

Atherectomy Today: Go Slow to Finish Fast

An update on the newest generation of atherectomy devices and how this technique is currently being used to treat peripheral vascular disease.

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“Go slow to finish fast” is the best motto for delivering an effective atherectomy result with each of the currently available atherectomy devices. The variety of currently available atherectomy devices allows operators to intervene in all aspects of complex superficial femoral artery (SFA) disease. Engineers have designed these devices with the specific intent to maximize debulking by increasing contact time with the plaque. This is achieved by going slower through the target area, which, when successful, results in shorter procedure times. When atherectomy devices are used too fast, the results are less effective, and a higher rate of complications (such as dissection, perforation, and embolization) can occur. Complications contribute to prolonged procedure time.

This article describes the mechanism of action of the currently available atherectomy devices that are approved by the US Food and Drug Administration (FDA) and this author’s opinion of the value of each device’s contribution to safety and effectiveness in treating complex SFA disease. Each of these devices brings its own contribution via different debulking mechanisms—directional, orbital, and rotational. The main principle of atherectomy is the capability of removing plaque without outward stretching or causing barotrauma to the target vessel wall.

BACKGROUND

Due to the complexity of atherectomy devices, the operator should follow the recommended Instructions for Use. Along with that, physician proctoring also provides valuable information and training to both physicians and staff on how to properly operate the atherectomy device.

Atherectomy devices have evolved in a progressive

pattern to accommodate increased safety and efficacy. Current atherectomy devices can be used through smaller sheath sizes (5–7 F), thus contributing to fewer groin complications. They also contribute to shorter procedural times due to the ease of preparation of the device from the time a decision is made to use the device to device insertion, activation, and debulking completion. Many devices have evolved into simple open-and-use devices in some cases or requiring fewer steps than previously necessary. These improvements have been made without compromising effective plaque-burden removal. Operators have optimized the use of these different devices and reached new frontiers

ORBITAL, ROTATIONAL, AND DIRECTIONAL ATHERECTOMY DEVICES

Orbital Atherectomy

- Diamondback 360° orbital atherectomy system (Cardiovascular Systems Inc., St. Paul, MN)

Rotational Atherectomy

- Jetstream Navitus (Pathway Medical Technologies, Inc., Kirkland, WA; recently acquired by Medrad Interventional)

Directional Atherectomy

- Crosser recanalization system (Bard Peripheral Vascular, Inc., Tempe, AZ)
- Excimer Laser (Spectranetics Corporation, Colorado Springs, CO)
- TurboHawk plaque-excision system (Covidien, Mansfield, MA)

TABLE 1. CAPITAL EQUIPMENT FOR CURRENTLY AVAILABLE ATHERECTOMY DEVICES

Type of Atherectomy	Capital Equipment Required?
Diamondback 360°	Yes
Excimer laser	Yes
Jetstream Navitus	Yes
Crosser recanalization	Yes
TurboHawk	No
Phoenix	No

of peripheral interventions that previously were not feasible.

Conceptually, the idea of atherectomy is to reduce the plaque burden without affecting the rest of the vessel wall. This concept is great functionally, although it is not completely practical because the vessel wall is still at risk, depending on the procedure and its complexity.

A one-size-fits all atherectomy device does not exist today, but we are fortunate to have multiple devices with different functions, all with the same goal of plaque modification and removal.

CURRENT DEVICES

Some of the current atherectomy devices have multiple functions. In addition to their ability to remove or reduce plaque, some also have the ability to aspirate while performing atherectomy, which provides such devices an advantage in treating lesions where a combination of plaque and thrombus reside together. In severely calcified plaque, some atherectomy devices can reduce the plaque burden and, at the same time, modify the vessel wall by changing its compliance. This reduces the likelihood of significant arterial dissection postintervention. Other devices offer treatment for chronically occluded vessels and function as crossing devices, thus reducing the plaque burden of soft thrombotic plaque as well as calcified plaque.

The currently available atherectomy devices, which are FDA-approved for use in the SFA, are listed in the *Orbital, Rotational, and Directional Atherectomy Devices* sidebar. The exact description of the mechanics of the atherectomy devices is broad and usually categorized into rotational and directional atherectomy. In reality, many of these devices utilize the mechanics of both directional and rotational atherectomy and also require different types of energy sources. Some require capital equipment to support the function of the atherectomy

TABLE 2. EFFECTIVENESS OF DIFFERENT TYPES OF ATHERECTOMY DEVICES FOR TREATING FORMS OF PLAQUE COMPOSITION AND THROMBUS^a

	Thrombus	Soft Plaque	In-Stent Restenosis ^b	Mild Calcification	Moderate Calcification	Severe Calcification
Diamondback 360°	--	+	—	++	++	++
Excimer laser	++	++	++	++	++	++
TurboHawk	--	++	++	++	++	+
Jetstream Navitus	++	++	+	++	+	+
Phoenix atherectomy	--	++	Not known	++	+	+
Crosser recanalization	++	++	++	++	++	++

+, effective; ++, very effective; —, less effective; --, ineffective.

