The Role of Atherectomy in the Femoropopliteal Artery

With the growing number of tools for femoropopliteal artery intervention, what is the role of atherectomy in the endovascular treatment of femoropopliteal artery disease?

BY IVAN P. CASSERLY, MB, BCH

The femoropopliteal (FP) artery refers to the composite of the superficial femoral artery (SFA) and popliteal artery and measures approximately 50-cm long in adults. Atherosclerosis of this vessel is characterized by diffuse involvement, a propensity for superimposed calcification, a high incidence of progression to occlusion, and a large plaque burden (Figure 1).[1,2] These factors present a significant challenge for endovascular interventions in this artery.

Despite these challenges, there has been a dramatic increase in percutaneous revascularization procedures in the FP artery, rising from 69 to 184 per 100,000 Medicare beneficiaries in the period from 1996 to 2006 (Figure 2).[3] This represents approximately 55% of all lower extremity endovascular procedures, highlighting the frequency of involvement of this arterial segment in patients with peripheral artery disease. Interestingly, the rise in the overall number of FP endovascular procedures is paralleled by the increased use of atherectomy (ie, a term used to describe a group of technologies that allow either ablation or removal of plaque) (Figure 3). In 2006, atherectomy was used in 42% of all FP endovascular procedures,[3] and with the recent availability of additional atherectomy technologies, this number is likely to be significantly higher today.

The rapid adoption of atherectomy as a therapeutic strategy in FP intervention has been criticized by some. It is true that there are no comparative studies of atherectomy versus conventional therapy with balloon angioplasty and/or stenting with nitinol stents, and there are no data showing a decrease in long-term restenosis rates with atherectomy. However, in the clinical practice of endovascular specialists, what is indisputable is that atherectomy has allowed the successful treatment of an increasing spectrum of FP disease and has provided the means to revascularize an increasing proportion of patients with FP disease without placing stents, which have significant limitations in this location. This is clearly one of those areas in medicine where the science lags behind the art of clinical practice.

This paper summarizes the potential beneficial aspects of atherectomy and provides a perspective of the challenges that remain in applying this technology in the FP artery.

EXPANDING THE SPECTRUM OF TREATABLE DISEASE

Ostial Disease

Involvement of the ostium of the SFA by atherosclerosis increases the likelihood of plaque shift into the profunda femoral artery (PFA) using conventional balloon and stent therapies (Figure 4). This risk is increased in patients with an acute angulation between the origins of the PFA and the SFA. Because the PFA serves as the sole arterial supply to the lower extremity via collaterals to the distal SFA and popliteal arteries in the presence of an occlusion of the SFA, significant plaque shift is a serious complication. The ability to debulk the SFA ostium certainly reduces the risk of plaque shift and allows interventionists to approach the treatment of ostial SFA disease with greater confidence.

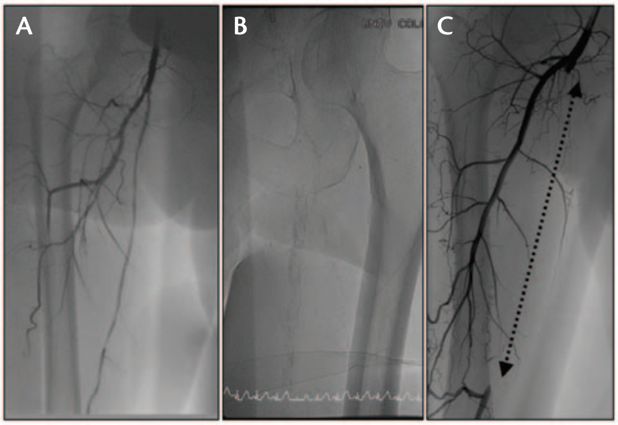

Figure 1. Typical pattern of atherosclerosis in the FP artery characterized by diffuse involvement (A), heavy calcification (B), and progression to complete occlusion (C).

