

Lesion-Specific SFA Device Selection

Key questions to consider for accurate diagnoses and tailored treatment decisions.

BY KOEN DELOOSE, MD

As we are all aware, a recent meta-analysis called into question the safety of paclitaxel delivery devices in peripheral vascular disease applications.¹ Although national regulatory authorities, professional societies, researchers, and industry have collaborated to evaluate and address the safety signal, alternative treatment options with the potential to offer favorable benefit-risk profiles based on currently available information are being used more frequently in many patients with claudication. This article explores the author's new femoropopliteal treatment algorithm for claudicants, taking in account the current issues surrounding paclitaxel use.

To match the ideal device to its appropriate setting, there are three essential questions: (1) Do we need to address severe calcium? (2) Is the patient/lesion a good responder to vessel preparation? And, (3) What is the risk for restenosis? These three questions are all essential in guiding optimal device-based treatment. However, summarily answering all three remains elusive in most cases because clear, objective criteria are lacking, making definitive algorithm generation particularly challenging.

IS SEVERE CALCIUM PRESENT?

Calcification represents a significant challenge to current endovascular strategies, not only on the treatment level, but also on the judging/diagnosing and scaling steps. On the one hand, calcium limits vessel expansion, and on the other, vessel preparation can overstretch nondiseased tissue, causing dissections, recoil, excessive injury, and inflammation, often with poor outcomes.² Furthermore, calcium forms a significant barrier to optimal drug absorption. Higher rates of late lumen loss and lower patency rates after the use of drug-eluting technologies are logical consequences.³⁻⁵

Despite the importance of this key factor in making a definitive treatment decision, there is a lack of objective quantitative vessel calcium measurement. Good examples are available in the coronary world, where noncontrast CTA measures the CT calcium score of the index lesion with dedicated software using the Agatston score.^{6,7} A routine application for the peripheral world is not currently avail-

able but will definitely bring more clarification on this topic in the near future. Nevertheless, there are some valuable and useful scoring systems available nowadays. The Peripheral Arterial Calcium Scoring System (PACSS) is an angiographic assessment, defining five grades classified by unilateral/bilateral location and length < 5 cm or ≥ 5 cm.⁸ An additional characterization based on calcium location (intimal, medial, or mixed) is outlined. The Compliance 360⁹ and the Peripheral Academic Research Consortium (PARC)¹⁰ scoring systems are also based on angiographic assessment but are slightly different than the PACSS. They describe four grades classified by circumferential (< 180° or ≥ 180°) and longitudinal (≤ 50% lesion length) calcium extension. For all three peer-reviewed grading systems, bilateral or circumferential extension of calcium is the most common marker of calcium severity (PACSS grade 3–4, Compliance 360° score 3–4, and PARC moderate/severe).

DID THE VESSEL RESPOND WELL WHEN OPTIMALLY PREPPED?

Based on the aforementioned calcium scoring rationale, calcified lesions defined as “severe” need to be prepped in an optimal fashion. Vessel preparation has become a crucial component of endovascular procedures in the peripheral vascular bed and an integral part of current endovascular procedures and treatment algorithms. Regardless of the final treatment strategy, vessel preparation is paramount and attempts to fulfill three objectives: (1) achieve luminal gain (< 30% residual stenosis prior to definitive therapy delivery), (2) minimize dissection within and adjacent to the target lesion (to reduce stenting), and (3) remodel the vessel to change its compliance.

If the severely calcified lesion responds well to adequate angioplasty-based vessel preparation, such that remodeling and sufficient luminal gain is achieved (to an almost 1:1 ratio with the reference vessel diameter), a crush-resistant vascular mimetic implant (eg, Supera peripheral stent system, Abbott Vascular) seems to be an ideal tool to manage eccentric calcified plaques. Supera is a 6-F-compatible, 0.018-inch, over-the-wire stent that has six pairs of closed-

ended interwoven nitinol wires arranged in a helicoidal pattern, is flexible and resistant to fracture, and is crush resistant if correctly implanted. Supera has shown excellent results in the femoropopliteal territory.¹¹⁻¹³

If the calcified lesion does not respond to vessel preparation, then the length of the lesion plays an even more important role. More focal, eccentric lesions can be prepped with atherectomy (mostly with directional atherectomy systems such as the HawkOne [Medtronic]) to obtain the most essential luminal gain. An additional Supera implantation in a nominal way can be performed afterward to improve durability over the longer term. More diffuse and longer lesions are more difficult to tackle with atherectomy, especially to achieve the same luminal gain over the full length of the lesion. One possible alternative may be the “pave and crack” technique, which is implantation of a Viabahn stent graft (Gore & Associates) to “pave” the lesion with the intention of protecting it from vessel rupture.¹⁴ Then, a very aggressive predilation is performed until the calcified plaque (and the vessel wall) cracks before lining the entire lesion with a Supera stent in the Viabahn stent graft. However, more experience and research are needed to determine the value and durability of this technique. The same can be stated about newer vessel preparation tools such as lithotripsy (Shockwave Medical, Inc.).

Of course, a safe and durable (venous) bypass remains a great option for severely and extended calcified lesions that do not respond to vessel preparation, although the focus of this article is on interventional options.

TABLE 1. RISK FACTORS FOR RESTENOSIS

Patient-Specific Factors	Lesion-Specific Factors
<ul style="list-style-type: none"> • Critical limb ischemia • Diabetes mellitus • End-stage renal disease • Poor runoff 	<ul style="list-style-type: none"> • Length • Small vessel diameter • Occlusion

IS THERE A HIGH RISK OF RESTENOSIS?

