

# Below-the-Knee Atherectomy Update

A look at devices in use or under investigation for treating CLI patients with complex lesions.

BY ROBERT M. BERSIN, MD, FSCAI, FACC

**P**ercutaneous transluminal angioplasty (PTA) is the most frequently applied therapeutic intervention for infrapopliteal disease in patients with critical limb ischemia (CLI). Many studies of PTA for CLI have been performed during the past 30 years, which have documented improved limb salvage and acute success rates over time. In a meta-analysis of 30 prospective trials of PTA for CLI, 1-year limb salvage rates were 86% with PTA as compared to 88.5% with surgery.<sup>1</sup> However, it is well known that many infrapopliteal lesions are not suitable for PTA, including calcified lesions and total occlusions. In an analysis of outcomes with PTA for CLI, the strongest predictor of a poor outcome was the presence of a TASC D lesion. TASC D lesions are defined as chronic total occlusions of the common femoral artery (CFA) or superficial femoral artery (SFA) ( $\geq 20$  cm, involving the popliteal artery) and/or chronic occlusion of the popliteal artery and proximal trifurcation



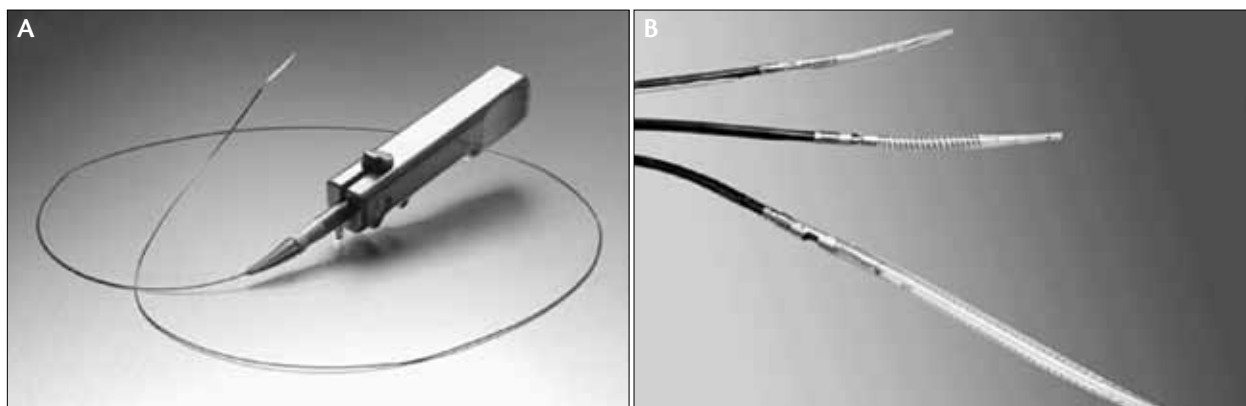
Figure 1. In the step-by-step technique, the guidewire advances a few millimeters into the occlusion. The laser is activated while advancing the laser catheter, ablating the lesion until its tip is flush with the guidewire. The process is then repeated until the occlusion is crossed. Reprinted from *J Vasc Surg*, May;51(5 Suppl), Bradbury AW, Adam DJ, Bell J, et al; on behalf of the BASIL trial Participants, 185-315, Copyright (2010), with permission from Elsevier.

vessels.<sup>2</sup> Unfortunately, TASC D lesions are common in CLI patients, and it is no surprise that the acute outcomes of PTA are inferior to surgery.<sup>3</sup>

In the BASIL trial, PTA was associated with a 20% incidence of immediate procedural failure and an additional



Figure 2. Severe tibial occlusive disease with long occlusion of the anterior tibial artery (A). After successful laser-assisted angioplasty of the anterior tibial artery (B). Reproduced with permission from the *Journal of Endovascular Therapy*. © Copyright 2006. International Society of Endovascular Specialists.



**Figure 3.** The SilverHawk plaque excision catheter. Upon device activation with a motorized unit connected to the proximal end (A), the distal portion of the catheter (B) pivots to appose atherosclerotic tissue, exposing the cutting blade and enabling plaque excision and storage. The catheter, which is compatible with 6- or 7-F sheaths, is a monorail design that is advanced over a 0.014-inch-diameter guidewire to treat the diseased segment. Reproduced with permission from the *Journal of Endovascular Therapy*. © Copyright 2006. International Society of Endovascular Specialists.

