

## Outcomes Associated with the Use of the Auryon Peripheral Atherectomy System in a Hospital Setting: 1-Year Outcome

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### Abstract

**Background:** Although endovascular approaches are the primary treatment for stenosis or occlusion of lower extremity arteries, major dissections and embolic events are the main risks. Therefore, there is a need to experiment with new technologies that not only limit these risks but also achieve the targeted clinical outcomes.

**Methods:** The Auryon (AngioDynamics) atherectomy system uses a 355nm wavelength laser platform that enables the use of longer wavelengths and shorter pulses to produce a groundbreaking delivery of short UV laser pulse combined with dedicated optical catheters. This study evaluated the safety and efficacy of this device in patients with Peripheral Artery Disease (PAD) treated at our hospital between October 2022 and October 2023.

**Results:** 12 patients were included. The mean age was  $66.1 \pm 9.0$  years, and 83.3% of patients were male. Lesions were all below the knee. Two patients had in-stent restenosis. Chronic total occlusions and critical limb ischemia were present in 49.9% of patients, respectively. Procedural success was reached in 84% of patients. No patients had amputations. No patient experienced procedure-related complications and no patient died.

**Conclusion:** The Auryon laser system was shown to be safe and effective in a hospital patient population, as patients did not present any adverse events or deaths due to the procedure and in fact reported an improvement in their baseline condition.

### Highlights

- Population of hospital patients with chronic total stenosis and intrastent critical occlusion.
- Procedural success was achieved in all patients.
- No patients experienced procedure-related complications.

### Keywords

Atherectomy, Peripheral arterial disease, Auryon laser.

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## Introduction

Peripheral artery disease (PAD) is a common vascular disease in close association with the risk of catastrophic cardiovascular events affecting both quality and life expectancy. PAD is a disease typically caused by the accumulation of fatty plaque (known as atherosclerosis) in the arteries that carry blood to the extremities, although PAD is not always caused by atherosclerosis. PAD affects more than 8.5 million people in the United States and more than 200 million worldwide [1]. The prevalence of PAD in men and women increases with age and other factors such as hypertension, smoking, diabetes, and high cholesterol. If left untreated, PAD can progress to life-threatening conditions such as coronary artery disease and cerebrovascular disease [2]. The endovascular procedure for PAD, which removes plaque from the artery wall, has become an important adjunctive therapy to THA or drug-coated balloons (DCBs) with increasing use of this combination of approaches [3]. Although endovascular treatments have evolved more than open surgical approaches for stenosis or occlusion of lower extremity arteries, these are associated with the risk of major dissections, perforations, embolic events [4-6]. Therefore, new technologies are being sought that while tending to reduce the risks of acute vessel injury and embolic events, improve the efficacy of removal of heavily calcified lesions, thereby reducing the rates of salvage treatment, major amputations, and the need for a recurrent procedure to revascularize the re-stenosed area.

The Auryon system (AURYON Atherectomy System, AngioDynamics, Queensbury, NY) is equipped with technologies and functions to treat any injury, all with a single device built to simplify PAD management. The Auryon system is a 355-nm, solid-state, short-pulsed laser that delivers energy to the diseased artery at preset fluence levels of 50 and 60 mJ/mm<sup>2</sup>. The system operates on 0.014-inch wires. Four sizes of catheters are available. For small catheters (0.9 and 1.5 mm), there is a designated lumen in the center of the inner beveled blade for a guide wire. Larger catheters (2 and 2.35 mm) have an eccentric lumen for the guidewire and include additional features, such as a suction port (for both 2 and 2.35 mm catheters) and an “*off-center*” mechanism (for the 2.35 mm catheter only). The suction function is intended for suctioning debris during debulking. The “*decentered*” function allows debulking of larger lumens beyond the catheter diameter (e.g., femoropopliteal arteries).

Our hospital has used this system extensively to treat patients with very complex lesions in AK arterial segments, including ipsilateral and contralateral femoral approaches. The present study illustrates twelve real cases in a single hospital evaluating the safety and efficacy of the Auryon atherectomy system in patients with PAD.

