



# Single-Center Experience With Optical Coherence Tomography-Guided Directional Atherectomy System for Below-the-Knee Critical Limb Ischemia

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## Abstract

**Background.** Below-the-knee (BTK) peripheral arterial disease (PAD) more often presents as critical limb ischemia. Endovascular revascularization strategies continue to evolve to achieve long-term limb-salvage outcomes. A single-center experience with optical coherence tomography (OCT)-guided atherectomy using Pantheris SV (Avinger) is reported. **Methods.** All patients with PAD in femoropopliteal or infrapopliteal vessels ( $n = 27$ ) who underwent plaque debulking by Pantheris SV were analyzed retrospectively. Baseline comorbidities, Rutherford classification, lesion length and characteristics, adjunctive treatment strategy, device-related failures/complications, and major adverse events were analyzed. Additionally, 6-month target-lesion revascularization (TLR) rate was available for 21 of 27 patients. **Results.** Mean patient age was 70.5 years, 16 patients (59%) were women, and 19 patients (70%) had Rutherford class 5 to 6 symptoms. A total of 58 vessels were treated, including 32 iliofemoropopliteal and 26 infrapopliteal vessels. Chronic occlusions were present in 19% of iliofemoropopliteal lesions and 17.2% of infrapopliteal lesions. The most commonly treated BTK lesion (12 of 26) was the anterior tibial artery (ATA). Following atherectomy, 21 were treated with angioplasty, 4 with angioplasty followed by coronary drug-eluting stent (DES), and 1 with cutting balloon and laser atherectomy. Four failures/complications occurred; 3 of these were device related (failure to pass through lesion due to proximal ATA angulation, coronary DES dislodgment while treating BTK in-stent restenosis, and 1 requiring laser atherectomy for no-flow post atherectomy and angioplasty). At 6 months, 2 of 21 patients (9.5%) required revascularization interventions. **Conclusion.** Treatment of BTK-PAD with imaging guided Pantheris SV atherectomy device appears to be safe, with low rate of TLR at 6 months. Future multicenter randomized trials are needed to confirm these findings.

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**Key words:** atherectomy, below-the-knee, critical limb ischemia, optical coherence tomography

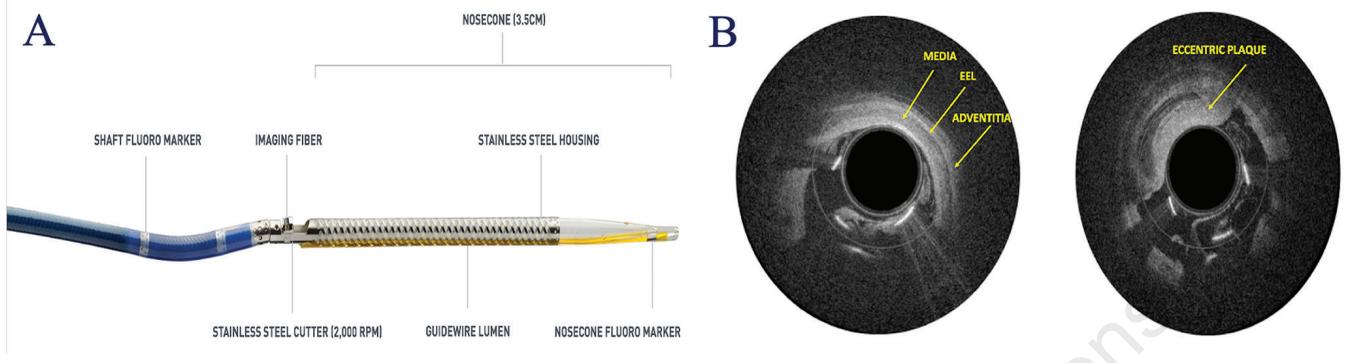
Long, below-the-knee (BTK) lesions present a clinical challenge as the current body of evidence supports long-term limb salvage outcomes with drug-eluting-stent (DES) therapy, but for use in short and focal lesions only. Adequate plaque debulking prior to choice of adjunctive treatment may also allow superior delivery of drug therapy and may achieve improved clinical outcomes for adjunctive treatment with percutaneous transluminal angioplasty (PTA) or stents.