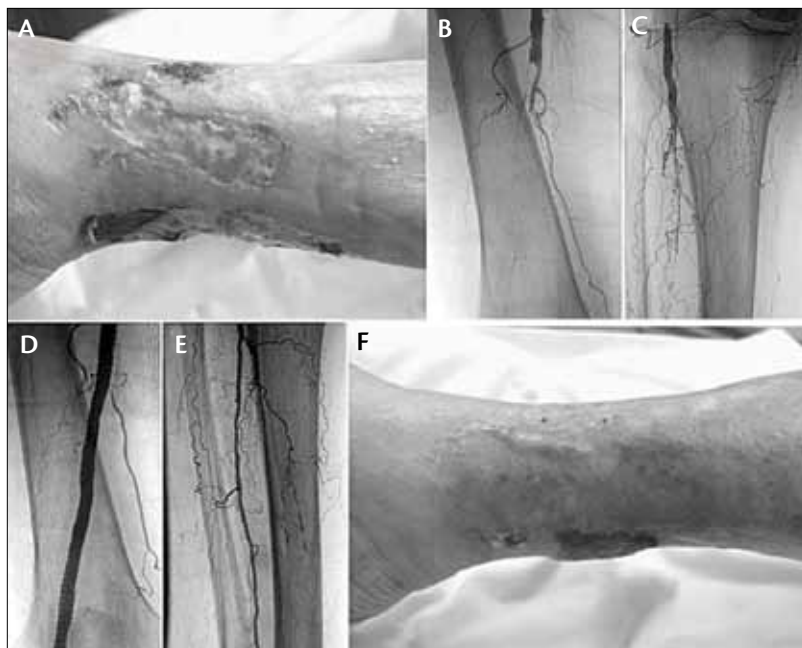
17% crossover rate to surgery at 3 months.<sup>3</sup> This suggests that the results of a below-the-knee intervention can be improved if devices are used that can address difficult lesions (eg, calcified, diffusely diseased, and/or totally occluded). A number of atherectomy devices have been developed specifically to address complex below-the-knee lesions and have contributed to successful below-the-knee interventions.

### EXCIMER LASER

The Spectranetics CVX-300 Excimer laser system (Spectranetics Corporation, Colorado Springs, CO) incorporates an optical fiber catheter to deliver ultraviolet-range light energy to ablate plaque and thrombus. This device is ideally suited to debulk diffuse disease and thrombus-containing lesions, including total occlusions. The Excimer laser was studied in CLI in the LACI trial.<sup>4</sup> In this trial, 145 patients with 155 critically ischemic limbs (Rutherford class 4–6) were treated with laser atherectomy and angioplasty (96%), with adjunctive stenting if needed (45%). Most of the adjunctive stent implants were in poor femoropopliteal lesions, with only 16% of tibial arteries undergoing adjunctive stent implantation.

An average of 2.7 lesions were treated, with an average total treatment length of 11 cm. Total occlusions were present in 91% of treated limbs. The step-by-step technique was frequently utilized (17% of cases) (Figure 1). The acute

procedural success rate was 86% in treated limbs, with a limb salvage rate of 93% at 6 months. Complications were few but included dissection (4% of patients), thrombus formation (3%), distal embolization (3%), and perforation (2%). The Excimer laser appears to be well suited for tibial-



**Figure 4.** Treatment of multilevel disease with plaque excision. A 91-year-old woman with intractable pain, ischemic ulceration (A), and an ankle-brachial index of 0.16 underwent angiography demonstrating occlusions of the proximal superficial femoral artery (B) and all tibioperoneal arteries (C). Following treatment with plaque excision and stenting in the superficial femoral artery (D) and plaque excision alone in the peroneal artery (E), the patient developed and sustained wound healing at 6-month follow-up (F). Reproduced with permission from the *Journal of Endovascular Therapy*. © Copyright 2006. International Society of Endovascular Specialists.



**Figure 5.** The calcium-cutting TurboHawk device (introduced in 2009) incorporates notches into the titanium-cutting blade that engages calcium more efficiently. Other enhancements include an improved fracture-resistant drive shaft and micro-efficient compression technology for improved compaction and capture efficiency of the excised plaque.

pedal lesions given the favorable ratio between the size of the device and the diameter of the vessel being treated. A representative case example from the LACI trial is shown in Figure 2.

### EXCISIONAL ATHERECTOMY

Excisional atherectomy (Figure 3) was developed to excise plaque from bulky, eccentric, calcified, and diffuse lesions to improve the acute interventional result of lower extremity interventions. The SilverHawk excisional atherectomy device (Covidien, Mansfield, MA) was evaluated in a prospective, multicenter registry of 160 lesions (74 limbs) in 69 patients with CLI.<sup>5</sup> In this study, 80% of lesions were moderate to severely calcified and 34% were totally occluded; acute procedural success was achieved in 99% of cases. Adjunctive PTA was performed in 11%, and an additional 6% of patients required adjunctive stenting. Acute complications were rare. Embolization and perforation were not observed. A representative case from the trial is shown in Figure 4.

