter. In cases of severe calcification, a 4 F introducer may be retrogradely inserted into distal vessels to improve support and facilitate device exchange.

To connect antegrade or retrograde guidewires, subintimal arterial wiring with antegrade-retrograde intervention (SAFARI) is performed [14]. After antegrade balloon angioplasty to create a subintimal space, the retrograde guidewire can be successfully advanced into the subintimal space, followed by wire externalization with a retrograde guidewire into an antegrade catheter or introducer to facilitate subsequent antegrade advancement of balloon or stent devices.

In other cases, if retrograde guidewire passage fails, retrograde balloon angioplasty may be performed to create a subintimal space for antegrade guidewire passage. In rare cases, the double-balloon technique may be used, involving simultaneous inflation of antegrade and retrograde balloons without overlap, allowing connection of different subintimal spaces [14].

Compared to antegrade dissection with re-entry using re-entry devices, the retrograde approach may be preferable in cases where antegrade guidewire passage fails due to its lower cost, fewer complications, and comparable success rates [15–17]. However, antegrade dissection techniques with re-entry devices may still be necessary if recanalization with SAFARI or other methods fails.

## TREATMENT STRATEGY

### Balloon angioplasty

For intraluminal recanalization, we recommend balloon angioplasty with extended inflation time. This study shows that a longer inflation time (180 s vs. 30 s) significantly reduces the likelihood of dissection and restenosis (14 vs. 43%, p=0.009) [18]. The diameter of the balloon catheter for preparation prior to drug-coated balloon (DCB) or stent placement should be 1 mm smaller than the diameter of the target artery [19]. For fibrotic or calcified plaques resistant to traditional angioplasty, we recommend switching to:

- a high-pressure balloon catheter (0.035 inch);
- a cutting or scoring balloon catheter.

Balloons with a full-length nitinol mesh coating are designed to maintain a uniform diameter during inflation. This design feature helps minimize the risk of edge dissection in the proximal or distal arterial segments. A study demonstrated a significant reduction in the rate of severe dissection: 4.2% in the percutaneous transluminal angioplasty group (n=48) versus 25% in the traditional angioplasty group (n=63), p=0.003 [20].

## Drug-coated balloons, metallic stents, drug-eluting stents, and atherectomy

A meta-analysis included 51 randomized controlled trials involving 8430 patients/lesions. It was found that DCBs outperform traditional balloon angioplasty in terms of primary patency and demonstrate lower rates of target lesion revascularization (TLR) with comparable all-cause mortality across short-term (<1 year), mid-term (1–2 years), and long-term (>2 years) follow-up periods.

DCBs were associated with:

- higher odds of primary patency (short-term: odds ratio [OR] 3.21; 95% confidence interval [CI] 2.44–4.24; long-term: OR 2.47; 95% CI 1.93–3.16);
- lower TLR rates (short-term: OR 0.33; 95% CI 0.22–0.49; long-term: OR 0.42; 95% CI 0.29–0.60);
- similar all-cause mortality risk compared to traditional balloon angioplasty [21].

Compared to drug-eluting stents (DES), such as the paclitaxel-eluting Zilver PTX stent, DCBs demonstrated similar rates of restenosis and clinically driven TLR. At 12 months, target lesion restenosis was observed in 22% of DCB-treated patients versus 21% of DES-treated patients (p=0.90). Clinically driven TLR was required in 14% of DCB patients versus 17% of DES patients (p=0.50) [22].

Based on these results, we recommend:

- DCB angioplasty when no long or flow-limiting dissections are observed after traditional balloon angioplasty;
- stenting in cases of long or flow-limiting dissections after angioplasty, preferring DES over bare-metal stents due to their superior outcomes [23].