^aThis table represents the opinion of the author based on personal experience and does not necessarily reflect data from clinical trials.

^bSome of these devices may be contraindicated for the treatment of in-stent restenosis.

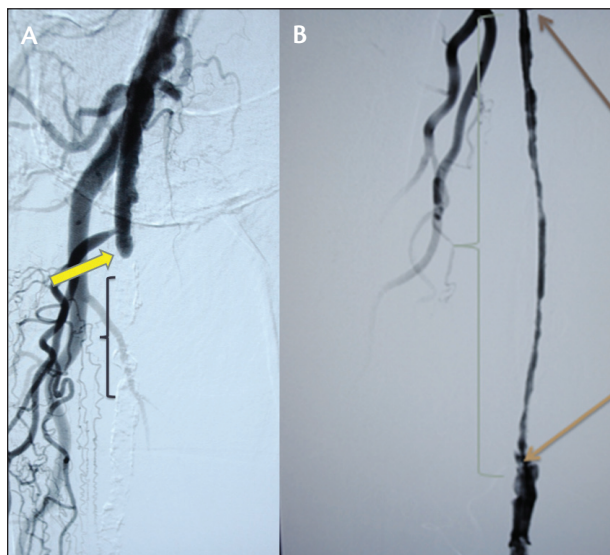


Figure 1. The SFA chronic total occlusion is severely calcified (A). Atherectomy results after using the newly approved atherectomy device, the Crosser (B).

device and some come without capital equipment and are completely disposable (Table 1).

When evaluating the mechanism of plaque removal per device, it is my opinion that there is an absolute difference among the currently available atherectomy devices (Table 2). The ability of these devices to remove plaque burden ranges from mild plaque removal (equivalent to the outer diameter of the atherectomy device) to a much larger diameter than the device's outer diameter. When the goal is to remove a larger plaque burden, multiple devices have the ability to perform in such a setting. Some atherectomy devices have tips that can deflect away from the center toward the outer perimeter of the vessel for maximum debulking. Some devices achieve the same result with an ergonomic design that allows the device to deviate from the center to the outer diameter by adding the weight and the rotational speed of the device. As the device spins faster, the circular diameter achieved is larger and is directly proportional to the acceleration portion of the debulking device.

The benefits of the current atherectomy devices vary. Each has a unique ability in the hands of different operators. Operator preference and comfort is a considerable factor in the decision of which atherectomy device should be used. The combination of the appropriate device and the skill of the operator is essential for successful plaque removal without increasing the risk of plaque dissection. Such plaque dissection can migrate deep into the vessel wall similar to what is prone to happen with balloon angioplasty alone. The combina-



Figure 2. The Crosser atherectomy device.

tion of appropriate atherectomy device reduces the risk of complications and increases the rate of success. A number of percutaneous atherectomy devices have been developed with various theoretical benefits and absolute advancements.

Crosser Recanalization System

The Crosser is the most recent device to receive FDA clearance for atherectomy (Figures 1 and 2). The Crosser CTO recanalization system generator and transducer convert AC power into high-frequency mechanical vibrations, which are propagated through a nitinol core wire to the metal tip of the Crosser catheter. During activation of the Crosser, saline flush is required to cool the catheter tip.

The Crosser was initially developed as a CTO coronary crossing device, and over time it evolved into an effective peripheral CTO crossing device. Operators began to notice after crossing long CTO segments that the Crosser was leaving a patent segment behind. These patent segments at times equaled the outer diameter of the Crosser catheter and occasionally created larger luminal gain. Due to this observation, approval as an atherectomy device was sought and granted.

As shown in Figure 1, a severely calcified CTO vessel was crossed with the Crosser catheter, creating a luminal diameter that was effective enough to provide TIMI 3 flow in the vessel.

