Managing Iatrogenic Injury and Arteriovenous Fistulae

Covered or bare-metal stents may be useful options for treating perforation and arteriovenous fistulae complicating below-the-knee arterial interventions.

BY DAVID L. DAWSON, MD

In determining a plan of care, the interventional specialist must consider the clinical circumstances of the patient, the alternate treatment options available, and the consequences of success or failure. With critical limb ischemia (CLI), the risk/benefit consideration may justify a more aggressive approach than would be reasonable for a patient without a limb-threatening condition.[1] The University of California Davis Vascular Center has adopted a treatment strategy for CLI that favors endovascular therapy as the primary approach for most patients, especially when the patient is considered high risk for surgical revascularization or when options for surgical bypass are limited.

The availability of newer technologies for tibial interventions[2] has increased both options for intervention and the willingness to "push the envelope" to achieve procedural success.

With this aggressive approach to CLI interventions, however, comes a risk of procedural complications associated with crossing chronically occluded arterial segments, dilation of calcified lesions, debulking with laser ablation, or excisional atherectomy. Strategies for management of vessel perforation or rupture are needed for consistent success in treating challenging CLI cases.[3]

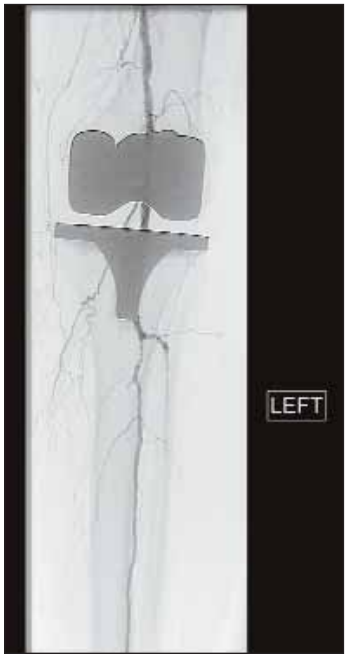

Figure 1. Angiography 6 months after atherectomy of the tibioperoneal trunk and balloon angioplasty of the anterior tibial artery. There was no significant occlusive disease proximal to the knee, but the infrapopliteal runoff was significantly diseased. The tibioperoneal trunk was diffusely renarrowed with an area of >80% stenosis. The posterior tibial artery was chronically occluded. The primary runoff to the foot was via the peroneal artery. The anterior tibial artery had reoccluded.

CASE 1

An 84-year-old diabetic woman was initially referred by her podiatrist for management of ischemic rest pain and ulcers on the left first and second toes. Although she had mild dementia, she lived in her own home and ambulated short distances without assistance.

Figure 2. There was moderately severe stenosis near the origin of the peroneal artery, but the remainder of the vessel was patent at the level of the ankle. This provided collaterals that reconstituted a lateral plantar artery.

Arteriography demonstrated severe infrapopliteal occlusive disease. Excisional atherectomy (ev3 Inc., Plymouth, MN) was used to treat high-grade stenoses of the tibioperoneal trunk and proximal peroneal artery. A chronic occlusion of the distal portion of the anterior tibial artery was crossed and opened with balloon angioplasty, but flow remained sluggish in this vessel due to the marginal runoff.

Short-term benefit was observed, with the patient's pain improved and partial healing of her ulcers; however, 6 months later, she had increasing pain, enlargement of the ulcer on the medial aspect of the first metatarsophalangeal joint, and recurrence of an ulcer on the second toe. Repeat angiography was performed.

Right common femoral artery access was achieved. A 5-F ContraFlush catheter (Boston Scientific Corporation, Natick, MA) was used for aortography and then for selective catheterization of the contralateral (left) lower-extremity vessels (Figures 1 and 2).

Intervention to treat the recurrent stenosis of the tibioperoneal trunk and peroneal artery was elected. After heparin anticoagulation, a 6-F Raabe sheath (Cook Medical, Bloomington, IN) was placed across the aortic bifurcation into the contralateral left superficial femoral artery for access. The .035-inch guidewire was removed and replaced with a .014-inch PT Graphix guidewire (Boston Scientific Corporation), which was used to cross the stenosis in the tibioperoneal trunk. The tip was positioned in the peroneal artery. Heparin was administered for anticoagulation.

