

Relative No-Stent Zones in the Femoropopliteal Arteries

Technological considerations for the infrainguinal arterial bed from one cardiology-based team.

**BY GARY M. ANSEL, MD, FACC; CHARLES F. BOTTI JR, MD, FACC;
AND MITCHELL J. SILVER, DO, FACC**

As endovascular therapy has revolutionized the treatment of lower extremity peripheral arterial disease (PAD) over the past decade, no single therapy has emerged as the clear gold standard. Acceptance of endovascular therapy has been quick among practitioners, but there remains question about which technology is best and most durable in any particular vascular bed. As techniques and technology have evolved, most vascular specialists have recognized there is no single best treatment option that can be generalized to all patient populations, and many patient and lesion variables play a role in choosing any particular technology.

For more than a decade, there has been a paucity of outcomes data, especially in the infrainguinal arterial bed. Only recently has any technology been proven superior to balloon angioplasty in the superficial femoral artery (SFA). Stents and stent grafts have emerged as two of the technologies that may promote more durable patency, especially in the SFA. These nickel titanium (nitinol) alloy stents and polytetrafluoroethylene (PTFE)-covered stent grafts have allowed for the treatment of even complex obstructive lesions in the lower extremity arteries. Newer stent designs are providing increased durability, flexibility, and radial force.

Several small, single-center and multicenter reports have demonstrated the efficacy of nitinol stents in the

“As techniques and technology have evolved, most vascular specialists have recognized there is no single best treatment option that can be generalized to all patient populations . . . ”

femoropopliteal arteries.¹ More recently, a prospective, randomized trial comparing balloon angioplasty to a nitinol stent has been published, showing improved primary patency as well as increased absolute claudication distance at 1 year.² The RESILIENT trial results have been presented and have also demonstrated the superiority of nitinol stents over balloon angioplasty, leading to the first US Food and Drug Administration approval of a nitinol tube-based stent for use in the SFA. Stent grafts have also demonstrated superiority to balloon angioplasty in a multicenter study.³ A randomized, multicenter study (VIBRANT) comparing nitinol stents and stent grafts in long lesions has recently been completed; these results will be released in the latter part of 2009.

Although stents have been shown to be efficacious, multicenter data from the first evaluation of a drug-eluting nitinol stent platform compared to a bare-metal stent noted an occurrence of stent fracture.⁴ In this mul-

ticenter, prospective, randomized trial, 27% of the stents demonstrated evidence of stent fracture. Fractures occurred in both the bare-metal and drug-eluting groups. In a follow-up study of shorter lesions with less stent overlap, only 17% demonstrated evidence of a stent fracture.⁵ Although neither of these two early studies noted an association of stent fracture with restenosis, one stent fracture did appear to lead to pseudoaneurysm formation. Not all nitinol stent platforms appear to have the same fracture rates. Schillinger's study reported a low fracture rate of < 2%.² Although nitinol stent patency is now showing improved results, restenosis continues to be problematic. Restenosis rates in long lesions (> 15 cm) have not yet been well studied, but one would expect the rate to be higher than that seen in currently completed trials looking at shorter lesion lengths.

Restenosis complicates the decision to use a permanent stent prosthesis. The treatment paradigm for in-stent restenosis continues to be elusive. Plain old balloon angioplasty, cutting-balloon angioplasty, and cryoplasty have not demonstrated much benefit in limited datasets.^{6,7} Until this problem is solved, the use of stents will continue to be debated.

Multiple technologies have been developed to try to improve upon the results of balloon angioplasty without the need for an indwelling prosthetic device (ie, stents). Atherectomy devices of several types have been designed to vaporize plaque (laser), grind down densely calcified lesions (rotating atherectomy), or remove the atheroma (directional atherectomy) and possibly even the calcification that may exist. Different balloon technologies have explored the application of temperature, from heating to freezing, in an effort to affect the programmed reaction to barotrauma, which may lead to intimal hyperplasia and restenosis.^{8,9}

More recently, even balloon technology has improved. Long balloons that allow for more uniform dilation of longer segments of disease are now available. Limited randomized datasets have recently shown drug-eluting balloons to decrease restenosis rates compared to untreated balloons with > 1-year follow-up.¹⁰ These nonstent technologies are especially attractive in the popliteal artery, which is an important source of collaterals. The geniculate collaterals around the knee provide an important source of circulation to the lower leg when atherosclerosis more extensively involves both the SFA and popliteal arteries.

