

Peripheral Rotablator™ Atherectomy: The Below-the-Knee Approach to Address Calcium Head On

Peripheral Rotablator's front-cutting, diamond-tipped burr provides stable rotation in calcified lesions.

BY SONYA S. NOOR, MD, FACS

There are multiple endovascular options for treatment of infrainguinal disease, but treatment of severe calcific disease of the superficial femoral artery (SFA), popliteal artery, and tibial vessels remains a challenge. Peripheral atherectomy is a unique treatment modality because it allows debulking of plaque with luminal gain and minimal barotrauma. This results in less injury to the vessel during initial treatment and theoretically reduces hyperplastic reaction to the initial treatment. In severely calcific vessels, calcium debulking changes the vessel wall compliance with the removal of calcium. It can then be treated with low-pressure balloon inflation with minimal injury to the vessel wall. This is now a particularly attractive concept with the availability of drug-coated balloons and drug-eluting stents, as the vessel can be prepared with atherectomy before delivery of these devices. This may ensure adequate drug delivery to the tissue, thereby reducing intimal hyperplastic reaction and increasing durability of

the procedures. Prevailing concerns with atherectomy (ie, dissection, perforation, clinically significant embolization, and durability) have prevented the widespread use of atherectomy.¹

The Peripheral Rotablator Rotational Atherectomy System (Boston Scientific Corporation) (Figure 1) is one of the newer additions to the peripheral atherectomy device field. The coronary Rotablator Atherectomy system has been used for the last 20 years, and it has been very successful in treating moderate and severe calcific coronary disease, with encouraging safety and efficacy data to support its use.² Our center has been one of the largest users of Coronary Rotablator Atherectomy, so when the Peripheral Rotablator Atherectomy System became available, we quickly adopted this technology to use in severely calcific vessels. We started using the Rotablator Atherectomy System to treat severe tibial vessel calcification and small popliteal vessels. As our experience grew, we then started to use Rotablator Atherectomy more broadly when treating

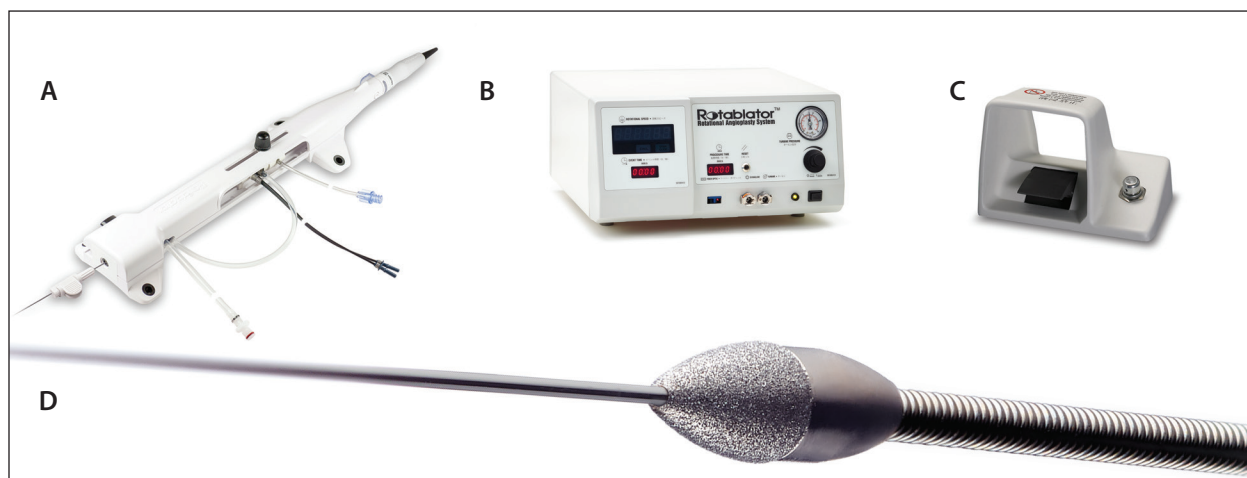


Figure 1. The Peripheral Rotablator Atherectomy System advancer (A), console (B), pedal (C), and burr (D).

The Rotablator Atherectomy System's front-cutting diamond burr is very useful in severe calcific stenotic lesions, as it can ablate its way through the calcium and create a channel that is smooth and has a predictable concentric lumen.

infrainguinal calcific disease, and found a reduction in the use of stents (or only focal stenting was required).