Excimer laser atherectomy was performed using a 1.7-mm CLirPath Turbo catheter (Spectranetics Corporation, Colorado Springs, CO). Three passes were made with a fluency of 60 mJ/mm^2 and a rate of 80 pps. The lasing duration was 42 seconds, 70 seconds, and 40 seconds on three passes. The laser catheter was then removed over the guidewire. At this point, the patient expressed discomfort and reported pain in her left leg. Angiography performed after the laser catheter was removed showed perforation with extravasation and an arteriovenous fistula at the level of the tibioperoneal trunk bifurcation. There was rapid filling of the adjacent tibioperoneal veins into the popliteal vein. Guidewire access across the target lesion was lost, but the wire was manipulated and repassed distally. A 2.5-mm X 80-mm Amphirion Deep balloon (ev3 Inc.) was then passed over the guidewire and positioned to occlude flow from the perforation into the arteriovenous fistula. Follow-up angiography with the balloon in place confirmed that this provided cessation of flow. The balloon was held in position for 10 minutes, deflated, and then follow-up angiography was performed, showing persistent arteriovenous fistula (Figure 3). The balloon was then reinflated, and to confirm positioning, the guidewire was removed to allow angiography through the wire lumen of the catheter. This injection showed the catheter had been placed with the distal tip into a peroneal vein. The balloon inflation may have enlarged the initial arteriovenous fistula. A PT2 hydrophilic guidewire (Boston Scientific Corporation) was then placed, and the balloon was removed.

A 4-F angled Glide catheter (Terumo Interventional Systems, Somerset, NJ) was placed over the guidewire and used for injection of contrast directly into the tibioperoneal trunk. This was also used to direct the guidewire into the peroneal artery, which was identified with roadmapping. With the wire in the peroneal artery, the Glide catheter was passed over the guidewire and into the proximal peroneal artery. A contrast injection confirmed intra-arterial positioning. The catheter was then brought back to the level of the arteriovenous fistula. Hand injection of contrast precisely identified the area of vessel injury. The PTA balloon was replaced over the guidewire

Figure 3. The fistula between the proximal peroneal artery and the adjacent veins resulted in rapid filling of the peroneal and proximal veins. With sufficient volume of contrast injected, late images showed the veins in the more distal part of the leg due to reflux of venous blood due to increased venous pressure.

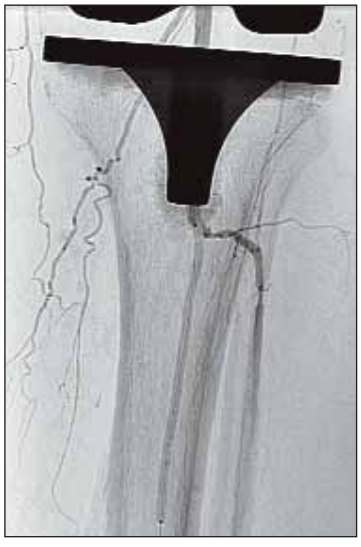

Figure 4. Inflation of an appropriately sized balloon catheter provides temporary occlusion of the arteriovenous fistula. In many cases, prolonged balloon inflation may be sufficient to manage a focal vascular injury. In this instance, it was suspected that because of a malpositioned guidewire, the initial balloon positioning was across the arteriovenous fistula.

Figure 5. A balloon-expandable, PTFE-covered stainless steel stent sealed the arteriovenous fistula and treated the refractory recurrent stenosis.

Figure 6. Significant occlusive disease in this 85-year-old diabetic patient with Rutherford grade 5 ischemia was limited to the popliteal and infrapopliteal arteries.

Figure 7. Severe infrapopliteal disease was demonstrated. A preocclusive stenosis at the bifurcation of the tibioperoneal trunk was present.

and positioned to provide hemostasis (Figure 4).

A covered stent was used to treat the arterial injury. A 3-mm X 16-mm Jostent GraftMaster (Abbott Vascular, Santa Clara, CA) was positioned and deployed with 10 atm pressure. The stent did not expand to profile, so it was postdilated with a 3-mm X 15-mm NC Ranger noncompliant balloon (Boston Scientific Corporation) inflated to 15 atm. Irregularity of the peroneal artery distal to the stent was treated with an additional inflation of the 2.5-mm X 80-mm Amphirion Deep balloon for 3 minutes. A follow-up angiogram showed minimal residual irregularity and no evidence of flow-limiting stenosis (Figure 5). More than 1 year later, the patient remains ambulatory with no requirement for reintervention.

Covered stents seem an intuitive solution to management of arterial disruption and arteriovenous fistulae. Peripheral interventionists should be familiar with the types of commercially available covered stents (Table 1). Although only the Gore Viabahn Endoprosthesis (Gore & Associates, Flagstaff, AZ) has FDA approval for femoral arterial applications, this and other covered stents may have endovascular roles in primary stenting applications, treatment of aneurysms, and as a bail-out option when managing iatrogenic injuries.

CASE 2

A covered stent may not be the only way to manage arterial injury and arteriovenous fistulae complicating a peripheral intervention. An 85-year-old man was referred by a dermatologist's wound care clinic for evaluation of superficial but nonhealing ulcers on his left heel and the tips of the first and second toes. He had diabetes, peripheral neuropathy, and no palpable pulses distal to the popliteal artery.