Most of these new, nonstent technologies have patient registry data evaluating their use. Although these data often show high technical success and acute efficacy, only drug-eluting balloons have randomized,

multicenter trials demonstrating superiority to standard balloon angioplasty. When making the case for these new technologies, many investigators focus on the difficult issue of in-stent restenosis. However, the issues of perforation, macro/microembolization, and pseudoaneurysm formation also need to be considered when using these more aggressive debulking and cutting/scoring technologies.¹¹⁻¹³

The infrainguinal vascular bed is a unique area of the body. There are two areas of joint-related flexibility (the common femoral artery and the popliteal artery), frequent and repetitive arterial compression and stretching, and muscular compartments that apply external force; the resultant disease process is often associated with significant thrombus and calcification.

This review discusses how our team of experienced cardiology-based endovascular specialists views the current state of infrainguinal endovascular technology and when nonstent technologies, such as atherectomy and new balloon technologies, seem to play a role in nonstent zones even before comparative long-term data may exist for the infrainguinal arterial bed.

SYMPTOMATIC CONSIDERATIONS

Claudication Versus Critical Limb Ischemia

Similar to lesion and anatomical considerations, symptomatology may also play a role in deciding which technology to use. Claudication treatment requires patency for as long as possible to decrease the potential for the return of symptoms. However, restenosis is less of an issue for the patient with critical limb ischemia, in whom temporary restoration of flow appears to offer amputation-free survival that can challenge the results of surgical bypass. Restenosis after a nonstent therapy may theoretically offer an easier path to retreatment at a later date than would in-stent intimal hyperplasia. The challenge is to use the most efficacious and economically attractive technology available.

ANATOMICAL CONSIDERATIONS

Common Femoral Artery

Anatomically, if we start at the inguinal ligament, we first encounter the common femoral artery. This bifurcation region is important to surgeons and endovascular specialists alike. The SFA originates in the femoral triangle as a direct continuation of the common femoral artery. The profunda femoral artery typically arises from the posterolateral side of the common femoral artery fairly high in the femoral triangle. The profunda femoral artery is the chief supply to the muscles of the thigh, although the common femoral artery itself gives off occasional small muscular branches. The femoral triangle is the



Figure 1. Angiogram showing severe right common iliac stenosis (A). Repeat angiography after directional atherectomy (B) and adjunctive balloon angioplasty (C).



Figure 2. Angiogram showing nitinol stent impingement of the profunda femoral artery.

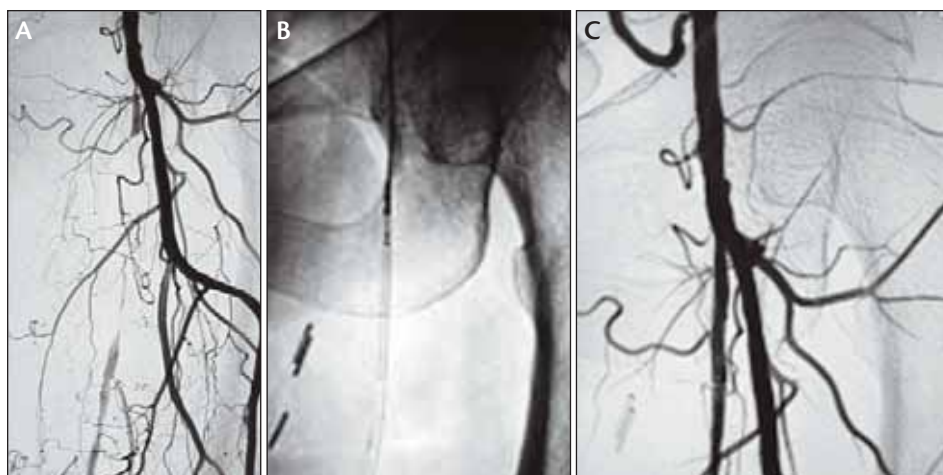


Figure 3. Angiogram showing severe stenosis of the left SFA ostium and proximal vessel (A). Radiograph of directional atherectomy device (B). Final angiogram after directional atherectomy (C).