## Methods and Results

This study analysed the results obtained from patients with PAD undergoing atherectomy with the Auryon system at the Vascular Surgery of the San Giuseppe Moscati Hospital of National Importance (Avellino), Italy. The study received ethical approval from the patients treated with the device between October 2022

and October 2023 who met the criteria for enrolment in that endovascular procedure. The study received ethical approval from the patients with infra-inguinal PAD who underwent atherectomy with the Auryon system between October 2022 and October 2023 and thus met the criteria for enrollment in this study and who had available follow-up data. Patient demographic information, medical history, procedural data, Intraoperative and postoperative treatment information and adverse events that occurred during and after the procedure were reviewed. Outcome data were evaluated for a time of six months after the procedure. Acute success of the procedure, defined as residual stenosis <30% without complications after laser atherectomy and adjunctive therapy, was considered as the primary efficacy endpoint. While, the primary safety endpoint was defined by the absence of serious adverse events, such as perforations, major dissections, unplanned amputation of the target limb, cardiovascular death, target lesion revascularization, and death. Descriptive analysis was performed on all twelve patients. Data were expressed as frequency counts and percentages, means, standard deviation (SD), minimum and maximum, using Microsoft® Excel® for Microsoft 365 MSO (16.0.13029.20232).

## Procedure

Femoral arterial access occurred in eight patients ipsilaterally while in four patients contralaterally. After arterial access was obtained, baseline angiography was conducted to choose the appropriate catheter size for the device, as well as any other vessel access devices that might be needed. The system consists of four different disposable catheters, with diameters ranging from 0.9 to 2.35 mm, which can be used below the knee, including the ankle. All catheters are traced on a standard rigid 0.014” guidewire. The 2 and 2.35-mm catheters are capable of integrated suctioning useful for actively removing debris, lowering the risk of distal embolization. The 2.35 mm catheter also has off centering capabilities for creating large lumens, allowing the catheter tip to be kept in the direction of the artery trajectory, allowing greater debulking without deviating from the vessel wall. After the catheter size was chosen, a 0.014” × 300 guide wire was inserted through the lesions and an intraluminal recanalization is performed. The selected Auryon catheter was connected to the laser system, washed with heparinized saline and inserted onto the guidewire. The distal tip of the catheter was advanced under fluoroscopy until it reached the lesion. The laser was activated periodically while the catheter was advanced at approximately 1 mm/s with pressurized saline simultaneously instilled through the introducer sheath (size: 6mm). A higher advancement rate was avoided, as it had the potential to reduce plaque removal efficiency. After laser treatment, the catheter was removed and additional angioplasty was performed with balloon and/or non-drug coated.

## Results

12 patients were treated to laser atherectomy with the Auryon system between October 2022 and October 2023. Table 1 shows the demographic data and clinical variables of patients undergoing to laser atherectomy with the Auryon system. The mean age was 66.1

± 9.0 years and 83.3 percent of the patients were male. Almost all patients had a history of smoking, diabetes mellitus, hypertension, and dyslipidemia. Chronic total occlusion or critical limb ischemia was present in 49.9 % of patients, and two patients (16.6%) had both conditions. Two patients presented with in-stent restenosis. Rutherford's classification ranged from 3 to 4. Table 2 shows the lesion and procedure data. There was a mean of 2.3 ± 1.0 lesions treated per patient (n = 12), ranging from 1 to 3 lesions. All patients had lesions above the knee, and the length of the lesions varied widely, with 50% of patients having lesion lengths greater than 20 cm. A 2 mm laser catheter was used for the majority (70.9%) of patients, with two catheters (0.9 and 1.5 mm) used to treat 1 patient and a 1.5 mm laser catheter was chosen for the lesions of five patients. Five patients received additional angioplasty with drug-coated balloon, while the remaining seven patients received balloon without drug coating. All patients were treated with Duoplavin alone before the procedure. Procedural success, characterized as residual stenosis <30% without complications, was achieved in all patients (84%). Two patients (16.6%) had residual stenosis >30%, and patency was restored in these patients. No procedure-related complications were reported before discharge for any patient, and none had recurrent thrombosis in the 30 days following the procedure. No patients needed amputation after surgery. No patients needed target lesion revascularization (TLR) within 30 days after the procedure. Restenosis/reocclusion was observed at a mean of 90.5 ± 22.5 days after the initial procedure. No deaths were correlated with the procedure or the background condition.