Arteriography demonstrated diffuse arterial calcifications. Distal to the knee joint, dense calcified plaque resulted in severe popliteal artery and tibioperoneal trunk stenosis (Figures 6 and 7). Contralateral access was established, and lesion crossing was achieved with a .014-inch Asahi Miraclebros 3 guidewire (Abbott Vascular). Predilation of a >90% focal stenosis of the distal popliteal artery was attempted with a 3-mm X 15-mm Flextome cutting balloon (Boston Scientific Corporation), but the crossing profile of this balloon was too large, and the lesion could not be traversed. Dilation of the popliteal artery and proximal tibioperoneal trunk was performed with a Sterling 4-mm X 40-mm balloon (Boston Scientific Corporation) inflated gradually to 8 atm to achieve profile. Follow-up arteriography, in addition to showing immediate recoil with >50% residual stenosis in the treated segment, demonstrated an arteriovenous fistula (Figure 8).

Management with prolonged inflations of the 4-mm balloon had no effect, neither on the residual narrowing, nor on the arteriovenous fistula. A bare-metal nitinol Xceed stent (Abbott Vascular) was deployed across the

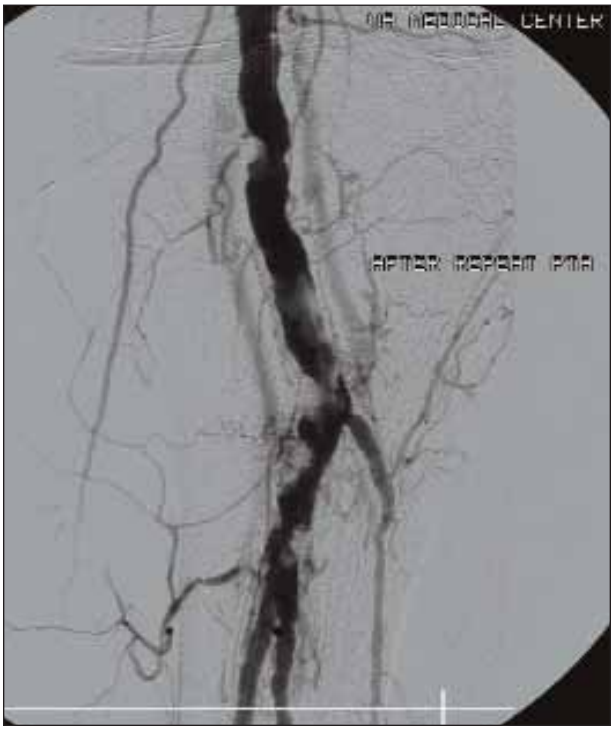

Figure 8. Significant residual stenoses persist from the irregular calcified plaque in the distal popliteal artery after angioplasty with a 4-mm balloon. Contrast can be seen filling the pair veins that accompany the artery below the knee. This arteriovenous fistula did not resolve after two low-pressure balloon inflations, each for 5 minutes. Of note, the tibioperoneal trunk plaque had been disrupted and dilated enough that flow into the posterior tibial artery was substantially improved.

segment and postdilated. Arteriovenous fistula flow was stopped. Additional balloon angioplasty was performed to treat a stenosis proximal to the stent. Completion angiography showed only modest residual stenosis in the treated segment and no periarterial extravasation of contrast (Figure 9).

DISCUSSION

Guidewire perforation is a risk in crossing chronic total occlusions (CTOs). It may be difficult to precisely control the wire tip within an occluded segment, and extensive or bulky calcified plaque may direct the wire into a subintimal passage that leaves very little adventitia outside the wire passage. Stiffer wires or those with hydrophilic coatings may be more likely to cause a full-thickness arterial wall perforation. Perforation risk can be affected by operator technique; the risk is minimized by careful fluoroscopic observation of wire tip behavior, roadmapping, and imaging with magnification. CTO crossing devices, such as the Frontrunner catheter (Cordis Corporation, Warren, NJ), can aid in traversing a refractory lesion, but avoidance of transmural perforation is dependent on operator experience.[4]

Newer technologies for CTO crossing seek to reduce the risk of guidewire perforation. A forward-looking, fiberoptic-guided device with guided radiofrequency energy directed by optical coherent reflectometry (Safe-Cross System, Kensey Nash Corporation, Exton, PA) has been used to open CTOs. In a small study (n=18), the reported success rate in crossing CTOs in patients in whom failed conventional wire crossing was 100%, with clinical success in 94% of these patients and no perforations or distal embolization. The Safe-Cross System may be considered for treatment of CTOs that fail crossing with conventional wires; the indirect visualization of the intraluminal positioning using optical coherent reflectometry technology may reduce vessel trauma and the risks of dissection, perforation, and distal embolization.[5]

