White Paper

Initial Clinical Experience with the Pantheris SV Catheter

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ABSTRACT

A pilot study was conducted of a small diameter atherectomy catheter for use in vessels below the knee. A total of 383 procedures were performed with the catheter in lesions from the superficial femoral artery (SFA) to the peroneal artery, resulting in a 77% decrease in the percent luminal stenosis of targeted vessels. The mean luminal stenosis was reduced from 88% pre-procedure (range 60% to 100%) to 20% (range 5% to 40%) after atherectomy with the Pantheris SV catheter. Following adjunctive therapy, primarily angioplasty, the mean residual stenosis decreased further to 7% (range 0 to 20%). Within this study, a total of 117 single lesions distal to the popliteal artery were treated—56 in the anterior tibial artery (AT), 33 in the posterior tibial artery (PT), 13 in the tibioperoneal trunk (TPT), and 15 in the peroneal artery. In these lesions, atherectomy alone decreased luminal stenosis by 78%. Atherectomy of infrapopliteal lesions by the Pantheris SV catheter shows promising technical and clinical outcomes in this initial pilot study.

Endovascular therapy has become a first-line revascularization strategy for patients with multilevel peripheral artery disease (PAD), including obstruction of tibial arteries. However, balloons and stents, have mixed results when used in lesions below the knee (BTK). Tibial arteries frequently have medial calcification, contributing to the limited effectiveness of percutaneous transluminal angioplasty (PTA) stemming from vessel recoil, dissection, and high rates of target vessel revascularization (TVR).[1] Use of vascular stents in BTK lesions can be complicated by under-expansion, compression and fracture while indwelling, and development of thrombosis.[2] In addition, no stent is yet cleared by the FDA for use in BTK lesions.

Atherectomy is an emerging endovascular approach to address BTK lesions associated with PAD through excision of diseased tissue. A directional atherectomy device with onboard image-guidance, Avinger's Pantheris catheter, has been available commercially since 2016 and reported a reduction in mean diameter stenosis from 79% pre-procedure to 30% after use of the Pantheris catheter alone, with low perforation and embolization rates when used in lower extremities.[3] Freedom from target lesion revascularization at 1 year post-procedure is reported to be 100%, with adjunctive therapy.[4] The SV model of the Pantheris catheter has been available commercially since July 2019. The purpose of this review was to determine the acute safety and efficacy of directional atherectomy of this new model of the Pantheris catheter in peripheral vessels below the popliteal artery.

Methods

Patient Population

Following FDA clearance of the Pantheris SV catheter, post-market surveillance of its use was conducted in patients who presented to multiple hospitals or clinics with claudication or critical limb ischemia (CLI). There was no restriction as to location or length of the target lesion. These cases were within the boundaries set by the intended use statement of the device. Patient demographics and history were captured by the physicians. All patients signed informed consent for the procedure.

Device Description

The Pantheris SV atherectomy catheter, a model within the Pantheris Catheter Family, recently received market clearance for plaque removal (atherectomy) from partially occluded vessels in the peripheral vasculature with a reference diameter of 2.0 to 4.0 mm. The catheter is a monorail (rapid exchange) device with a working length of 140 cm. The catheter is 6 French in outer diameter and compatible with an 0.014-inch guidewire. The distal end of the catheter is comprised of a nosecone (to capture and store excised tissue), a cutting head, and an imaging

