Early Experience With the Auryon Atherectomy System

An in-depth look at the Auryon system, including clinical data, a real-world case report, and advantages over other available laser atherectomy systems.

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Vascular centers across the world increasingly rely on minimally invasive techniques to treat peripheral artery disease (PAD), reserving open surgery for endovascular failures. Endoluminal therapies have exponentially increased,[1] with new devices and methods constantly being added to the existing armamentarium. This dramatic expansion has quickly outpaced the scientific evidence needed to substantiate its efficacy. Given the increasing use of endoluminal therapy and the growing number of patients with PAD, determining the most effective treatment for this condition is extremely valuable.

Atherectomy provides a revascularization alternative to conventional angioplasty and stenting. In contrast to angioplasty and stenting, which expands the arterial lumen while leaving plaque behind, atherectomy decreases plaque burden and reduces vessel injury. It is widely believed that atherectomy represents a more permanent and effective revascularization technique. Several modifications of atherectomy devices have been developed since the initial excitement over early devices in the mid-1980s.[2] Nevertheless, long calcified lesions and in-stent restenosis (ISR) remain the biggest challenges for all of these techniques.

A welcome addition to the available atherectomy devices is the Auryon system (AngioDynamics, Inc.), previously known as the B-Laser. The Auryon system is currently indicated for the treatment of infrainguinal atherosclerotic lesions, including ISR. The Auryon system produces a beam of high-energy ultraviolet radiation through an array of optical fibers, which ablates atherosclerotic plaque, and is supported by a blunt blade at its distal tip ("B") to complement the laser effect. Our institution has used the Auryon system successfully in above-the-knee (ATK) and below-the-knee (BTK) cases, and as our experience has grown, laser atherectomy has become our first-line therapy for patients with PAD.

OVERVIEW OF THE PERIPHERAL AURYON SYSTEM

The Auryon system (Figure 1) is a 355-nm, solid-state, short-pulse laser that transmits energy to the diseased

Figure 1. The Auryon system.

CASE STUDY

A 66-year-old man with diabetes mellitus presented to our office with rest pain and three nonhealing wounds affecting his right foot. The wounds were located at the base of the great toe, the lateral aspect of the foot, and above the medial malleolus (Figure 2). His past medical history included a right iliofemoral endarterectomy and a right fifth-toe amputation due to a nonhealing toe ulcer. After duplex ultrasound revealed significant tibial lesions, the patient was offered a right leg angiogram with possible endovascular revascularization. Angiography of the right lower extremity revealed patent right common femoral and deep femoral arteries. There were several femoropopliteal stenoses that appeared nonsignificant. The patient had a single tibial runoff through the anterior tibialis artery, and the posterior tibial artery was completely occluded from its origin, with no reconstitution. The peroneal artery had a 4-cm proximal occlusion, but it reconstituted in the upper calf (Figure 3A). The right dorsalis pedis (DP) artery had a critical focal stenosis at the dorsum of the foot. The decision was made to treat the peroneal and DP lesions. A 0.014-inch Roadrunner wire (Cook Medical) was used to successfully traverse the right peroneal occlusive lesion. Intraluminal distal confirmation was achieved by advancing

