

Remote Endarterectomy Update

An endovascular alternative to bypass?

BY JOHN D. MARTIN, MD

Treating the superficial femoral artery (SFA) is still one of the most highly debated topics among vascular specialists. The SFA has unique characteristics that require special consideration when deciding on treatment options. Arterial disease in the SFA is generally more occlusive than stenotic and, with few collateral vessels, long-segment diffuse disease is not uncommon. In addition, the mechanical forces of the SFA, in particular near the abductor canal, exert significant stresses and result in challenges for endovascular devices.

Bypass surgery has long been accepted as the standard of care of patients who have long-segment SFA disease, but it also carries the highest risk of complications, including wound infection, myocardial infarction, early graft failure, acute leg ischemia, operative mortality, and the need for surgical revision. Where ePTFE is the graft of choice, there is even greater risk of complications associated with graft occlusion.

Remote endarterectomy (RE), a hybrid of minimally invasive open and endovascular techniques, offers a new, less-invasive treatment option for long-segment disease. This procedure achieves extensive debulking of the entire involved segment of the artery, re-establishing flow with a minimal incision. This hybrid approach offers a low morbidity alternative, shorter length of hospital stay, and allows preservation of venous conduits for future intervention if needed. Recent US and

European clinical study results are encouraging, with primary patency rates of 60% to 70% at 24 months, demonstrating results comparable to above-the-knee femoropopliteal bypass surgery.^{1,2}



Figure 1. An angiogram of the reconstitution point.

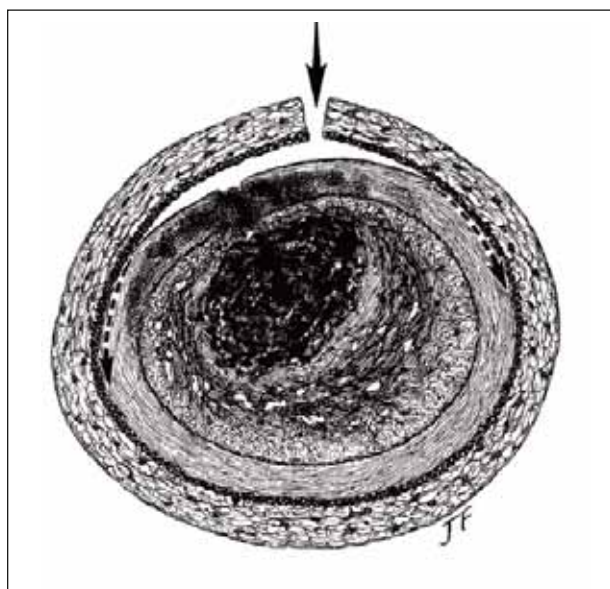


Figure 2. The plane dissection.

TREATMENT OPTIONS

Numerous percutaneous treatment options are available for the treatment of the SFA, including balloon angioplasty, stents, laser-assisted angioplasty, and rotational atherectomy. Many of these techniques have been evaluated in clinical trials for lesions less than 10 cm long and have demonstrated reasonable results. However, these techniques have demonstrated disappointing long-term results when addressing long-segment SFA disease.³⁻⁸

As a result of poor endovascular outcomes, surgical bypass is the most common procedure performed for the treatment of long-segment SFA disease. A recent review by Klinkert et al⁴ of numerous studies assessing the patency results of bypasses demonstrated that patency at 2-years was 81% for venous conduits and 67% for PTFE grafts. At 5 years, patency decreased to 69% and 49% for veins and ePTFE, respectively. As noted by Jackson et al,⁹ the complications associated with restenosis or occlusion of prosthetic bypass grafts can be detrimental to the patient, resulting in acute limb ischemia, emergency revascularization, and in some cases, amputation.

REMOTE ENDARTERECTOMY

Remote endarterectomy is a hybrid of minimally invasive surgical and endovascular techniques that offers a safe and effective option for treatment of long-segment SFA disease with a single small incision in the groin. This minimally invasive procedure provides extensive debulking using specifically designed surgical instru-

mentation combined with standard endovascular equipment.

