Cath Lab Digest
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CLINICAL CASE UPDATE

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Insights into Acute Limb Ischemia Management With Rotarex™ Atherectomy System

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Peripheral artery disease (PAD) affects over 21 million Americans and more than 236 million people worldwide.[1,2] It is a potentially debilitating disease that can lead to increased risk of cardiovascular complications and limb amputation. The rate of acute limb ischemia (ALI) cases is approximately 1.5 cases out of 10,000 individuals per year.[3] ALI results in rapid decrease in lower limb perfusion and is usually caused by thromboembolic events.[3,4] Hence, it is important to have rapid and effective revascularization after an episode of ALI to improve disease prognosis.[5] The treatment of atherothrombotic lesions should ideally aim to remove the thrombus and treat the underlying lesion, differing from traditional treatments for arteriosclerotic occlusions and embolization.[5] Management of thrombotic lesions include open surgical revascularization, catheter-directed thrombolysis and percutaneous mechanical thrombectomy. The treatment approach will be influenced by factors such as the type of occlusion, location, conduit type (artery graft), Rutherford classification, duration of ischemia, and co-existing conditions.[5] Open surgical revascularization and thrombolysis often require longer hospital stays and increase the risk of major bleeds.[5] Percutaneous mechanical thrombectomy offers debulking and serves as a less invasive option for thrombus removal compared to open surgery.[5]

The Rotarex™ Atherectomy System is designed to efficiently remove both plaque and thrombus by utilizing three distinct mechanisms of action, making it effective for treating various PAD lesions including in-stent restenosis in peripheral arteries. Offering dual functionality as both an atherectomy and thrombectomy device, the rotating atraumatic catheter head with blunt facets modifies and detaches mixed morphology lesions. Additional luminal gain is achieved by a vortex created around the rotating cylinder. The rotating internal helix creates continuous negative pressure at the tip, actively aspirating and transporting material away. The Rotarex™ Atherectomy System comes in two different size options: 6 French and 8 French. These sizes allow flexibility in treating various vessel diameters. In the lab, time and space are crucial. The Rotarex™ Atherectomy System is easy to set up, with a small plug-and-play capital component. Its reusable catheter handle is easily draped, and the system does not require warm-up or infusion.

This case study showcases a patient diagnosed with acute limb ischemia (ALI) who underwent treatment using the 6 French Rotarex™ Atherectomy System.

Case Summary

A 54-year-old woman experienced persistent pain in her right lower extremity while at rest. Her medical history included hypertension, type 2 diabetes, and coronary artery disease. She had a history of smoking and was previously diagnosed with peripheral arterial disease in 2020, which led to a failed attempted bypass and ultimately resulted in a left above-the-knee amputation. Despite undergoing right superficial femoral artery (SFA) stent placement at an outside vascular facility, her most recent revascularization ultimately resulted in rapid thrombosis.

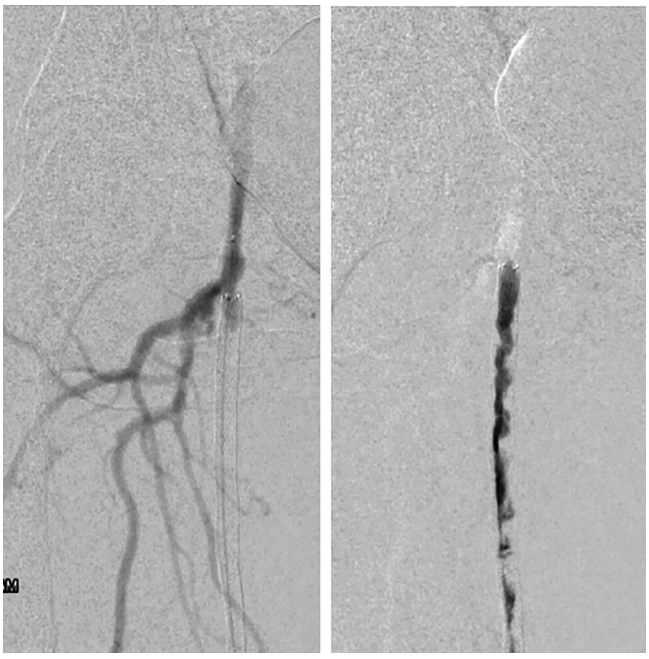

Figure 1A-B. Intravascular ultrasound was used in the common femoral artery, extending proximally through the sheath positioned in the dorsalis pedis artery. It confirmed the presence of thrombus within the right femoral-popliteal stent construct.

