

# Vessel Preparation and Plaque Modification of Infringuinal Lesions

Defining the terms, discussing the data, and reviewing perspectives on current practices.

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Successful endovascular therapy of infringuinal lesions requires three steps: lesion crossing, vessel preparation, and delivery of definitive therapy. Vessel preparation improves the outcomes of all endovascular interventions including angioplasty and stent implantation. However, the advent of drug-coated balloons (DCBs) has led to a reemphasis on the importance of vessel preparation and plaque modification as a determinant of short- and long-term outcomes, especially for the treatment of complex lesions. A focus on vessel preparation ensures maximal lumen expansion, lower rates of dissection, and may also improve the ability for paclitaxel to penetrate the lesion, thereby resulting in a more robust antirestenotic effect. This article discusses the goals of and challenges to vessel preparation and presents current adjunctive techniques that can be used to optimize vessel preparation.

## GOALS OF VESSEL PREPARATION

Broadly, the goal of vessel preparation is to achieve optimal angioplasty, which is typically defined as < 30% residual stenosis and absence of any significant flow-limiting dissection (Table 1). Additional factors that may contribute to optimal angioplasty include improved vessel compliance and minimal vessel recoil.

Maximizing luminal gain ensures that no residual hemodynamically significant stenosis remains after intervention. All balloon angioplasty creates some localized fracture of the plaque, and early intravascular ultrasound studies demonstrated that some dissection occurs after all balloon angioplasty.<sup>1</sup> Therefore, balancing the needs of optimal vessel expansion with the likelihood of significant dissection remains the primary challenge of vessel preparation. Although data are scarce on the topic, one study showed that prolonged balloon angioplasty (3 minutes) versus

TABLE 1. CHARACTERISTICS OF AND CHALLENGES TO OPTIMAL VESSEL PREPARATION

Characteristics	Challenges
<ul style="list-style-type: none"> <li>Defined as &lt; 30% residual stenosis</li> <li>Minimal dissection (none, grade A, grade B)</li> </ul>	<ul style="list-style-type: none"> <li>Long lesion length</li> <li>Chronic total occlusion</li> <li>Lesion calcification</li> </ul>

short-duration balloon angioplasty (30 seconds) is associated with lower rates of significant dissection or residual stenosis.<sup>2</sup> As such, prolonged balloon inflation at the lowest-possible atmosphere to obtain balloon expansion is recommended when optimizing vessel preparation.

The significance of a given dissection after infringuinal balloon angioplasty remains an active area of debate. Dissections are typically graded as A through F, with type A dissection associated with minor radiolucent areas after balloon angioplasty and type F associated with no antegrade flow after balloon angioplasty. Recent data from a large Japanese registry demonstrated that dissection grades of C (dissection with contrast outside the lumen) or higher were observed in 42% of balloon angioplasty cases, and presence of a type C or higher dissection was associated with higher rates of bailout stenting, lower primary patency, and higher rates of target lesion revascularization (TLR).<sup>3</sup> Interestingly, there was a stepwise relationship between dissection severity and restenosis, suggesting a continuum of risk for dissections graded C through F. Based on these data, the goal of any vessel preparation should be to achieve a dissection grade of C or better in order to minimize the risk of restenosis and TLR.

Compared with data regarding dissection severity and restenosis after standard balloon angioplasty, the contri-

bution of residual dissection to restenosis and clinically driven TLR after DCB angioplasty remains uncertain. Preliminary results have suggested that high-grade dissections after DCB angioplasty are not associated with restenosis, possibly due to vessel remodeling or an altered healing process in the presence of paclitaxel.<sup>4</sup> More data are necessary on the prognostic impact of dissection grades after DCB angioplasty, and these data will inform the need for bailout stent or scaffold placement.

## CHALLENGES TO VESSEL PREPARATION

Because all vessel preparation represents a balance between lesion expansion and dissection, factors that increase the likelihood of dissection despite 1:1 balloon inflation represent barriers to optimal vessel preparation. The variables that predispose to dissection after angioplasty are the same as those associated with lesion complexity: long lesion lengths, chronic total occlusions (CTOs), and vessel calcification (Table 1). Long lesion lengths are more likely to dissect after balloon angioplasty because the compliance of the vessel varies depending on the plaque composition. Most balloon angioplasty applies the same force across all parts of the vessel and will therefore result in differential expansion along the length of the lesion. CTOs are associated with both complex plaque morphology and high rates of subintimal crossing during wire recanalization. As a result, balloon dilation after CTO crossing is more frequently associated with significant dissection.

