Nitinol Stenting for a Long SFA Lesion Via a 4-F System

A case report that supports smaller sheath sizes to minimize access site bleeding during percutaneous peripheral vascular intervention.

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Atherosclerotic stenosis or occlusion of the superficial femoral artery (SFA) can lead to claudication and contribute to chronic critical limb ischemia. Should aggressive peripheral artery disease (PAD) risk factor modification and exercise therapy fail to improve symptoms, revascularization is indicated and is often successfully undertaken via a percutaneous approach. Percutaneous peripheral vascular intervention (PPVI) for infrainguinal PAD is commonly performed via puncture of a common femoral artery (CFA) and placement of an introducer sheath. The procedure frequently includes the use of anticoagulants, so it can be complicated by access site bleeding.

Periprocedural bleeding and the need for blood product transfusion surrounding percutaneous coronary intervention (PCI), also classically performed via CFA access, have been associated with increased morbidity and mortality, and the same likely holds true for PPVI.[1,2] Bleeding complications may be minimized surrounding PPVI by using smaller introducer sheath sizes, but many available tools for percutaneous revascularization are not compatible with small sheaths. In this article, we report the first implantation in the United States of a Pulsar-18 self-expanding nitinol stent (Biotronik, Inc., Lake Oswego, OR) using a 4-F system in a long SFA atherosclerotic stenosis via the contralateral CFA.

CASE REPORT

A 64-year-old man with a significant medical history of hypertension, hyperlipidemia, coronary artery disease, and PAD—including a previously placed right common iliac stent—was referred to our clinic for evaluation of left lower extremity claudication, which was Rutherford

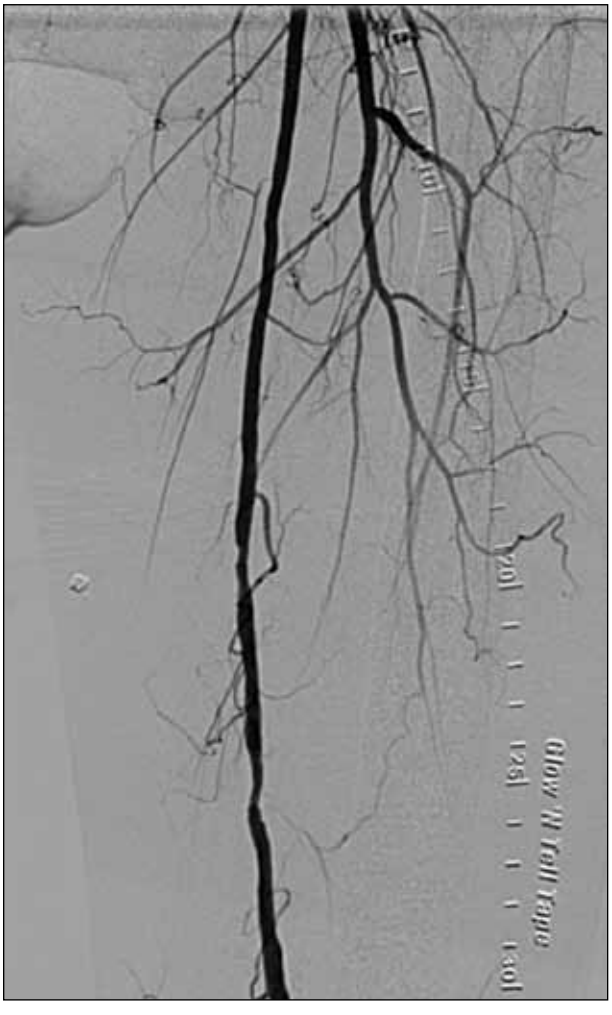

Figure 1. The left SFA, showing 80% occlusion.

Figure 2. A non–flow-limiting dissection of the distal SFA.

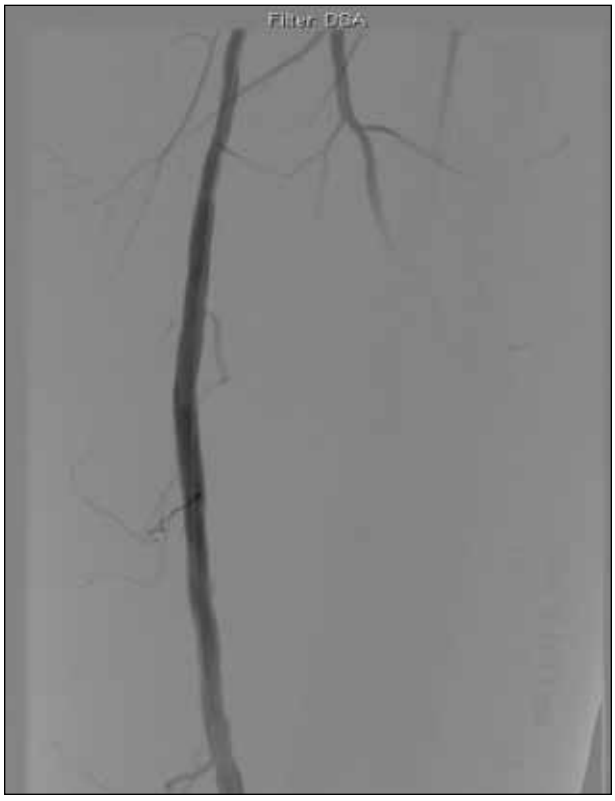

Figure 3. Final result in the left SFA.

class 3 in nature. The ankle-brachial index obtained in the office was 0.7 in the left lower extremity, and peak systolic velocity by Doppler ultrasound was 280 m/s in the distal left SFA. The patient was scheduled for left lower extremity angiography with planned PPVI in the culprit lesions.