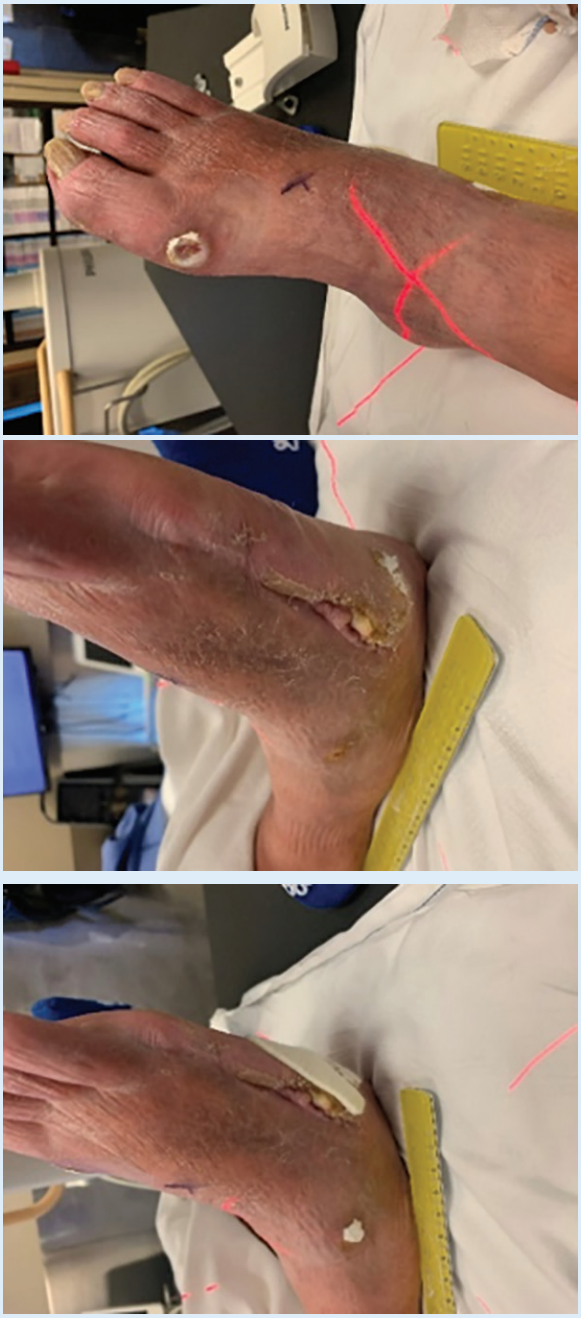

Figure 2. Three nonhealing wounds on the right foot.

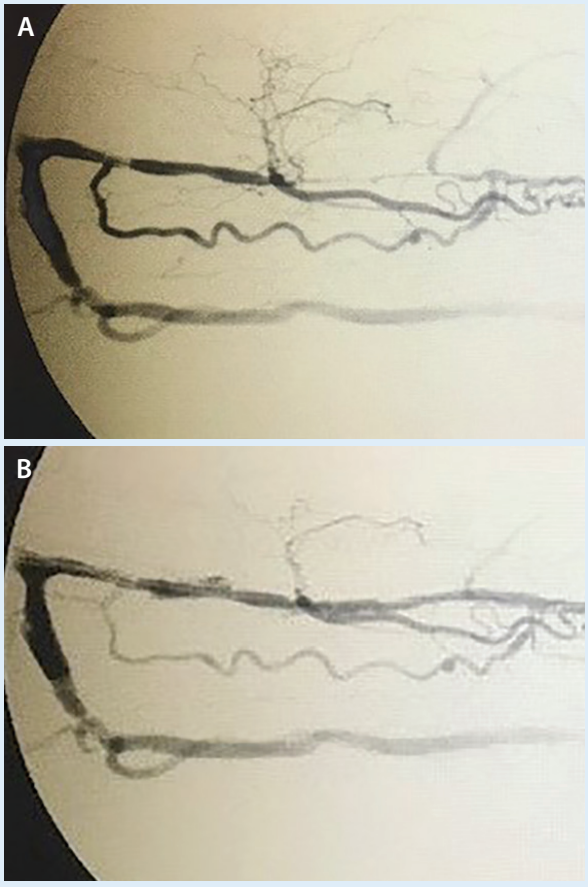

Figure 3. The right 4-cm proximal peroneal occlusion before (A) and after (B) treatment with the Auryon system.

Figures courtesy of Luis R. Leon Jr, MD, RVT, FACS.

CASE STUDY (Continued)

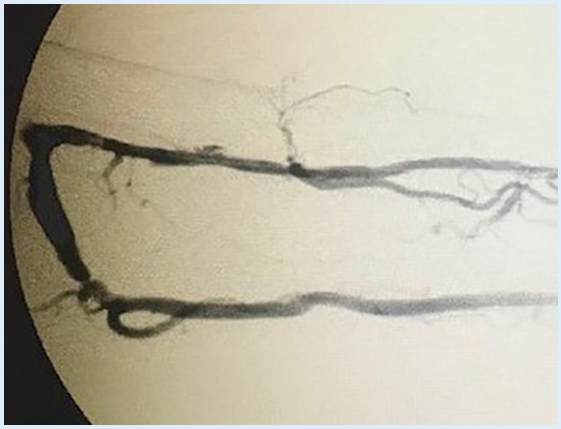

Figure 4. The right 4-cm proximal peroneal occlusion after treatment with the Auryon system and angioplasty.