The RE procedure involves standard surgical exposure of the common femoral artery and proximal portion of the SFA. An arteriogram is then performed to identify the point of reconstitution, which is the endpoint for the RE (Figure 1). The patient is then heparinized and a longitudinal arteriotomy in the proximal SFA is performed. Flow to the leg is maintained during the procedure through the profunda femoris. This not only reduces ischemia time but also provides retrograde flow back up the SFA during endarterectomy, eliminating the risk of distal embolization. A dissection plane is then established, ideally, between the media and the smooth elastic lamina of the adventitia (Figure 2).

In the exposed SFA area, blunt dissection for approximately 3 cm to 4 cm is performed using standard endarterectomy instruments separating the core of plaque from the wall of the vessel. Once the plane is created proximally, the dissection is then continued under fluoroscopic guidance down the entire length of the obstruction with either a Martin Dissector (Vascular Architects, San Jose, CA) or an appropriately sized ring dissector.

Once the dissection has been completed to the endpoint identified on the arteriogram, the dissection device is removed and a MollRing Cutter (Vascular Architects) is passed over the atheromatous core along the same dissection plane to the same endpoint (Figure 3). The plaque is then remotely transected and the entire atheromatous core is removed. The atheromatous cores, which are typically >20-cm-long cores and range in weight from 4 g to 17 g, are removed through the small proximal incision in the SFA (Figure 4).

The final step of



Figure 3. The MollRing cutter transecting plaque during RE.



Figure 4. Excised atheroma core removed after RE (14 grams, 29 cm in length).

the procedure is to tack down the distal dissection flap where the transection occurred and provide a smooth transition zone to the popliteal artery.¹² This is completed using a variety of endovascular techniques, including passing a guidewire across the endpoint and performing balloon angioplasty and stent placement (Figure 5).

DISCUSSION

The introduction of new instrumentation has facilitated more efficient and effective performance of the procedure. Additionally, issues related to effective management of the distal endpoint have become less challenging with the advent of new stent technology and

design. Advances in antiplatelet therapy and understanding of the need for diligent, ongoing surveillance of the patient and vessel have led to improved durability and potential for reintervention when required.

Recent clinical study has involved performing RE in combination with placement of a distal aSpire Covered Stent (Vascular Architects). This stent consists of a crush-resistant nitinol framework shaped into a spiral design. The entire framework is covered in ePTFE eliminating metal in contact with the vessel wall, in contrast to bare-metal designs. This helical design offers a combination of exceptional radial strength and flexibility capable of withstanding torsional stresses at the knee