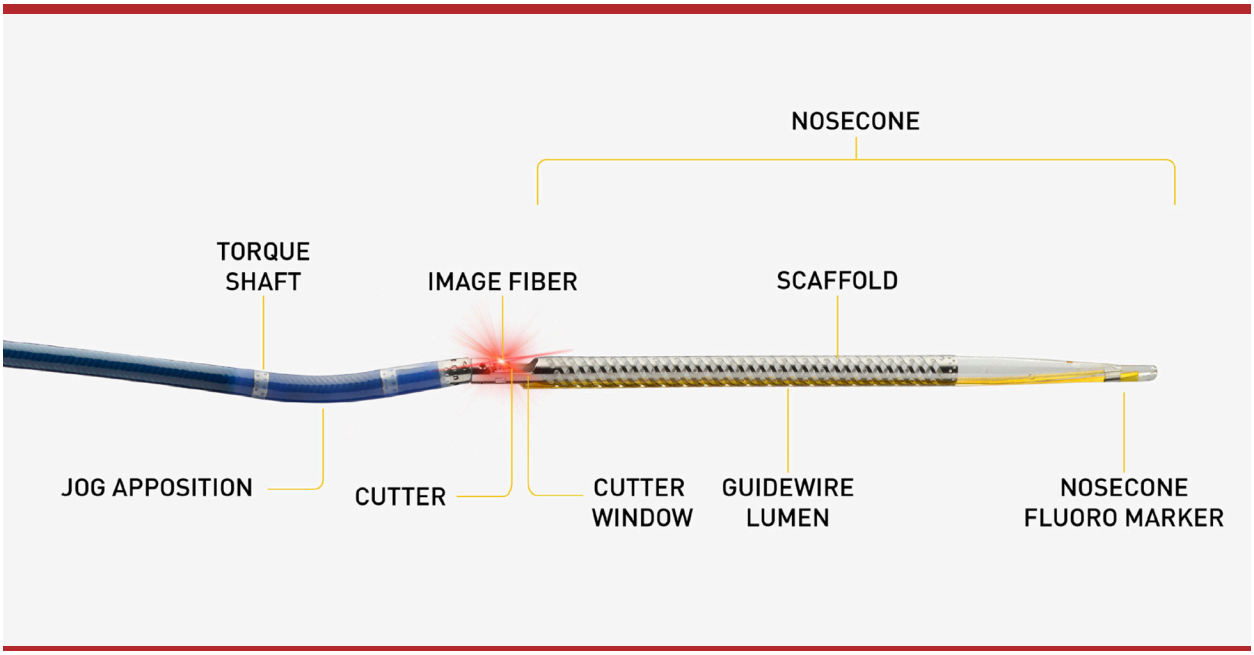

Figure 1. The distal assembly of the Pantheris SV catheter

element just proximal to the edge of the cutter enabling intravascular optical coherence tomography (OCT) (Figure 1). The OCT imaging is an adjunct to fluoroscopy with visualization of the vessel lumen, wall structures, and vessel morphologies.

The information collected was recorded on standardized collection forms. The physicians determined lesion and disease parameters, including lesion location and length, degree of calcification of the lesion, and percent stenosis pre-procedure, post-atherectomy, and post-adjunctive therapy. Peri-procedure adverse events were noted, with device-associated events considered to be perforation or dissection of the vessel during the procedure. Technical success was defined as successful vascular access, completion of the endovascular procedure, and immediate morphological success with < 30% residual diameter stenosis by angiography. Device success was defined as exact deployment of the device according to the instructions for use, as documented with suitable imaging modalities. Procedural success was defined as the combination of technical success, device success, and absence of procedural complications. Data are reported as means for continuous variables and counts for categorical variables.

Results

Between July 2019 and April 2020, a total of 383 procedures were performed with the Pantheris SV catheter in 16 institutions by 18 physicians. The majority (77%) of the lesions treated were *de novo*, with 23% being restenotic lesions, and 12 instances of in-stent restenosis. Of this total, data from 12 procedures were either incomplete or lesion location was not noted, leaving 371 procedures for review. Lesions in which the Pantheris SV catheters were used were comprised of multiple locations as well as single anatomical sites, with lengths ranging from 20 to 300 mm (mean length 106.3 mm). Overall, these lesions were predominantly (46%) mild in calcium burden, followed by moderate (33%), none (14%), and severe (7%).

The treatment success rate was 97% for all lesions and 99% for lesions distal to the popliteal artery. Device success was 100% for all lesions, irrespective of location. Procedural success was 98% for lesions distal to the popliteal artery.

The mean pre-procedural stenosis was 88% (range 60% to 100%) as compared to a mean residual stenosis after atherectomy by the Pantheris SV catheter of 20% (range 5% to 40%). Adjunctive therapy, primarily percutaneous transluminal angioplasty (PTA), was performed after atherectomy in 94% of the cases; in 23 cases (6%) no adjunctive treatment was performed. The mean percentage of stenosis after adjunctive treatment was 8% (range 0% to 20%).

