Revascularization of Long FP Arterial Occlusions

Preliminary experience with the Outback Re-Entry Catheter suggests that it is an important tool in the endovascular management of femoropopliteal arterial occlusions.

BY MARK W. MEWISSEN, MD

Today, the technical success of percutaneous endovascular revascularization procedures is partly predicated upon the safe passage of a guidewire through the lesion to be treated as well as tracking and delivering a device of choice to the remote vascular site. When analyzed on an intention-to-treat basis, a low technical success associated with a revascularization procedure will negatively impact the primary patency of the procedure.[1] Long femoropopliteal (FP) arterial occlusions continue to pose an endovascular challenge, in part because a guidewire cannot always be passed through the lesion. For such lesions, surgical revascularization methods continue to be the recommended treatment of choice.[2] Although it is likely that future generations of intravascular devices will tilt current practices in favor of endovascular treatment strategies, gaining true lumen access beyond the lesion to be treated will remain a key step in achieving high technical success rates.

In selected patients, percutaneous intentional extraluminal recanalization (PIER), or subintimal angioplasty, has been advocated as an alternative to surgery for the treatment of long FP occlusions.[3-7] Although the technical success of PIER is reportedly as high as 80%, safe and predictable reentrance into the reconstituted true lumen distal to the occlusion remains the limiting technical step of the procedure.[3]

The Outback Re-Entry Catheter (LuMend, Inc., Redwood City, CA) is a relatively new low-profile device that may play an important role in the technique of re-entering the true lumen distal to an FP occlusion. The technique described herein is based on preliminary experience with a few patients.

THE DEVICE

The Outback catheter (Figure 1A and B) is a single-lumen catheter designed to facilitate access and positioning of a guidewire within the peripheral vasculature, from a remote vascular entry site. A control knob, a rotating hemostasis valve, a catheter shaft with a distal nose cone, and a distal guide tip comprise the major elements of the device. The distal curved-tip cannula consists of a controllable, nitinol sharp needle activated via the proximal end of the catheter and used to puncture the true lumen of a vessel under controlled fluoroscopic guidance. Upon prox-

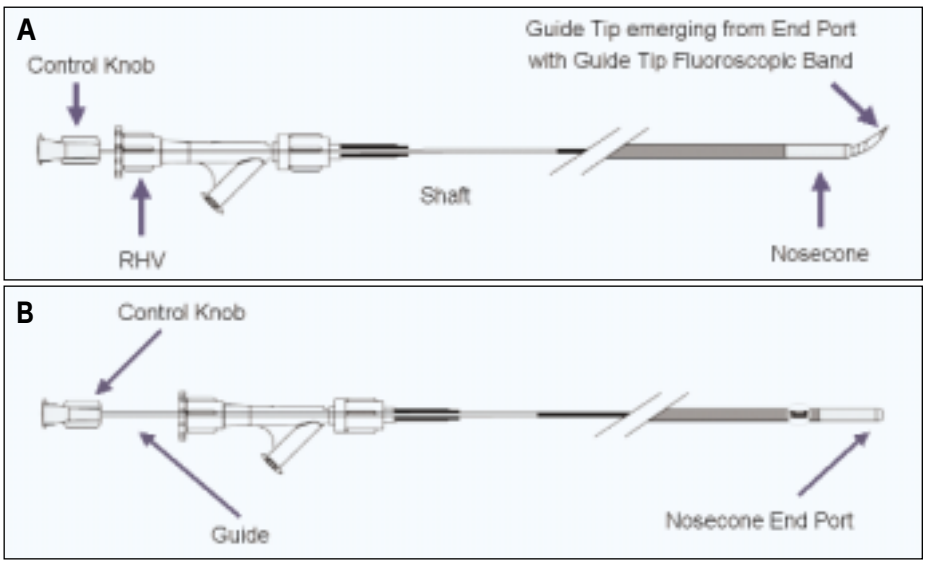

Figure 1. The Outback catheter with guide tip extended. The Outback catheter is composed of four primary elements: 1) control knob, 2) rotating hemostasis valve, 3) catheter shaft with distal nose cone, and 4) guide/guide needle tip (A). The Outback catheter with guide tip retracted (B).