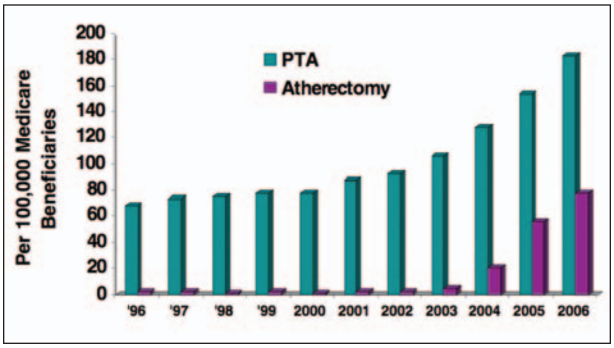

Figure 2. Frequency of endovascular procedures in the FP artery between 1996 and 2006 per 100,000 Medicare beneficiaries. Adapted from Goodney et al. J Vasc Surg (2009;50:54-60).[3]

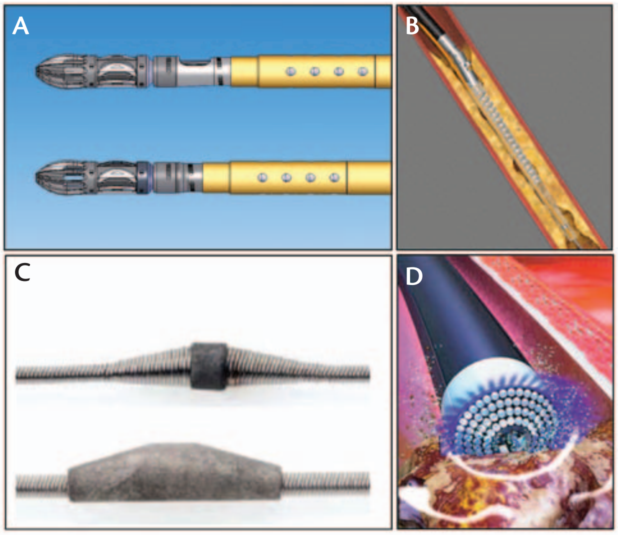

Figure 3. Tools currently available to perform atherectomy or plaque ablation: Jetstream® catheter (A), SilverHawk (B), Diamondback 360º (C), and Turbo Elite laser catheter (D).

Popliteal Disease

The popliteal artery crosses the knee joint and therefore is regarded as a site where stenting should be avoided if possible. Before the availability of atherectomy technologies, the unpredictability of a balloon-angioplasty-alone outcome resulted in some reluctance to approach such disease using endovascular techniques.

Calcified Plaque

Densely calcified plaque in the FP artery was previously a major limitation for the endovascular approach to revascularization. Balloon angioplasty of such plaque was often ineffective due to failure to achieve adequate balloon expansion. The use of higher balloon pressures in an attempt to achieve expansion often resulted in an increased risk of flow-limiting dissections due to trauma to the compliant noncalcified portion of the media. Significant deformity and incomplete expansion of stents at the sites of dense calcification was also a problem.

New atherectomy tools allow the treatment of calcified plaque with a high degree of success (Figure 5). The Diamondback 360º device (Cardiovascular Systems Inc., St. Paul, MN) was specifically designed to treat calcified disease and has proven very effective in clinical practice. The Jetstream® catheter (Pathway Medical Technologies,

Figure 4. Plaque shift into the profunda femoral artery after placement of a stent at the ostium of the superficial femoral artery.