a catheter and placing it at the distal right peroneal artery. When this was confirmed, a 1.5-mm Auryon laser atherectomy device was used to treat the right peroneal artery (Figure 3B), followed by balloon angioplasty using a 2.5- X 60-mm percutaneous transluminal angioplasty (PTA) balloon with excellent angiographic results (Figure 4). Next, a 0.014-inch wire was advanced across the DP lesion. After intraluminal distal confirmation, angioplasty was performed on the right DP artery using 1.5- X 40-mm and 2- X 40-mm PTA balloons, and nitroglycerin was injected, with improved results. No immediate complications were noted.

artery at preset fluency levels of 50 and 60 mJ/mm^2. The system works over 0.014-inch wires. There are four available catheter sizes. For the small catheters (0.9 and 1.5 mm), there is a designated lumen for a guidewire at the center of the inner blunt blade. The larger catheters (2 and 2.35 mm) have an eccentric guidewire lumen and include additional features, such as an aspiration port (both the 2- and 2.35-mm catheters) and an "off-center" mechanism (the 2.35-mm catheter only). The aspiration feature is intended for debris suction during debulking. The "off-center" feature allows for larger lumen debulking beyond the catheter's diameter (eg, femoropopliteal arteries). The system can be applied for a maximum 10 minutes of "lasing," even though the times typically seen during clinical application are shorter.

In preclinical studies, the Auryon system showed a higher affinity for ablation of fibrotic material than endothelium, thus reducing the risk of vessel injury or other complications that impact current atherectomy practice.[3,4] The device successfully recanalized calcified cadaveric leg arteries and was shown to be safe in vivo in porcine iliac vessels, with no histopathologic evidence of thermal necrosis, no wall damage to the treated arteries, and no significant impact on hematologic and biochemical indices.[5] Human trials so far include the EX-PAD-03 investigational device exemption (IDE) study[6] and the first-in-human EX-PAD-01 study (Kuczmik W, Kruszyna L, Stanisic MG, et al, manuscript in preparation). Both of these prospective multicenter trials assessed the safety and efficacy of the Auryon system in patients with symptomatic infrainguinal PAD (Rutherford class 2-4), with promising results. The IDE trial led to FDA clearance of this technology, and commercial activity started in May 2019.

Our center has extensively used this system to treat patients affected by highly complex calcific lesions in ATK and BTK arterial segments, including antegrade and retrograde pedal approaches. A retrospective analysis of our first 93 patients (Rutherford class 3-6; 224 lesions treated from March 2019 to February 2020) is currently under preparation. This will be the first reported real-world case series assessing the safety and efficacy of the Auryon system in patients with infrainguinal PAD. Similar to previously published trials, this study hypothesizes that the system is safe and effective, with no evidence of procedural distal embolization or major adverse events in any patient during the follow-up period (Luis LR Jr, Green CS, Vazquez F, Pacanowski JP Jr, manuscript in preparation).

PROCEDURAL STEPS

For atherectomy of proximal or mid superficial femoral arterial lesions using the Auryon system, contralateral femoral access is preferred. For the patients with distal superficial femoral artery or infrapopliteal artery occlusive disease, ipsilateral antegrade femoral access is our method of choice. Intravenous heparin is routinely administered. After angiographic confirmation, the lesion is traversed with a wire. Unlike other atherectomy systems, any wire can be used with the Auryon system for the atherectomy procedure (hydrophilic coated or not). A heparinized saline solution is connected to the groin sheath to wash out columnar blood that could interact negatively with the laser application. Once across the lesion, a catheter is used to exchange the crossing wire for a 0.014-inch wire. For heavily calcified lesions, even when the catheter does not easily cross the lesion, angioplasty is rarely per-

formed as first-line therapy because the Auryon system achieves lesion crossing without predilatation in most cases. If the exchange catheter easily crosses the lesion, an appropriately sized Auryon catheter is advanced across the lesion at a suggested advancement speed of 1 mm per second. For the largest devices (2 and 2.35 mm), suction tubing is connected to prevent distal embolization.