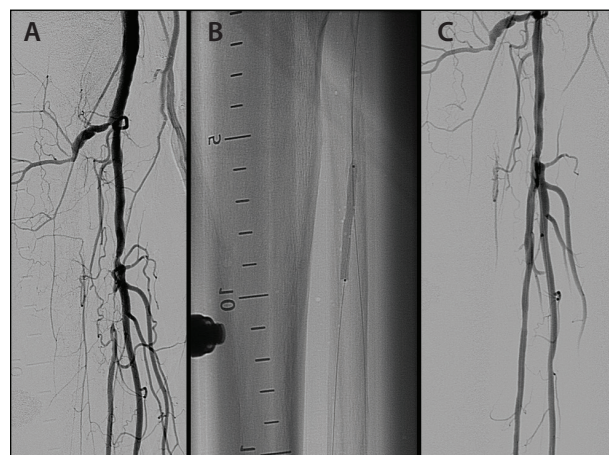
Calcium represents a common and significant barrier to adequate vessel preparation. Intravascular ultrasound studies have demonstrated that localized deposits of calcium are associated with dissection location and severity after balloon angioplasty.<sup>5</sup> Multiple scoring systems have been developed to identify angiographically severe calcium, including the peripheral arterial calcium scoring system, which grades angiographic calcification severity based on unilateral or bilateral calcification that is < 5 cm of  $\geq 5$  cm in length.<sup>6</sup>

Even after adequate vessel dilation, the presence of severe calcification may limit drug delivery, as concentric calcium within the lesion can act as a barrier to paclitaxel diffusion. An analysis of vessel calcification with multiple modalities suggested that severe calcification was associated with higher rates of restenosis after DCB angioplasty.<sup>7</sup> Another study demonstrated that the severity of calcification was associated with late lumen loss after DCB angioplasty.<sup>8</sup> In comparison, a single-center study of orbital atherectomy combined with DCB angioplasty demonstrated that use of orbital atherectomy was associated with lower rates of bailout stent implantation (due to fewer flow-limiting dissections) and similar patency compared to standard vessel preparation, despite the use of orbital atherectomy in more complex and heavily calcified lesions.<sup>9</sup>

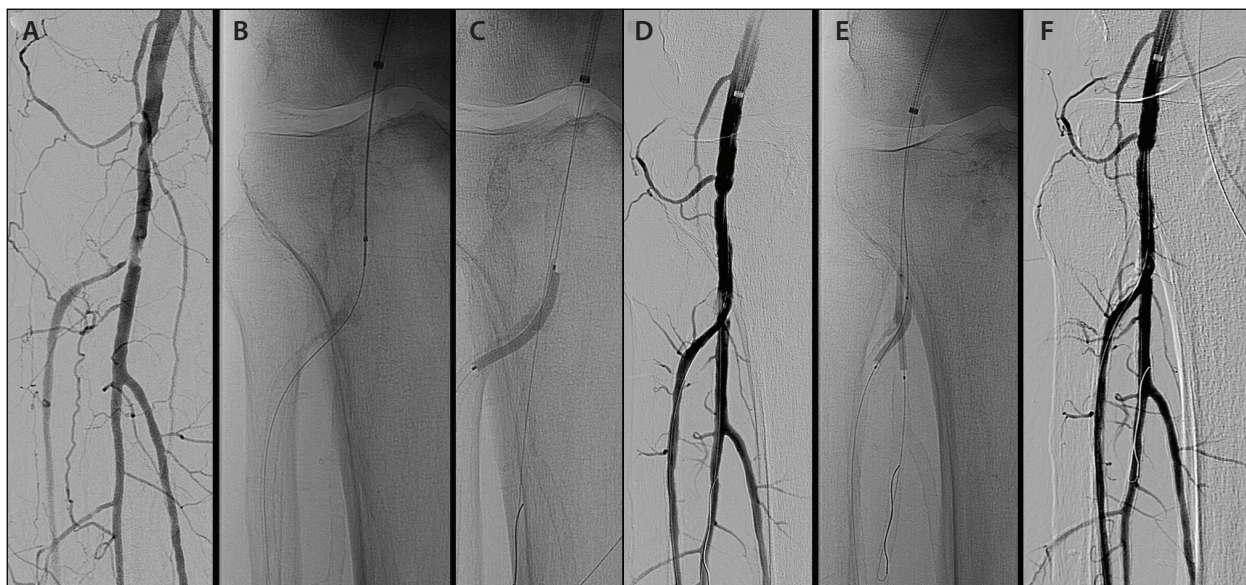
## ADJUNCTIVE THERAPIES TO OPTIMIZE VESSEL PREPARATION

Several devices have been developed to improve vessel preparation by increasing luminal gain and minimizing dissection. Each device has important applications in the treatment of complex lesions. The decision to use a given device is based on the perceived complexity of the lesion, the presence and extent of calcium, and the goals of therapy.