**Table 1:** Demographic and clinical variables of patients undergoing Auryon Atherectomy system (AngioDynamics) (n=12).

Age, years (mean ± SD)	66.1±9.3
Sex, n (%)	
Male	10 (83.3%)
Female	2 (16.7 %)
Race, n (%)	
White	12 (100 %)
Non-white	0
Smoking history, n (%)	6 (50%)
Diabetes mellitus, n (%)	5 (41.6 %)
Hypertension, n (%)	11(91.6 %)
Dyslipidemia, n (%)	10 (83.3%)
Coronary artery disease n (%)	5 (41.6 %)
End-stage renal disease, n (%)	2 (16.7 %)
Duoplavin use prior to procedure, n (%)	12 (100%)
Intermittent claudication, n (%)	10 (83.3%)
Chronic total occlusion, n (%)	4 (33.3%)
Critical limb threatening ischemia, n (%)	2 (16.6%)
In-stent restenosis, n (%)	2 (16.6%)
Rutherford classification	
3	10 (83.3%)
4	2 (16.7 %)
TASC, n (%)	
C	5 (41.6%)
D	7 (58.3%)

**Table 2:** Procedural data of patients undergoing Auryon atherectomy system (AngioDynamics) (n=12).

Number of lesions treated (mean ± SD)	2.3±1.0
Lesions treated per patient	
1	1(8.33%)
2	6 (50%)
3	5 (41.6%)
4	0
Lesion location, n (%)	
Above the knee	0
Below the knee	28(100%)
Both	0
Lesions length, n (%)	
<5 cm	1 (8.33%)
5–10 cm	0
10–15 cm	1(8.33%)
15–20 cm	4 (33.3%)
>20 cm	6 (50%)
Reference vessel diameter, mm (mean ± SD)	5.66 ±1.0
Procedural time, minutes (mean ± SD)	135.5±5.0
Contrast volume, mL (mean ± SD)	
Laser catheter used, n (%)	
0.9 mm	0
1.5 mm	5 (41.6%)
2.0 mm	6 (50%)
0.9 mm and 1.5 mm	1 (0.74%)
Angioplasty balloon, n (%)	
Cutting or scoring	0
Non-drug coated balloon	7 (58.3%)
Drug coated balloon	5 (41.6%)
Stent placed, n (%)	0
Procedural success, n (%)	84%

## Discussion

The present report has shown that the short-pulse laser atherectomy system combined with a coated and non-drug balloon is extremely safe and provides better short-term clinical outcomes in a hospital setting. Procedural success was found in all treated patients, and no dissections, perforations or dissections, perforations or embolic events related to the procedure. The use of the Auryon (AngioDynamics) system laser with a short pulse duration is extremely beneficial compared with traditional 308-nm laser technology, as it allows higher peak energy to be delivered with a shorter pulse duration, making it ideal for the treatment of occlusions, thus reducing the effects that heat can cause on the target tissue without thereby having thermal damage. In addition, Auryon catheters by presenting a blunt tip facilitate plaque removal and decrease the potential dangers of vessel perforation. A recent study [7] demonstrated that the Auryon laser system was safe and effective in a population of 55 real patients without procedural adverse events or deaths and with improved patient outcomes. The patient population and treatment approach of our study differ in some respects from both the initial FDA-approved controlled clinical trial (Investigational Device Exemption, IDE) (NCT03157531) [8,9] that studied the safety and efficacy of Auryon atherectomy

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and the recent study of Kovaleski [7]. Despite the differences, procedural success, improvement in the category of Rutherford and freedom from device-related perioperative complications up to 30 days postoperatively were comparable with both studies. There were no cardiovascular deaths, amputations, or the need for revascularization of clinically driven target lesions during the 30-day post-procedure period in either study. The present study has a very important strength in that it is not a retrospective study that limits the ability to draw firm conclusions from the results obtained, but is the result of endovascular procedures practiced safely and effectively in a real hospital population. Additional benefit of this study is the angiographic imaging data that can confirm the study results to determine long-term patency. Finally, the study design, which is non-randomized and non-retrospective, helps to draw objective conclusions about the regarding the comparison of results between the 355 nm laser used and a standard 308 nm laser or with other revascularization modalities. Nevertheless, prospective, randomized studies would be needed to fully define the difference in safety and efficacy between these technologies.

## Conclusion

The use of the Auryon laser system in a real-world population of hospital patients was associated with positive clinical outcomes without procedure-related adverse events.

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