ADVANTAGES OF THE AURYON SYSTEM

Based on our experience, the Auryon laser system offers multiple logistical, practical, theoretical, and real advantages over other available atherectomy systems, including other laser-based technologies. The Auryon system includes an intuitive, Windows-based touch screen in a small console (29 X 15 X 37 inches, 187 lb) that favorably compares with existing laser competitors. It is less noisy than competitors, has no special installation requirements, and plugs into existing outlets using 110 V. The console is easy to move for staff and does not take up a significant amount of space. It also does not require calibration and demands minimal warm-up time.[7]

The system is also highly adaptable. An increasing number of our patients require distal retrograde access. The very low profile needed for the smaller Auryon catheters allows us to perform the entire intervention from a distal approach. The Auryon system is meant to be applied to all levels of calcification, treats infrainguinal lesions at all levels (ATK and BTK), and in the largest catheter, has the built-in capability to achieve a larger luminal gain than the catheter size.

The Auryon system interacts with specific tissues in a very particular manner that minimizes the chances of arterial perforation. It is known that different tissue types respond differently to certain laser wavelengths. Longer wavelengths are absorbed at shallower depths than shorter ones, resulting in lower photon energies. The available excimer laser used for atherectomy operates at relatively short wavelengths of 308 nm. The radiation of the excimer laser has shown to be readily absorbed by tissue chromophores, creating a concentration of energy delivery at a shallow penetration depth. Consequently, there appears to be a relative bias toward the ablation of vessel wall surface material compared with deeper fibrotic plaque when using an excimer laser. The 355-nm wavelength of the Auryon system is highly absorbed in blood, resulting in increased photomechanical effects, and absorbed at a shallower depth in the endothelium, resulting in vessel wall preservation. Its 3.5-eV photon energy is high enough to ablate lesions but low enough to preserve the vessel wall,[3,5] thus minimizing the risk of arterial perforation.

For laser devices to exert their effect over the target tissue without thermal damage, the energy delivered needs to be faster than the time it takes for the heat to diffuse. The Auryon system has a very short (< 25 ns) pulse width, allowing for the delivery of greater power to ablate severely calcified lesions. This shorter pulse width produces greater amplitudes, which can deposit energy before thermal diffusion occurs.[8]

The Auryon system is nonreactive to contrast media. This allows for simultaneous ablation and observation of fluoroscopy images. With other laser devices such as excimer, a relatively high radiation peak pressure is generated in an ablation field containing blood and contrast media. This can increase the risk of vessel damage, as seen in coronary arteries. This risk is due to the high optical absorption in contrast media that creates elevated radiation pressure, as compared to blood without contrast. To avoid this situation, saline flushes are required to remove contrast prior to excimer laser ablation at 308 nm. Thus, to avoid arterial damage, fluoroscopic observation cannot be conducted during excimer laser atherectomy.

Lastly, the Auryon system includes built-in aspiration to minimize distal embolization. We routinely use embolic protection devices (EPDs) with other available laser atherectomy systems. In our experience, procedures performed with the Auryon system did not require EPDs, even in high-risk patients with single-vessel runoff and in lesions felt to be high risk for embolization. Additionally, no major arterial embolization was evident during the index procedures. Avoiding the use of EPDs translates into significant time and cost reduction.

FUTURE EXPERIENCE WITH AURYON

The experience detailed herein is early, mostly short-term, and requires longer follow-up validation. The PATHFINDER-I registry is a pilot study that will enroll 100 patients at approximately 10 sites in the United States to evaluate the periprocedural, intermediate, and long-term safety and efficacy of the Auryon system in the treatment of patients with PAD in a real-world setting.[9] The primary safety endpoints will be freedom from periprocedural major adverse events (dissection, embolization, bailout stenting, major limb amputation, target vessel perforation, or death). The primary efficacy endpoint (acute procedural success) will be successful revascularization of the target vessel, defined as ≤ 30% residual stenosis at the index lesion

after atherectomy, and final adjunctive treatment (if required), as evaluated by angiographic core lab. The study duration is expected to be 2.5 years (6 months to enroll and 2 years of follow-up).

CONCLUSION

In our early experience with the Auryon system, we have found the device to be safe and effective. It has been particularly effective at treating calcified vessels, with no intraprocedural vessel injury. However, longer-term experience and larger studies are necessary to further validate its ease of use, efficacy, and safety. ■

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Indications for Use: The AURYON™ Atherectomy System is indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions, including in-stent restenosis (ISR).

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