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Endovascular Treatment of Infrapopliteal Arterial Disease

Orbital atherectomy for revascularization of calcified lesions below the knee.

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When peripheral artery disease (PAD) affects the infrapopliteal vessels alone or in addition to the more proximal vessels, limb-threatening ischemia and tissue loss often occur. In the United States, between 150,000 and 300,000 cases of critical limb ischemia (CLI) are diagnosed each year.[1] Within 1 year of diagnosis, 30% of CLI patients will have had a major amputation, and 25% will have died; at 3 years, the mortality rate is 60%, predominantly due to ischemic cardiovascular disease.[2]

Treatment of infrapopliteal arterial disease has several unique challenges compared to the treatment of proximal lower extremity disease. Small vessel size, prevalence of diffuse calcific disease,[3] and fewer suitable target vessels for bypass,[4] particularly in patients with diabetes or renal failure or both, complicate treatment. Compared to patency rates achieved with interventions above the knee, these infrapopliteal factors, along with poor runoff, reduce the clinical success of either open surgical or percutaneous balloon angioplasty for restoring blood flow below the knee.

Innovative endovascular approaches to revascularize small-diameter, calcified, diseased arteries below the knee have gained acceptance, with less mortality, less morbidity, very low procedure-related complication rates, and reduced cost relative to surgical revascularization.[5-7] In fact, lower extremity revascularizations over the last decade have shifted away from surgery toward endovascular interventions to include percutaneous transluminal angioplasty (PTA) and cutting balloon angioplasty, stenting, cryotherapy, and a variety of atherectomy devices. PTA has been the default endovascular therapy in the tibial vessels but has a lower success rate with increased risk of dissection, especially in calcified arteries.[8] The other technologies are designed and indicated for the removal or modification of plaque morphologies based on their characteristic mechanism of action. For atherectomy devices specifically, plaque reduction is achieved by orbital sanding, rotational cutting, directional excision, or laser ablation.

Figure 1. The STEALTH 360® System (Cardiovascular Systems, Inc., St. Paul, MN).

ORBITAL ATHERECTOMY

The STEALTH 360® System (Figure 1) is a novel percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for PTA.

This system provides a unique advantage for treating CLI patients with focal or diffuse disease within the infrapopliteal arteries.[9] The device uses a diamond-coated crown that is eccentrically mounted on a wire to selectively remove noncompliant calcified and fibrotic atheroma to increase arterial compliance. The goal of the therapy is to reduce plaque thickness, improve vessel compliance, and, therefore, reduce the occurrence of dissection when PTA is

Figure 2. The Classic Crown is used with the 0.014-inch X 335-cm ViperWire Advance® guidewire (Cardiovascular Systems, Inc.) and is powered by the device control handle.

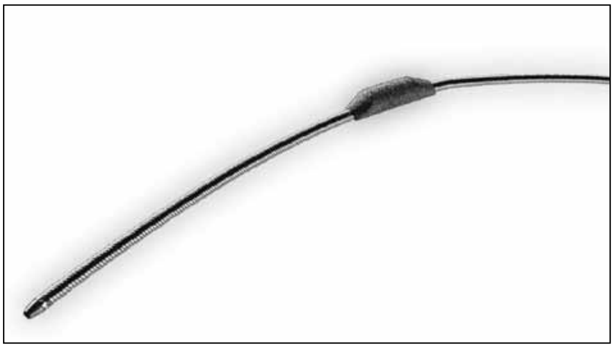

Figure 3. The Solid Crown is made from tungsten and has added eccentricity to provide increased centrifugal force for high-level plaque reduction.

indicated to achieve a satisfactory angiographic outcome. As the diamond-coated crown orbits within the lesion, noncompliant plaque is sanded away while the compliant arterial wall flexes away, minimizing trauma to healthy tissue. This unique action is referred to as differential sanding. The abraded atheroma particles are generally smaller than circulating red blood cells and average in size from 2 to 3 µm.[10] The particles are dispersed distally within the antegrade flow to be absorbed through the reticuloendothelial system.

Crown configurations include a Classic Crown (Figure 2) and a heavier-weight Solid Crown (Figure 3), with sizes ranging from 1.25 to 2 mm to allow for the treatment of lesions within a range of vessel sizes. The 1.25- and 1.5-mm crowns are typically used in the tibial vessels, and the 1.25-mm crown is typically used for diseased segments below the ankle.

The 145-cm length of the STEALTH 360® System catheter allows infrapopliteal interventions to be performed with access from the contralateral side. Crown sizes (1.25–2 mm) can be operated within a 6-F sheath. For tibioperoneal lesions, a 55- or 70-cm sheath positioned well within the superficial femoral artery provides additional support for crossing long, severely diseased segments.