ROTABLATOR FEATURES AND MECHANISM OF ACTION

The Peripheral Rotablator Atherectomy System is fairly simple to use and requires a connection to the console, a power source, a compressed nitrogen tank, and an IV fluid mix to start using the device. The foot pedal starts the rotational atherectomy. Usually, 20- to 30-second runs are done under live fluoroscopy. This device uses a front-cutting diamond-coated burr to ablate the calcium particles, while rotating at 160,000 to 180,000 RPM in the lumen of the vessel. The coronary literature has studied the ablation particles over the last 20 years, and when proper technique is employed, the ablation particles generated measured about 5 μm , which is smaller than a red blood cell. These particles are then washed downstream during the treatment and picked up by the reticular endothelial system. For this reason, embolic protection devices are of no use, as the pore size of embolic protection devices are generally in the range of 100 μm and would not catch the ablation particles. Rotablator Atherectomy can only be performed with a 0.009-inch wire, which does not support the use of embolic protection devices, either.

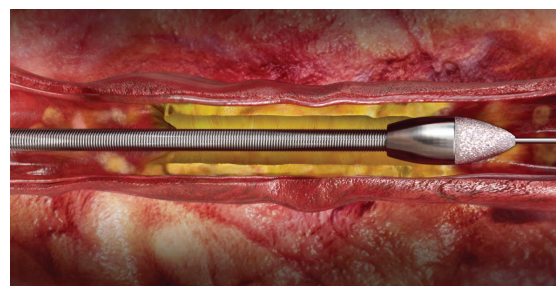
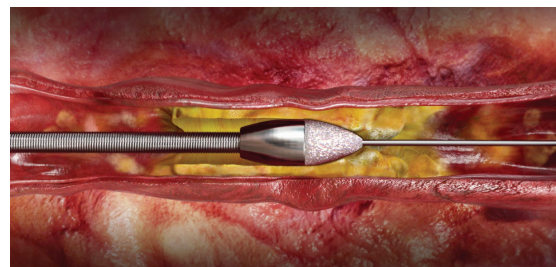
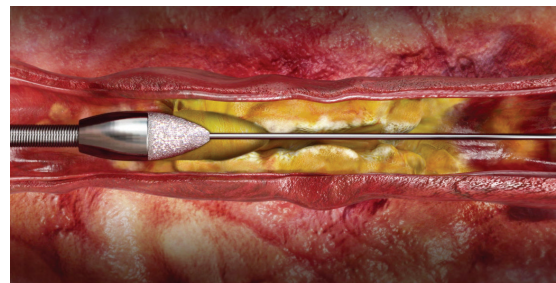
The Rotablator Atherectomy System's front-cutting diamond burr is very useful in moderately and severe calcific stenotic lesions, as it can ablate its way through the calcium and create a channel that is smooth and has a predictable concentric lumen.

Other devices have a leading edge, which has to be introduced first through the lumen before the device can be introduced and treatment can be performed, requiring predilatation or dottering, and causing barotrauma to the vessel prior to treatment. We have found this front-cutting feature particularly helpful in moderate and severe calcific disease and when negotiating even a predilatation balloon catheter can prove difficult.

As the diamond-coated burr engages the lesion while it rotates on the RotaWire™ (Boston Scientific Corporation), it has a stable circular rotation that creates a smooth, predictably concentric lumen. It ablates the plaque with predictable ablation particles with minimal injury to the vessel wall, which can be a concern with other atherectomy devices in small vessels. Average Rotablator™ Atherectomy run times, even in

ABLATION TECHNIQUE: COMMON CONSIDERATIONS

- 160,000 to 180,000 RPM setting is optimal for above- and below-the-knee calcific lesions
- Run for 20 to 30 seconds under live fluoroscopy
- One-burr approach is common
- Limit RPM drop to under 5,000 RPM
- Plaque modification: burr-to-artery ratio, 70%–85% to native lumen diameter



(Images courtesy of Boston Scientific Corporation.)

long, diffuse lesions, are typically 3 to 4 minutes per vessel, making this an efficient treatment modality.

ROTABLATOR BEST PRACTICES

As with other atherectomy devices, the Rotablator Atherectomy System has its own learning curve and performs well when proper technique is employed. We have used the Rotablator™ Atherectomy System in severe calcific disease as the first line of treatment for these lesions. We currently use it in the SFA, popliteal, and tibial vessels as the first line of treatment. Rotablator Atherectomy proves to be an effective tool for calcific ablation requiring low atmospheric balloon postdilatation and only focal stenting, if at all necessary. We are also starting to use Rotablator Atherectomy for vessel preparation before drug-coated balloon usage in order to potentially improve drug uptake in the vessel wall.

