

Case Reports: The Auryon Atherectomy System Above and Below the Knee

A discussion of the PATHFINDER I postmarket trial and case experience from two centers demonstrating successful use of the Auryon laser in severely calcified lesions.

With Jason Yoho, MD, FACC; Venkatesh Ramaiah, MD, FACS;
and Harrison Lewis, DMSc, MS, PA-C

The Auryon laser atherectomy system (AngioDynamics, Inc.) is a 355-nm, solid-state, third-harmonic, Nd:YAG, short-pulsed laser cleared by the FDA for the treatment (including atherectomy) of infrainguinal stenoses and occlusions, including in-stent restenosis (ISR). The Auryon laser system has been shown to have higher affinity for plaque than for endothelium and no concern for causing thermal necrosis.¹ A prospective, single-arm, multicenter, international, open-label study assessed the safety and efficacy of the Auryon laser atherectomy system in 97 patients. The study demonstrated safety and efficacy above and below the knee across all lesion types and calcification levels, including chronic total occlusions (CTOs) and ISR. There was no flow-limiting dissection or distal embolization. After Auryon laser atherectomy, a stenosis reduction > 30% was demonstrated in all lesion categories with atherectomy alone. Follow-up at 30 days and 6 months revealed patency rates of 96.8% and 85.6%, respectively.²

The Auryon laser system comes with four catheter sizes. The 0.9- and 1.5-mm catheters are intended to be used below the knee, and the 2- and 2.25-mm catheters are intended to be used above the knee and come with built-in aspiration. The 355-nm laser over a short-pulse duration of < 10 ns gives it an advantage over the older 308-nm laser technology by delivering higher peak or shorter pulse duration, making it ideal for treating calcified occlusions. The catheter is fitted with a blunted tip to facilitate plaque dissection.¹

AngioDynamics is currently conducting the postmarket PATHFINDER I registry of the Auryon atherectomy

device (NCT04229563). The United States–based multicenter, prospective, single-arm, observational postmarket registry is a pilot registry toward a large pivotal registry (PATHFINDER II). PATHFINDER I aims to evaluate the safety and efficacy of the Auryon atherectomy system in treating de novo restenotic and ISR lesions in infrainguinal arteries of patients with peripheral artery disease (PAD) in a real-world setting. The trial will enroll 100 patients across 10 sites in the United States, with primary endpoints of effectiveness and safety. The primary effectiveness endpoint is defined as acute, core lab–adjudicated procedural success (\leq 30% residual stenosis) after Auryon laser atherectomy and adjunctive therapy. The primary safety endpoint is defined as freedom from major adverse events, including unplanned target limb amputation, cardiovascular death, clinically driven target lesion revascularization, and target vessel revascularization. Follow-up at 6, 12, and 24 months will evaluate patency rate and clinical outcomes.³

This article details two laser atherectomy cases that demonstrate the device's efficacy and safety both above and below the knee in severely calcified lesions, a CTO lesion, and ISR. The cases were performed in a hospital-based lab and an office-based lab. Both patients were enrolled in the PATHFINDER I postmarket trial.

1. Herzog A, Ozskinis G, Planer D, et al. Atherectomy using a solid-state laser at 355 nm wavelength. *J. Biophotonics*. 2017;10:1271–1278. doi: 10.1002/jbio.201600209

2. Rundback J, Chandra P, Brodmann M, et al. Novel laser-based catheter for peripheral atherectomy: 6-month results from the Eximo Medical B-Laser™ IDE study. *Catheter Cardiovasc Interv*. 2019;94:1010–1017. doi: 10.1002/ccd.28435

3. Post-market registry of Auryon™ atherectomy device in subjects affected with infrainguinal peripheral artery disease (PATHFINDER-I). Clinicaltrials.gov website. Accessed October 20, 2020. <https://www.clinicaltrials.gov/ct2/show/NCT04229563>

Case 1: Severely Calcified Right Anterior and Posterior Tibial Artery Stenoses in a Hospital-Based Lab



Jason Yoho, MD, FACC

Interventional Cardiologist
Heart and Vascular Institute of Texas
New Braunfels, Texas

*Disclosures: Paid consultant to
AngioDynamics, Inc.*

A 61-year-old woman presented with severe claudication and rest pain. She was Rutherford class 5 with bilateral symptoms that were worse on the right side. Noninvasive imaging revealed severe PAD below the knees. Her risk factors included PAD with history of a slow-healing right lower extremity ulcer, diabetes mellitus, myocardial infarction, hypertension, and dyslipidemia. On examination, she had decreased peripheral pulses with coolness to her bilateral lower extremities. Arterial duplex ultrasound revealed monophasic waveforms in the distal anterior tibial artery, dorsalis pedis, and peroneal arteries at the ankle. Toe-brachial indices in the right and left extremities were 0.88 and 0.73, respectively.