Regarding DES comparison, the Eluvia stent (Boston Scientific, Marlborough, MA, USA) was evaluated against the Zilver PTX stent (Cook, Bloomington, IN, USA). Non-inferiority was demonstrated for both efficacy and safety endpoints at 12 months. Primary patency was 86.8% (231/266) in the Eluvia group and 81.5% (106/130) in the Zilver PTX group, with a difference of 5.3% (one-sided lower bound of 95% CI 0.66; p <0.0001) [24].

In cases of total occlusion containing thrombus, various strategies may be considered, including primary stenting, thrombolysis, thrombectomy, or a combined approach.

It is important to note that atherectomy or intravascular lithotripsy catheters should not be routinely used in total occlusions with severe calcification, as there is no clinical evidence supporting a reduction in restenosis or TLR risk [7–9]. However, in special cases where lesions cannot be crossed or dilated, or insufficient stent expansion is anticipated, devices such as directional atherectomy (HawkOne), orbital atherectomy (Diamondback 360), rotational and aspiration atherectomy (Jetstream), laser, or intravascular lithotripsy catheters may be considered for lesion preparation.

## Specific lesions

For impassable lesions, a low-profile coronary balloon may be used initially to create access through dense occlusions. Additionally, externalization techniques such as the “push-and-pull” method may be applied, where the guidewire is carefully advanced through the lesion to facilitate access for interventional devices.

Atherectomy devices have proven effective in such cases, particularly when hard or calcified tissue impedes passage. The percutaneous intravascular needle puncture of calcified plaque (PIERCE) technique, which involves needle fracturing, is another innovative method used to penetrate particularly resistant lesion areas. Applying precise needle force allows access through dense occlusions without causing excessive vessel trauma [25].

For non-dilatable lesions that do not respond to balloon dilation despite adequate balloon size, an atherectomy device remains necessary, as it can help reduce the volume of hard plaque and prepare the vessel for further intervention.

Coronary non-compliant balloons (CNBs) are also critical in these cases, as their rigidity allows for higher inflation pressures, making them more effective in dilating rigid lesions. When CNBs are insufficient, escalation to larger (0.035 inch) peripheral CNBs provides additional force to address the lesion, particularly in larger peripheral arteries.

In more complex cases involving calcified nodules or large calcified plaques, such as those in the common femoral artery (CFA), advanced devices such as the Jetstream or HawkOne atherectomy systems are particularly useful. The Jetstream device combines resection and aspiration for effective removal of severe calcification while reducing the risk of distal embolization [26]. The HawkOne