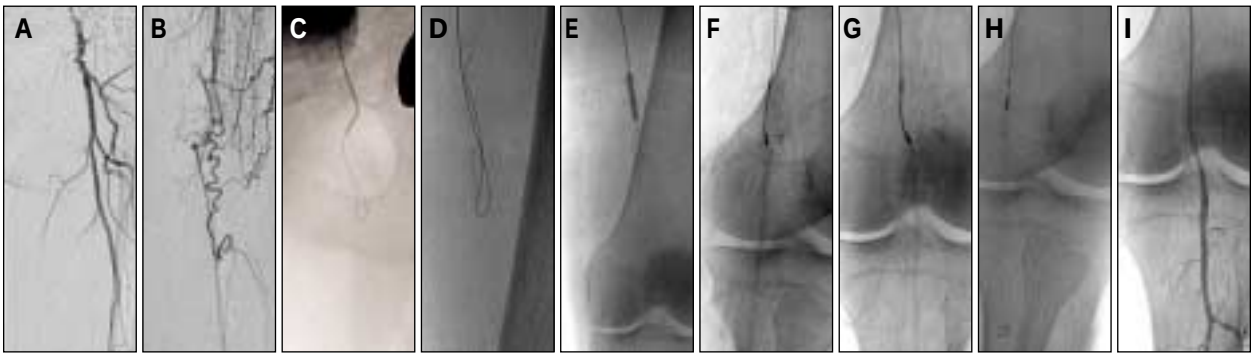

Figure 2. Angiogram showing occlusion of the SFA (A) and reconstitution of the popliteal artery (B). Gentle probing of the proximal SFA occlusion with a curved-tip Glidewire engaged into the subintimal space (C,D). The balloon catheter is inflated at sites of resistance (E). The Outback device is pointed toward the reconstituted lumen. This step is facilitated by a radiopaque marker on the distal tip of the nose cone (F,G). The wire is advanced into the punctured true lumen (H). Intraluminal access is confirmed by angiography (I).

imal retraction, the curved tip of the cannula is positioned coaxially within the nose cone of the catheter. This configuration allows the catheter to be tracked over a guidewire to the selected vascular target site. The guidewire is then retracted into the cannula, allowing the curved cannula needle tip to be advanced from the nose cone distal end into the target vessel. Upon proper placement of the cannula tip, the guidewire may be advanced through the cannula and into the desired vascular site. The cannula tip is subsequently retracted into the nose cone and the catheter is proximally retracted, leaving the guidewire in place in the vessel.

THE TECHNIQUE

Prior to re-entering the true lumen of the targeted vessel with the Outback catheter, the technical steps involved include safe tracking of the device through the created subintimal dissection (Figure 2). Angiography should demonstrate a proximal "nipple," identifying the proximal stump of the occluded superficial femoral artery (SFA), as well as distal reconstitution of the true lumen to be re-entered with the Outback catheter (Figure 2A and B). The contralateral common femoral artery is punctured in a retrograde fashion using standard Seldinger techniques. A 6-F sheath of choice is passed around the aortic bifurcation, with its tip parked at the level of the proximal ipsilateral common femoral artery. The proximal SFA occlusion is probed and engaged with a 5-F, angled catheter to allow passage of an angled Terumo Glidewire (Ann Arbor, MI), used to initiate the proximal dissection plane (Figure 2C and D). This step may require probing with a stiffer wire, such as the back end of a regular Terumo wire. The 5-F catheter is then exchanged for a 5-F, 5-mm X 2-cm PTA balloon catheter advanced over the looped Glidewire into the subintimal space and gently dilated at sites of tight resistance (Figure 2E). This will progressively facilitate passage to the level of the reconstituted artery, monitored via small quantities of contrast material injection through the proximal sheath. Great care must be taken not to extend the dissection beyond this point.

The Glidewire is then exchanged for a 0.014-inch or an 0.018-inch coronary wire to track the Outback catheter advanced to the proximal level of the reconstituted artery. The tip of the device is then pointed toward the arterial lumen via torque manipulation, and is confirmed by means of two angiographic images obtained at least 45º apart (Figure 2F and G). The needle is then advanced with a forward motion to engage the true lumen. The coronary wire is then gently advanced beyond the needle tip (Figure 2H). The intraluminal wire should advance freely into the true lumen. Should resistance occur, the needle is retracted into the nose cone, the wire is retracted into the needle shaft, and the process is repeated. The device is carefully removed and exchanged for a 5-F catheter to confirm intraluminal access (Figure 2I). Balloon angioplasty of the neolumen is then initiated, with or without additional stent support. The steps described above can also be performed via an ipsilateral antegrade common femoral approach, if the contralateral access is not possible or if severe tortuosity of the iliac arteries precludes easy passage of the sheath and subsequent catheters around the aortic bifurcation.