DIAGNOSTIC ANGIOGRAPHY

Femoral access was achieved in the left common femoral artery, and angiography was performed with runoff

from the sheath. The right anterior tibial artery had a 20% to 30% proximal stenosis. The right mid-anterior tibial artery was severely calcified with an 85% stenotic lesion. The right anterior tibial artery provided flow into the dorsalis pedis artery. The right tibioperoneal trunk had a 20% distal stenosis (Figure 1). The right peroneal artery tapered significantly to < 1 mm in diameter, with diffuse distal disease. The right posterior tibial artery was approximately 2.5 mm in diameter and severely calcified (Figure 2), with a long tubular 90% stenosis and a 99% subtotal stenotic lesion in the foot (Figure 3).

INTERVENTION

A 6-F, 90-cm Destination sheath (Terumo Interventional Systems) was inserted up and over the iliac bifurcation and advanced into the right superficial femoral artery (SFA). A Sion black wire (Asahi Intecc USA, Inc.) inserted within a CXI catheter (Cook Medical) was advanced in the anterior tibial artery, across the lesions and into the distal dorsalis pedis artery. A second Sion black wire was inserted into a CXI catheter and advanced from the right posterior tibial artery into the plantar arch. There was difficulty advancing the wire past the lesions in the pedal arch. Given the severity of disease, it was felt necessary to improve outflow to ensure procedural success. A 1.5- X 12-mm Trek coronary balloon (Abbott) was inserted over the wire, and balloon angioplasty was performed in the severely tortuous and calcified mid-posterior tibial artery to predilate the lesions. The balloon was removed, and intravascular ultrasound revealed a vessel of approximately 2.5 mm in diameter, with severe 360° calcification.

Laser atherectomy was performed with the Auryon laser atherectomy system. A 0.9-mm Auryon laser atherectomy catheter was inserted over a 0.014-inch, 300-cm guidewire and advanced to the anterior tibial artery. Laser atherectomy was performed at a fluency of 50 mJ/mm², with an advancement rate of approximately 1 mm/sec for two passes. After atherectomy of the anterior

Courtesy of Hurricane Cardiology.



Figure 1. Angiogram showing runoff with diffuse narrowing in the anterior and posterior tibial arteries.



Figure 2. Heavy calcification in posterior tibial artery.



Figure 3. Severely calcified and tortuous posterior tibial and plantar arch with a long tubular 90% stenosis and 99% subtotal stenotic lesion in the foot.

Courtesy of Hurricane Cardiology.



Figure 4. Angiogram of runoff post balloon angioplasty showing excellent recanalization after Auryon laser.



Figure 5. Angiogram post balloon angioplasty showing improved distal flow after Auryon laser.

tibial artery, the Auryon laser catheter was removed and exchanged onto the wire of the posterior tibial artery, and atherectomy was performed at a fluency of 50 mJ/mm² with an advancement rate of approximately 1 mm/sec for two passes.

Adjunctive balloon angioplasty of the anterior tibial artery and posterior tibial artery was completed with 2.5- X 120-mm Armada (Abbott) and Chocolate (Medtronic) balloons. Postadjunctive therapy intravascular ultrasound revealed significant luminal gain with excellent flow down the anterior and posterior tibial arteries. There was < 20% residual stenosis of the posterior tibial artery and < 10% residual stenosis of the anterior tibial artery (Figure 4). Examination of the right foot revealed improved perfusion of the entire anterior and posterior arch (Figure 5).

Case 2: Long Right SFA With ISR and CTO in an Office-Based Lab



Venkatesh Ramaiah, MD, FACS

Chief Vascular and Endovascular Surgery
Honor Heath Network
Co-Founder

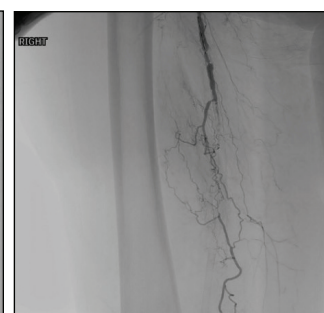
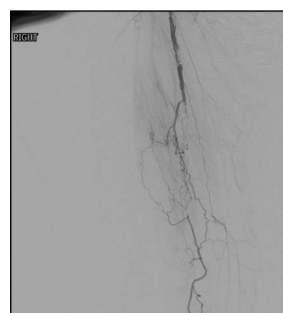
Pulse Cardiovascular Institute
Scottsdale, Arizona

*Disclosures: Paid consultant to
AngioDynamics, Inc.*

An 80-year-old woman presented with severe right leg pain at rest. She had a history of PAD with multiple previous bilateral percutaneous interventions and right SFA and right popliteal stents. Other risk factors included coronary artery disease and diabetes mellitus. Duplex/Doppler ultrasound revealed severe monophasic flow below the right proximal SFA.

DIAGNOSTIC ANGIOGRAPHY

Access was gained in the left common femoral artery and a 6-F Raabe sheath (Cook Medical) was placed. Angiography was performed of the left leg with runoff of the foot through the sheath in the left common femoral artery. Angiography was also performed of the right leg with runoff to the foot through the sheath in the left common femoral artery. Up-and-over placement of a 6-F Destination sheath was performed in the right common femoral artery. An angiogram of



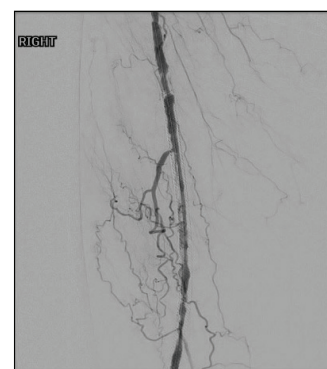
Courtesy of Dr. Ramaiah.