Guidewire perforations during tibial CTO crossing attempts may not require any specific management, especially if the wire exits in the occluded segment. Occluded

TABLE 1. COMMERCIALLY PRODUCED COVERED STENTS CURRENTLY AVAILABLE IN THE US WITH POTENTIAL

Device Name	Manufacturer	Approved Indications	Stent Design	Stent Material
Fluency Plus	Bard Peripheral Vascular	Tracheobronchial	SE	Nitinol
GraftMaster (Jostent)	Abbott Vascular	Coronary or saphenous graft perforation	BE	Stainless steel 316L
iCast	Atrium	Tracheobronchial	BE	Stainless steel 316L
Viabahn	Gore & Associates	Superficial femoral artery	SE	Nitinol

SE, self-expanding; nitinol, nickel/titanium alloy; ePTFE, expanded polytetrafluoroethylene; BE, balloon-expandable.

Figure 9. Completion arteriography after placement and postdilation of the bare-nitinol stent showed resolution of the arteriovenous fistula.

segments do not bleed much. Significant clinical sequelae seem rare. Extravasation and hematoma are more likely if the perforation involves a patent segment or branch and may be more likely with concomitant use of glycoprotein IIb/IIIa inhibitors or thrombolytic therapy.

Small guidewire perforations or vessel wall ruptures from interventions may be sealed with prolonged inflation of an angioplasty balloon in the injured segment.[6] Inflation times of 3 to 5 minutes may tack down fractured plaque or dissected intima, sealing any leak.

Arterial injuries from larger devices may present a greater challenge than those from guidewires. Laser atherectomy for infrapopliteal arterial occlusive disease is most often used as an adjunctive technology for treating infrapopliteal occlusive disease, debulking, and creating a lumen before balloon angioplasty, but it can be used as a stand-alone technique. Data from the LACI trial suggest that the excimer laser can facilitate success in complex CLI cases,[7] but arterial wall injury and perforation can result.[8-11] In the first case presented in this article, we describe laser treatment of an arterial segment that had been previously treated with excisional atherectomy. It may be that this segment was at increased risk for perforation with the subsequent photoablative therapy.

Conventional balloon angioplasty, however, may be sufficiently traumatic to cause arterial perforation. Perforation is a recognized complication of angioplasty of vessels below the knee, and surgical management may be needed.[12] Extensive calcification, irregular or eccentric plaques, or severe focal stenoses (such as with the second case) are risk factors for perforation. Predilation with a smaller angioplasty balloon may help avoid perforation, although that maneuver was not successful in the case presented.

The use of covered stents is an established technique for management of iatrogenic arterial injuries,[13,14] and in a few cases, covered stents have been successfully employed in infrapopliteal arteries to manage pseudoaneurysms or arteriovenous fistulae.[15-18]

The Jostent GraftMaster Coronary Stent Graft System is FDA approved only for treatment of free perforations in native coronary vessels or saphenous vein bypass grafts >2.75 mm in diameter, but because of the available sizes, this covered stent can be considered for use in tibial artery applications, such as in the case presented. These PTFE-covered, balloon-expandable 316L stainless steel stents are available in 3- to 5-mm diameters and in 12-, 16-, 19-, and 26-mm lengths. The Jostent GraftMaster deploys over a .014-inch guidewire, and it can be delivered through a 7-F guiding catheter or a 5-F sheath. Other currently available covered stents with FDA-approved or off-label peripheral arterial applications, including the Viabahn (Gore & Associates), iCast (Atrium Medical Corporation, Hudson, NH), and the Wallgraft (Boston Scientific Corporation), are too large for use in

OFF-LABEL APPLICATIONS MANAGING COMPLICATIONS OF POPLITEAL OR INFRAPOPLITEAL INTERVENTIONS

Covering Material	Sheath Size Required (F)	Guidewire Size (inch)	Available Diameters or Expansion Range (mm)	Available Lengths (mm)
ePTFE	8, 9	.035	6–10	40, 60, 80
ePTFE	5	.014	3–5	12, 16, 19, 26
ePTFE	6, 7	.035	5–12	16, 22, 38, 59
Heparin-bonded ePTFE	7, 8	.035	5–8	25, 50, 100, 150

tibial arteries. Experience from coronary applications suggests that use of combined antiplatelet therapy with both aspirin and clopidogrel may improve long-term patency with the use of the Jostent GraftMaster.[19]

CONCLUSION

Covered stents may provide a useful bail-out option when complicated arterial injures occur during interventions below the knee. There is little published experience with the use of bare-metal stents to manage perforation and arteriovenous fistulae resulting from endovascular therapies, although as illustrated by the second case, this may be a viable option. Knowledge of this technique may be especially useful to interventionists who do not have a complete range of covered stents and sizes on hand. ■

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