CASE PRESENTATION

A 76-year-old, insulin-dependent, diabetic woman with severe coronary artery disease presented with a nonhealing ulcer of the right foot. Her history included bilateral infrainguinal vein bypasses 6 years earlier for the relief of rest pain in the right foot and a nonhealing ulcer on the left foot. Arterial duplex examinations demonstrated an occluded bypass on the right side and a patent but dis-

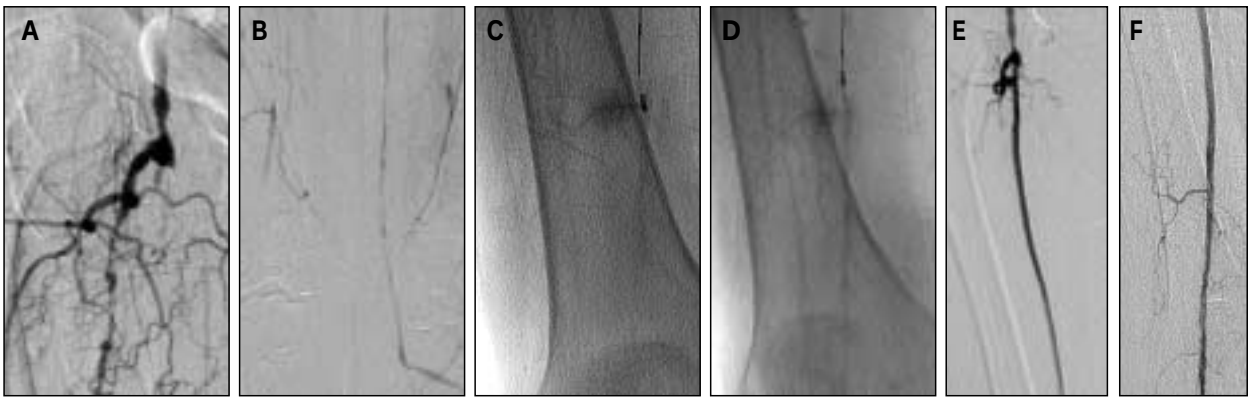

Figure 3. A right anterior oblique angiogram shows the SFA "nipple" slightly lateral to the origin of the occluded bypass graft (A). A bilateral lower-extremity runoff angiogram shows a small reconstituted right popliteal artery and diseased, but patent, left bypass graft (B). An x-ray image of the Outback catheter pointing toward the reconstituted popliteal artery before (C) and after (D) needle tip puncture. Note the radiopaque marker on the distal tip of the needle. After successful PIER with the Outback catheter (E). An angiogram of the right leg after stent recanalization of the occluded SFA (F).

eased bypass on the left. On the right side, Doppler-derived pressure measurements revealed a toe pressure of less than 20 mm Hg. Her ankle-brachial index was elevated due to noncompressible vessels. Angiography showed an occluded right bypass and a reconstituted small but patent proximal popliteal artery (Figure 3A and B). There was occlusion of the distal popliteal artery with reconstitution of the proximal anterior tibial artery, continuous into the foot. The posterior tibial and peroneal arteries were occluded. PIER was successfully performed with the Outback device (Figure 3C and D), and the SFA was treated with three self-expanding Smart stents (Cordis Corporation, a Johnson & Johnson company, Miami, FL) (Figure 3E and F).

At 6 weeks, the ulcer was healed and the stents were shown to be patent, as determined by routine surveillance duplex imaging. To date, since December 2003, five PIER procedures have been successfully performed with the Outback device in five similar patients who presented with critical ischemia of the lower extremity and limited vascular surgical options due to severe comorbid risks and lack of a suitable vascular conduit. There has been no failure to re-enter the distal lumen at a predictable anatomical level with use of the Outback catheter.

DISCUSSION

Currently, percutaneous intentional extraluminal recanalization of long FP occlusions plays a significant role in the management of patients who present with critical limb ischemia and limited surgical revascularization options.[4-6] The technical steps of the procedure have been described in detail by Reekers and Bolia.[3] In our experience with PIER, guidewire re-entry is the single limiting step that defines the technical success of the procedure. Guidewire access into the extraluminal space and distal guidewire manipulation and advancement are always possible, if there is a proximal "nipple" at the ostium of the occluded SFA. Thus, a safe and predictable re-entry maneuver into the true vascular lumen will elevate the technical success of PIER. Currently, because the reported results after PIER have not matched the results obtained after surgery, the technique with current angioplasty devices plays a limited role in patients with lower-limb claudication. As newer devices yield improved patency rates, the endovascular indications will continue to expand if the techniques of device delivery prove safe and reliably performed with a high technical success. The Outback Re-Entry Catheter may become an important tool in the hands of the endovascular specialist. ■

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