To date, there are limited data available for the role of directional atherectomy (DA) in endovascular treatment of BTK peripheral artery disease (PAD). The Pantheris small vessel (SV) DA catheter (Avinger) is an optical coherence tomography (OCT)-guided atherectomy system for the treatment of small-vessel lower-extremity PAD. Direct visualization of plaque

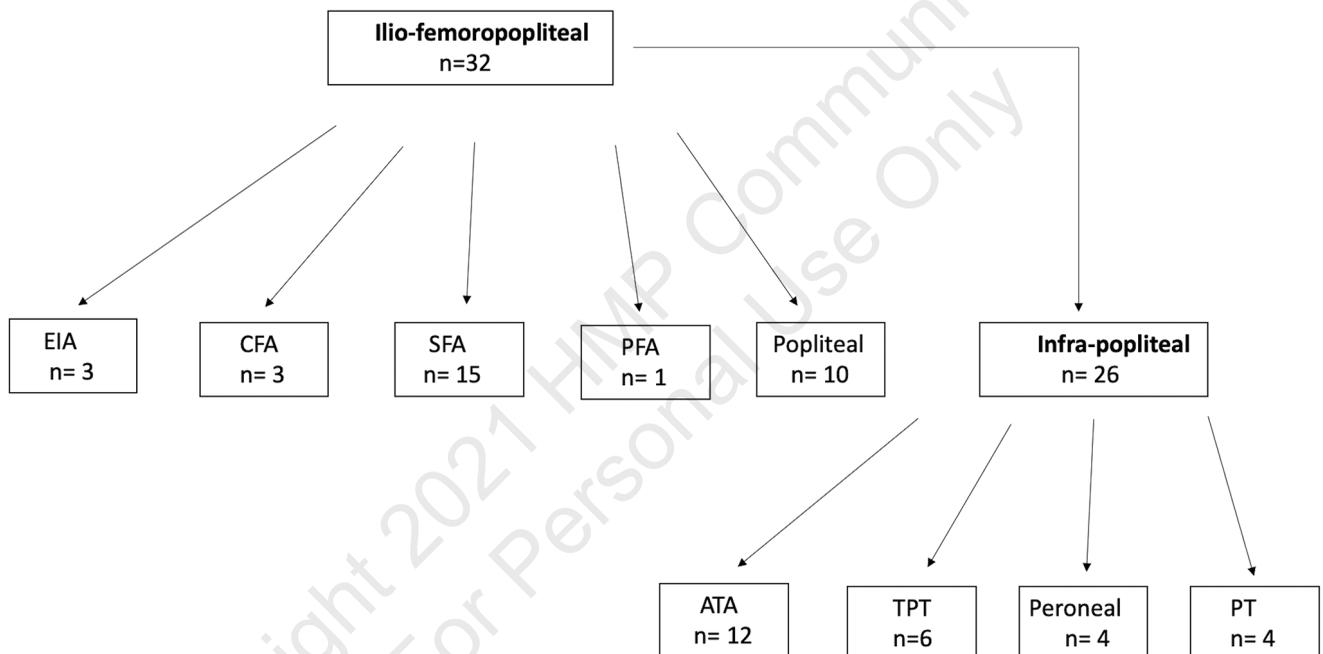
with the addition of an OCT imaging modality, as offered by the Pantheris SV catheter, avoids unintended adventitial injury, which has been linked to higher restenosis rates.<sup>1</sup> A single-center experience with feasibility, safety, and durability of treatment of severe claudicants and critical limb ischemia (CLI) patients with the OCT-guided Pantheris SV atherectomy device is reviewed.

## Methods

**Study design.** The Pantheris SV atherectomy system was introduced to our institution in July 2019 and all patients ( $n = 27$ ) who underwent DA with the device were included in a single-center, observational, retrospective analysis of device use from July 2019 through July 2020. All patients provided informed consent for



**FIGURE 1.** (A) Pantheris SV catheter and its components. (B) Arterial layers labeled as seen on optical coherence tomography (OCT) and eccentric plaque as seen on OCT.



**FIGURE 2.** All lesions types (above and below the knee) treated with optical coherence tomography-guided Pantheris SV device. ATA = anterior tibial artery; CFA = common femoral artery; EIA = external iliac artery; PFA = profunda femoris artery; PT = posterior tibial artery; SFA = superficial femoral artery; TPT = tibioperoneal trunk.

the procedure in accordance with the institution's policy and following guidelines outlined by Good Clinical Practices, the Declaration of Helsinki, and the International Conference on Harmonization.

The procedures were performed at a teaching hospital with 2 high-volume endovascular operators and 2 fellows in training under their close supervision. The data were extracted from the institution's cardiac catheterization angiography and procedure documentation system. Patient-related baseline characteristics, including coexisting comorbidities, Rutherford classification, antiplatelet/anticoagulation regimen, type of vessel treated

(femoropopliteal or infrapopliteal), and embolic protection device (EPD) use, were extracted. The lesion-related characteristics collected were length, amount of calcification, number of chronic total occlusion (CTO) lesions present, pre- and postatherectomy luminal stenosis, and final stenosis (post Pantheris and adjunctive treatments). The extent of luminal stenosis was adjudicated by fluoroscopy. Major adverse events related to device-associated failures or complications and procedure-related limb threat or amputation for all subjects, as well as target-lesion revascularization (TLR) or limb amputation 6 months after the procedure, were analyzed.