Right CFA access was achieved using a micropuncture technique and a 4-F system. Distal abdominal aortography, via a 4-F Omni Flush catheter (AngioDynamics, Latham, NY), revealed moderate atherosclerosis without angiographically significant stenoses in bilateral iliac systems, including a patent stent in the right common iliac artery. A 0.035-inch angled Glidewire (Terumo Interventional Systems, Inc., Somerset, NJ) was used to facilitate delivery of the Omni Flush catheter into the left CFA for a runoff, revealing approximately 120 cm of moderate-severe stenosis in the mid-to-distal SFA, which was 80% occlusive at its most severe segment (Figure 1). Three-vessel runoff to the ankle had no significant below-the-knee stenoses.

A Fortress 4-F, 45-cm reinforced introducer sheath (Biotronik, Inc.) was delivered to the left CFA over a 0.035-inch Rosen wire (Cook Medical, Bloomington, IN). Bivalirudin was used for anticoagulation. A 0.018-inch V-18 wire (Boston Scientific Corporation, Natick, MA) was used to cross the index lesion, and a 25-mm Hg pressure gradient was present across the distal SFA upon pullback of a 0.035-inch QuickCross catheter (Spectranetics Corporation, Colorado Springs, CO). The lesion was predilated with prolonged, slow, low-pressure inflation of a 5- X 120-mm Passeo-18 balloon (Biotronik, Inc.). A non–flow-limiting dissection of the distal SFA was present after balloon angioplasty (Figure 2). A 6- X 150-mm Pulsar-18 self-expanding nitinol stent was deployed across the index lesion and postdilated with the same Passeo-18 balloon. An excellent angiographic result was achieved (Figure 3). The Fortress sheath was exchanged for a 4-F, 10-cm introducer sheath, which was sutured in place and subsequently removed with 8 minutes of manual compression upon dissipation of anticoagulation. There were no periprocedural complications.

Two weeks later, the patient reported complete resolution of his left lower extremity claudication. Daily clopidogrel was continued for 4 weeks following stent implantation, and he remained claudication free at 6-month office follow-up.

DISCUSSION

Potent antiplatelet and antithrombotic pharmacologic therapies help to reduce ischemic complications during and after PPVI, often at the expense of access site

bleeding complications. Bleeding complications following infrainguinal PPVI via the CFA can exceed 15% in the setting of antegrade puncture and 6-F introducer sheaths.[3] In our experience, 7-F sheaths are most commonly used during CFA access. In PCI, smaller sheath sizes and prompt sheath removal positively affect the bleeding complications that are frequently associated with CFA access.[4] Moreover, radial artery access decreases the rate of local vascular complications when compared to CFA access for PCI, and not surprisingly, the use of radial access for PCI is on the rise.[5]

Radial artery complications increase as the size of the introducer sheath placed within it increases.[6] Therefore, radial access for PPVI is often limited to the treatment of nonoccluded vessels above the CFA, as currently available endovascular equipment is either not long enough to reach the infrainguinal vessels or too large for introducer sheaths that can be safely placed in the radial artery. From antegrade and retrograde CFA access sites, the compatibility of balloons, stents, re-entry devices, and atherectomy devices with the introducer sheath is often the limiting factor when attempting to minimize the bleeding complications of PPVI by using smaller sheath sizes.

Pulsar-18 is available outside the United States in 4- to 7-mm diameters and 30- to 200-mm lengths, all of which are 4-F compatible. The safety and efficacy of Pulsar-18 is currently under investigation in BIOFLEX-I, a prospective, nonrandomized, multicenter, investigational device exemption study that continues to enroll at select sites in the United States, Canada, and Europe. Data from 12-month follow-up of patients enrolled in 4EVER (a trial investigating the safety of 4-F endovascular treatment of infrainguinal arterial stenotic disease) were presented at the 2013 LINC congress in Leipzig, Germany.[7] One hundred twenty patients received Astron Pulsar (Biotronik, Inc.) and Pulsar-18 stents at five sites in Belgium and Germany. The mean lesion length was 72.42 mm, and primary stent patency was 81.4%. All 4-F sheaths were removed, with a mean manual compression time of 8.12 minutes.

Our first United States implant of a long, self-expanding nitinol stent in the SFA via a 4-F system highlights the need for continued development of PPVI equipment that facilitates the use of smaller sheath sizes. Short segment (< 50 mm) SFA lesions are amenable to percutaneous transluminal angioplasty (PTA) alone based on nonstatistically significant differences in outcomes when compared to nitinol stents.[8] PTA can be performed today via 4-F systems with equipment that is currently available in the United States. When PTA results in vessel dissection or residual stenosis, when lesions are more appropriately treated with stents or atherectomy (> 50 mm), or when total occlusion and subintimal crossing necessitates re-entry devices, small sheath sizes are not currently feasible.

CONCLUSION

Bleeding complications surrounding CFA access in PPVI are common, but likely minimized with smaller introducer sheaths. Placement of self-expanding nitinol stents across long-segment SFA lesions via 4-F systems is currently available abroad and was recently introduced in the United States under an investigational device exemption study. PCI data suggesting fewer bleeding complications, reduced hospitalization, and decreased mortality as CFA sheath size is reduced likely applies to PPVI. Continued investigation is necessary to safely bring 4-F–compatible equipment to endovascular specialists in the United States. ■

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