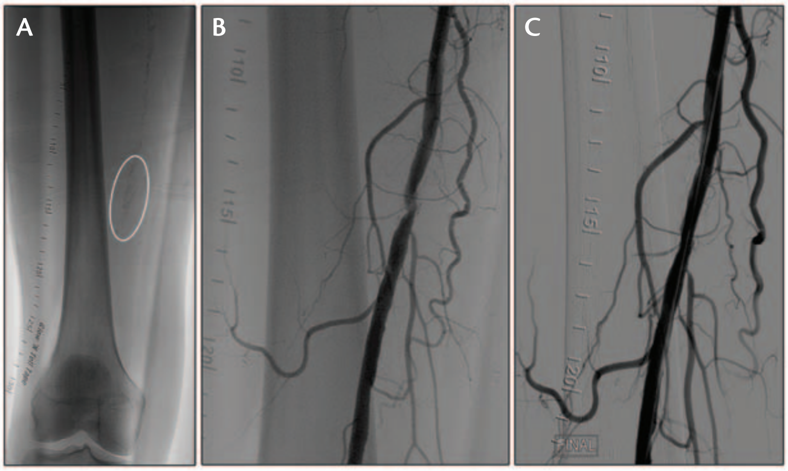

Figure 5. Treatment of calcified plaque. Fluoroscopic image showing severe calcification at the site of stenosis (circle) (A). Baseline angiogram (B). Angiogram after treatment with 1.5- and 2.25-mm Diamondback 360º catheters and low-pressure angioplasty showing stent-like result (C).

Inc., Kirkland, WA) has also demonstrated success in case reports of heavily calcified disease. The SilverHawk LS-C (RockHawk) (ev3 Inc., Plymouth, MN) has specific design changes in the geometry and the material of the cutting blade to aid the treatment of calcified lesions. The Turbo Elite laser ablation catheter (Spectranetics Corporation, Colorado Springs, CO) is also effective in the treatment of calcified disease. In summary, the availability of these tools has transformed the confidence with which heavily calcified disease can be approached with the expectation of a successful result.

Diffuse Disease

Using conventional balloon and stent therapy, diffuse involvement of the FP artery is problematic for a number of reasons. With balloon angioplasty, the risk of flow-limiting dissections increases with the length of disease. Stenting of diffuse disease often requires the placement of multiple overlapping stents with extension into the popliteal artery, which all increase the risk of stent fractures and in-stent restenosis.

Atherectomy tools typically produce a more stable vascular lumen, reducing the risk of flow-limiting dissections even when adjunctive PTA is applied, and decrease the need for the placement of stents (Figure 6). In practice, treatment of diffuse disease with the SilverHawk device is made more difficult by the need to empty the nosecone intermittently, necessitating repeated removal and re-introduction of the catheter, although recent modifications of the packing system of the nosecone has attenuated this problem. Because there is no mechanism for removal or aspiration of plaque, the use of the Diamondback 360º device as a stand-alone treatment for long diffuse disease raises some concern because of the potential burden of embolized microparticles to the distal circulation, particularly in patients with critical limb ischemia. The Pathway Jetstream® and Turbo Elite ablation catheter systems may have an advantage for the treatment of diffuse disease, but both require patient advancement of the respective catheters along the length of disease to achieve an optimal result.

LIMITATIONS OF STENTING IN THE FP ARTERY

The availability of self-expanding nitinol stents represented a major advancement in the endovascular treatment of FP disease. They allowed endovascular specialists to achieve a highly predictable acute angiographic result, are easy to use, and require relatively little time to deploy. To date, they are the only technology proven to reduce the rate of restenosis compared to angioplasty in the treatment of long disease in the SFA.[4]

However, there are significant limitations to stenting of the FP artery. There is clear evidence in the form of stent fractures that stents in the FP artery are subject to biomechanical forces that disrupt the integrity of the stent architecture to varying degrees.[5] The frequency of stent fracture has been related to the stent length, the use of overlapping stents, patient activity, and stent type.[6,7] Although still debated, there does appear to be a relationship between the presence of stent fractures and the rate of in-stent restenosis.[7] Further, there have been rare reports of more serious consequences of stent fracture such as acute thrombotic occlusion[8] and vessel perforation.[9]

Using three-dimensional models of the FP artery generated in patients undergoing routine angiography in the catheterization lab, we recently reported a quantitative analysis of the conformational change in the FP artery between the straight leg and crossed leg positions.[10,11] The SFA and popliteal arteries shortened by a mean of 18.2 ± 13 mm and 32.2 ± 12.9 mm, respectively. This represents 6% and 15.8% of their entire lengths, respectively. There was an increase in the mean curvature along the length of the SFA and popliteal arteries of 0.04 ± 0.04 cm^{-1} and 0.2 ± 0.09 cm^{-1}, respectively. The mean twist angle for the SFA and popliteal arteries per centimeter length of vessel was