Characteristics	Patients (n = 27)
Age (years)	70.5 (49-86)
Female gender	16 (59.3%)
Body mass index (kg/m <sup>2</sup> )	24.71
<b>Risk factors and coexisting conditions</b>	
Tobacco use	10 (37.0%)
Hypertension	27 (100%)
Hyperlipidemia	26 (96.3%)
Diabetes mellitus	20 (74.1%)
Peripheral artery disease	23 (85.2%)
Previous stroke	5 (18.5%)
Coronary artery disease	17 (63.0%)
Coronary artery bypass graft	5 (18.5%)
Heart failure	9 (33.3%)
Chronic kidney disease	7 (26.0%)
Chronic obstructive pulmonary disease	4 (14.8%)
<b>Rutherford classification</b>	
Rutherford class 1 and 2	0 (0.0%)
Rutherford class 3	8 (29.6%)
Rutherford class 4	6 (22.2%)
Rutherford class 5	3 (11.1%)
Rutherford class 6	10 (37%)
<b>Medications</b>	
Statin therapy	26 (96.3%)
Lovastatin 10 mg	1 (3.8%)
Simvastatin 20 mg	1 (3.8%)
Atorvastatin 10 mg	1 (3.8%)
Atorvastatin 20 mg	1 (3.8%)
Atorvastatin 40 mg	6 (23.1%)
Atorvastatin 80 mg	13 (50.0%)
Rosuvastatin 20 mg	1 (3.8%)
Rosuvastatin 40 mg	2 (7.7%)
<b>Antiplatelet/anticoagulant regimen</b>	
ASA 81 mg	1 (3.7%)

Characteristics	Patients (n = 27)
ASA 81 mg + clopidogrel 75 mg	19 (70.4%)
ASA 81 mg + apixaban 5 mg BID	1 (3.7%)
Clopidogrel 75 mg + apixaban 5 mg BID	1 (3.7%)
ASA 81 mg + prasugrel 10 mg daily	1 (3.7%)
Clopidogrel 75 mg + rivaroxaban 20 mg daily	2 (7.4%)
ASA 81 mg + clopidogrel 75 mg + rivaroxaban 2.5 mg BID	1 (3.7%)
ASA 81 mg + clopidogrel 75 mg + rivaroxaban 20 mg daily	1 (3.7%)
<b>Lesion Characteristics (n = 58)</b>	
<b>Lesion location</b>	
Iliac/common femoral artery	6 (10.3%)
Superficial femoral artery/profunda femoris artery	16 (27.6%)
Popliteal	10 (17.2%)
Tibioperoneal trunk	6 (10.3%)
Anterior tibial artery	12 (20.7%)
Peroneal	4 (6.9%)
Posterior tibial artery	4 (6.9%)
<b>Chronic total occlusion</b>	
Iliofemoropopliteal chronic total occlusion	11 (19.0%)
Infrapopliteal chronic total occlusion	10 (17.2%)
<b>Calcification by fluoroscopy</b>	
None	6
Mild	13
Moderate	7
Severe	1
Lesion length by fluoroscopy (mm)	97.4 ± 36.9
Preprocedural stenosis by fluoroscopy (%)	85.0
<b>Embolic protection device use</b>	
Iliofemoropopliteal	6 (22.2%)
Infrapopliteal	2 (7.4%)

Data presented as median (range), mean ± standard deviation, or number (%). ASA = acetylsalicylic acid.

**Device description.** The Pantheris SV catheter is a lumivascular, OCT-guided DA system for the treatment of BTK disease in peripheral vessels with a luminal diameter of 2-4 mm. It is advanced over an 0.014" guidewire and within a 6 Fr vascular

sheath. Device components include an imaging fiber to allow visualization of arterial layers and a 3.5 cm nosecone to house the plaque excised by a stainless-steel cutter (Figure 1). Importantly, it excludes the opposition balloon used in other models of the

**TABLE 2. Lesion type stratified by adjunctive treatment for all iliofemoropopliteal and infrapopliteal lesions.**

	PTA Alone	PTA + DES	PTA + BMS	DEB	DEB + BMS	PTA + LA
<b>Ilio-femoropopliteal lesions</b>						
EIA	1					
EIA-CTO	1		1			
CFA						
CFA-CTO	3					
SFA	4	4 <sup>a</sup>	1 <sup>d</sup>			
SFA-ISR				1	1	
SFA-CTO	2	1 <sup>b</sup>	1 <sup>d</sup>			
PFA	1					
Popliteal	7		1 <sup>d</sup>			
Popliteal CTO	2					
<b>Infrapopliteal lesions</b>						
ATA	5					
ATA-CTO	4	3 <sup>e</sup>				
TPT	6					
Peroneal	3					
Peroneal CTO	1					
PT	1					
PT-ISR		1 <sup>c</sup>				
PT-CTO	1					1