Diamondback 360° Orbital Atherectomy System

The Diamondback 360° is a percutaneous orbital atherectomy system that is designed to remove or



Figure 3. The evolution of the Diamondback 360° device.

reduce occlusive material and restore luminal patency using a rotating, eccentric, diamond-coated crown. The system is available in a 0.014-inch platform for use with a special 0.014-inch guidewire called the Viper. The Viper is an extra support wire uniquely designed to accommodate both the high-speed rotational spin of the shaft and the orbital rotation of the crown of the Diamondback 360°. The latest version is available with an electrical handle that has simplified speed adjustments, allowing for more precise control during the procedure. The design of the device allows for intelligent differential sanding, which is a mechanism of action that is unique to the Diamondback 360°.

Differential sanding provides the ability to sand hardened plaque while the healthy vessel wall flexes away from the crown of the device. The device creates luminal gain by centrifugal force, which allows orbital atherectomy to be performed while the device is activated. Centrifugal force is mass multiplied by rotational speed squared, which is equal to the radius of the orbit.

The Diamondback 360° provides three different types of crowns (Figure 3). The Classic Crown is recommended for compromised flow, vessel bends, ostial lesions, and distal below-the-knee lesions. The Solid Crown has more diamond-coated surface area and is recommended for maximum plaque removal in the shortest amount of time. The Predator Solid Crown is the longest of the three crowns with more tapered edges, allowing engagement of complex lesion types. These crowns utilize the addition of a heavier metal (tungsten), which increases the eccentricity of the rotational device, therefore increasing the orbital force for a higher level of plaque reduction.

The Stealth electrical generator (Figure 4) is a significant improvement from the previous capital equip-

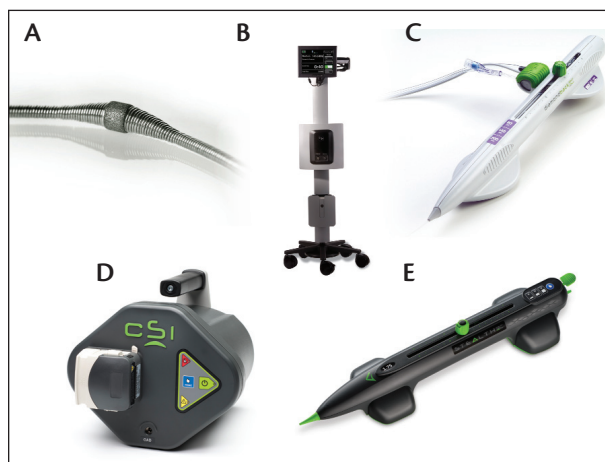


Figure 4. The Diamondback 360° classic crown (A), controller (B), Gemini handle (C), Stealth generator (D), and Stealth handle (E).

ment because it can be set up fairly quickly and is simple to use. By removing the hardened plaque and changing the compliance of the lesion with the Diamondback Classic Crown or Predator Solid Crown first, low-pressure balloon angioplasty can be used to finish the procedure, which may reduce the potential

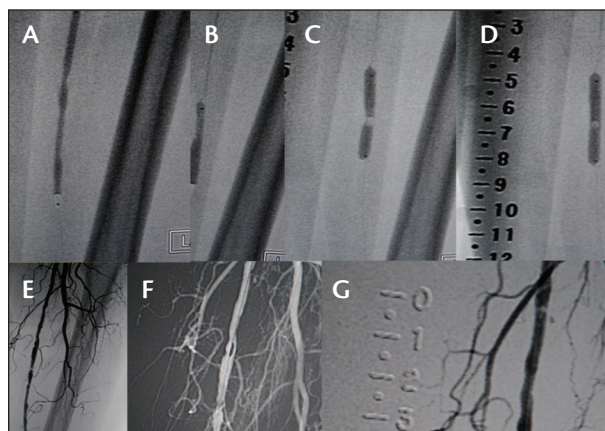


Figure 5. Five-millimeter balloon angioplasty at 4 atm after Diamondback atherectomy showing persistent waist on the balloon (A). Focal 5-mm balloon angioplasty at 4 atm with persistent waist on the balloon (B). After repeated atherectomy 6-mm balloon angioplasty at 4 atm with improved but persistent waist (C). After final Diamondback atherectomy followed with 6-mm balloon angioplasty at 4 atm with complete resolution of the balloon waist (D). Severely calcified SFA before intervention (E). Diamondback Stealth during atherectomy in between balloon angioplasty (F). Final angiogram showing excellent flow without any flow-limiting dissection after repeated atherectomy followed with repeated balloon angioplasty (G).