An embolic protection device was used in 38% of these procedures. There were no episodes of angiographic apparent distal embolization whether a distal protection device was used or not.

Of the 371 procedures with data sufficient for analysis,

TABLE I. LOCATION AND CHARACTERISTICS OF SINGLE LESIONS TREATED WITH THE PANTHERIS SV CATHETER

ARTERIAL LOCATION OF THE LESION	NO.	MEAN LESION LENGTH, MM (RANGE)	LEVEL OF CALCIFICATION
SFA	16	78 (30 –100)	1 None (6%) 12 Mild (75%) 3 Moderate (19%) 0 Severe
POP	20	82 (40 – 150)	8 None (40%) 6 Mild (30%) 4 Moderate (20%) 2 Severe
AT	56	116 (40 – 300)	4 None 34 Mild (71%) 15 Moderate (28%) 3 Severe (10%)
TPT	13	57 (60 – 140)	1 None (8%) 8 Mild (61%) 3 Moderate (23%) 1 Severe (8%)
PT	33	118 (40 – 300)	6 None (18%) 15 Mild (45%) 9 Moderate (27%) 3 Severe (9%)
Peroneal	15	89 (30 – 120)	1 None (7%) 10 Mild (66%) 3 Moderate (20%) 1 Severe (7%)

***SFA** = superficial femoral artery, **POP** = popliteal artery, **AT** = anterior tibial artery, **TPT** = tibioperoneal trunk, **PT** = posterior tibial artery*

153 atherectomy procedures were completed on single lesions in one vessel location (Table I).

Use of the Pantheris SV Catheter in Single Lesions Below the Knee

The Pantheris SV catheter was deployed in 117 single lesions located in vessels distal to the popliteal artery (Figure 2). These infra-popliteal lesions had a mean length of 106 mm (range 30 to 300) and a mean stenosis of the vessel lumen of 90% (range 60% to 100%). After atherectomy with the Pantheris SV catheter, the mean stenosis was 18%, (range 0% to 60%) and following adjunctive therapy the mean stenosis was 7% (range 0% to 25%) (Figure 3). Ten of the lesions were treated only with atherectomy, with mean percentage of stenosis measured as 90% prior to atherectomy and 8% after atherectomy alone.

In lesions below the popliteal artery, PTA was the only adjuvant therapy in 62% of adjuvant treatments; drug-coated balloons (DCBs) or drug-eluting stents (DESs) were used fewer times (19%).

Lesion length did not have an impact on the efficacy of atherectomy with the Pantheris SV catheter, with the reduction in residual stenosis comparable for all categories of lesion lengths (Table II).

Affect of Calcium on Residual Occlusion Following Atherectomy

Each physician ranked the extent of calcium present in these lesions as either none (N=12), mild (N=67), moderate (N=30) or severe (N=8). Prior to atherectomy,

