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Vessel Preparation With Laser Atherectomy and Scoring Balloon Angioplasty Before Drug-Coated Balloon Angioplasty

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Drug-coated balloon (DCB) angioplasty has significantly advanced the treatment options for femoropopliteal artery disease. Clinical trials have demonstrated patency rates with DCB use similar to those of nitinol stents, with the advantage of not leaving behind a permanent metallic implant.[1,2] Initial registries have also suggested acceptable outcomes of DCB use for the treatment of longer and real-world lesions.[3] For these reasons, DCBs are increasingly used as first-line therapy for the treatment of femoropopliteal lesions.

Despite the promise of DCB angioplasty, limitations of this therapy still need to be addressed. All of the data from DCB trials are based on an adequate predilation without significant residual stenosis or flow-limiting dissection. In studies that included more complex and longer lesions, the rates of bailout stent placement have averaged 20% to 40%.[4] Additionally, treatment of more complex lesions such as femoropopliteal in-stent restenosis,* long-segment disease, or heavily calcified lesions may limit the efficacy of DCB angioplasty due to insufficient drug penetration or residual stenosis. For these reasons, vessel preparation before DCB insertion is crucial to optimizing the outcomes of endovascular intervention. A focus on adequate predilation (achieving a residual stenosis < 30%) and minimization of significant dissection (achieving dissection grade < C) before DCB angioplasty ensures optimal procedural and long-term outcomes.[5]

As part of vessel preparation, laser atherectomy and scoring balloon angioplasty can have important roles in optimizing outcomes of complex lesions. Laser atherectomy vaporizes plaque, thrombus, and other mixed morphology at the site of the lesion or in-stent restenosis. Scoring balloon angioplasty provides focal force dilation at the site of balloon angioplasty via interconnected nitinol scoring elements. This scoring ensures luminal gain at the site of plaque and minimizes the likelihood of significant dissection. These two modalities therefore have complementary roles in vessel preparation prior to DCB angioplasty. The following cases demonstrate the utility of laser atherectomy and scoring balloon angioplasty for optimization of DCB angioplasty in the treatment of complex femoropopliteal lesions.

CASE 1: LONG-SEGMENT SUPERFICIAL FEMORAL ARTERY OCCLUSION

Figure 1 demonstrates a case of a long-segment superficial femoral artery (SFA) occlusion. The patient was a 67-year-old man with a long-standing history of claudication that had recently worsened to the point that he could only walk 50 yards before reaching an absolute claudication distance (consistent with Rutherford class 3 claudication). Initial angiography demonstrated a long-segment occlusion of the SFA with reconstitution at the adductor canal (Figures 1A and 1B). The occlusion was successfully crossed with a straight stiff Glidewire (Terumo Interventional Systems), and the true lumen position was confirmed distally. The Glidewire was exchanged for a supportive 0.014-inch guidewire. Laser atherectomy was then performed with a 2-mm laser at a fluence of 60 mJ/mm^2 and a rate of 45 Hz, for a total of three passes (Figure 1C). Subsequent angiography before balloon angioplasty revealed impressive luminal gain with minimal residual stenosis (Figure 1D). Further vessel preparation was performed with a 6- X 200-mm AngioSculpt scoring balloon (Spectranetics Corporation) at 6 atm for 2 minutes (Figure 1E); follow-up angiography revealed < 30% residual stenosis and no flow-limiting dissections. DCB angioplasty was performed with overlapping 6- X 150-mm In.Pact Admiral DCB (Medtronic)