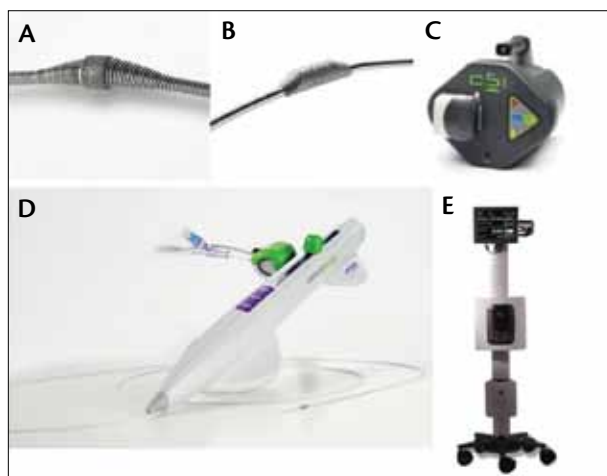
Since that trial was performed, the calcium-cutting TurboHawk device (Covidien) (Figure 5) was introduced in 2009, which improved the cutting efficiency in calcified lesions. The DEFINITIVE LE trial recently enrolled 800 patients who were treated with either the SilverHawk or the TurboHawk peripheral plaque excision systems, of which 201 patients had CLI (Rutherford class 4–6). The average lesion length in the CLI subgroup was 7.1 cm. Overall, embolization was observed in 3.8% of patients and perforation in 3.4%. The limb salvage rate in the CLI

subgroup was 97.3% at 210 days; the primary patency rates were 88.1% in nondiabetic patients and 87.1% in diabetics. This study demonstrates that in a large number of CLI patients, excisional atherectomy can be performed safely with a high limb salvage rate using the current generation of SilverHawk and TurboHawk devices.

### ORBITAL ATHERECTOMY

The Diamondback orbital atherectomy device (Cardiovascular Systems, Inc., St. Paul, MN) is specifically designed to ablate heavily calcified lesions and debulk plaque to modify lesion compliance and facilitate PTA and other adjunctive therapies (Figure 6). This device has a diamond abrasive crown that spins eccentrically around a dedicated guidewire (the ViperWire [Cardiovascular Systems, Inc.]), unlike the Rotablator (Boston Scientific Corporation, Natick, MA), which spins concentrically. As the rotational speed of the ablative crown increases, the crown spins into an increasingly larger orbit around the guidewire, hence the term *orbital atherectomy*.

The device also exhibits deferential cutting properties whereby inelastic plaque and calcium are preferentially ablated while sparing relatively healthy elastic tissues from ablative damage. This makes the device ideally suited for treating heavily calcified plaque (Figure 7) and eccentric lesions on angulated bends, such as at the origins of the tibial arteries (Figure 8). In CALCIUM 360°, the Diamondback orbital atherectomy demonstrated an acute procedural success rate (defined as a  $\leq 30\%$  residual stenosis with no type C–F dissection) of 92.6% as compared to 78.8% with PTA.<sup>6</sup>



**Figure 6.** The Diamondback orbital atherectomy catheter is composed of a diamond abrasive crown (classic, A; solid, B), which is powered by a compressed gas generator (C) and controlled by an advancer handle (D). The larger gas generator has been replaced with an electric generator (E) for the latest-generation Stealth advancer.