During device operation, the drive shaft and crown are used with a 0.014-inch X 335-cm-long ViperWire Advance® guidewire. A protective sheath covers the drive shaft proximal to the crown and also delivers a saline and lubricant solution over the spinning shaft and into the distal microvasculature.

PROCEDURE

Assess tibial flow to the foot angiographically before intervention to help determine a treatment algorithm. If the patient has a wound, treatment should be directed at the tibial artery feeding to the territory at risk. Second, opening another vessel may restore collateral flow to the wound or reveal reconstitution of the primary vessel. If possible, distal lesions should be treated first to optimize distal runoff pending treatment of proximal, larger-diameter, diseased segments.

Cross the lesion with the 0.014-inch ViperWire Advance® guidewire and position the guidewire tip to make sure there is sufficient distance between the guidewire spring tip and the distal end of the shaft (10-cm minimum at all times). If the ViperWire Advance® cannot be placed as a primary guidewire, use a stepwise approach to cross the lesion with a specialized crossing guidewire. A support catheter, such as Quick-Cross (Spectranetics Corporation, Colorado Springs, CO), may facilitate guidewire placement. The ViperWire Advance® should be within the true lumen of the vessel; subintimal use of the device may be ineffective.

Test device operation before inserting the STEALTH 360® catheter into the access sheath. The device should be fully prepared and loaded on the guidewire, and the saline pump should be ready for use.

Administer systemic anticoagulation with intravenous heparin (100 IU/kg) or bivalirudin (0.75 mg/kg bolus followed by 1.75 mg/kg/h infusion) is recommended to prevent thrombus formation in the tibial vessels.

Advance the selected STEALTH 360º catheter over the ViperWire to position the crown approximately 1-cm proximal to the lesion. Once placed, pull back on the catheter shaft to remove any redundant slack from the system. This prevents inordinate movement of the crown at the start of rotation.

Dilate the distal microvasculature with an infusion of 200 to 400 µg of nitroglycerin, administered through the sheath before initial treatment. Additional nitroglycerin boluses of up to 400 µg are suggested after every second treatment.

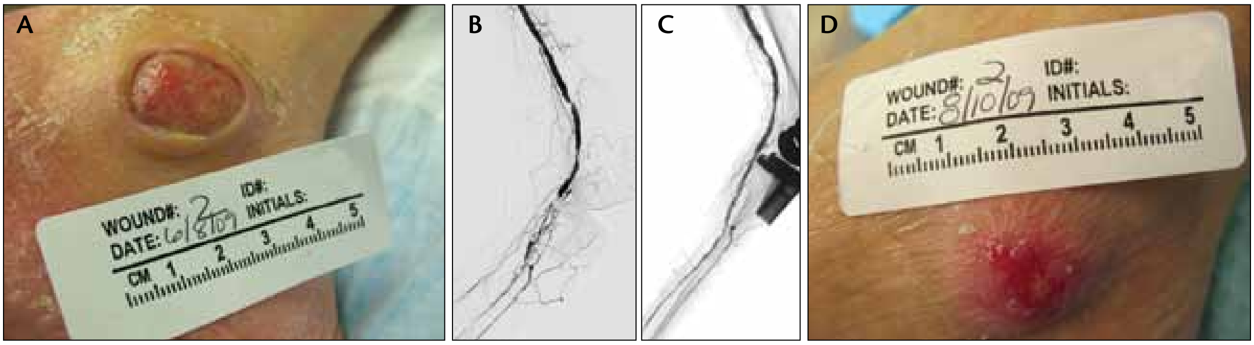

Figure 4. An 87-year-old woman with occlusion of the popliteal artery, multiple peroneal artery stenoses, and a left lateral malleolus ulcer was treated with orbital atherectomy (1.5- and 2.25-mm Classic Crowns) and adjunctive PTA (A). A prosthetic knee complicated visualization of the lesions (B). Excellent blood flow was re-established to the malleolus after treatment (C). A 1-month posttreatment wound photo shows wound healing had advanced (D).

Initial speed is automatically set to low (60,000 RPM), with speed increments dependent on the angiographic result and careful consideration of reference vessel diameters, proximal and distal to the lesion.

Depress the start button to increase pump speed and activate the crown's orbital spinning motion.

Perform the first treatment at the low speed, with speed increments increased once a pilot hole has been created. The catheter shaft and crown should always be advanced under fluoroscopy at a rate of 1-cm per second or less. An "eraser technique" using short (1 to 2 cm) forward and backward movements of the crown augments the sanding process by allowing centrifugal force to increase and thereby affecting further plaque reduction. Each run should not exceed 20 to 30 seconds and should be followed by an equivalent rest period to allow the particulate to pass through the distal capillary bed.