large diameter, the common femoral vessel would appear to be a reasonable area to attempt debulking and/or angioplasty rather than stent therapy. Thus, this is the first area in which atherectomy (often requiring adjunctive balloon angioplasty due to larger vessel diameter) or advanced balloon technologies may decrease the need for stents (Figure 1).

junction where various surgical procedures, such as aortobifemoral, femorofemoral, axillofemoral, and femoropopliteal bypasses, will be anastomosed. Leaving this site clear for a potential bypass appears to be reasonable; however, the scarring that is associated with surgical arteriotomy may also make future percutaneous access problematic and cannot be discussed as a no-risk option.

Depending on the clinical situation, endovascular intervention at the level of the common femoral artery may be justified if attempted with techniques that could theoretically decrease the need for stenting and not complicate the potential for future surgical repair. The plaque in the common femoral artery area commonly arises from the posterior wall and is associated with significant calcification (coral reef calcification). With its relatively

Ostial SFA

The commonly found vascular angles and vessel size at the bifurcating ostia of the SFA/profunda femoral artery can be problematic to treat effectively. The ostia of both of these branch vessels are often angulated, and placing a stent to treat a diseased ostium will often not cover the entire vessel circumference or lead to compromise of the adjacent vessel (Figure 2). Our anecdotal experience also finds that stents placed near or at the ostium have increased rates of restenosis. Further, the plaque in this area is often associated with significant plaque burden in the common femoral artery itself, making it difficult to land a stent into a nondiseased vessel segment.

Although typically successful (Figure 3), debulking of this area may be problematic in some instances due to

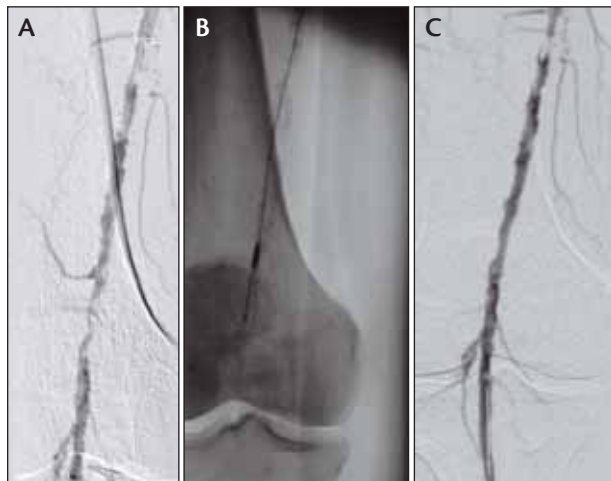


Figure 4. Angiogram showing severe heavily calcified stenosis of the popliteal artery (A). Radiograph of the rotating atherectomy device (B). Final angiogram after stand-alone atherectomy (C).

the saddle of vessel that lies at the SFA/profunda bifurcation. If not directed away from this crotch, any atherectomy device may shear tissue at this level with the potential for perforation. Directional atherectomy may have an advantage in this type of situation because the direction of cutting can usually be controlled. Cutting or scoring types of balloon angioplasty can also be effective here.

Popliteal Artery

The mid- to distal popliteal artery is the next area for which there are little stent data, and it may be best treated with nonstent technology. Anecdotally, we

believe that standard balloon angioplasty in this often-calcified vessel location frequently leads to a flow-limiting dissection. Dissections, especially those that limit flow, appear to be less frequent when alternative therapies are applied to this vascular bed. The rotational atherectomy devices appear to be well suited for treating eccentric calcified lesions in this vascular territory. The new rotational atherectomy devices may even lead to a favorable stand-alone result when used in vessels of this diameter (Figure 4).