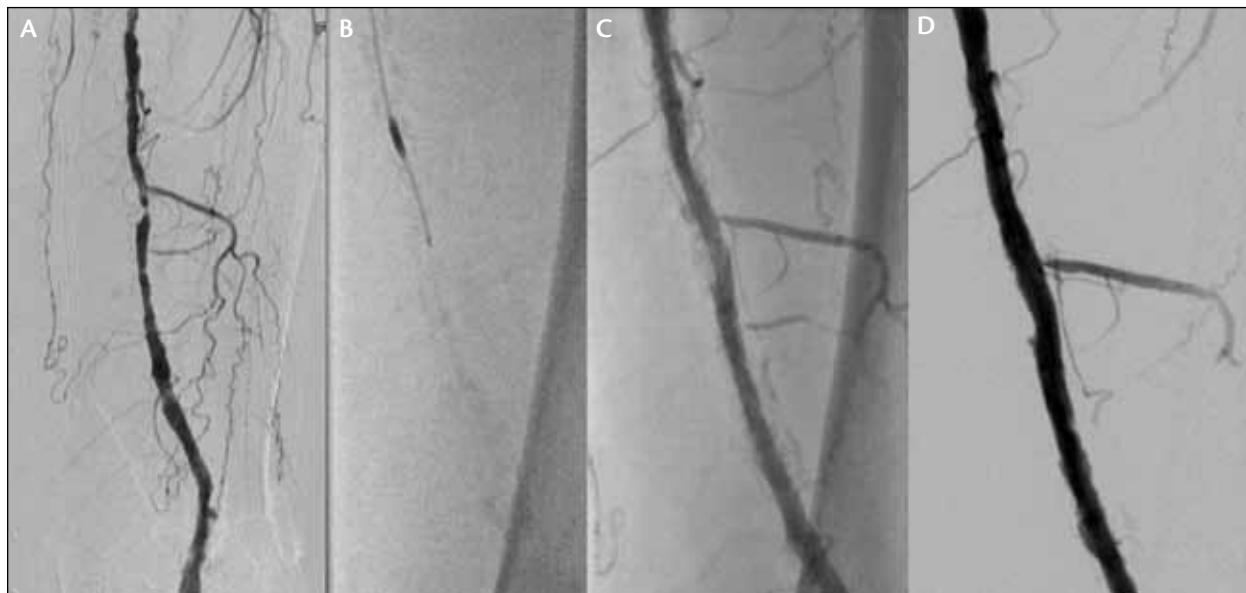


Figure 7. An example of modified lesion compliance using the Diamondback orbital atherectomy device. Diffusely calcified superficial femoral artery (A). A 2.25-mm Predator solid crown device (Cardiovascular Systems, Inc.) is used to debulk the vessel (B). Result following orbital atherectomy (C). Result following adjunctive PTA (D).

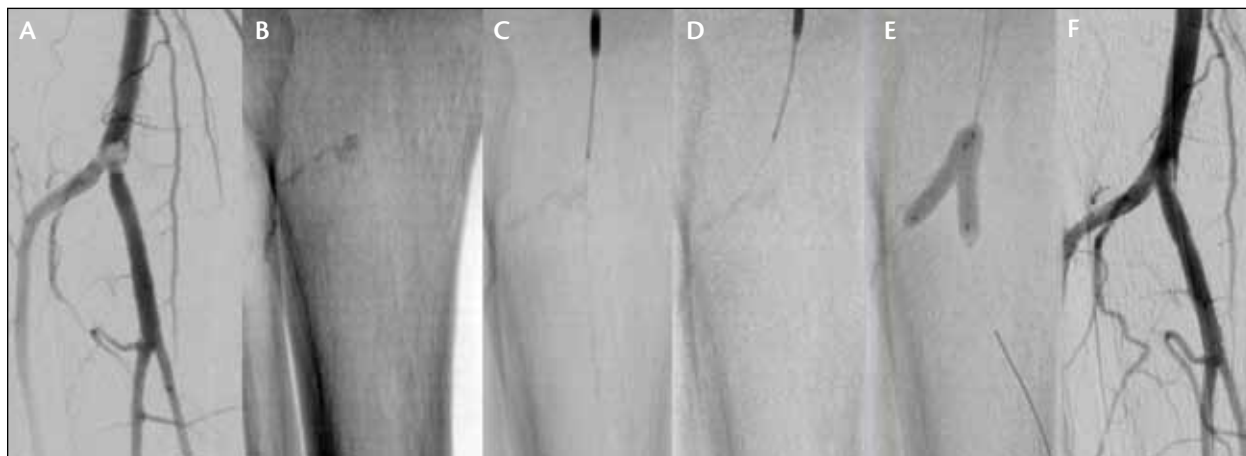


Figure 8. Heavily calcified bifurcation lesion (A, B) of the distal popliteal artery in a patient with Rutherford class 4 rest pain treated with bifurcation Diamondback orbital atherectomy and PTA (C, D). The debulking of this calcified lesion facilitated the final kissing balloon PTA (E), with minimal residual stenosis and no dissection (F).

### ASPIRATION AND RECANALIZATION DEVICES

Two other unique atherectomy devices combine concentrically rotating cutting blades with aspiration of the ablated plaque material. The first to gain approval for use is the Jetstream (Bayer Radiology and Interventional, Indianola, PA). This device has exposed rotating cutting blades of two different diameters, depending on the direction of rotation, and a central aspiration port mounted behind the blades. It is best suited for debulking of diffuse soft plaque and for

thrombectomy (Figures 9 and 10).