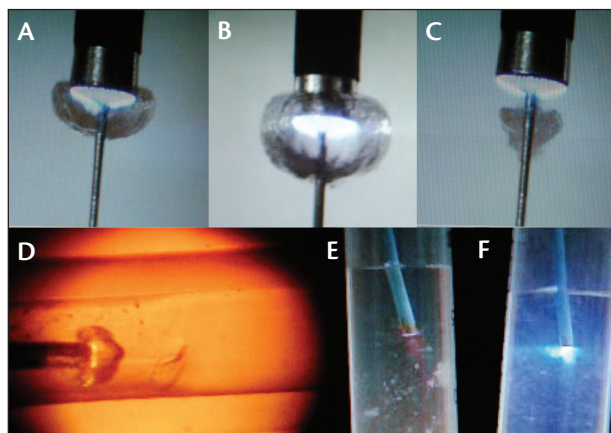


Figure 6. Fluence and laser bubble in gel. 45 mJ/mm² (A), 60 mJ/mm² (B), vapor bubble dissipating after stepping off pedal (C), bubble in gel (D), contrast media (E), saline solution (F).

for barotrauma to the vessel. The result of the procedure is a smooth, concentric, and open vessel that appears to be a normal size and allows robust blood flow. Occasionally, a lesion continues to show a “waist” after Diamondback atherectomy. This should be treated with repeated Diamondback atherectomy followed with repeated low-pressure balloon angioplasty as shown in Figure 5.

Excimer Laser

The Excimer Laser is a device that can be used in all lesions. It is most effective when the laser catheter size to vessel size ratio does not exceed 2:3. For the SFA, it is best to use 2-, 2.3-, and 2.5-mm laser catheters.

The addition of the Turbo-Booster to the laser is designed to direct the laser tip away from the center of the vessel toward the vessel wall where plaque resides. This addition to the laser it to fall into the family of directional atherectomy. The Turbo-Booster is rotated causing the laser to rotate resulting in atherectomy in all quadrants of a diseased SFA. The Turbo-Booster excimer laser’s mechanism of action includes a vapor bubble at 45 mJ/mm² (fluence). Absorption vibrates the molecular bonds of the plaque, and vibration of the bonds heats intracellular water, creating a vapor bubble. The vapor bubble increases as fluence increases. The expanding vapor bubble forms in 100 millionths of a second, which is 1,000 times the duration of the actual laser energy emission. Expansion and collapse

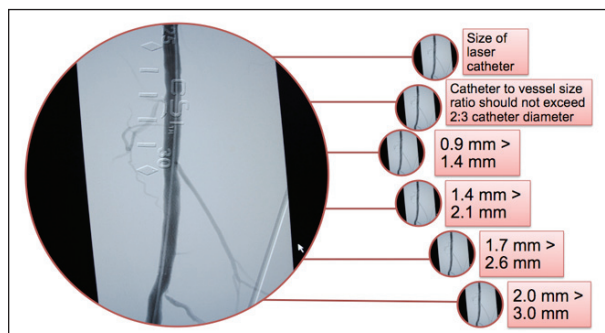


Figure 7. For successful laser debulking, the sizing of the laser catheter to vessel size is crucial.

of the vapor bubble breaks down tissue and clears byproducts away from the tip. Stepping off of the foot pedal allows for immediate dissipation of laser energy. Slow advancement of the laser catheter allows for the vapor bubble to stay in front of the laser catheter, ablating at 50 μm depth. If advancing faster than the recommended 1 mm/s, the vapor bubble will form behind the catheter tip and not allow adequate ablation.

Figure 6 shows the importance of using saline flush while lasing. When the laser is activated in saline, the light is not absorbed, creating an optimal lasing environment. If the laser is activated in contrast, the energy is absorbed, creating microbubbles and the potential for dissection (Figures 6 and 7).

Jetstream Aspiration Thrombectomy

The Jetstream Navitus is a rotational atherectomy device that requires capital equipment. Its unique features include its dual-action capability, which allows it to perform atherectomy and aspiration at the same time. The device is designed to perform debulking of the target



Figure 8. The Jetstream device demonstrating blade-in and blade-out technology. Expandable blade technology enables treatment of the SFA and other arteries and treats all lesion morphologies.