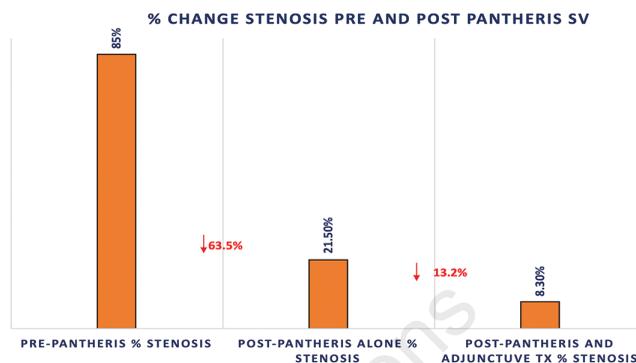
<sup>a</sup>Two Zilver PTX and 2 Eluvia stents. <sup>b</sup>Zilver PTX stent. <sup>c</sup>Synergy; <sup>d</sup>Supera stent; <sup>e</sup>Two Xience and 1 Synergy drug-eluting stent.

CTO = chronic total occlusion; ISR = in-stent restenosis; BMS = bare-metal stent; DES = drug-eluting stent; PTA = percutaneous transluminal angioplasty; EIA = external iliac artery; CFA = common femoral artery; SFA = superficial femoral artery; PFA = profunda femoris artery; ATA = anterior tibial artery; PT = posterior tibial artery; TPT = tibioperoneal trunk.

Pantheris catheter line and thus has a lower crossing profile as well as a longer catheter length than the 7 Fr Pantheris catheter (0.086" vs 0.100" and 140 cm vs 110 cm, respectively).

## Results

A total of 27 patients presenting with peripheral lesions in both iliofemoropopliteal and infrapopliteal locations were treated with the Pantheris SV device over a 1-year period (Figure 2). The most commonly treated femoropopliteal vessel was the superficial femoral artery (SFA), of which 2 were in-stent restenosis (ISR) and 4 were CTOs. Of the 15 lesions treated in the SFA, 8 required stent implantation. As expected, these patients were



**FIGURE 3.** Percent change in stenosis pre and post Pantheris SV and post Pantheris SV plus adjunctive treatment.

of advanced age and had metabolic comorbidities (Table 1); most (59%) were women. The mean patient age was 70.5 years (range, 49-86 years) and the majority (85%) had PAD with prior stroke events (18.5%) or coronary artery disease (63%). Importantly, 19 of 27 patients (73%) had CLI, as indicated by reporting symptoms placing them in Rutherford classes 4-6. Medical management of these patients included statin therapy or a combination of antiplatelet/anticoagulation regimen, with the most common being aspirin 81 mg and clopidogrel 75 mg (Table 1).

**Treatment of BTK lesions.** The most commonly treated BTK vessel in this patient group was the anterior tibial artery (ATA), for a total of 12, of which 9 received adjunctive treatment with PTA alone and three had DES implantation after atherectomy (Table 2). The tibioperoneal trunk (TPT) was the second most commonly treated BTK vessel, all of which were treated with PTA alone following atherectomy with the Pantheris SV catheter. The posterior tibial (PT) artery was the least commonly treated vessel in the series; following atherectomy, 2 patients received adjunctive PTA, a coronary DES was placed in 1 patient, and 1 patient required combined treatment with a cutting balloon and adjunctive laser atherectomy (Table 2). Eleven lesions (19%) were iliofemoropopliteal CTOs while 10 (17.2%) were infrapopliteal CTOs. Thirteen of 27 had mild calcification and 7 of 27 had at least moderate calcification (Table 1). EPDs were used in conjunction with atherectomy in 22.2% of femoropopliteal lesions and 7.4% of infrapopliteal lesions without any complications.

Fluoroscopy determined a mean preprocedural luminal stenosis of 85% and residual stenosis post atherectomy of 21.5%, a decrease in the extent of stenosis of 63.5%. The final mean residual luminal stenosis post Pantheris SV and adjunctive treatments was 8.3%, which was a further mean decrease in stenosis of 13% (Figure 3).

**Adverse events.** There were no periprocedural cardiovascular-related deaths and no unplanned major index-limb amputations at 6 months post procedure in available data from 21 of the 27 patients. There was 1 major bleeding event, a retroperitoneal

**TABLE 3. Stenosis reduction by treatment cohort and major adverse events.**

Mean Percent Stenosis	
Percent stenosis pre Pantheris	85%
Percent stenosis post Pantheris alone	21.50%
Final percent stenosis post Pantheris + adjunctive treatment	8.30%
Major Adverse Events	
Cardiovascular-related periprocedure death (n = 27)	0 (0.0%)
Unplanned major index limb amputation peri procedure (n = 27) and 6 months post procedure (n = 21)	0 (0.0%)
Device-related events (n = 27)	3 (11.1%)
Major bleeding during procedure (n = 27)	1 (7.4%)
Target-lesion revascularization at 6 months (n = 21)	2 (9.5%)