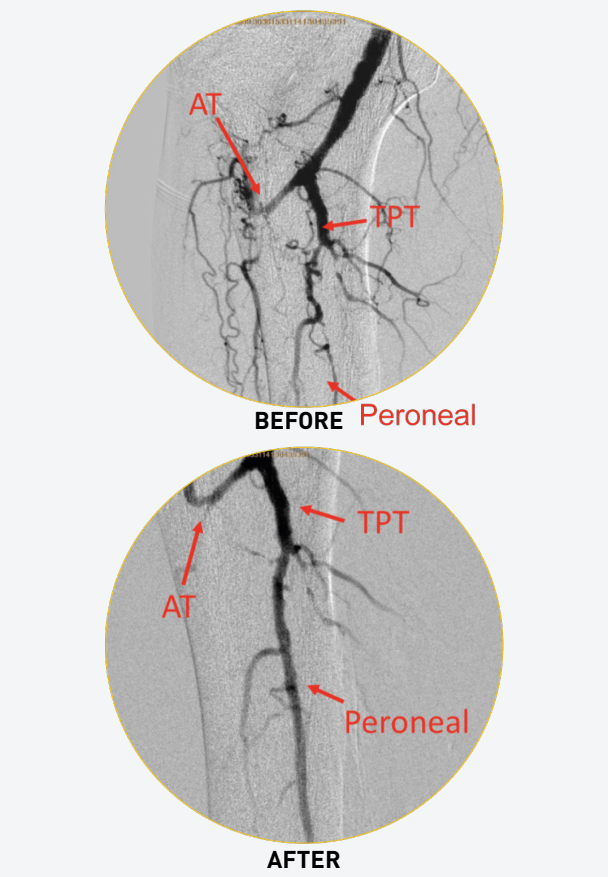

Figure 2. Angiogram showing stenosis of the AT, PT and peroneal arteries before (top) and after (bottom) atherectomy with the Pantheris SV catheter.

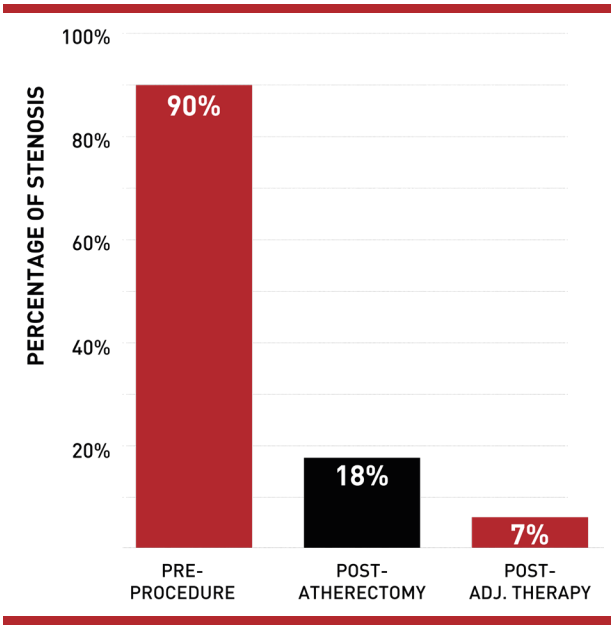

Figure 3. Mean percent stenosis of BTK lesions prior to and after atherectomy with the Pantheris SV catheter and then after adjunctive therapy.

the mean percentage of occlusion ranged from 88% to 91%; following atherectomy with the Pantheris SV catheter, the percentages of the occlusion were 14% in lesions with no calcium present, 19% in lesions with mild levels, 22% in lesions with moderate levels, and 12% with severe levels of calcium present in the lesions.

Tissue that was excised during atherectomy was collected from a small sub-set of cases and analyzed. As noted in Figure 4, the amount of tissue removed during a case can be considerable, which correlates to the substantial reduction in stenosis of these small vessels following atherectomy reported in this pilot study. More importantly, with real-time optical coherence tomography imaging during the procedure, the physician can visualize the position of non-diseased structures in the vessel and navigate the cutting element of the catheter away in order to reduce the potential for vessel wall injury.

Imaging BTK Lesions with Optical Coherence Tomography

The Pantheris SV catheter contains an imaging element and uses optical coherence tomography (OCT) to visualize the target vessel and lesion. Intravascular OCT imaging measures the intensity of reflected near-infrared light from tissue to develop images on the Pantheris system, permitting the physician to diagnose the condition, monitor the treatment mechanics, and assess whether additional treatment is necessary. OCT images have a higher resolution and faster acquisition than IVUS imaging in peripheral arteries. Since it is integrated into the atherectomy catheter, OCT imaging provides real-time visual assessment of the procedure without needing to exchange the imaging catheter for the treatment catheter in the middle of a procedure.

These OCT images clearly displayed both layered and non-layered structures in the target vessels (Figures 5, 6 & 7), as well as deposition of calcium in the vessel walls (Figure 8).

The diameter of arteries distal to the popliteal artery range from 3.5 mm (anterior tibial artery) to 3.0 mm (fibular artery)[5]. Due to these narrow wall structures, the control of the depth of excision of plaque is essential in order to reduce the potential for injury to non-diseased components of the vessel wall. OCT imaging provides the physician real-time guidance so that the cutter head can be redirected when it moves through plaque and becomes adjacent to either the EEL (Figure 5) or the media (Figure 6).

