

Can Radial Access Be a Practical Alternative to Treat Peripheral Vascular Disease (PVD)?

A Different (Safer) Approach to Treat PVD: Experience With a Radial Sheathless Guide

Richard R. Heuser, MD, FACC, FACP, FESC, MSCAI, Chief of Cardiology, St. Luke's Medical Center; Professor of Medicine, University of Arizona School of Medicine; Phoenix Heart Center, Phoenix, Arizona



Richard Heuser, MD

Disclosure: Dr. Heuser reports equity in Radius Medical.

The authors can be contacted at richard.heuser@steward.org.

Percutaneous transluminal angioplasty has been the most widely used endovascular modality to treat peripheral arterial occlusive disease, with its first use in 1979.¹ Endovascular treatment is less invasive compared to surgical revascularization. It is relatively easy to perform with high rates of procedural success in the hands of experienced operators. Carotid stenting has been shown by randomized trials with experienced operators to be at least non-inferior to carotid endarterectomy (SAPPHIRE and ACT 1 trials).

The classic access to approach peripheral arterial disease has been via the femoral route. The obvious dilemma in patients who present with peripheral vascular disease as well as carotid disease is the tendency of these patients to have diffuse disease with an inherent risk of vascular bleeding. Total aortic occlusion or severe iliac disease are not unusual, making the groin approach difficult, if not nearly impossible.

When performing carotid interventional treatment, dilation of the carotid territory results in bradycardia and hypotension, which may continue for 24-48 hours post procedure. When the procedure is performed via the groin, this hemodynamic response creates a clinical dilemma as to whether it is due to a normal physiologic response or a more serious problem, such as a retroperitoneal bleed.

The radial approach has been embraced worldwide in a way to reduce vascular complications in all aspects of coronary intervention. Our cath lab has been a radial-first facility for the last decade, but with a large local population of critical limb ischemia patients, as well as our use as an international resource for complex peripheral arterial disease intervention, we have been partnering (and in some cases imploring) with our industry partners to make an array of radial products in order to treat aortic, iliac, femoral, and carotid disease via this safer approach. Although the radial approach for carotid intervention can be used with

some commercially available products, a 6.5 French or greater size precludes the use of a radial approach in many of these patients. This is particularly difficult, because our center (like many others) doesn't utilize sedation in carotid patients so we can evaluate even subtle neurologic changes during the procedure.

We have been using the R2P Destination Slender (Terumo) and the attendant equipment in over 2 dozen cases during the last 6 to 8 months. We present three case examples to illustrate the promise of these sheaths, wires, and balloons, as well as the application of other technologies that potentially can be more widely applied in conjunction with their use.

Case #1

A 60-year-old heavy smoker first presented with heart failure and underwent cardiac catheterization. An outside cardiologist attempted to perform the procedure via the groin, but could not pass the 100% occluded aorta. Two months later, the patient presented with bilateral