We have found that the 160,000 to 180,000 RPM setting is optimal for both above- and below-knee calcific lesions. Twenty- to 30-second runs under live fluoroscopy and a slow, deliberate pecking action with the burr engaging the lesion for a second or two, followed by a gentle pullback, results in successful luminal gain. It is important to engage the lesion with the burr, but also pull back for 1 to 2 seconds, which allows dissipation of frictional heat and flushing of microparticles into the distal circulation. Overzealous advancement of the burr can lead to the device stalling within calcific disease and distal embolization, which should be avoided.

CASE 1*

A 71-year-old African American woman with end-stage renal disease, a previous cerebrovascular accident, coronary artery disease, and coronary artery bypass

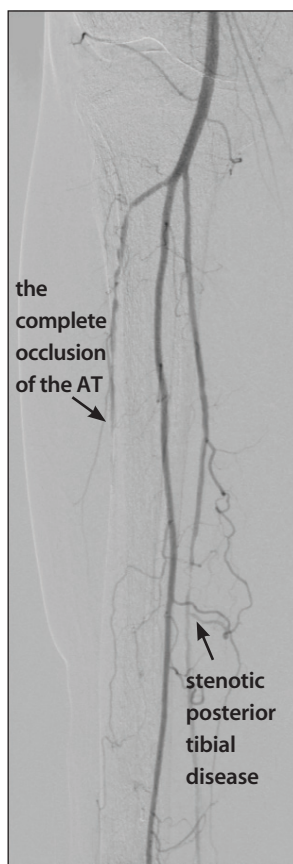


Figure 2. A diagnostic angiogram showing severe stenotic disease of the posterior tibial artery (arrow) and complete occlusion of the anterior tibial artery (bracket) with distal reconstitution.

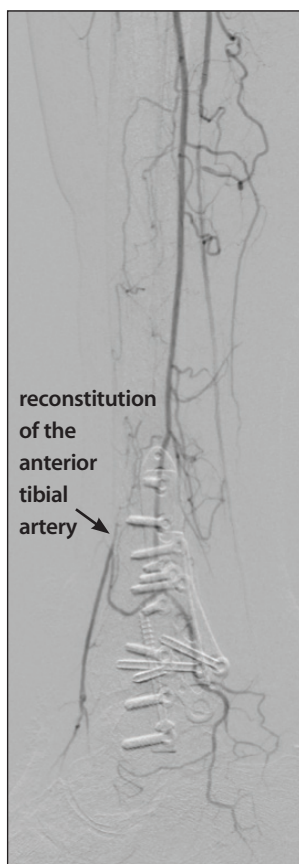


Figure 3. A diagnostic angiogram showing complete occlusion of the anterior tibial artery with distal reconstitution (arrow) and no flow in the distal posterior tibial artery.

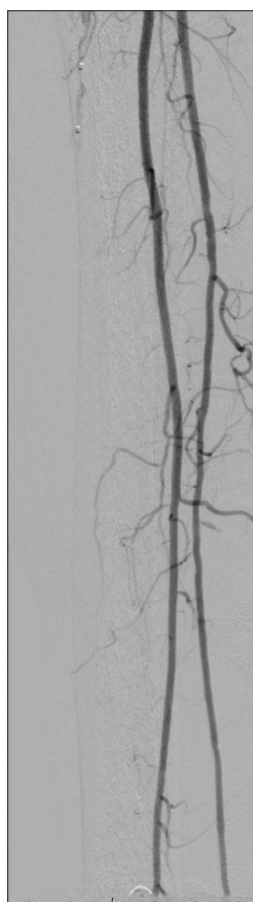


Figure 4. Angiogram after posterior tibial Rotablator Atherectomy showing healthy flow in the posterior tibial artery.



Figure 5. After Rotablator Atherectomy was performed in the posterior tibial and anterior tibial arteries, healthy flow was seen in both vessels down to the foot.

*Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

TABLE 1. ROTABLATOR ATHERECTOMY SYSTEM SIZING

Burr (mm)	Diameter (inches)	Minimum Recommended Introducer/Guide Sheath Size (F)
1.25	0.049	4 / 5*
1.50	0.059	5
1.75	0.069	6
2.00	0.079	6 / 7*
2.25	0.089	7
2.50	0.098	7 / 8*

* For a given French size guide sheath or introducer sheath, the internal lumen and hemostasis valve will vary from manufacturer to manufacturer. When using an introducer for the first time, it should be tested with the largest Peripheral RotaLink Plus burr intended to be used with it.

graft surgery presented with a left heel ulcer that was not healing despite treatment for many months. The patient's arterial Doppler showed noncompressible vessels and a toe-brachial index of 0.1, with reduced waveforms at all levels.