TABLE II. MEAN LENGTH AND MEAN PERCENTAGES OF STENOSIS PRE-PROCEDURE, POST-ATHERECTOMY, AND POST-ADJUNCTIVE THERAPY OF LESIONS LOCATED BELOW THE KNEE TREATED WITH THE PANTHERIS SV CATHETER

LESION LOCATION	MEAN LESION LENGTH	MEAN STENOSIS PRE-PROCEDURE	MEAN STENOSIS POST-ATHERECTOMY	MEAN STENOSIS POST-ADJUNCTIVE THERAPY
AT (N=56)	115.9 mm	88%	20%	8%
PT (N=33)	116.2 mm	89%	18%	6%
TPT (N=13)	56.9 mm	89%	11%	4%
Peroneal (N=15)	88.7 mm	89%	21%	8%

LESION LENGTH CATEGORY	MEAN LESION LENGTH	MEAN STENOSIS PRE-PROCEDURE	MEAN STENOSIS POST-ATHERECTOMY	MEAN STENOSIS POST-ADJUNCTIVE THERAPY
1 to 50 mm (N=20)	33.7 mm	86%	19%	6%
51 to 100 mm (N=53)	80.6 mm	85%	20%	7%
101 to 150 mm (N=25)	135.2 mm	94%	16%	6%
>151 mm (N=19)	212.1 mm	88%	19%	8%

***SFA** = superficial femoral artery, **POP** = popliteal artery, **AT** = anterior tibial artery, **TPT** = tibioperoneal trunk, **PT** = posterior tibial artery*

Figure 4. Plaque excised from an anterior tibial artery with the Pantheris SV catheter (left). The tissue had a weight of 52.2 mg. Histological analysis of the tissue collected noted that the majority was plaque, with two small fragments of media (outlined in blue circles) and no evidence of adventitia (right).

Discussion

Atherectomy of infrapopliteal lesions by OCT-guided atherectcomy using the Pantheris SV catheter shows promising technical and clinical outcomes in its initial use. The extent of luminal stenosis was reduced from 90% to 18% following atherectomy and to 7% following adjunctive therapy. There were no adverse events in patients in this study, which were defined as dissection, perforation, or embolization.

Balloon angioplasty remains the predominant treatment modality for infrapopliteal lesions. Drug-coated angioplasty has been studied in these vessels; however,

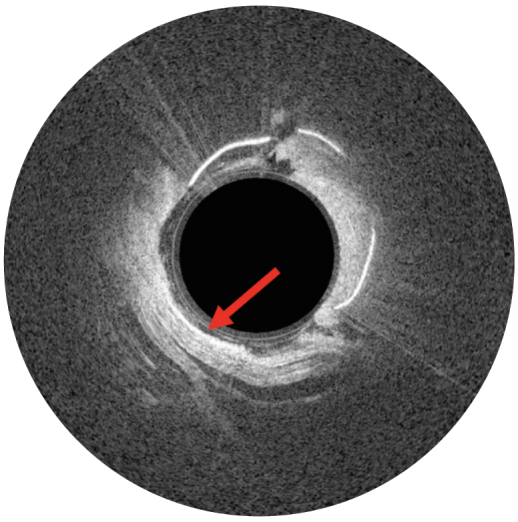

Figure 5. The external elastic lamina (EEL) displayed under OCT imaging.

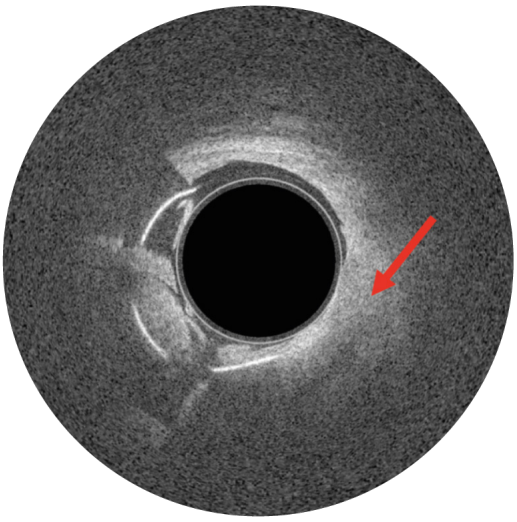

Figure 6. Fibrous plaque displayed under OCT imaging.