Femoropopliteal Bypass

Incidences of femoropopliteal-bypass anastomotic restenosis are very difficult lesions to address. Most vein graft anastomotic stenoses peak at 4 to 12 months. Repeat surgery, although effective, is associated with intraoperative complications, which may reach up to 11% of cases.¹⁴ In limited data, stenting of femoropopliteal bypass restenosis appears to be associated with a patency rate of < 40% at 1 year.¹⁵ However, Cotroneo et al demonstrated reasonable efficacy for infragenicular bypass.¹⁶ Our anecdotal experience is that stenting of above-the-knee bypasses is also associated with increased incidence of complex and potentially catastrophic stent fracture (Figure 5). Gonsalves et al studied 87 failing venous bypasses.¹⁷ Success with percutaneous transluminal angioplasty was best predicted by variables that include short lesions (< 2 cm), vein caliber > 3.5 mm, and restenosis occurring > 3 months from index operation. Late reintervention occurred in only 10% in this optimal group.

We have found these lesions to be very fibrotic, and we frequently address venous bypass anastomotic restenosis



Figure 5. Radiograph showing complex fracture of a nitinol stent placed into a failing femoropopliteal bypass graft.



Figure 6. Angiogram showing a severe distal anastomotic stenosis of a prosthetic femoropopliteal bypass (A). Repeat angiography demonstrating a large perforation after directional atherectomy (B).

(Courtesy of Timothy Sullivan, MD.)

with cutting/scoring balloon angioplasty or atherectomy (venous only) with excellent acute results. Cutting/scoring balloons seem to be a reasonable technical choice to treat such lesions by providing a symmetrical and controlled rupture of these hyperplastic lesions, apparently resulting in lesser degree of recoil. Several investigators have reported trends of superiority of cutting-balloon angioplasty for failing venous bypasses. However, larger series would be required for a definitive answer to this question.¹⁸⁻²⁰

One single-center series of cutting-balloon angioplasty showed similar patency to surgery.²¹ Although present results in the literature do not allow for definitive conclusion, it appears that cutting-balloon angioplasty is a useful method for treating vein graft stenosis. However, atherectomy of PTFE anastomotic stenosis and even theoretically cutting/scoring balloon-type angioplasty may cut the suture line and could lead to pseudoaneurysm formation or dehiscence of the graft (Figure 6). Other nonstent technologies—or, in carefully selected patients, stent grafts—appear to be reasonable options, with repeat bypass being reserved for endovascular failure. One constant among all of the literature is the continued need for surveillance to treat recurrent stenosis formation.

SUMMARY

Although there should always be a demand for safety as well as short- and longer-term efficacy data for any endovascular technology, patient-driven clinical situations may exist and justify select use of certain technologies pending data development. This appears to be especially true in the infrainguinal vascular bed, where these procedures can be applied with minimal invasiveness. Both atherectomy-type devices and advanced balloon technologies have gained US Food and Drug Administration approval for use before even minimal comparative patency data have been developed. Anecdotally, in our group's experience, we believe that these technologies may have application in the common femoral artery, ostial SFA/profunda arteries, mid- to distal popliteal arteries, and anastomotic bypass stenosis. We do, however, believe that continued study of these technologies is needed, and we support the formation of a national database for outcomes data, especially for niche applications in which any single-center experience will be limited. ■

Gary M. Ansel, MD, FACC, is Director of the Critical Limb Care Center at Riverside Methodist Hospital in Columbus, Ohio. No specific manufacturers are mentioned in this article; however, Dr. Ansel has disclosed that he has an affilia-

tion with or financial interest in several companies that manufacture products that are used in lower extremity interventions. Dr. Ansel may be reached at (614) 262-6772; gansel@mocvc.com.

Charles F. Botti Jr, MD, FACC, is with MidOhio Cardiology and Vascular Consultants at Midwest Research Foundation, Riverside Methodist Hospital in Columbus, Ohio. He has disclosed that he holds no financial interest in any product or manufacturer pertaining to this article. Dr. Botti may be reached at (614) 262-6772.

Mitchell J. Silver, DO, FACC, is with MidOhio Cardiology and Vascular Consultants at Midwest Research Foundation, Riverside Methodist Hospital in Columbus, Ohio. He has disclosed that he holds no financial interest in any product or manufacturer pertaining to this article. Dr. Silver may be reached at (614) 262-6772.