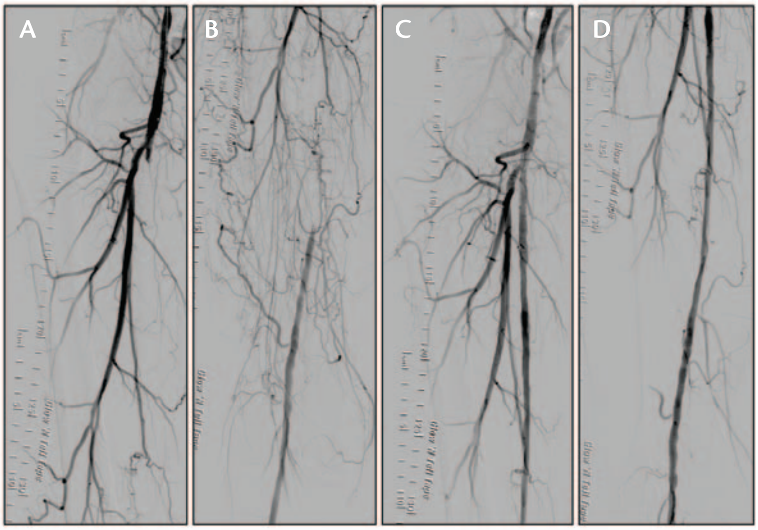

Figure 6. Treatment of a long occlusion of the superficial femoral artery. Baseline angiography (A, B). Angiographic appearance after treatment with the Jetstream® catheter and low-pressure angioplasty (C, D).

1.69°/cm ± 1.01°/cm and 3.46°/cm ± 1.90°/cm, respectively. Finally, a mean of 2.4 new flexion angles > 15° were generated in the popliteal artery (Figure 7). These findings reinforce the conclusion that significant axial compression, twisting, and bending forces are exerted upon the FP artery during leg movement.

In addition, a recent study by Nikanorov et al that subjected a variety of stents in a cadaver model to what were believed to be clinically relevant axial compression and bending forces showed high rates of stent fracture for all except one of the stents studied.[12] Taken together, it is clear that future stent designs require some modification such that they can withstand the forces exerted upon them and prevent the development of stent fractures. The challenge of designing new-generation stents with sufficient radial force to withstand the large and often calcified plaque burden in the FP artery and sufficient conformability to withstand the physical forces exerted on the vessel is significant. The new, wire-interwoven, nitinol Supera stent (IDev Technologies Inc., Houston, TX) purports to meet this challenge, but long-term clinical data are clearly required before making a final judgment.

In addition to stent fracture, the other major limitation of stenting in the FP artery is the high rate of restenosis and the lack of an effective therapy for the treatment of in-stent restenosis. For younger patients who are being treated for claudication, this is a significant limitation because recurrent intervention every 6 to 12 months is not an effective or realistic option.

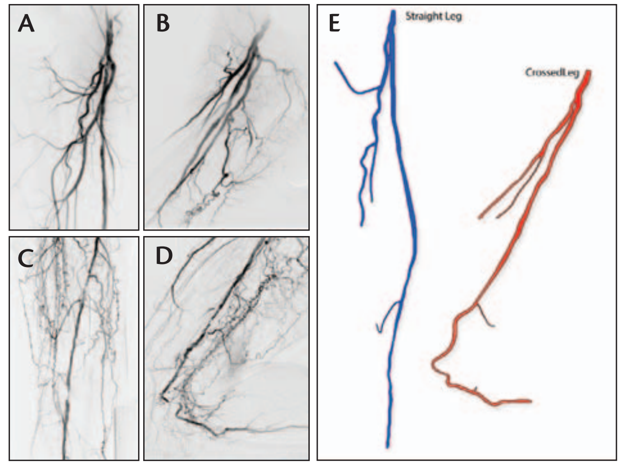

Figure 7. Orthogonal angiographic images of the FP artery in the straight leg and cross-leg position (A through D) in a patient with peripheral artery disease, with corresponding three-dimensional models of the FP artery (E). Reprinted with permission from Klein AJ et al. Cathet Cardiovasc Interv (May 7, 2009).[11]