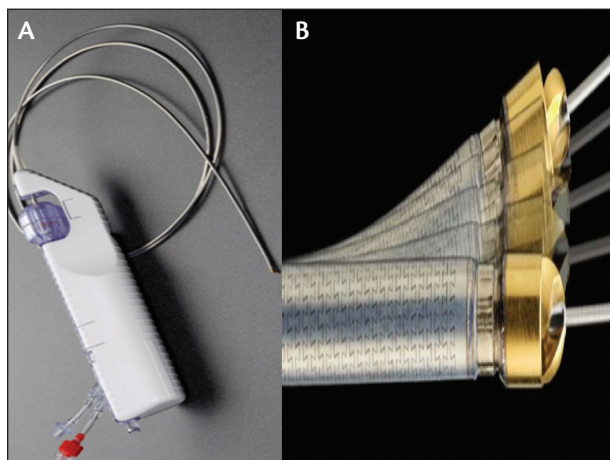


Figure 9. The Phoenix device (A) with flexible head (B).

vessels by an expandable cutting tip that has distal ports, which are designed to provide independent infusion and aspiration functions for the active removal of fluid, excised tissues, and thrombus from the vascular treatment site.

The catheter is a sterile, single-use unit that is connected to a console. The console houses two peristaltic pumps for aspiration and infusion, which power the Jetstream catheter device.

One of the things that make it effective in larger-vessel diameters such as the SFA is its expandable blade technology that allows atherectomy of a larger cross-sectional diameter compared to when the blades are not flared (Figure 8). Its double means of atherectomy (one with blades down and one with blades up) make it helpful when treating a tight lesion. The operator can advance through the tight lesion initially with the blades down and then repeat a second passage with the blades up to increase luminal gain. It can be very effective in lesions where thrombus is suspected to be present along with plaque burden.

Phoenix Atherectomy Catheter

The Phoenix Atherectomy Catheter (AtheroMed, Inc., Menlo Park, CA) is CE Mark approved and is limited to investigational use only in the United States. It is designed to cut, capture, and convey arterial plaque into an external bag visible to the physician. The front-cutting catheter has a deflectable tip engineered to treat a range of blood vessel sizes with a single insertion of one single-use device (Figures 9 and 10). It is most effective in soft to moderate plaque calcification.

TurboHawk Plaque Excision System

The TurboHawk Plaque Excision System does not require capital equipment and is completely disposable.

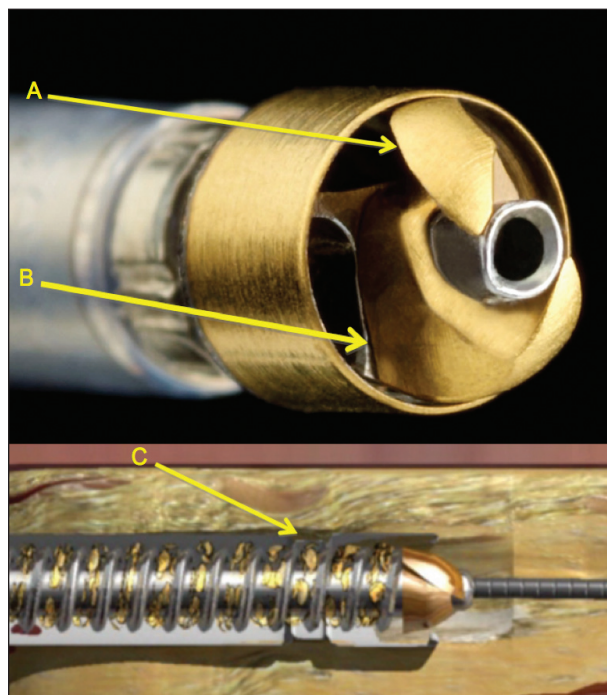


Figure 10. A closer look at the helical cutting blade (A) on the Phoenix device, which is designed to cut inward and transport the removed tissue into a storage bag outside of the body (B). This is a single-insertion device. Archimedes screw clears the tissue from the tip to the base of the catheter (C).

It is very quick to set up and use. It does require intermittent removal from the body to empty the nosecone and reinsertion if the need is still present. Newer TurboHawk devices have a longer nosecone with MEC (microefficient compression) technology (Figure 11). MEC technology provides laser-cut microholes in the wall of the storage segment of the nosecone. These microholes release fluid and retain the tissue, which leads to an increased tissue capturing capacity. This technology increases the insertion time and tissue capture by up to 30%.

The TurboHawk Smooth Cutter debulking blade rotates at a high speed (rotation) and the blade is housed in the device at a junction where it deflects the rotating blade away from the center of the vessel toward the target plaque. It requires a nonspecialized 0.014-inch guidewire. The TurboHawk's blades are unique and very effective. The newer devices have the ability to treat a broad spectrum of lesions from soft plaque to calcified plaque.