The Phoenix atherectomy catheter (AtheroMed, Inc., Menlo Park, CA) also incorporates a concentrically spinning cutting blade that differs from the Jetstream in that the cutting blade is not exposed, and the ablated plaque is conveyed to a collection bag by an internal Archimedes' screw that pulls rather than aspirates the plaque out of the drive shaft (Figure 11). Like the Jetstream, it is best suited for treating soft to moderately calcified plaque and thrombus-containing lesions. It is currently under investigation in the

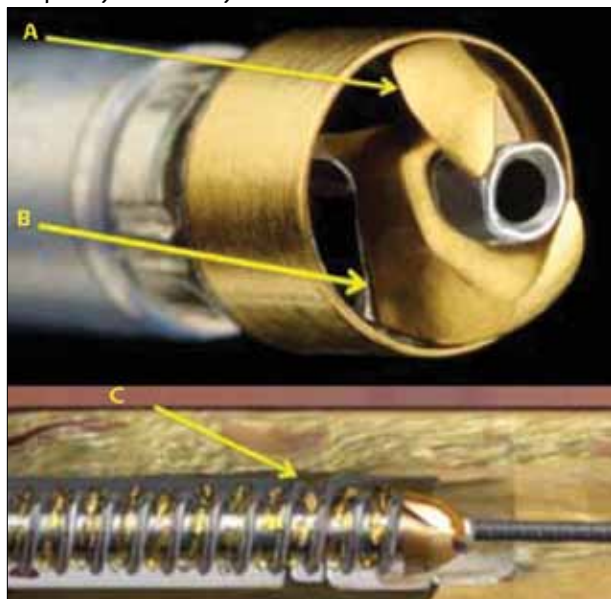




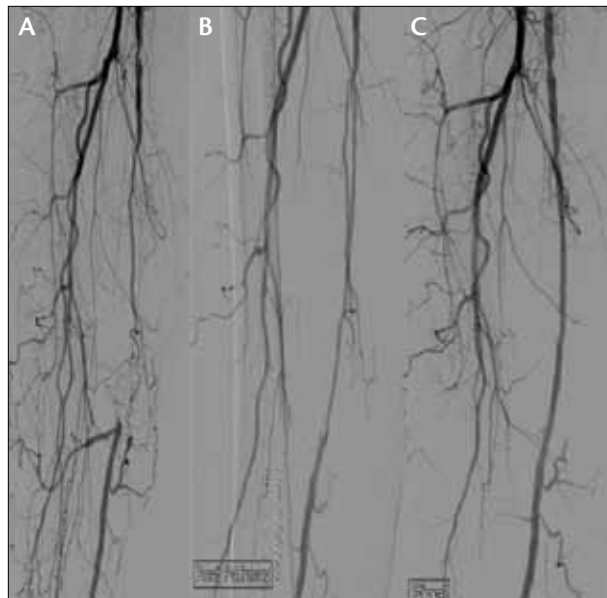
**Figure 9.** The family of Jetstream devices. The Navitus is the largest-diameter device and is intended for use in the femoral and popliteal arteries. The G3 SF 1.6- and 1.85-mm devices are intended for use in smaller tibioperoneal vessels.

EASE FDA investigational device exemption trial. Neither device has been specifically investigated for outcomes in patients with CLI.

One other device that is worthy of mention is the Crosser CTO recanalization device (Bard Peripheral Vascular, Inc., Tempe, AZ). This device is an ultrasonic vibratory catheter designed to cross and recanalize chronic occlusions by virtue of the energy delivered to the tip as a result of its high-frequency mechanical vibration. It has been shown to result in recanalization channels larger than the catheter, which is suggestive of a mechanical atherectomy effect; it is now labeled and indicated as an atherectomy device. It is well suited for treating total occlusions of infrapopliteal vessels and therefore is a useful tool for treating CLI patients who frequently have totally occluded vessels.



**Figure 11.** The Phoenix atherectomy catheter. The atherectomy blades (A) are not exposed, and the aspiration ports (B) convey the atherectomy material via an internal Archimedes' screw (C).



**Figure 10.** Long-segment thrombotic chronic total occlusion of the superficial femoral artery (A). Initial result following Jetstream atherectomy using the Navitus device (B). Final result following adjunctive thrombolysis (C). Images courtesy of Dr. Felix Vladimir.

## SUMMARY

There are now six atherectomy devices for the treatment of lower extremity peripheral artery disease. The evidence is accumulating that these devices can improve the acute outcomes of interventions in difficult lesion subsets, including diffuse disease, total occlusions, and in calcified and thrombotic lesions. They are now being investigated specifically in patients with CLI. These devices appear to be safe when applied in a careful, lesion-specific approach to CLI patients, and the outcomes can be superior to PTA. ■

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