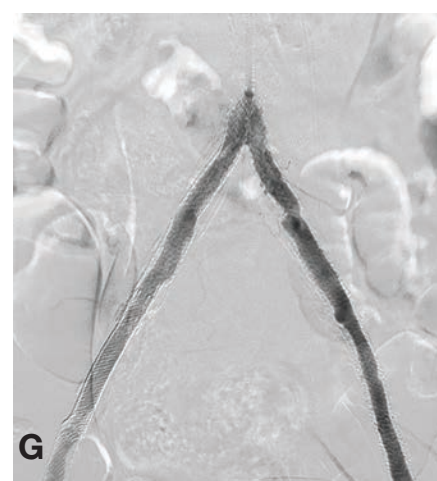
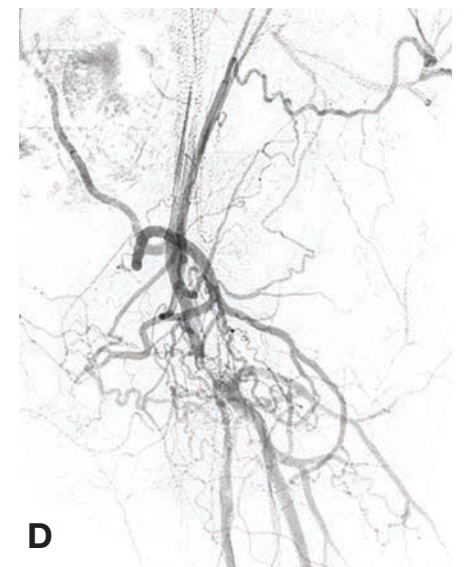
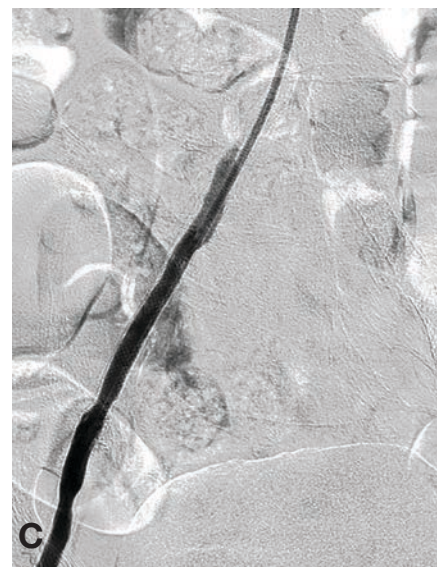
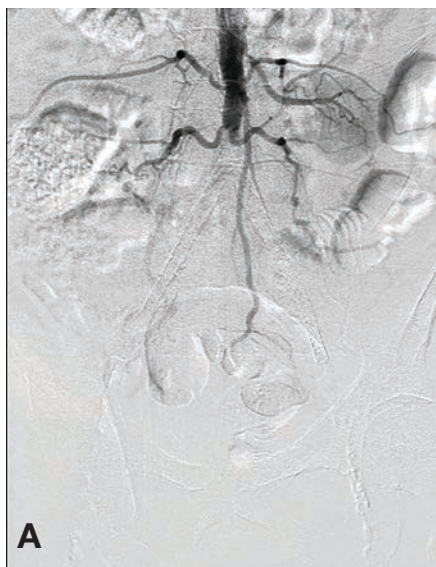


Figure 1A-G. Case #1. A) Radial angiogram reveals total occlusion of the aorta. B) Angiogram after recanalization of both iliac arteries. Note iliac artery restenosis. C) Iliac angiogram after dilation of the iliac stent restenosis. D) Left femoral angiogram revealing common femoral stenosis at bifurcation. E) Angiogram immediately post atherectomy. F) Angiogram after focused balloon angioplasty and drug-coated balloon angioplasty. G) Distal abdominal angiogram post procedure.