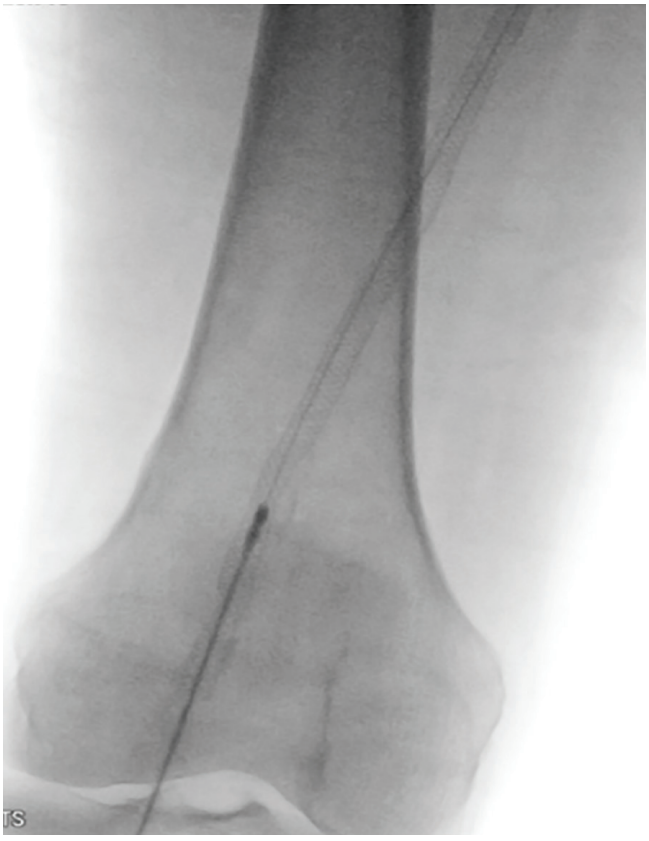

Figure 1C. The 6 French Rotarex™ Atherectomy System effectively removed the thrombus that had formed within the right femoral-popliteal stent.

An hour after intervention of her right SFA, while being monitored in the postoperative recovery unit, the patient lost pulses in her right foot. She was promptly taken to the interventional radiology suite. Using a 21-gauge micropuncture needle, the right dorsalis pedis artery was accessed under ultrasound guidance. A 6 French thin-walled sheath was then placed over an .018-inch guidewire, and a catheter was advanced to the right common femoral artery. Intravascular ultrasound (IVUS) was used in the common femoral artery, extending proximally through the sheath positioned in the dorsalis pedis artery. It confirmed the presence of thrombus within the right femoral-popliteal stent construct (**Figure 1A-B**). The 6 French Rotarex™ Atherectomy System effectively removed the thrombus that had formed within the right femoral-popliteal stent (**Figure 1C**) with a single back-and-forth motion through the lesion. After the thrombectomy, a 6 mm x 40 mm bare metal stent was added to the distal end of the femoral-popliteal stent, and the entire stent column was dilated to 6 mm with a percutaneous transluminal angioplasty dilatation catheter. The post-intervention arteriogram confirmed brisk three-vessel flow to the foot. Flow was successfully restored within

Figure 1D. Flow was successfully restored within the recently thrombosed stent column, and distal pulses returned after the procedure.

the recently thrombosed stent column, and distal pulses returned after the procedure (**Figure 1D**). At the 6-week follow-up, the patient had palpable pulses in her right foot.

Discussion

ALI is a severe condition characterized by inadequate blood flow to the extremities. Patients presenting with ALI need prompt diagnosis and interventions to prevent limb loss and potential mortality. In the case described here, we employed the Rotarex™ Atherectomy System to reestablish blood flow through a thrombosed stent in a patient who experienced a sudden loss of pulses in her right foot one hour after a prior SFA intervention where a stent was placed. In my practice, the Rotarex™ Atherectomy System has addressed our need for thrombus aspiration.

I have found the Rotarex™ Atherectomy System serves a specific and valuable purpose. Serving as both a thrombectomy and atherectomy solution, it addresses acute, subacute, and chronic peripheral occlusions. It has become my exclusive choice for rotational atherectomy, especially in the femoral-popliteal and proximal tibial arteries (3 mm or greater in size), and I have found it is particularly useful for treating in-stent restenosis in peripheral arteries. It is also highly suitable for managing thrombotic occlusions, as the case report presented herein demonstrates. Given that severe bleeding risk can cause significant challenges for many patients, thrombolysis may not always be effective, making the Rotarex™ Atherectomy System for thrombectomy my treatment of choice.