Multiple specialty balloons have been developed for optimization of lesion expansion while minimizing dissection. The VascuTrak balloon (Bard Peripheral Vascular, Inc.) and UltraScore balloon (Bard Peripheral Vascular, Inc.), which has recently been cleared by the US Food and Drug Administration (FDA), are semicompliant balloons with two external wires along the length of the balloons that deliver focal force during balloon angioplasty to optimize lesion expansion. The AngioSculpt balloon (Spectranetics Corporation) is a scoring balloon that contains a nitinol wire that wraps around the balloon and provides scoring elements during balloon inflation. This device optimizes balloon angioplasty while minimizing plaque shift. Figure 1 demonstrates use of scoring balloon angioplasty to treat an infrapopliteal bifurcation lesion. The Chocolate balloon (Medtronic) contains a nitinol-constraining structure that creates a pattern of pillows and grooves with balloon inflation. This constraining system delivers a more uniform atmospheric pressure across the lesion, thereby minimizing dissection. The Serranator (Cagent Vascular) is a new balloon that has recently received FDA 510(k) clearance.



**Figure 1.** Scoring balloon angioplasty to treat an infrapopliteal bifurcation lesion. A 68-year-old man presented with critical limb ischemia of the fifth digit. The lower extremity angiogram showed a subtotal occlusion of the distal tibioperoneal trunk and origin of the peroneal artery (A). After wire crossing, a 3-X 40-mm scoring balloon was inflated at 4 atm for 3 minutes (B). A final angiogram demonstrated minimal residual stenosis with a small, non-flow-limiting dissection (C).



**Figure 2.** Orbital atherectomy for treatment of a heavily calcified infrapopliteal lesion. A 72-year-old man presented with a necrotic wound of the first toe. A baseline angiogram demonstrated a heavily calcified distal popliteal artery and subtotally occluded anterior tibial artery (A). A 1.25-mm solid orbital atherectomy crown was used to debulk the calcified lesion and improve vessel compliance prior to balloon angioplasty (B). A 3-X 40-mm balloon was inflated at 6 atm (C). Angiography revealed minimal residual stenosis after vessel preparation (D). Final balloon angioplasty was performed with two 2.5-mm balloons (E). The final angiogram showed excellent flow to the anterior tibial artery with no residual stenosis or dissection (F).

The Serranator has four serrated strips embedded on the outside of a semicompliant balloon. It is designed to create linear, interrupted scoring along the endoluminal surface to enhance arterial expansion. The Flex scoring catheter (Venture Med Group) is a nitinol-based device that creates linear scoring marks along the lesion without requiring high-pressure barotrauma.

Atherectomy devices modify the plaque components either by improving vessel compliance or by mechanical removal of the plaque to increase the luminal gain. Orbital atherectomy utilizes an offset crown to modify calcium within complex femoropopliteal and infrapopliteal lesions. The CALCIUM 360 study was a small randomized study of balloon angioplasty versus orbital atherectomy plus balloon angioplasty among patients with critical limb ischemia. Use of orbital atherectomy was associated with significantly lower balloon atmospheric pressures and lower rates of dissection, suggesting that orbital atherectomy improved the compliance of the target lesion.<sup>10</sup> Figure 2 demonstrates use of orbital atherectomy to treat a heavily calcified infrapopliteal lesion. The CELLO study included patients with long-segment femoropopliteal disease treated with laser atherectomy and reported a need for stent placement in 23% of cases.<sup>11</sup> Excisional atherectomy has also resulted in low rates of stent placement in large studies in the treatment of infrainguinal lesions.<sup>12</sup> Figure 3 demonstrates use of excisional atherectomy of the superficial femoral artery (SFA) prior to DCB angioplasty. Ongoing studies are investigating the additive utility of these and other atherectomy

methods<sup>13</sup> in improving the outcomes of DCB angioplasty for the treatment of complex femoropopliteal lesions.