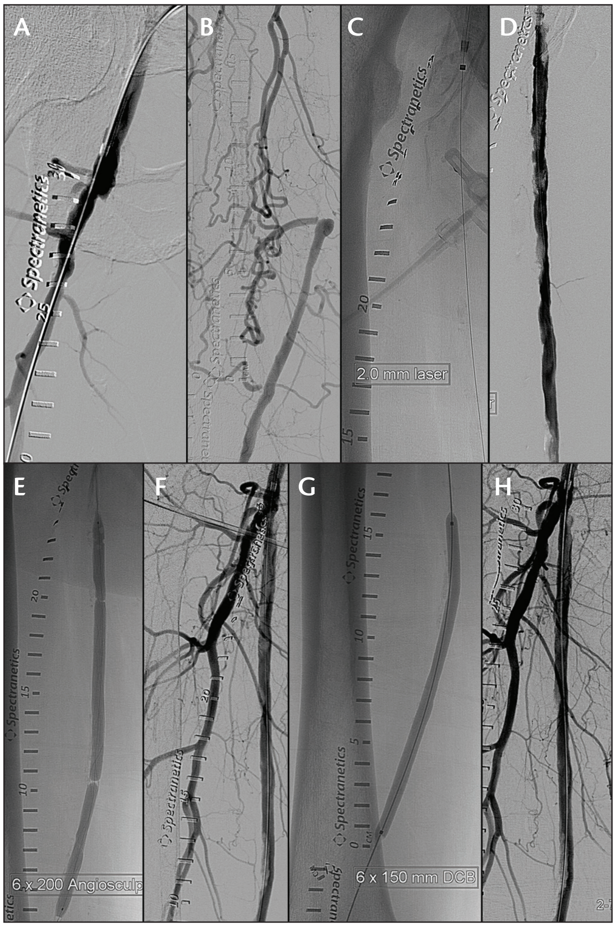

Figure 1. A long-segment SFA occlusion.

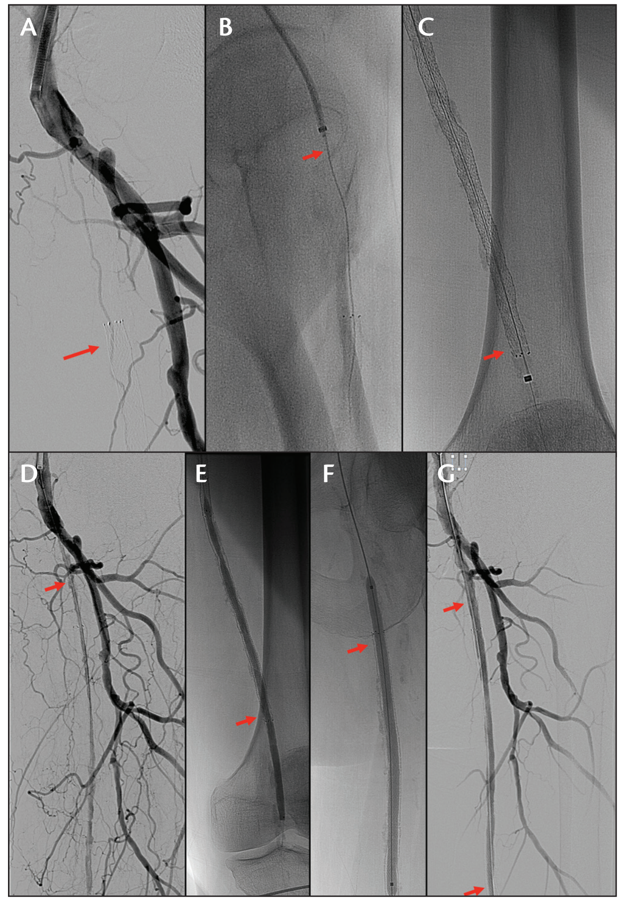

Figure 2. An in-stent occlusion.

(Figure 1F). Final angiography demonstrated minimal residual stenosis and no significant dissections. The patient had immediate relief of claudication, and follow-up duplex ultrasound at 1 year demonstrated continued patency without evidence of restenosis.

Previous studies have demonstrated the efficacy of laser atherectomy for the treatment of complex de novo femoropopliteal disease, including patients with long-segment occlusions and those with multilevel critical limb ischemia.[6,7] Overall, these studies demonstrated that laser atherectomy was associated with high rates of lesion crossing and procedural success, as well as lower rates of bailout stenting when compared to balloon angioplasty alone. Combining laser atherectomy with scoring balloon angioplasty as a technique for vessel preparation in complex femoropopliteal disease before DCB angioplasty may help minimize the need for bailout stent placement and potentially improve paclitaxel diffusion into the vessel by minimizing barriers to drug diffusion.