FUTURE CHALLENGES

Significant challenges remain in the application of atherectomy in the endovascular treatment of FP disease. The safety and efficacy of this technology is heavily dependent on remaining within the true lumen of the FP artery during the recanalization portion of the procedure. Subintimal recanalization of long occlusions, which is a common event in contemporary practice even with the recent availability of crossing tools,[13] is problematic for atherectomy technologies for two reasons. First, the risk of perforation and the creation of arteriovenous fistulae with the deep femoral vein are likely increased (Figure 8). Although tools that perform directional atherectomy (ie, SilverHawk) as opposed to concentric atherectomy (ie, Pathway Jetstream®, Diamondback 360º) might have a theoretic advantage in this regard, the inability to currently guide directional atherectomy in three-dimensional space with image guidance likely nullifies this potential advantage. Second, the ability to achieve effective atherectomy of the plaque burden is decreased because a variable area of the media forms a portion of the newly formed vascular channel. It remains unclear whether the inability to achieve effective debulking will have an impact on the long-term patency rates achieved with atherectomy.

Even when recanalization occurs entirely within the true lumen of the FP artery, it is common for the channel in which the wire lies to have an eccentric location within the arterial lumen. Balancing the risk of perforation and/or arteriovenous fistula formation versus effective plaque debulking at the sites of maximum eccentricity remains an important consideration.

In addition to the short-term safety issues of arteriovenous fistula formation and perforation, the long-term issue of the risk of pseudoaneurysm formation due to trauma to the media with atherectomy tools needs to be assessed carefully. Individual cases of pseudoaneurysm formation with the SilverHawk device have been reported.[14] Although atherectomy catheters that remove plaque in a concentric manner may be less prone to this problem, long-term studies that specifically assess this issue are required.

Distal embolization is a particular problem in the application of atherectomy technologies that needs to be addressed. Atherectomy produces a significant disruption of a large plaque burden within the FP artery that may have superimposed thrombus. Although the Pathway Jetstream® device has the theoretic advantage of combining aspiration with atherectomy and the SilverHawk catheter removes plaque deposited in the nosecone, clinical studies are required to demonstrate

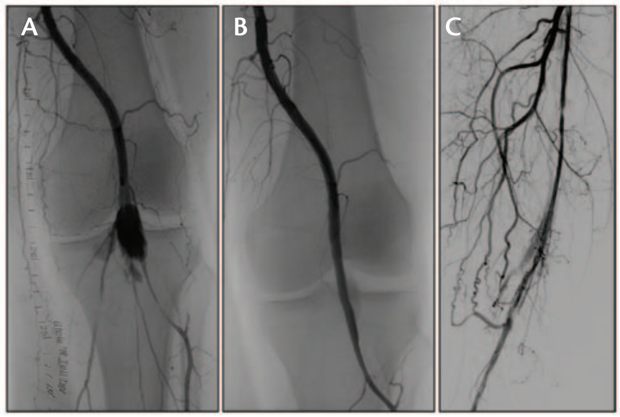

Figure 8. Potential complications of atherectomy in the FP artery. Perforation of the popliteal artery after treatment of occlusion with SilverHawk catheter (A) requiring treatment with a Viabahn covered stent (W. L. Gore & Associates, Flagstaff, AZ) (B). Arteriovenous fistula of the FP artery after atherectomy of the FP artery (C).

the clinical efficacy of this approach over other atherectomy technologies. The utilization of distal embolic protection filters during atherectomy procedures adds expense and has certain technical challenges that are unique to peripheral intervention such as the inability to visualize the filter during all interventional maneuvers along the length of the FP artery. Compatibility issues between the atherectomy catheters and the various filters also need to be resolved. Despite these issues, the author recommends the use of embolic protection devices in high-risk anatomic and clinical situations when atherectomy is used, such as single vessel tibial runoff in patients with critical limb ischemia.