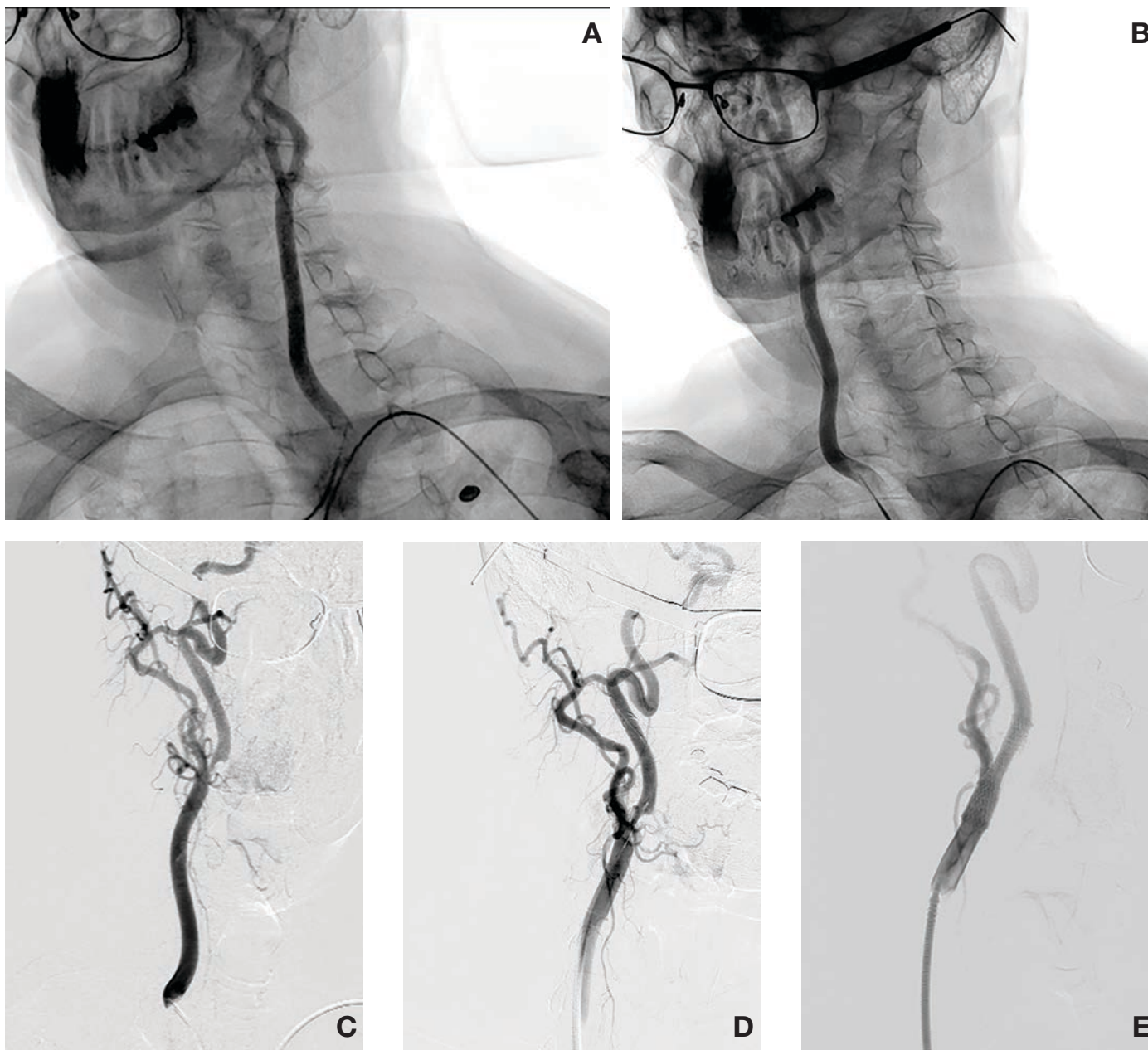


Figure 2A-E. Case #2. A) Left carotid angiogram. B) Digital carotid angiogram pre-procedure. C) Carotid angiogram revealing severe internal carotid stenosis. D) Magnified right carotid angiogram. E) Right carotid angiogram after stenting.

The classic access to approach peripheral arterial disease has been via the femoral route. The obvious dilemma in patients who present with peripheral vascular disease, as well as carotid disease, is the tendency of these patients to have diffuse disease with an inherent risk of vascular bleeding.

critical limb ischemia. We did not have the Terumo sheath available at this time, so we used a radial approach and a Jacky catheter (Terumo) to visualize the common femoral arteries, allowing femoral access. Using kissing balloon technique, balloon-expandable stents were deployed in both common iliac arteries. Although the flow in the right femoral system was adequate, the left side still had significant disease at the common femoral and superficial femoral artery (SFA) deep femoral trifurcation. The patient

presented 7 months later with left leg claudication. The right radial was accessed, and we passed the 6 French (Fr) Terumo Designation Slender (119 cm). Utilizing the CXI (Cook Medical) support catheter and the Terumo soft guidewire (350 cm), we crossed into the SFA. We exchanged for a Cougar .014-inch wire (Medtronic) and performed multiple cuts with HawkOne atherectomy (Medtronic). We then utilized a 7 mm x 4 mm AngioSculpt scoring balloon (Spectranetics) and the In.Pact Admiral

7 mm x 40 mm drug-coated balloon (Medtronic). We decided not to approach the deep femoral artery because the common femoral and SFA vessels had been treated with an excellent result. The patient's claudication improved dramatically.