Figure 6. Angiograms showing runoff of the long right SFA with CTO and ISR.

the right leg with runoff to the foot was obtained through the sheath in the left common femoral artery. Angiography revealed a severely calcified 30-cm-long right SFA with ISR and CTO (Figure 6).

INTERVENTION

Crossing of the occluded long-segment SFA and occluded stents was achieved with a 0.014-inch Command ES wire (Abbott) and a 0.035-inch TrailBlazer catheter (Medtronic).



Courtesy of Dr. Ramaiah.

Figure 7. Angiogram showing the right SFA after Auryon laser atherectomy.

THE AURYON LASER ATHERECTOMY SYSTEM

Sponsored by AngioDynamics, Inc.

Courtesy of Dr. Ramiah.

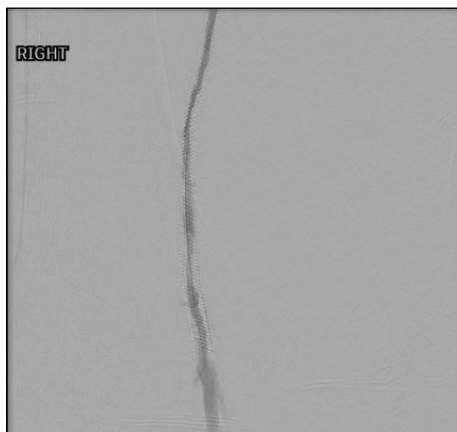


Figure 8. Angiogram showing the right distal SFA after Auryon laser atherectomy.

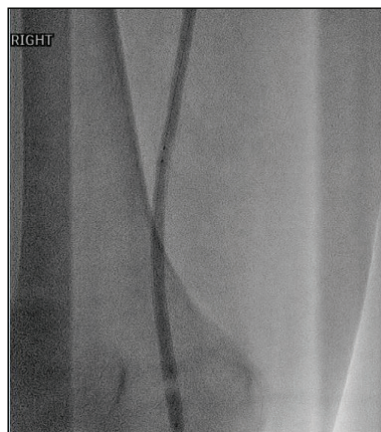


Figure 9. Distal SFA after atherectomy with the Auryon laser catheter and adjunctive balloon angioplasty.

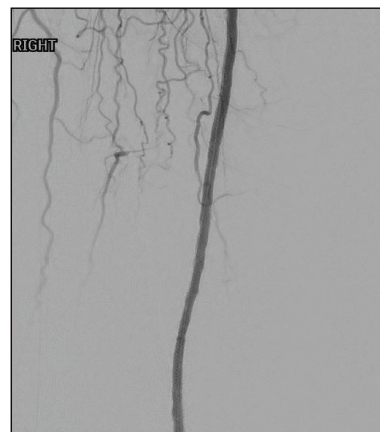


Figure 10. Distal SFA post angioplasty and stent placement.

A 6-mm SpiderFX (Medtronic) embolic protection device filter was placed into the popliteal artery. Laser atherectomy was performed using the Auryon Laser at a fluency of 50 mJ/mm² for two passes, with an advancement rate of approximately 1 mm/sec throughout the in-stent segment with interval angiograms (Figures 7 and 8). A 2- or 2.35-mm Auryon laser catheter device with aspiration is indicated for the treatment of ISR. The total lasing time was 4 minutes. Adjunctive therapy was completed with balloon angioplasty of the

entire stented segment with a 5- X 200-mm NanoCross balloon (Medtronic), including the popliteal as well as the proximal SFA (Figure 9). Completion angiography was performed through the sheath in the right common femoral artery of the entire right leg, with runoff to the foot. The sheath in the left common femoral artery was removed and the puncture site was closed with a Celt closure device (Veryan Medical). Excellent luminal gain was achieved with improved flow (Figure 10).

Conclusion

The Auryon atherectomy system appears to be a safe and effective treatment above and below the knee, including for critical limb ischemia. The 355-nm laser in conjunction with adjunctive treatment of highly calcified lesions significantly improves distal flow. Initial experiences in both cases demonstrated the device to be safe, with no dissections, perforations, or distal embolization. The device proved to be efficient and easy to use and showed excellent recanalization of severely calcified lesions. Postmarket data from the PATHFINDER I study and eventual PATHFINDER II

study will further demonstrate the safety and efficacy of the Auryon device and its ability to treat all lesion types and calcifications above and below the knee. ■



Harrison Lewis, DMSc, MS, PA-C

Medical Science Liaison

AngioDynamics, Inc.

Latham, New York

harrison.lewis@angiodynamics.com

Disclosures: Employee of AngioDynamics, Inc.