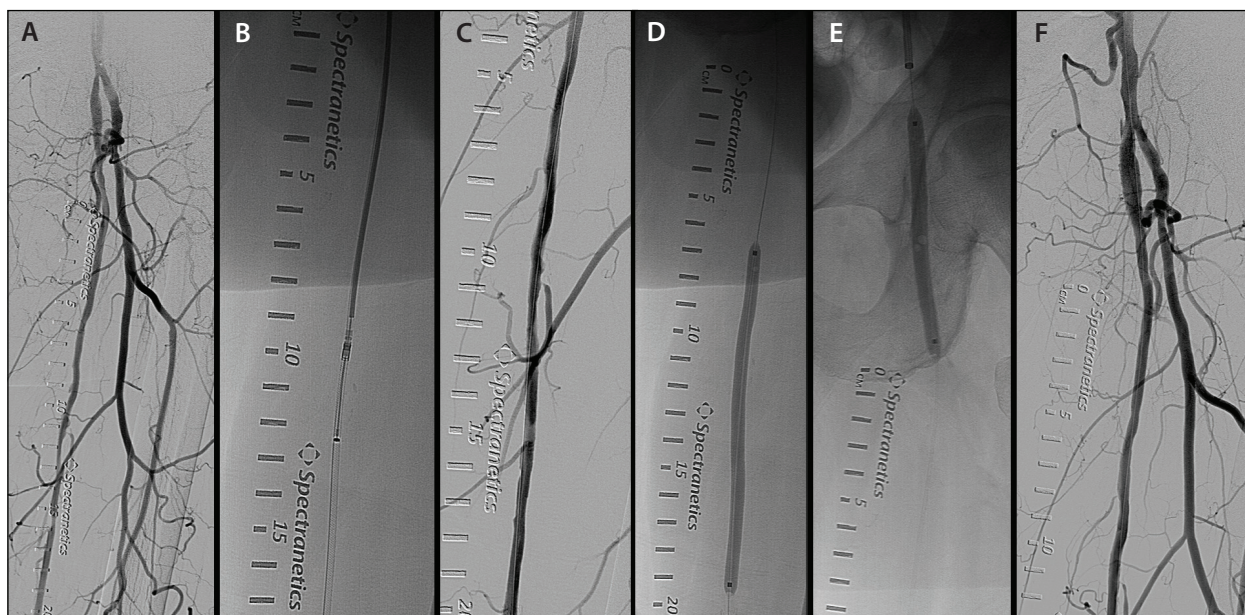
### NOVEL DEVICES TO MODIFY CALCIUM

Most current endovascular therapies act from within the vessel lumen to modify plaque. A limitation of this approach is that deeper calcium within the lesion cannot be modified or disrupted and may therefore present a continued barrier to vessel preparation and/or drug diffusion despite the use of specialty balloons or atherectomy devices. The Shockwave lithoplasty system (Shockwave Medical, Inc.) is a novel lithotripsy device that delivers a focused ultrasound wave through the lesion. The subsequent fracturing of deeper and medial calcium allows subsequent balloon dilation at lower atmospheric pressures and may also facilitate DCB angioplasty. The DISRUPT PAD I and II studies showed promising results with lithoplasty. The ongoing DISRUPT PAD III study will evaluate the additive benefit of lithoplasty to DCB angioplasty for the treatment of heavily calcified femoropopliteal lesions. Figure 4 demonstrates use of lithoplasty for treatment of a severely calcified femoropopliteal lesion.

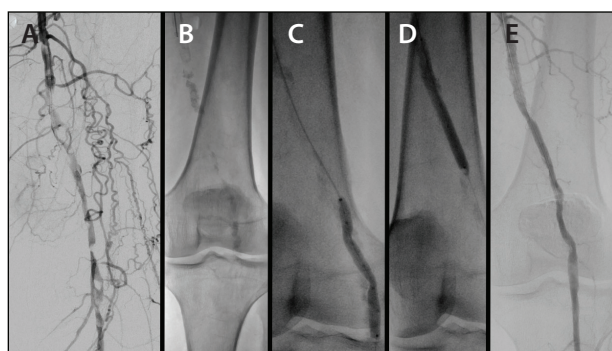
### CONCLUSION

Vessel preparation is an integral part of all endovascular procedures. Maximizing lesion expansion while minimizing dissection makes it more likely to allow a leave-nothing-behind strategy. As increasingly complex lesions are treated with endovascular therapy, a number of devices have been





**Figure 3.** Excisional atherectomy for treatment of a diffused SFA lesion. The baseline angiogram showed a severe ostial SFA stenosis and diffuse stenosis of the proximal to mid-SFA (A). A HawkOne LX (Medtronic) device was used to debulk the SFA (B). Angiography revealed minimal residual stenosis after excisional atherectomy and no significant dissection (C). DCB angioplasty was performed with a 5- X 120-mm and 6- X 60-mm In.Pact Admiral DCB (Medtronic; D, E). The final angiogram showed < 10% residual stenosis and no flow-limiting dissection (F).



**Figure 4.** Lithoplasty for treatment of a heavily calcified femoropopliteal lesion. The baseline angiogram revealed a long-segment CTO and subtotal occlusion of the mid-SFA (A). Results of nonsubtracted angiography were consistent with severe calcification (B). Lithoplasty was performed with 4.5- and 5.5-mm lithoplasty balloons (C, D). The final angiogram showed < 30% residual stenosis and no significant dissection (E).

developed to facilitate lesion preparation and improve the results of definitive therapy. ■

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