The four currently available atherectomy/plaque ablation technologies (SilverHawk, Diamondback 360º, Turbo Elite, Pathway Jetstream®) have very distinct mechanisms of action, and their ability to treat atherosclerotic disease with different morphologies (eg, fibrotic, calcific) is unlikely to be uniform. While the individual companies clearly have a vested interest in promoting their technology for the broadest range of FP disease morphology, clinicians must learn to tailor the application of each of these technologies to the characteristics of the plaque in the individual patient. The further refinement of atherectomy technologies to allow a consistent and predictable result in the broadest range of plaque morphologies by interventionists with varying experience will simplify this task.

Finally, but not least, it must be highlighted that no atherectomy tool has been shown to reduce the long-term rate of restenosis in the FP artery. Comparative clinical studies need to be performed to address this issue, and should they prove negative, the search for adjunctive biological therapies to complement the acute mechanical revascularization achieved with atherectomy will be needed.

CONCLUSION

Endovascular intervention of the FP artery remains a significant challenge. Atherectomy technologies have expanded the spectrum of FP disease in which a successful acute procedural result can be achieved, and has decreased the proportion of cases in which a stent is required to achieve this result. Significant challenges remain in improving the safety and effectiveness of atherectomy and in addressing the vexing issue of poor long-term patency of endovascular interventions in the FP artery. ■

Ivan P. Casserly, MB, BCh, is with the Cardiac & Vascular Center, University of Colorado Hospital, Anschutz Medical Campus in Aurora, Colorado. He has disclosed that he is a member of the scientific advisory board for Pathway Medical. Dr. Casserly may be reached at (720) 848-6508; ivan.casserly@ucdenver.edu.

1. Walsh DB, Powell RJ, Stukel TA, et al. Superficial femoral artery stenoses: characteristics of progressing lesions. J Vasc Surg. 1997;25:512-21.
2. Whyman MR, Ruckley CV, Fowkes FG. A prospective study of the natural history of femoropopliteal artery stenosis using duplex ultrasound. Eur J Vasc Surg. 1993;7:444-7.
3. Goodney PP, Beck AW, Nagle J, et al. National trends in lower extremity bypass surgery, endovascular interventions, and major amputations. J Vasc Surg. 2009;50:54-60.
4. 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;354:1879-88.
5. Allie D, Hebert CJ, Walker CM. Nitinol stent fractures in the SFA. Endovasc Today. 2004;7:22-34.
6. Iida O, Nanto S, Uematsu M, et al. Effect of exercise on frequency of stent fracture in the superficial femoral artery. Am J Cardiol. 2006;98:272-274.
7. Scheinert D, Scheinert S, Sax J, et al. Prevalence and clinical impact of stent fractures after femoropopliteal stenting. J Am Coll Cardiol. 2005;45:312-315.
8. Barbato JE, Wholey MH. Use of AngioJet mechanical thrombectomy for acute peripheral ischemia associated with stent fracture. Cathet Cardiovasc Interv. 2007;70:795-798.
9. Lewitton S, Babaev A. Superficial femoral artery stent fracture that led to perforation, hematoma and deep venous thrombosis. J Invasive Cardiol. 2008;20:479-481.
10. Klein AJ, Casserly IP, Messenger JC, et al. In vivo 3D modeling of the femoropopliteal artery in human subjects based on x-ray angiography: methodology and validation. Med Phys. 2009;36:289-310.
11. Klein AJ, James Chen S, Messenger JC, et al. Quantitative assessment of the conformational change in the femoropopliteal artery with leg movement. Cathet Cardiovasc Interv. Published online ahead of print May 7, 2009.
12. Nikanorov A, Smouse HB, Osman K, et al. Fracture of self-expanding nitinol stents stressed in vitro under simulated intravascular conditions. J Vasc Surg. 2008;48:435-440.
13. Bown MJ, Bolia A, Sutton AJ. Subintimal Angioplasty: Meta-analytical Evidence of Clinical Utility. Eur J Vasc Endovasc Surg. 2009;29:323-337.
14. Penugonda N, Duncan K, Schreiber T. Popliteal artery pseudoaneurysm following FoxHollow atherectomy: a rare complication. J Invasive Cardiol. 2008;20:477-478.