CASE 2: IN-STENT RESTENOSIS

Figure 2 demonstrates a case of SFA in-stent occlusion. The patient had a history of critical limb ischemia with a long-segment SFA occlusion that was treated 3 years earlier with overlapping nitinol stents. The patient's wound healed at that time, and he had done well until the last 6 months, when he developed severe claudication. Duplex ultrasound demonstrated occlusion of the left SFA stents, prompting referral for lower extremity angiography and endovascular intervention.

Baseline angiography (Figure 2A) demonstrated a flush occlusion of the SFA ostium with an occluded stent (arrow) that reconstituted in the mid-popliteal artery. A 7-F Flexor Ansel guiding sheath (Cook Medical) was placed and a 150-cm NaviCross support catheter (Terumo Interventional Systems) and a straight stiff Glidewire were used to access the occluded stent (Figure 2B). A 2.3-mm Turbo-Power laser atherectomy catheter (Spectranetics Corporation) was advanced to the occluded stent (Figure 2C) and was advanced at

1 mm/sec at a fluence of 60 mJ/mm^2 and a rate of 60 Hz. A total of four passes were performed, with directional ablation utilized via rotation of the torque wire. Follow-up angiography after laser atherectomy (Figure 2D) demonstrated excellent luminal gain with antegrade flow and no flow-limiting dissections. A 5- X 200-mm AngioSculpt scoring balloon was inflated at 8 atm for 2 minutes to optimize the luminal gain (Figure 2E), increase stent expansion, and limit dissection. Overlapping 5- X 150-mm In.Pact paclitaxel-coated balloons were inflated at 8 atm for 3 minutes (Figure 2F). Final angiography (Figure 2G) demonstrated minimal residual stenosis, no significant dissection, and excellent antegrade flow through the previously occluded stent.

Laser atherectomy has demonstrated superiority over balloon angioplasty for the treatment of in-stent restenosis based on the EXCITE-ISR trial as well as real-world registry data.[8,9] More recently, clinical application of the Turbo-Power laser atherectomy catheter has allowed directional atherectomy, thereby increasing the luminal gain and vaporizing a greater percentage of neointima. A small study has also suggested that the combination of laser atherectomy with DCB angioplasty is superior to DCB angioplasty alone for the treatment of in-stent occlusions.[10] The mechanisms of this benefit are uncertain but may include better luminal gain and/or increased paclitaxel penetration after laser atherectomy. For this reason, the combination of laser atherectomy with DCB angioplasty is especially attractive for the treatment of femoropopliteal in-stent restenosis.

CASE 3: SEVERELY CALCIFIED SFA STENOSIS

Figure 3 demonstrates a case of a patient with severe claudication and a heavily calcified SFA. The patient had a history of coronary artery disease and previous myocardial infarction and was prescribed optimal medical therapy including an antiplatelet agent, statin, and angiotensin-converting enzyme inhibitor. The patient's subsequent cardiac rehabilitation was limited by severe left lower extremity claudication. Physiologic studies demonstrated a normal right ankle-brachial index but a left ankle-brachial index of 0.65. Based on the patient's symptoms, despite optimal medical therapy and attempts at an exercise program, he was referred for lower extremity angiography.