If the lesion is not particularly calcified, another question arises concerning whether there is a higher risk for restenosis. As previously investigated and described,¹⁵⁻¹⁸ there are patient- and lesion-specific criteria related to a higher risk of restenosis (Table 1). If one or more of these criteria are present, the use of drug-eluting technology is currently considered by most to be the best option. Accepting the potential risk of using paclitaxel devices is justified by having the outstanding efficacy benefit for patients at high risk for restenosis and repeat intervention (as is also stated in the FDA communication and other recommendations).

Again, aside from the essential goal of obtaining luminal gain and vessel remodeling, vessel preparation will be the determining factor for the next step in definitive treatment. If the lesion responds to angioplasty, continuing treatment with a drug-coated balloon (DCB) seems to be the ideal option due to the efficient and durable results.¹⁹⁻²⁷

When the lesion is at higher risk for restenosis and displays a flow-limiting dissection or recoil > 50% immediately after vessel preparation with plain old balloon angio-

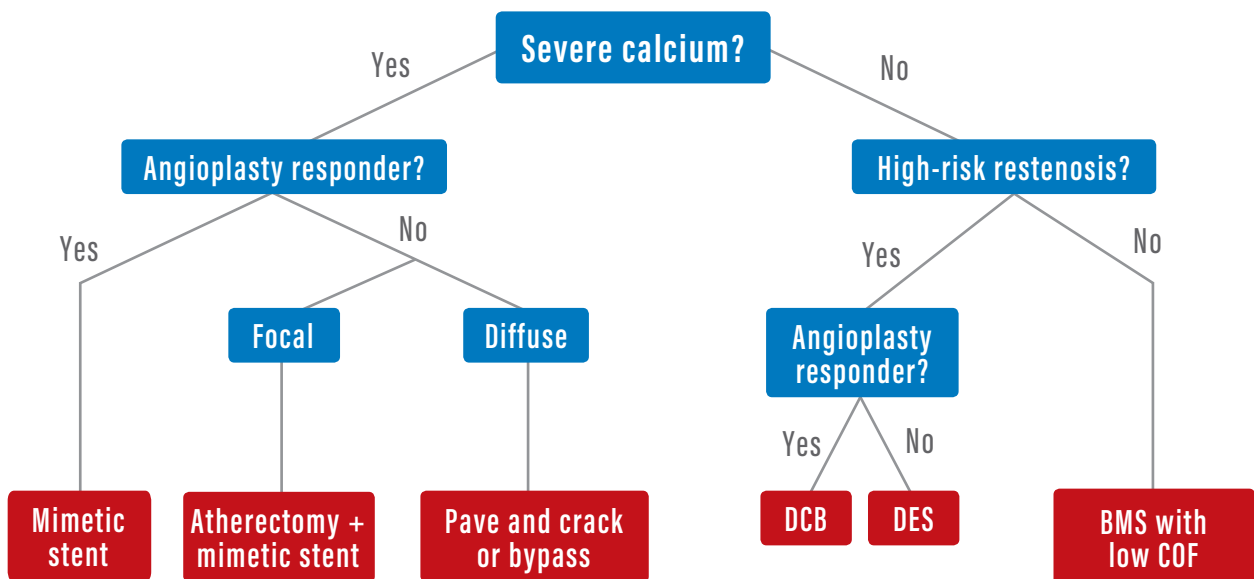


Figure 1. The author's current superficial femoral artery interventional treatment algorithm, taking into account ongoing FDA and European recommendations. Note: Some techniques are investigational. COF, chronic outward force.

plasty, the lesion is categorized as an “angioplasty nonresponder” and treatment with a stent system is warranted. Drug-eluting stents (DESs) offer a solution in this setting. Currently, two DESs are available: Zilver PTX (Cook Medical) and Eluvia (Boston Scientific Corporation), each with good longer-term clinical data available.²⁸⁻³⁰

If the lesion (or patient) is not considered to be at high risk for restenosis, a bare-metal scaffold should be used rather than plain old balloon angioplasty alone. Nowadays, a modern generation of nitinol stents are available. Longer stent lengths, greater flexibility, low to moderate chronic outward force, sufficient radial resistive force, and high crush resistance have created significantly improved patency and target vessel revascularization rates for short- and medium-length lesions (up to 15 cm). Characteristics such as stent design, strut thickness and width, stent material (spring constant), as well as the amount of oversizing with respect to the vessel diameter are important determinants in selecting the right device for the right indication.³¹⁻³³

CONCLUSION

Based on current FDA and European recommendations concerning the use of drug-eluting technologies, treatment algorithms can be adapted in a pragmatic way. The clear answers on two main questions and one repetitive subquestion steer the interventionalist through his or her own algorithm (Figure 1 reflects the author’s current algorithm). Determining calcium severity, risk for restenosis, and response to vessel preparation will lead to the answers regarding definitive treatment selection. A good angioplasty response to a severely calcified superficial femoral artery lesion can be followed with the use of the Supera stent. Focal, nonresponding, severely calcified lesions need to be prepped with other tools such as (directional) atherectomy, followed by Supera implantation. Diffuse, extended, calcified lesions may warrant a “pave and crack” approach or bypass treatment.

If the patient/lesion is at high risk for restenosis and recurrent reinterventions, benefits of drug-eluting technologies should be weighed against the inconclusive and unexplained potential risk of mortality. DCBs should be used in lesions that respond to angioplasty, whereas DESs should be used in angioplasty-nonresponding pathology. If the risk for restenosis is low, a modern-generation nitinol stent with the right properties remains a durable solution when implanted correctly in appropriate candidates. ■

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