Case #2

A 72-year-old patient presented with symptomatic right carotid artery stenosis. Although he had hyperlipidemia and hypertension, there was no history of smoking or family history of heart disease. We approached via the left radial artery, as is our usual approach with a contralateral stenosis. With a Simmons Sidewinder (Terumo) catheter, we were able to perform diagnostic right and left carotid angiography. A significant right internal carotid stenosis was seen, we passed the .035 mm TAD wire (350 cm) (Abbott Vascular), and then over the TAD wire, we passed the Terumo Destination Slender 6 Fr (119 cm). After deploying the Emboshield (Abbott Vascular), predilation was performed with a Viatrac 4.0 mm balloon (Abbott Vascular), and an 8/6 mm x 30 mm Xact stent (Abbott Vascular) was deployed and post-dilated with an excellent result. Interestingly, the

patient had a baseline blood pressure of 132/78 mmHg. Following post dilation, his blood pressure did drop to 85/51 mmHg. He responded to a bolus of neosynephrine, but required an infusion of neosynephrine to maintain a blood pressure over 90 mmHg systolic. This was continued for approximately 14 hours and with a blood pressure of 130/70 mmHg, he was discharged the next morning with no neurologic symptoms.

Case #3

A 75-year-old former smoker had previously undergone 3 separate femoral-popliteal bypass procedures, all resulting in failure of the graft with subsequent severe claudication in the left leg. Two years ago, after his last occlusion of the graft, the treating vascular surgeon told him he needed to have an amputation of the leg. We successfully recanalized the graft at that time using the CrossLock (Radius Medical) centering balloon and standard techniques via the right groin. The patient now had an occlusion of the left fem-pop graft, documented as re-occluded for at least the last 8 months. He had severe iliac/femoral disease on the right side, making contralateral access quite difficult without dissecting the iliac artery and compromising his already severely diseased iliofemoral system on the right side. Since this bypass graft has been compromised and most likely had thrombus present, it looked likely that the patient needed a prolonged infusion of tPA. With the inability to go via the contralateral approach and the antegrade approach difficult because the graft occlusion was too close to the common femoral artery, we decided to go via the right brachial approach. The 119 cm Terumo guide would very likely not allow us to get further down into the vessel in the radial approach and the longer sheath would preclude the use of the centering CrossLock device, since it is only 150 cm. If we used the Penumbra device, we would also run out of room. We accessed the right brachial artery and placed the 119 cm Terumo Designation Slender 6 Fr. After heparinizing the patient and passing a Miracle Bros .014-inch wire (Abbott Vascular), we passed the CrossLock. Using the centering of the CrossLock, we very quickly subtended the 100% occlusion, also utilizing a FineCross catheter (Abbott Vascular). We used the Cragg-McNamara catheter (Medtronic) and infused 8 mg of tPA over several minutes. We passed the Indigo System CAT5 aspiration catheter (Penumbra) and performed suction through the mid portion of the bypass graft, being somewhat limited by the length from reaching the popliteal or inferior popliteal territory. Balloon inflation with 3.0 mm to 5.0 mm Bard catheters was performed and arteriography confirmed excellent, even pedal and digital flow following the procedure. The procedure took 62 minutes and the patient was discharged from the outpatient center 2 hours later. He remains on clopidogrel and Xarelto (rivaroxaban).