Procedural Details

Left common femoral artery ultrasound and puncture was performed with placement of a right side sheath, and a diagnostic angiogram was obtained, which clearly showed complete occlusion of the posterior tibial and anterior tibial artery (Figures 2 and 3). The patient underwent placement of a 5-F, 70-cm sheath and was heparinized before successful crossing of the posterior tibial artery occlusion and subsequently, the anterior tibial artery. The patient underwent Rotablator Atherectomy with a 1.75-mm burr of the posterior tibial artery first (Figure 4), followed by the anterior tibial artery. The total run time was 4 minutes, and the 180,000 RPM setting

was used in both arteries. After atherectomy was completed, low-pressure balloon angioplasty was performed using a 2.5-mm X 220-mm balloon, for a total of 2 minutes for each inflation.

Completion angiography showed no evidence of dissection, perforation, or distal embolization (Figure 5).

At 5-month follow-up, the patient was found to have almost completely healed ulcers, and arterial Dopplers showed improved waveforms at all levels, noncompressible ankle-brachial indices (ABIs), and a toe-brachial index of 0.5.

CASE 2*

A 65-year-old man presented with severe claudication and ischemic ulceration of the right second toe. Arterial Doppler exam showed an ABI of 0.58 on the right and 0.90 on the left. Pulmonary vascular resistance waveforms indicated distal SFA and popliteal artery disease.

Procedural Details

The patient underwent left common femoral artery access with placement of a 5-F sheath. Diagnostic angiography confirmed complete occlusion of the right SFA and popliteal artery at the adductor canal (Figure 6), with reconstitution of a popliteal artery at the knee joint and some mild diffuse tibial vessel disease. The patient underwent placement of a 7-F, 70-cm sheath, after which the patient was heparinized. A stiff Glidewire (Terumo Interventional Systems) and a 0.035-inch Quick-Cross catheter (Spectranetics Corporation) was used to cross the total occlusion, and reentry into the popliteal artery was confirmed. The RotaWire was placed into the tibial vessels, and Rotablator Atherectomy was performed using a 2.5-mm burr. A setting of 170,000 to 180,000 RPM was used for a total of 5 minutes. Then a 5- X 220-mm-long Sterling™ Balloon (Boston Scientific Corporation) was used for low-pressure angioplasty of 4 atm, for a total of 3 minutes. A follow-up angiogram (Figure 7) revealed excellent



Figure 6. A diagnostic angiogram showing occlusion of the distal SFA and popliteal artery.



Figure 7. Angiogram after Rotablator Atherectomy and low-pressure angioplasty. Restoration of flow is noted in the SFA and popliteal artery.

*Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

flow, good luminal gain, and no evidence of perforation, dissection, or significant embolization.

The patient was seen in follow-up 1 month after the procedure with no complaints of claudication, near complete ulceration healing, and arterial Doppler exams that showed an ABI of 0.84 on the right and 0.77 on the left, with good waveforms at all levels.

CONCLUSION

The Rotablator Atherectomy System has been used to treat moderate and severe calcific disease safely and efficiently for over 20 years in the coronary vasculature, and we started to use Rotablator Atherectomy to treat similar calcific disease in the periphery. At our center, we now use Rotablator Atherectomy as the first line of treatment whenever we encounter moderate or severe calcific disease. We have found the Rotablator Atherectomy System to be easy to set up and use, and it is efficient in ablating and treating calcium with short procedure times. There have been minimal dissections, perforation, or clinically significant embolization. As with all atherectomy devices, it is important to use proper technique while handling the device to minimize complications. The benefit of the front-cutting diamond burr is

especially useful in negotiating tight stenotic or occlusive lesions (where no predilatation is necessary), thereby minimizing barotrauma to the vessel before treatment. The stable rotation of the burr engages the calcium and ablates it, leaving a predictable concentric lumen. We have been successful in changing vessel compliance with calcium ablation, allowing minimal adjunctive therapy (such as low-pressure angioplasty, no stenting, or only focal stenting). We are also starting to use the Rotablator Atherectomy System to remove the calcium plaque burden and prep the vessel before use of drug-coated balloons. It remains to be seen if this strategy enhances drug uptake into the vessel wall, and therefore increase the durability of this procedure. ■

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2. Reisman MD. *Guide to Rotational Atherectomy*. Birmingham, MI: Physicians Press; 1997.