Data presented as percentage or number (%).

hemorrhage, requiring the transfusion of 2 units of blood and placement of a covered stent (Table 3). Three device-related failures or complications occurred in this patient set: (1) the inability to advance the Pantheris SV catheter within a proximal ATA due to proximal vessel angulation for which only balloon angioplasty was performed of the mid and distal vessel; (2) no restoration of blood flow in a PT following DA and PTA requiring use of angioplasty with a cutting balloon followed by laser atherectomy; and (3) dislodgment of an indwelling coronary DES due to strut entanglement by the device, which was treated by snaring the stent and placement of another coronary DES (Table 4). Only 2 TLR events occurred after 6 months in data available for 21 of the patients (Table 3). The first included ISR of an SFA stent and CTO of a PT previously treated with DA and PTA, while the second

**TABLE 4. Pantheris SV OCT-guided atherectomy as performed in type of artery (y axis) and type of adjunctive treatment (x axis). All device-related failures and complications and subsequent therapeutic interventions.**

Type of Lesion	Device Failure or Complications	Intervention Required
ATA-CTO	Inability to pass device past proximal segment due to ATA angulation	DA <sup>a</sup> of proximal portion only, mid and distal segment treatment with PTA only
PT-CTO	No flow after PTA and DA <sup>a</sup>	Adjunctive cutting balloon and laser atherectomy
EIA-CTO	Perforation with retroperitoneal hemorrhage after BMS and balloon angioplasty from oversizing	Treated with covered stents
PT-ISR	Coronary DES dislodgment from strut entanglement with device	Treated with snaring of stent, repeat PTA, and DES placement

<sup>a</sup>Optical coherence tomography (OCT)-guided directional atherectomy with Pantheris SV.  
 ATA = anterior tibial artery; CTO = chronic total occlusion; DA = directional atherectomy; DES = drug-eluting stent; EIA = external iliac artery; PTA = percutaneous transluminal angioplasty; PT = posterior tibial artery; ISR = in-stent restenosis.

was noted to have TPT restenosis and CTOs in both peroneal and PT arteries. All underwent wire-based recanalization and adjunctive PTA or intramedial temsirolimus infusion as part of the TAP-DANCE study in case of the SFA-ISR (Table 5).

## Discussion

**Current evidence of BTK therapy.** Endovascular treatment of BTK disease is often in the setting of CLI, as symptoms are most

**TABLE 5. All patients requiring reinterventions post OCT-guided atherectomy during a 6-month follow-up.**

	Rutherford Classification	Original Intervention	Timing of Reintervention After Initial Treatment	Etiology	Type of Reintervention
Patient 1	3	DA <sup>a</sup> , PTA, and Zilver PTX DES of SFA DA <sup>a</sup> and PTA of Peroneal	5 months	60%-70% ISR of SFA Mid peroneal CTO	PTA of SFA with intramedial temsirolimus infusion as part of TAP-DANCE study PTA of peroneal
Patient 2	4	DA <sup>a</sup> and PTA of TPT + popliteal stenosis CTO of peroneal and PT	3 months	80%-90% TPT stenosis CTO of proximal peroneal and mid PT-CTO	PTA of TPT, peroneal and PT

<sup>a</sup>Optical coherence tomography (OCT)-guided directional atherectomy with Pantheris SV.  
 CTO = chronic total occlusion; DA = directional atherectomy; DES = drug-eluting stent; ISR = in-stent restenosis; PT = posterior tibial artery; PTA = percutaneous transluminal angioplasty; SFA = superficial femoral artery; TPT = tibioperoneal trunk.

likely manifested when more than 1 tibial vessel has severe atherosclerotic/calcific disease.<sup>2</sup> BTK-CLI patients also predominantly have diabetes as a risk factor which, when present, is associated with a 5-year survival rate of only 25% and higher incidence of limb amputation and TLR.<sup>3</sup>