Treatment should not be stopped in or distal to the lesion at the end of the run interval, but rather stopped after the crown has been withdrawn, while spinning, into a nondiseased proximal segment.

Angiography is recommended after every second treatment interval to assess procedural success. The orbiting speed can then be increased until adequate compliance change has been achieved.

If adjunctive PTA is needed to further increase vessel diameter, low-pressure balloon inflations (≤ 4 atm) can be used to produce an excellent angiographic outcome while minimizing the risk of dissection associated with high-pressure balloon inflations.[8]

A final angiogram of the treated artery and runoff to the foot should be obtained once the target lesion has been treated and blood flow through the artery has improved.

When orbital atherectomy is used in a stepwise approach in diseased tibial arteries, a satisfactory outcome can be achieved with or without adjunctive low-pressure angioplasty, as illustrated in the following case study.

CASE PRESENTATION

An 87-year-old woman with a long-standing ulcer of the left lateral malleolus (Figure 4A) was referred from the wound care clinic. The diagnostic angiography demonstrated occlusion of the popliteal artery behind the knee and multiple critical stenoses of the peroneal artery. Diffuse calcification was seen at each of the index lesions. A prosthetic knee complicated visualization of the lesions (Figure 4B).

Treatment

An antegrade puncture was done. With the knee bent and hip rotated out, the occlusion was crossed with a 0.035-inch angled Glidewire (Terumo Interventional Systems, Somerset, NJ), and the wire was directed into the peroneal artery. After wire exchange with the ViperWire Advance®, a 1.5 mm Classic Crown was spun for multiple intervals through the popliteal and peroneal lesions for a total treatment time of three minutes. A 2- X 100-mm Fox sv PTA catheter (Abbott Vascular, Santa Clara, CA) was used at 6 to 8 atm. A 2.25-mm Classic Crown was then used to further change compliance of the popliteal artery. Adjunctive balloon therapy was used to complete treatment for all lesions with a 5- X 80-mm Fox sv balloon inflated to profile. Brisk blood flow was re-established (Figure 4C) to the malleolus.

Results

One month after treatment, a photo (Figure 4D) shows that wound healing had advanced. Two months later, the malleolar ulcer was healed.

DISCUSSION

Treatment of infrapopliteal arterial disease is more challenging when compared to the treatment of proximal lower extremity disease due to a higher degree of diffuse calcification in infrapopliteal lesions. Bishop et al found that calcium plaque content increases with decreasing burden of fibrofatty plaque more distally in the arterial tree. Sharp variations between mean plaque burden in popliteal arteries compared to tibial arteries were also noted.[11] The STEALTH 360® System provides a unique alternative to treat these calcific lesions in the lower leg. The orbiting action of the diamond-coated crown selectively removes noncompliant calcified and fibrotic atheroma to increase arterial compliance resulting in effective treatment of these calcific lesions.

Historically, bypass surgery has been the preferred treatment for patients with infrapopliteal PAD. Early use of PTA for treating infrapopliteal lesions was reserved for short stenotic lesions or patients who were poor candidates for bypass surgery.[12] The less-invasive nature of percutaneous intervention relative to open surgical bypass makes it a more acceptable option for patients with lower extremity vascular disease.[13] However, a number of complications are associated with PTA of infrapopliteal lesions, including dissection, perforation, and the need for bailout stenting. Shammas et al found that the freedom from these complications were lower (93.1% vs. 82.4%) in a group treated with orbital atherectomy plus adjunctive low-pressure balloon angioplasty versus a group treated with balloon angioplasty alone. In this prospective randomized study called CALCIUM 360, freedom from target vessel revascularization (TVR) and all-cause mortality at 12 months was 93.3% versus 80% in the orbital atherectomy plus adjunctive low-pressure balloon angioplasty arm compared to the balloon angioplasty alone arm.[14] These high rates of procedural success and long-term patency have led a number of physicians to adopt endovascular intervention as the first-line modality in patients with chronic lower extremity disease.

CONCLUSION

Orbital atherectomy with the STEALTH 360® System represents an innovative endovascular treatment that provides a new option for difficult arterial lesions below-the-knee. The system is used in a stepwise, systematic approach to differentially sand calcified, noncompliant plaque while simultaneously allowing the compliant arterial wall to flex away from the rotating crown. Satisfactory outcomes in difficult lesions can be achieved with or without adjunctive low-pressure angioplasty. Improvement of blood flow to the lower extremity allows for wound healing and preservation of lower limb function. ■

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