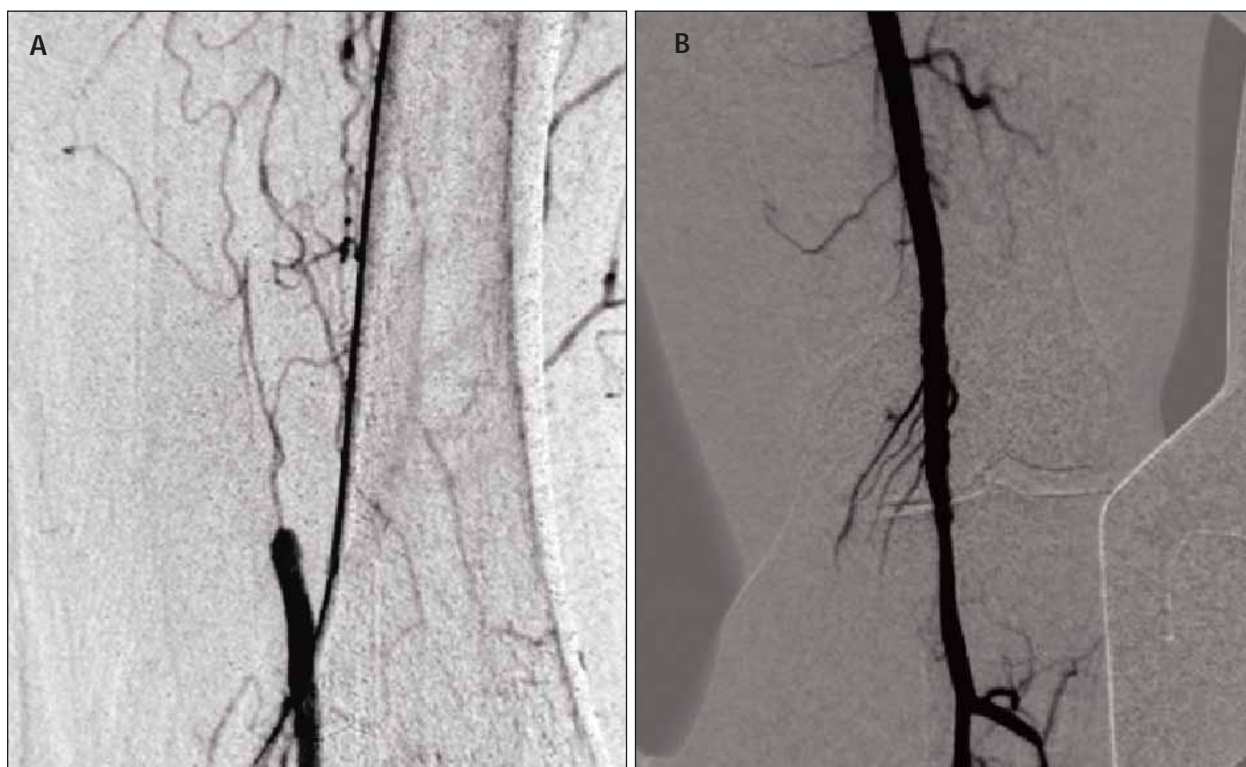


Figure 5. Pre- and post-RE images.

joint. The stent delivery mechanism allows evaluation of stent placement and positioning prior to final stent deployment. If adjustments are required, the stent may be "wrapped down" and repositioned before final deployment. This allows accurate placement within the vessel without compromising collateral flow.

Rosenthal et al recently reported medium-term results of RE and distal aSpire stenting.¹ Between October 2000 and July 2003, 40 patients underwent RE of the distal SFA with distal aSpire stenting. All subjects had documented SFA occlusions >13 cm in length (TASC C) and were considered candidates for a revascularization procedure. RE was selected when the proximal popliteal artery was >4 mm in diameter. The indications for intervention were assessed using the suggested standards for reports dealing with lower-extremity ischemia by Rutherford et al.¹³ Indications included claudication in 36 patients and limb salvage in four patients. The average length of lesion or occlusion was 26.2 cm.

RE was performed as described previously and the distal outflow track was tacked utilizing the aSpire Covered Stent. All patients underwent clinical evaluation after the procedure, and evaluation for restenosis and calculation for primary and assisted primary patency rates.

The primary cumulative patency rate by means of life table analysis was 68.6+13.5% (SE) at 18 months (mean, 13.2 months; range, 1-31 months) (Figure 6). Repeat radiologic intervention was necessary in six patients (four PTA, two stent angioplasty), for a primary assisted patency rate of 88.5+8.5% at 15 months. The locations of the stenoses after RE included two over the course of the SFA, two at the adductor canal, and two at the distal stent. One above-the-knee amputation was performed during follow-up in an elderly diabetic patient who had gangrene of the foot. There were no deaths, and one wound complication occurred. The mean hospital length of stay was 2.1+0.5 days. Ankle-brachial indices rose from 0.58 (+0.14) preoperatively to 0.95 (+0.04) postoperatively.

These data have subsequently been verified with our personal experience of more than 100 SFA REs. Each of these patients were considered femoropopliteal bypass candidates. In our series, 40% underwent surgery for limb-threatening ischemia. Perioperative morbidity was remarkably low and limb salvage occurred in all but two patients. Primary patency was 70% at 30 months by life table analysis and, more importantly, of the 19 late failures we have treated, only one had to go emergently to the operating room for intervention. This is distinctly different than what has been observed with standard

ePTFE bypass as reported by Jackson et al.⁹ Acute limb-threatening ischemia is common with failed ePTFE bypass patients.

Optimal case selection remains a challenge due to the unpredictability of the ease of dissection and core extraction in those patients with heavily calcified arteries. Technical issues precluded successful endarterectomy in 10% of our patients in whom we intend to perform RE. Early in our experience, we avoided RE in these heavily calcified patients, but now with the new tools and techniques, and encouraged by our long-term success, we are aggressive with these patients as well.