Review of the literature shows that the treatment algorithm for BTK disease has evolved significantly in recent years. PTA is associated with elastic recoil and flow-limiting dissections in diseased peripheral vessels, which yield low long-term patency results from restenosis and the return of symptoms that affect patient quality of life.<sup>4</sup> The BASIL trial comparing PTA with bypass surgery in CLI patients for infrainguinal disease showed similar amputation-free survival outcomes after 6 months between the 2 arms, with surgery associated with higher short-term cost, helping to pioneer BTK endovascular treatment.<sup>5</sup> Comparison of placement of a bare-metal stent (BMS) with the use of PTA in BTK disease has noted poor mid-term outcomes with the BMS due to ISR from inflammation and neointimal hyperplasia initiated by stent placement, thus favoring a primary treatment strategy of PTA and use of BMS as bail-out option. Similarly, a propensity-matched analysis of 357 patients with BTK-CLI who were treated with a BMS vs PTA showed a higher target-extremity revascularization rate following stenting than with PTA (18.9% vs 11.1%, respectively;  $P < .01$ ) over 1 year.<sup>6</sup> In contrast with the use of BMS, DES therapy has shown promising results. Three multicenter randomized control trials, ACHILLES, YUKON-BTX, and DESTINY, have illustrated lower restenosis rates with DES than PTA (ACHILLES trial) and superior event-free survival and primary patency rates when comparing DES with BMS (YUKON-BTX and DESTINY trials).<sup>7-9</sup> These findings were confirmed in the 5-year long-term follow-up PADI trial where paclitaxel-eluting stent compared with PTA-BMS had superior event-free survival and amputation rates (31.8% vs 20.4% [ $P = .04$ ] and 26.2% vs 15.3% [ $P = .04$ ], respectively) in addition to having higher long-term patency rates.<sup>10</sup>

Drug-coated balloon (DCB) technology for treatment of longer infrapopliteal lesions was first investigated in the DEBATE-BTK trial, with a mean lesion length of  $129 \pm 83$  mm. The study concluded that DCB in comparison with PTA had lower 1-year restenosis rates (27% vs 74.3%, respectively) and lower major adverse events (31% vs 51%, respectively, driven by TLR and ulcer healing), but no difference in amputation rate, limb salvage, or mortality.<sup>11</sup> However, the prospective, multicenter, randomized IN.Pact Deep CLI trial of 358 CLI patients comparing DCB with PTA in a 2:1 fashion showed no difference in primary endpoint of late lumen loss or TLR, but a non-significantly higher amputation rate in the DCB group (8.8% DCB vs 3.6% PTA;  $P = .08$ ) over a 12-month period.<sup>12</sup> Currently, the best practice for BTK adjunctive treatment favors DES therapy; however, most lesions in the randomized trials are short and focal in nature and therefore a class IA or appropriate recommendation is given for  $<120$ - $140$  mm infrapopliteal lesions only.<sup>7-9,13</sup>

**DA and BTK disease.** Atherectomy devices (directional, orbital, rotational, or OCT guided) are infrequently utilized in BTK disease, which may in part be due to lack of dedicated device technology for BTK small-vessel disease and increased perceived risk of complications with their use. The TALON study, wherein infrapopliteal lesions were treated with SilverHawk DA, had a mean lesion length of 68.5 mm and required adjunctive treatment in 73.3% of lesions with stent deployment in 6.3% of lesions. The 6- and 12-month freedom from TLR rates were 90% and 80%, respectively.<sup>14</sup> The DEFINITIVE LE cohort of 189 infrapopliteal vessels treated with SilverHawk DA had a mean lesion length of  $58 \pm 44$  mm with 20% occlusions and a primary patency rate of 84% at 1-year follow-up and freedom from major amputation rate of 97.1%, with significant clinical and quality of life improvements.<sup>15</sup> A recent retrospective study of 97 patients with BTK-CLI comparing different treatment strategies in a single-center, retrospective observational manner over a period of 5 years showed reocclusion rates at 30 months post intervention to be higher with PTA alone (58.1%) than with adjunctive atherectomy and PTA (33.3%) or atherectomy with stenting (50%).<sup>16</sup> The atherectomy devices used at the center included HawkOne, SilverHawk, TurboHawk (Medtronic), or orbital atherectomy. It has been demonstrated that drug absorption can be greatly reduced when deposited onto plaque vs directly onto the intra-arterial layers. Therefore, achieving greater plaque debulking with direct visual guidance can greatly impact the efficacy and resorption of drug-eluting therapies, ie, DCB or DES.<sup>17</sup>

**Pantheris SV and benefits of OCT-guided DA.** The Pantheris SV atherectomy catheter received Food and Drug Administration marketing clearance for the treatment of PAD in vessels with diameters of 2-4 mm in April 2019. The lumivascular technology allows for visualization of intra-arterial wall structures with identification of media, internal and external elastic lamina, and adventitia, along with stent struts and dissections. Plaque morphology (calcium, fibroatheromas, thrombus, necrotic core) can also be readily identified.<sup>18</sup> Adventitial disruption has been associated with a 97% 1-year incidence of restenosis in comparison with 11% when its not disrupted.<sup>1</sup> OCT-guided plaque debulking can avoid this disruption and may provide improved outcomes. The seminal single-arm, multicenter VISION trial, which evaluated first-generation outcomes with femoropopliteal Pantheris DA device, showed a high rate of plaque-only debulking with  $<1\%$  adventitia measured on histologic plaque specimens and no dissections or perforations.<sup>19</sup> In contrast, fluoroscopy-guided DA with the TurboHawk DA catheter found a mean volume of 16% adventitia noted in tissue collected during atherectomy in 1 study.<sup>20</sup> The 6- and 12-month TLR rates reported in the VISION trial were 6.4% and 14%, respectively,<sup>16</sup> as compared with a 6-month TLR rate of 10% reported in the TALON registry, where 601 patients were treated with fluoroscopy-guided SilverHawk DA.<sup>19</sup> The more recently completed DEFINITIVE LE study evaluated 799 patients