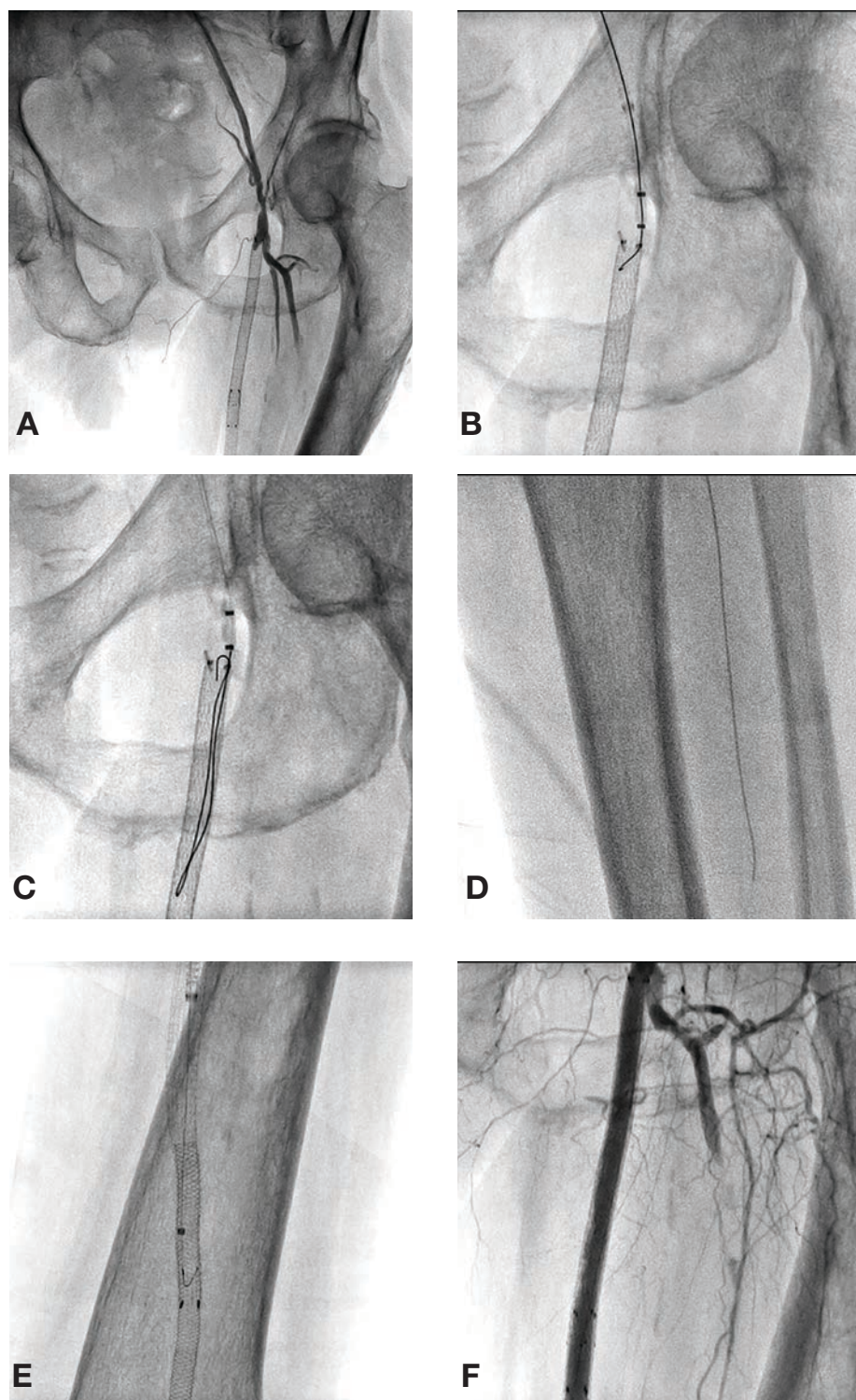


Figure 3A-F. Case #3. A) Left femoral angiogram via right brachial approach. The femoral popliteal graft is 100% occluded at its origin. B) The Terumo Destination sheath easily allows placement of the CrossLock catheter at the original of the chronic total occlusion. C) Still picture showing passage of the .014-inch wire through the Destination sheath and CrossLock. D) The angled Glide catheter is now present in the infra-popliteal vessel. E) The Terumo sheath with placement of the Penumbra catheter to remove thrombus. F) The proximal view angiogram after successful thrombolysis inside the femoral popliteal graft. The thrombus is seen deep in the femoral artery. This did not result in any sequelae. After recanalization, there was TIMI-3 flow in the graft.

Conclusion

Many companies do not understand the necessity of creating sheaths that are hydrophilic and not necessarily just low profile. Low-profile catheters that are not hydrophilic do cause some friction, particularly in the brachial territory, which causes a cascade of spasm. In some cases, even with sedation, this cascade results in severe pain and a cycle of spasm that often makes it impossible to continue with the radial approach. Not only has this not been the case with the Terumo sheaths, but

we have had patients who have previously undergone the groin approach in peripheral arterial disease intervention thank us for the procedure, relating that it was less painful. ■

Reference

1. Wong G, Lahsaei S, Aoun J, et al. Management of common femoral artery occlusive disease: A review of endovascular treatment strategies and outcomes. *Catheter Cardiovasc Interv.* 2019 Feb 15;93(3):514-521. doi: 10.1002/ccd.27983.

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