The benefits associated with RE include use of a single, short groin incision, making the operation less invasive while still allowing common femoral and profunda femoris endarterectomy, if required. The associated reduction in surgical trauma facilitates more rapid patient recovery, reduced postoperative leg edema, and earlier hospital discharge. Avoiding the use of ePTFE bypass reduces infection risk and the acute ischemia that often accompanies thrombosis of these types of bypasses. Finally, preservation of venous conduits,

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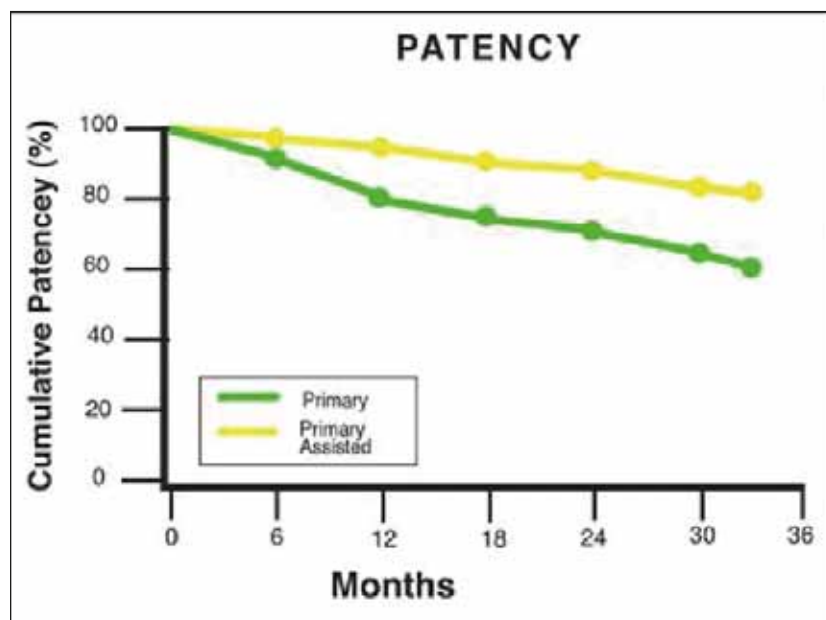


Figure 6. Cumulative RE patency.

specifically the saphenous vein, makes subsequent use in the cardiovascular or peripheral circulation possible.

RE is our primary strategy for long-segment infrainguinal disease. Restenosis due to intimal hyperplasia and inability to complete dissection of the desired endpoint (due to heavy calcification) remain the limiting factors of the procedure. However, experience and new instrumentation has greatly expanded our application and ability to successfully treat complex cases. Managing fractured cores, calcified vessels, small perforations, and difficult-to-manage endpoints are no longer the stumbling blocks they once were. The effort to become proficient with the new tools and techniques has been well worth the investment in our practice.

Vigilant attention to surveillance is critical for optimal results because restenosis continues to plague the SFA even after complete debulking. Secondary procedures with percutaneous angioplasty and stenting extend the patency of the original procedure in many who exhibit focal restenosis. Fortunately for most patients, the failure sites are often focal and even when a reocclusion occurs, the patients do not fall all the way back to their pretreatment state. The remainder of the SFA remains open with collaterals, and many if not most can avoid additional interventions, even with restenosis. Van der Heijden et al¹⁰ previously reported that nearly half of failed endarterectomies remained asymptomatic. Given this observation, the decision for repeat intervention can be made on the basis of clinical symptoms. As stated previously, RE leaves the saphenous vein intact in the

event more extensive revascularization is needed once minimally invasive options have been exhausted.^{12,13}

CONCLUSION

The treatment of femoropopliteal occlusive disease with RE continues to evolve. Growing experience has demonstrated that RE is a safe and durable procedure that enables the preservation of SFA collateral vessels. With long-term patency rates rivaling to those of above-the-knee femoropopliteal bypass grafting, RE may prove to be a reasonable endovascular alternative to bypass surgery for the treatment of long-segment SFA disease. Further developments in RE are focused on drug-eluting stents, pharmaceuti-

cal innovations, and advances in instrumentation for the procedure. ■

John D. Martin, MD, is from Cardiology Associates, PC, and is Director, Vascular Institute Anne Arundel Medical Center, Annapolis, Maryland. He has disclosed that he has a patent or part ownership in the product mentioned herein and is an owner or shareholder in the company. Dr. Martin may be reached at (410) 571-8430; jmartin@cardiologassociatespc.com.

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