treated with SilverHawk and TurboHawk DA systems and reported a primary patency rate of 78% for all lesions and 65% in CTO lesions at 12 months post procedure.<sup>15</sup> OCT-guided DA is also helpful in planning adjunctive therapy, as it can identify short segments of plaque burden or flow-limiting dissections avoiding unnecessarily longer stents. Lesion length measurements performed with OCT imaging in the VISION trial were significantly longer than the lengths measured by fluoroscopy (72.4 mm vs 53.1 mm, respectively;  $P < .001$ ).<sup>19</sup> Fluoroscopy times can also be greatly reduced with OCT-guided DA, as most plaque debulking can be accomplished without radiation with improved adherence to the “as low as reasonably allowable” radiation principle.

**Implications of Pantheris SV on BTK treatment.** Image-guided BTK atherectomy with the Pantheris SV catheter appears to be safe, with a low incidence of device failure or complications and appreciably low freedom from TLR at 6 months post procedure. While this study demonstrated that the catheter can be successfully utilized for all types of BTK lesions, including CTOs and ISRs, ATA angulation appears to present a challenge for device advancement. Further prospective analysis on the angles that deem the device difficult to advance should be undertaken. There was 1 stent dislodgment in treating a PT lesion, which was adequately treated with snaring the stent and restenting that portion of the vessel. It is important to note that this complication occurred early, within 2 months of introduction of the device at a teaching institution. Thus, a larger sample is needed to formally evaluate outcomes of Pantheris SV DA for treatment of BTK-ISR. The 1 case with no flow post DA and PTA may be related to a multitude of factors, including distal embolus, arterial spasm, or thrombus. This particular lesion was also noted to contain severe calcification and required use of a coronary cutting balloon and laser atherectomy in order to reduce luminal stenosis sufficiently to restore blood flow. The device’s performance in severely calcified lesions also necessitates further investigation. There were also only 2 TLRs over a 6-month follow-up available for 21 of the patients, signaling durable mid-term clinical outcomes.

Enrollment for a IMAGE-BTK clinical study evaluating the safety and efficacy of the Pantheris SV for the treatment of BTK disease began in January 2020, with 30-day, 6-month, and 1-year freedom from TLR and primary patency outcomes to be determined for a total of 60 patients.<sup>21</sup> The present study is the first to provide observational procedural safety, efficacy, and 6-month TLR outcomes with use of the Pantheris SV.

**Study limitations.** This study is an observational, retrospective, small-sample size analysis of all patients undergoing treatment with Pantheris SV atherectomy in the past year at a teaching institution with a high volume of endovascular procedures; as such, biases like the expertise of the operator cannot be determined. A randomized trial comparing OCT-guided atherectomy with adjunctive treatment vs non-imaging guided atherectomy

would yield stronger evidence in favor of one treatment over the other. The adjunctive treatment also needs randomization to ascertain which interventional treatment is best suited in BTK lesions with added DA. The antiplatelet/anticoagulant regimen also varied among study subjects. Given the benefits of low-dose rivaroxaban in the COMPASS and VOYAGER-PAD trials, especially in CLI patients, the outcomes may differ with uniform treatment cohorts.<sup>22,23</sup> Finally, due to relatively high loss to follow-up ( $n = 6$ ; 22%), these outcomes including TLR rates may be underestimated.

## Conclusion

OCT-guided DA with the Pantheris SV catheter appears to be safe and effective, with a low number of complications and low TLR rates at 6 months. Larger, multicenter, randomized trials are needed to further validate these results.