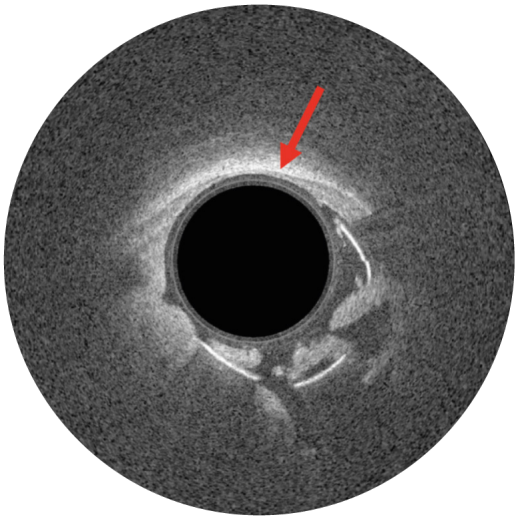

Figure 7. Media wall layer displayed under OCT imaging.

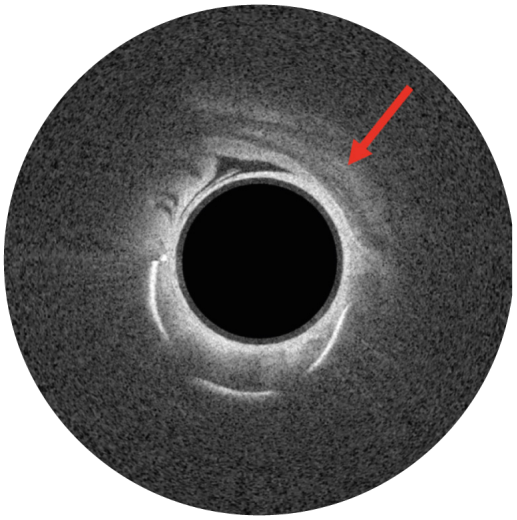

Figure 8. Calcium deposition within the vessel wall displayed under OCT imaging.

the IN.PACT DEEP trial found no difference between use of a drug-eluting balloon versus use of a balloon without drug; procedural success was 79.7% versus 78.2% respectively.[6] In that randomized trial, procedural complications were noted in 9.7% of subjects with the drug-coated balloon and in 3.4% of subjects with the non-coated balloon, with a number of post-procedural dissections, 12.3% and 19.2%, respectively. These success and dissection rates are comparable to other studies with drug-coated and non-coated balloons.[7,8]

Atherectomy in vessels in the lower extremity has been little studied to date. Directional atherectomy of 189 infrapopliteal lesions was assessed with subgroup analysis of the DEFINITIVE data sets (the DEFINITIVE LE

data) and noted a procedural success rate of 89.1% and mean percent vessel stenosis after use of the SilverHawk device to be 24.3%.[9] While embolic protection was used in 22.4% of those cases, distal embolization occurred in 3.8% of the procedures. Vessel wall dissection (2.3%) and perforation (5.3%) rates with the SilverHawk device were substantially lower than rates noted following angioplasty, which supports use of directional atherectomy in these vessels. Use of the Pantheris SV catheter in these initial clinical cases did not result in any dissections or perforations.

The results from this initial assessment of the Pantheris SV catheter were not adjudicated independently, so comparison to the DEFINTIVE LE data is somewhat subjective; however, peri-procedure complications rates are similar with the two devices, with lower luminal stenosis post-atherectomy with the Pantheris SV catheter noted.

Conclusion

Initial experience with the Pantheris SV catheter and its OCT-guided directional atherectomy of lesions in peripheral arteries was completed with no major adverse events. Image-guided atherectomy can be a promising new modality to treatment of small vessels. Further studies are needed to validate the initial positive results of this pilot study.

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