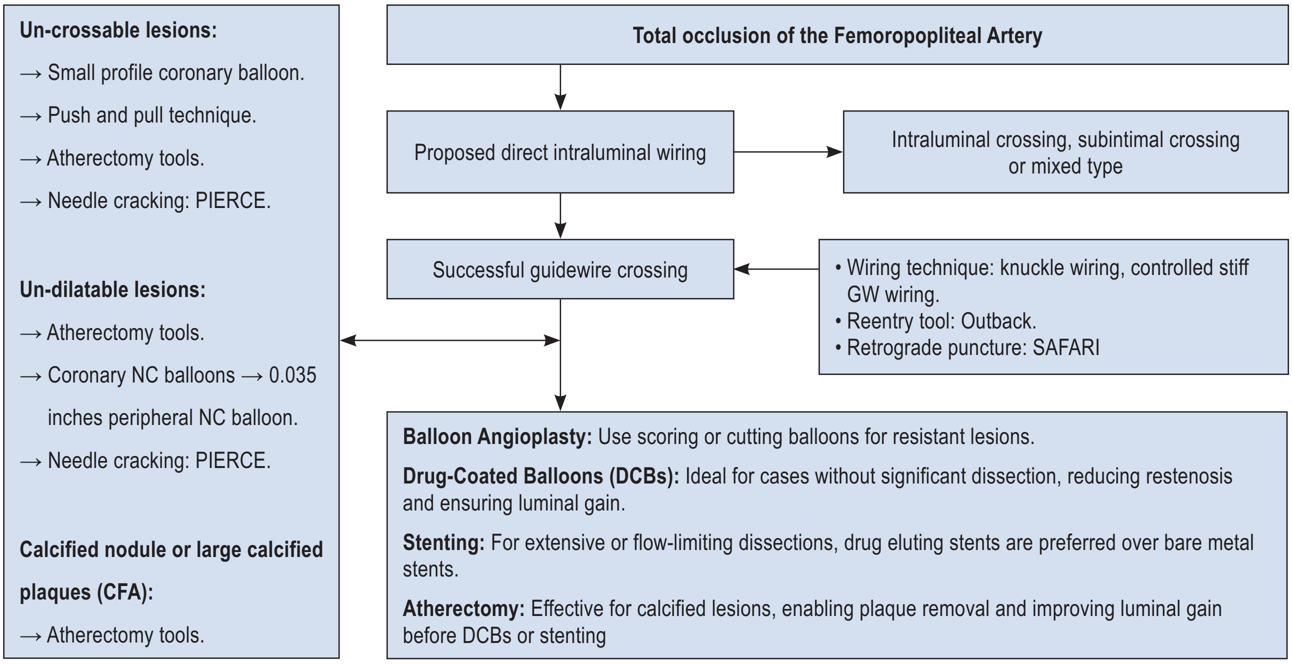


**Fig. 3.** **Algorithm of procedural and treatment strategies for total occlusion of the femoropopliteal artery (figure by the authors of this article)**

device, designed for directional atherectomy, is similarly developed to excise large plaques, especially when precise plaque removal and lumen enlargement are critical for restoring blood flow and preventing future restenosis [27]. These devices offer significant advantages in treating complex, heavily calcified lesions where other methods may be ineffective.

## COMPARISON OF ENDOVASCULAR REVASCULARIZATION AND SURGICAL BYPASS

Endovascular revascularization and surgical bypass are the two main approaches to treat total occlusions of the femoropopliteal artery/segment, each with its own advantages and limitations.

Endovascular methods have gained popularity due to their minimal invasiveness, which ensures shorter recovery time, reduced hospital stay, and lower initial costs compared to surgical bypass. These advantages are particularly important for patients at high surgical risk due to comorbidities such as advanced age, diabetes, or cardiovascular disease [28].

However, surgical bypass remains an acceptable option, especially for patients with long or complex occlusions, long-segment involvement, or those with previous failed endovascular interventions. Bypass surgery, often using autologous venous grafts, has been shown to provide superior long-term patency rates in certain patient subgroups. Despite this, the invasiveness of the procedure, combined with higher risks of morbidity and mortality associated with major surgery, often makes it a less favorable option for frail or elderly patients [1, 2, 28, 29].

The UK Bypass vs Angioplasty in Severe Ischemia of the Leg (BASIL-1) trial, involving 452 participants, showed that patients with chronic limb-threatening ischemia (CLTI) expected to survive two years or more and having a suitable vein for bypass should be offered venous bypass as a first option instead of balloon angioplasty [30]. The **Best Endovascular vs Best Surgical Therapy in Patients with Critical Limb Ischemia (BEST-CLI)** trial, which enrolled 1,830 participants — mostly from the United States — evaluated patients with optimal (single-segment) venous grafts. Among the 1,434 such patients, the rate of the composite primary endpoint (major adverse limb events or death) was significantly lower in the venous bypass group compared to the best endovascular therapy group.

Major adverse limb events occurred in 302 of 709 patients (42.6%) in the surgical group versus 408 of 711 patients (57.4%) in the endovascular group (hazard ratio [HR] 0.68; 95% CI 0.59–0.79; p <0.001).

However, in a second cohort of 396 participants without optimal venous grafts, outcomes were similar between the two treatment groups. Major adverse limb events occurred in 83 of 194 patients (42.8%) in the surgical group and in 95 of 199 patients (47.7%) in the endovascular group (HR 0.79; 95% CI 0.58–1.06; p=0.12) [31].