1. Ansel GM, Silver MJ, Rocha-Singh K, et al. Functional and clinical outcomes of nitinol stenting with and without abciximab for complex superficial femoral artery disease: a randomized trial. *Cathet Cardiovasc Interv.* 2006;67:288-297.
2. Schillinger M, Sabeti S, Loewe C, et al. Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. *N Engl J Med.* 2006;354:1879-1888.
3. Saxon RR, Dake MD, Volgelzang RL, et al. Randomized, multicenter study comparing expanded polytetrafluoroethylene-covered endoprosthesis placement with percutaneous transluminal angioplasty in the treatment of superficial femoral artery occlusive disease. *J Vasc Interv Radiol.* 2008;19:823-832.
4. Duda SH, Pusich B, Richter G, et al. Sirolimus-eluting stents for the treatment of obstructive superficial femoral artery disease: 6-month results. *Circulation.* 2002;106:1505-1509.
5. Duda SH, Bosiers M, Lammer J, et al. Drug-eluting and bare nitinol stents for the treatment of atherosclerotic lesions in the superficial femoral artery: long-term results from the SIROCCO trial. *J Endovasc Ther.* 2006;13:70-110.
6. Karthik S, Tuite DJ, Nicholson AA, et al. Cryoplasty for arterial restenosis. *Eur J Vasc Endovasc Surg.* 2007;33:40-43.
7. Dick P, Sabeti S, Mlekusch W, et al. Conventional balloon angioplasty versus peripheral cutting balloon angioplasty for treatment of femoropopliteal artery in-stent restenosis. *Radiology.* 2008;248:297-302.
8. Dion YM, Dionne G. Hot-tip laser angioplasty for peripheral vascular disease: clinical experience with 18 patients. *Can J Surg.* 1990;33:400-406.
9. Laird J, Jaff MR, Biamino G, et al. Cryoplasty for the treatment of femoropopliteal arterial disease: results of a prospective, multicenter registry. *J Vasc Interv Radiol.* 2005;16:1067-1073.
10. Werk M, Langner S, Reinkensmeier B, et al. Inhibition of restenosis in femoropopliteal arteries: paclitaxel-coated versus uncoated balloon: femoral paclitaxel randomized pilot trial. *Circulation.* 2008;118:1358-1365.
11. Nikam SD, Morgan JH, Zakhary EM, et al. Native superficial femoral artery peripheral atherectomy site pseudoaneurysm: a case report. *J Vasc Surg.* 2007;46:565-568.
12. Penugonda N, Duncan K, Schreiber T. Popliteal artery pseudoaneurysm following FoxHollow atherectomy: a rare complication. *J Invas Cardiol.* 2008;20:477-478.
13. Suri R, Wholey MH, Postoak D, et al. Distal embolic protection during femoropopliteal atherectomy. *Cathet Cardiovasc Interv.* 2006;67:417-422.
14. Mills JL, Fujitani RM, Taylor SM. The characteristics and anatomic distribution of lesions that cause reversed vein graft failure: a five-year prospective study. *J Vasc Surg.* 1993;17:195-204.
15. Siskin GP, Stainken BF, Mandell VS, et al. Management of failing prosthetic bypass grafts with metallic stent placement. *Cardiovasc Interv Radiol.* 1999;22:375-380.
16. Cotroneo AR, Iezzi R, Quinto F, et al. Assisted patency with primary stent placement in distal anastomotic stenoses of lower limb bypass grafts. *J Vasc Interv Radiol.* 2007;18:25-30.
17. Gonsalves C, Bandyk DF, Avino AJ, et al. Duplex features of vein graft stenosis and the success of percutaneous transluminal angioplasty. *J Endovasc Surg.* 1999;6:66-72.
18. Engelke C, Morgan RA, Belli AM. Cutting balloon percutaneous transluminal angioplasty for salvage of lower limb arterial bypass grafts: feasibility. *Radiology.* 2002;223:106-114.
19. Kasirajan K, Schneider PA. Early outcome of cutting balloon angioplasty of infrainguinal vein graft stenosis. *J Vasc Surg.* 2004;39:702-708.
20. Vikram R, Ross RA, Bhat R, et al. Cutting balloon angioplasty versus standard balloon angioplasty for failing infra-inguinal vein grafts: comparative study of short and mid-term primary patency rates. *Interv Radiol.* 2007;30:607-610.
21. Schneier PA, Caps MT, Nelken N. Infrainguinal vein graft stenosis: cutting balloon angioplasty as the first-line treatment of choice. *J Vasc Surg.* 2008;47:960-966.