The TurboHawk Smooth Cutter system delivers the platform advancement for the treatment of mild to moderately calcified lesions with the added convenience of on-the-wire cleaning. It consistently cuts across a wider vessel range with a unique versatile

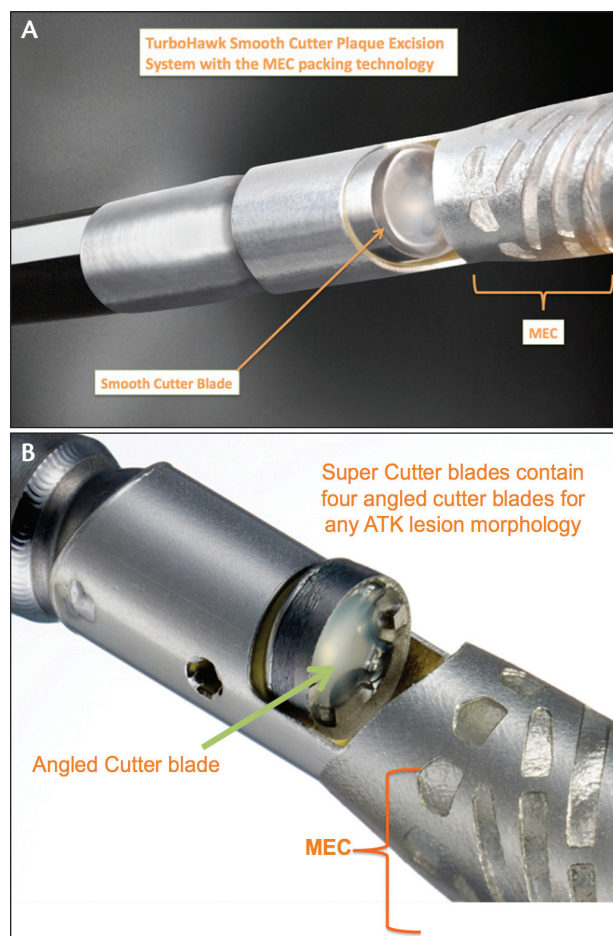


Figure 11. Close-up view of TurboHawk Smooth Cutter blades (A) and of the earlier-generation Super Cutter blades (B).

dual-jog configuration, which reduces the need for multiple catheters and is effective in vessels ranging from 3.5 to 7 mm. This device provides smoother passes with less effort to cut through the lesion.

The TurboHawk Super Cutter blade contains four angled cutter blades that are designed to address all plaque morphologies including moderate-to-severely calcified lesions and provides efficient cutting action versus chipping of tough calcified lesions.

INTRAVASCULAR IMAGING

The use of intravascular imaging, such as optical coherence tomography, intravascular ultrasound, and angiography, has added significant value in understanding postatherectomy intravascular in vivo morphology. Ultrasound, virtual histology, and other imaging modalities also help to guide interventions by identifying the type of plaque morphology (soft plaque, calcified plaque, or thrombus). Identifying the type of disease morphology

makes informed device choice possible, with superior and more predictable and superior outcomes.

In addition, our knowledge of peripheral arterial disease continues to expand, with emphasis on the understanding of the composition and pathophysiology of peripheral plaque. This additional knowledge provides interventionists with more options to evaluate these lesions by utilizing tests such as noninvasive duplex ultrasound, computed tomographic angiography, and magnetic resonance angiography, all of which can be used to characterize accessible peripheral vessels (presence of calcium, thrombus, soft plaque) and guide the choice of treatment modality. Adequate imaging (whether it is angiography, intravascular imaging, or noninvasive testing) is essential for peripheral intervention and aids in the choice among the multitude of the currently available atherectomy devices.

FUTURE DIRECTIONS

Tens of thousands of atherectomy procedures are performed annually, with little data to support its use over angioplasty/stenting. Complete and comprehensive comparative studies have not been performed to address the question of superiority, durability, and long-term patency among atherectomy versus balloon angioplasty versus stenting. The small amount of data available to suggest that atherectomy is superior to balloon angioplasty need to be validated by larger studies to answer the question of superiority.

SUMMARY

Atherectomy has paved the way for the therapy of complex peripheral vascular disease. Today we have the ability to modify severely calcified plaque. In addition, we are able to remove a large plaque burden from a long SFA segment. The removal modalities are many which allow more options and increases the rate of procedural success. Atherectomy will continue to evolve and will be a major part of our endovascular therapy options for the increasingly complex peripheral vascular disease that continues to challenge us. ■

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