The **randomized BASIL-2 trial** specifically compared venous bypass with the best endovascular therapy as the first-line revascularization strategy for patients with critical limb ischemia requiring below-knee, proximal infrainguinal revascularization (or without it). Between July 22, 2014, and November 30, 2020, a total of 345 participants were enrolled and randomly assigned either to the venous bypass group (n=172) or to the best endovascular therapy group (n=173).

Major amputation or death occurred in 108 of 172 patients (63%) in the venous bypass group and in 92 of 173 patients (53%) in the best endovascular therapy group (adjusted HR 1.35 [95% CI 1.02–1.80]; p=0.037).

Mortality occurred in 91 of 172 patients (53%) in the venous bypass group and in 77 of 173 patients (45%) in the best endovascular therapy group (adjusted HR 1.37 [95% CI 1.00–1.87]) [32].

These data suggest that the severity and anatomical distribution of atherosclerosis, as well as the quality of venous grafts, may influence treatment decisions and outcomes in critical limb ischemia.

Emerging evidence indicates that a **hybrid approach** — combining endovascular and surgical techniques [33–42] — may yield the best outcomes for selected patients by maximizing patency rates and minimizing recovery time [42–54]. Further studies directly comparing these strategies across different patient populations will be critical for guiding clinical decision-making.

## CHALLENGES AND CONTROVERSIES IN ENDOVASCULAR REVASCULARIZATION

Despite substantial advances in the field, several challenges and controversies remain in the endovascular management of femoropopliteal occlusions.

One major debate centers on the use of DCBs versus stents. Although DCBs have shown promising results in reducing restenosis, their efficacy in complex or heavily calcified lesions remains under scrutiny. Similarly, the choice between DES and bare-metal stents often depends on lesion characteristics and individual patient factors, with no clear consensus on the optimal approach for all cases.

The role of **atherectomy** in treating calcified occlusions is another ongoing topic of discussion. While atherectomy devices can facilitate lesion preparation and improve stent expansion, their routine use is not universally recommended due to concerns about procedural complications and a lack of robust evidence supporting long-term benefits.

Moreover, the management of **chronic total occlusions** presents particular challenges, as various techniques — such as subintimal recanalization and re-entry devices — are employed with variable success rates. The choice of the most appropriate strategy often depends on the surgeon’s expertise and the specific features of the occlusion.

## CONCLUSION

Endovascular revascularization has evolved significantly, offering a range of effective treatments for femoropliteal occlusions. Drug-coated balloons, atherectomy devices, and advanced crossing techniques have improved procedural success; however, challenges persist in managing complex calcified lesions.

Although drug-coated balloons show promise in reducing restenosis, their role in heavily calcified disease remains debated. The use of hybrid strategies — combining endovascular and surgical methods may provide optimal outcomes in selected patients.

Further research is needed to refine these techniques and improve long-term patency, ultimately leading to better outcomes for patients with PAD.

## ADDITIONAL INFORMATION

**Author contribution.** Conceptualization of the work, A.A. Kuchay, A.N. Lipin; acquisition, A.A. Kuchay, A.N. Lipin, K.L. Kozlov and N.N. Gruzdev; analysis, A.A. Kuchay, N.N. Gruzdev; interpretation of data for the work, A.A. Kuchay, A.N. Lipin; drafting and revising the work, A.N. Lipin, K.L. Kozlov; final approval of the version to be published and agree to be accountable for all aspects of the work, A.A. Kuchay, A.N. Lipin, K.L. Kozlov and N.N. Gruzdev.

All authors made a substantial contribution to the conception of the study, acquisition, analysis, interpretation of data for the work, drafting and revising the article, final approval of the version to be published and agree to be accountable for all aspects of the study.

**Competing interests.** The authors declare that they have no competing interests.

## ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

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Все авторы внесли существенный вклад в разработку концепции, проведение исследования и подготовку статьи, прочли и одобрили финальную версию перед публикацией.

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