## References

1. Tarricone A, Ali Z, Rajamanickam A, et al. Histopathological evidence of adventitial or medial injury is a strong predictor of restenosis during directional atherectomy for peripheral artery disease. *J Endovasc Ther.* 2015;22:712-715.
2. Jaff MR, White CJ, Hiatt WR, et al. An update on methods for revascularization and expansion of the TASC lesion classification to include below-the-knee arteries: a supplement to the inter-society consensus for the management of peripheral arterial disease (TASC II): the TASC Steering Committee. *Ann Vasc Dis.* 2015;8:3343-3357.
3. Spiliopoulos S, Theodosiadou V, Katsanos K, et al. Long-term clinical outcomes of infrapopliteal drug-eluting stent placement for critical limb ischemia in diabetic patients. *J Vasc Interv Radiol.* 2015;26:1423-1430.
4. Katsanos K, Spiliopoulos S, Krokidis M, et al. Does below-the-knee placement of drug-eluting stents improve clinical outcomes? *J Cardiovasc Surg (Torino).* 2012;53:195-203.
5. Adam DJ, Beard JD, Cleveland T, et al. Bypass versus angioplasty in severe ischemia of the leg (BASIL): multicenter, randomized controlled trial. *Lancet.* 2005;366:1925-1934.
6. Ahn J, Rha S. One-year follow-up of stenting versus standard balloon angioplasty for the below-knee arteries in Korean patients: a propensity score-matched analysis [TCTAP abstract A-0880]. *J Am Coll Cardiol.* 2018;71:551.
7. Scheinert D, Katsanos K, Zeller T, et al. A prospective randomized multicenter comparison of balloon angioplasty and infrapopliteal stenting with the sirolimus-eluting stent in patients with ischemic peripheral arterial disease: 1-year results from the ACHILLES trial. *J Am Coll Cardiol.* 2012;60:2290-2295.
8. Rastan A, Tepe G, Krakenberg H, et al. Sirolimus-eluting stents vs bare-metal stents for treatment of focal lesions in infrapopliteal arteries: a double-blind, multi-center, randomized clinical trial. *Eur Heart J.* 2011;32:2274-2281.
9. Bosiers M, Scheinert D, Peeters P, et al. Randomized comparison of everolimus-eluting versus bare-metal stents in patients with critical limb ischemia and infrapopliteal arterial occlusive disease. *J Vasc Surg.* 2012;55:390-398.
10. Spreen MI, Martens JM, Knippenberg B, et al. Long-term follow-up of the PADI trial: percutaneous transluminal angioplasty versus drug-eluting stents for infrapopliteal lesions in critical limb ischemia. *J Am Heart Assoc.* 2017;6:e004877.
11. Liistro F, Grotti S, Porto I, et al. Drug-eluting balloon in peripheral intervention for the superficial femoral artery: the DEBATE-SFA randomized trial (drug eluting balloon in peripheral intervention for the superficial femoral artery). *JACC Cardiovasc Intervent.* 2013;6:1295-1302.

12. Zeller T, Baumgartner I, Scheinert D, et al. Drug-eluting balloon versus standard balloon angioplasty for infrapopliteal arterial revascularization in critical limb ischemia: 12-month results from the IN.PACT DEEP randomized trial. *J Am Coll Cardiol*. 2014;64:1568-1576.
13. Klein AJ, Jaff MR, Gray BH, et al. SCAI appropriate use criteria for peripheral arterial interventions: an update. *Catheter Cardiovasc Interv*. 2017;90:E90-E110.
14. Ramaiah V, Gammon R, Kiesz S. Midterm outcomes from the TALON registry: treating peripherals with SilverHawk: outcomes collection. *J Endovasc Ther*. 2006;13:592-602.
15. McKinsey JF, Zeller T, Rocha-Singh KJ. Lower extremity revascularization using directional atherectomy: 12-month prospective results of the DEFINITIVE LE study. *JACC Cardiovasc Interv*. 2014;7:923-933.
16. Thunuguntla S, Echeruo O, Mild C, et al. Superior short-term patency of stents over balloons in infrapopliteal artery disease. *School of Medicine Publications and Presentations*. 2020:81.
17. Virmani R. The relevance of paclitaxel dose and coating for efficacy and safety. Paper presented at: LINC 2015; January 25, 2015; Leipzig, Germany.
18. Avinger I. Avinger receives FDA clearance of Pantheris SV device. Published April 10, 2019. Available at <https://apnews.com/58a0e96aef1c2bef2992770aefbad84d>. Accessed on February 14, 2021.
19. Schwindt AG, Bennett JG Jr, Crowder WH, et al. Lower extremity revascularization using optical coherence tomography-guided directional atherectomy: final results of the evaluation of the Pantheris optical coherence tomography imaging atherectomy system for use in the peripheral vasculature (VISION) study. *J Endovasc Ther*. 2017;24:355-366.
20. George JC. Characterization of atherectomy samples from long SFA CTOs in correlation with clinical outcomes. Paper presented at: LINC 2016; January 26, 2016; Leipzig, Germany.
21. Avinger enrolls first patient in IMAGE-BTK clinical study evaluating safety and efficacy endpoints for Pantheris SV. Published January 23, 2020. Accessed at <https://apnews.com/1891fc3ccf65d9f3314a6d590a294e0>. Retrieved on February 14, 2021.
22. Eikelboom JW, Connolly SJ, Bosch J, et al. Rivaroxaban with or without aspirin in stable cardiovascular disease. *N Engl J Med*. 2017;377:1319-1330.
23. Capell WH, Bonaca MP, Nehler MR, et al. Rationale and design for the vascular outcomes study of ASA along with rivaroxaban in endovascular or surgical limb revascularization for peripheral artery disease (VOYAGER PAD). *Am Heart J*. 2018;199:83-91.

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