IVUS is essential in determining my treatment approach with the Rotarex™ Atherectomy System. Before formulating a strategy, I conduct a comprehensive IVUS evaluation of each lesion. While the dimensions of the native vessel and the shape of the plaque inform my treatment choices, it is the plaque morphology that is pivotal to my entire treatment protocol. Instances of loosely attached plaque, lipid-rich plaque, or fresh thrombus within lesions often go undetected in angiography but are revealed through IVUS. This imaging, combined with the patient's clinical history, duplex ultrasound findings, and angiographic imagery, is crucial in determining the suitability of the Rotarex™ Atherectomy System for specific arterial lesions. Guided by visual and auditory cues, I navigate the Rotarex™ Atherectomy System through complex lesions. I begin by marking the lesion's extent for treatment and proceed to inch the device forward along the guidewire, ensuring aspiration is active to evacuate any fragmented debris. While it is patient-dependent, in many of my cases, the first pass is effective enough to proceed with potential adjunctive therapies. In scenarios with more dense lesions, a noticeable shift in sound or a hint of resistance prompts me to reduce the catheter advancement to 1 mm per forward motion. Repeating this process until the auditory or tactile feedback ceases indicates that I have effectively reduced the lesion's bulk to the extent possible. The post-atherectomy IVUS provides a straightforward confirmation.

From a clinical perspective, the Rotarex™ Atherectomy System offers numerous benefits. The head of the device is beveled at the tip and has a nominal speed of 40,000 or 60,000 revolutions per minute depending on the catheter size, detaching the material from the arterial wall and fragmenting it into small pieces that are then transported out of the artery through two openings within the catheter tip. The rotating helix creates continuous negative pressure at the tip, actively aspirating and transporting material away.

In my practice, I have found that the Rotarex™ Atherectomy System differentiates itself through its powerful aspiration force, which helps to reduce the risk of peripheral embolization. Additionally, I have not observed any hazardous depletion of blood volume with the 6 or 8 French Rotarex™ Atherectomy System, a complication that can occur with conventional aspiration using thrombectomy catheters for acute thrombotic or embolic lesions. The device's low-profile design also allows for pedal access with a slender 6 French sheath. The debulking capability of the Rotarex™ Atherectomy System, along with its straightforward setup process for my technologists, solidified its role in our procedures.

Conclusion

In conclusion, the Rotarex™ Atherectomy System stands out as a tool in the management of acute limb ischemia, providing an option for thrombus removal compared to open surgery. Patients with ALI, who are typically at high risk for complex revascularization procedures, can benefit from the system. Offering dual functionality as both an atherectomy and thrombectomy device, the Rotarex™ Atherectomy System is designed to efficiently remove a wide variety of PAD lesion morphologies. ■

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Disclosure: Dr. Watts reports he is a consultant/speaker for BD. The opinions and clinical experiences presented herein are for informational purposes only. The results from this case study may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes. The physician has been compensated by BD for this paper.

The Rotarex™ Atherectomy System is intended for use as an atherectomy device and to break up and remove thrombus from native peripheral arteries or peripheral arteries fitted with stents, stent grafts or native or artificial bypasses. The Rotarex™ Atherectomy System is contraindicated · In patients not suitable for atherectomy/thrombectomy · In the cardiopulmonary, coronary, carotid, cerebral and renal vasculature · In vessels that are undersized for the particular device used · In the venous vasculature. Potential adverse events include, but are not limited to: · Embolization, especially distal embolization · Pulmonary embolisms of all degrees of severity · Thrombosis · Re-occlusion · Vessel wall injury · Vessel dissection / perforation/ rupture · Perforation as a result of mural calcium being torn out of the vessel wall · Arteriovenous fistula / pseudo-aneurysm · Hematoma, bleeding, hemorrhage · Organ perforation · Implants such as stents / stent grafts / bypass grafts getting damaged, caught or dislodged · Disruption of the catheter: debris remaining in the body · Allergic reactions, including allergic reactions to device components · Infections or necrosis at the puncture site · Catheter induced sepsis · Death. Please consult product labels and instructions for use for indications, contraindications, hazards, warnings, and precautions.

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