Baseline angiography demonstrated multifocal areas of severe stenosis in the proximal and mid-SFA (Figure 3A). Nonsubtracted angiography confirmed severe calcification in the areas of stenosis (Figure 3B). A 7-F Ansel sheath was placed and the lesion was crossed with a 0.014-inch guidewire. A 2.3-mm Turbo-Power laser atherectomy catheter was advanced to the lesion (Figure 3C)

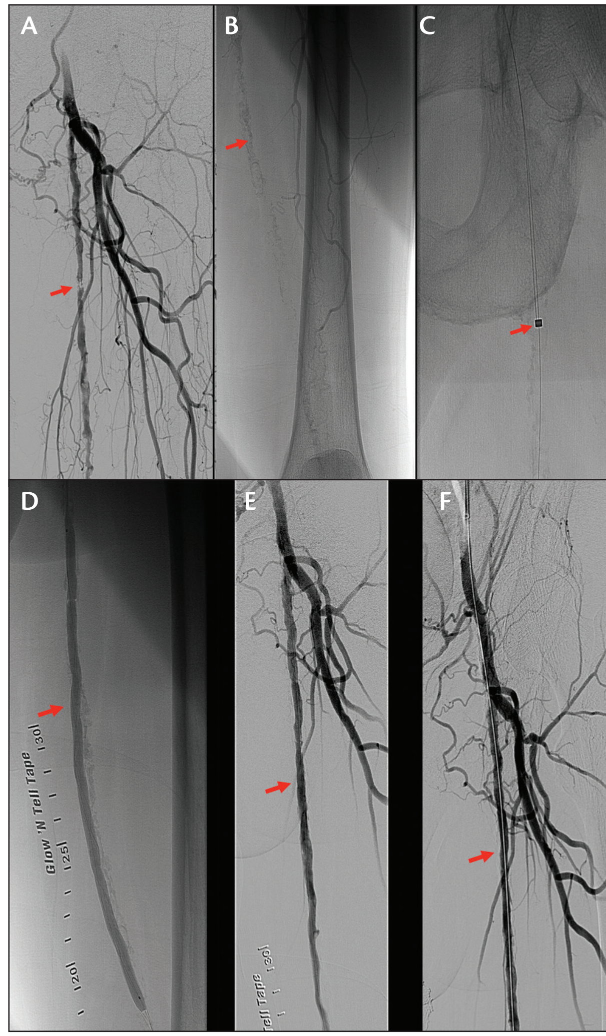

Figure 3. A heavily calcified SFA.

at 1 mm/sec using an initial fluence of 45 mJ/mm^2 and rate of 60 Hz. The torque wire of the laser catheter was used to direct the laser tip toward the areas of eccentric calcification, thereby maximizing lesion ablation and the kinetic energy of vapor bubble formation. A 5- X 200-mm AngioSculpt balloon was then inflated at low pressure (6 atm was sufficient to maximize scoring balloon inflation) (Figure 3D). Subsequent angiography demonstrated excellent luminal gain without evidence of dissection (Figure 3E). After subsequent DCB angioplasty with a 6- X 150-mm In.Pact Admiral DCB, the final angiographic result was excellent (Figure 3F). The patient had resolution of his claudication symptoms and was able to complete cardiac rehabilitation.

Although DCBs have demonstrated excellent patency in many femoropopliteal lesions, calcification remains a significant limitation on outcomes. Calcium is associated with increased rates of dissection, inadequate lumen expansion, and may also limit drug diffusion into the vessel. Consistent with this, initial studies have suggested the presence of severe calcification is associated with lower patency rates after DCB angioplasty.[11,12] The combined use of laser atherectomy and scoring balloon angioplasty ensured maximum lesion preparation before the delivery of paclitaxel and may therefore be associated with improved patency. Ongoing studies are further investigating the potential benefits of adjunctive atherectomy in the treatment of calcified lesions.

CONCLUSION

DCBs have significantly expanded the treatment options for patients with symptomatic femoropopliteal artery disease. Vessel preparation is crucial before DCB angioplasty, especially for complex lesions. Laser atherectomy can effectively vaporize plaque and create a pilot channel through complex lesion morphology, while scoring balloon angioplasty can maximize lesion expansion and minimize dissection. As we continue to advance endovascular options for patients with peripheral artery disease, the use of adjunctive technologies to maximize vessel preparation will become increasingly important in realizing the goal of long-term femoropopliteal patency after endovascular intervention. ■

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*The Stellarex DCB is not currently indicated for use in femoropopliteal in-stent restenosis.

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