Each year, approximately 200,000 patients in the United
States receive stent implantation during intervention for
peripheral arterial disease (PAD). It is estimated that
within 12 months, 30%-40% of patients receiving stents will re-
quire repeat revascularization at the same lesion site following
re-occlusion, termed in-stent restenosis (ISR). Despite recent
advances in atherectomy tools for ISR, the clinical outcomes re-
main poor, with a recent randomized study demonstrating 39%
primary patency and 57% reintervention rate at 12 months. Poor stent patency is multifactorial, likely including residual
plaque burden, polymer-related inflammation, and mechanical
disturbances.

In an attempt to improve both acute and long-term outcomes
for endovascular therapies, interventionalists are increasingly
adopting intravascular imaging, which has demonstrated clinical
benefits during percutaneous coronary intervention for the
diagnoses and characterization of plaque burden and location,
and to gauge optimal therapeutic endpoints. Specifically, these
imaging modalities include intravascular ultrasound (IVUS) and
optical coherence tomography (OCT). With a 10-fold increased
resolution compared to IVUS, OCT has been shown to reveal
superior image resolution of vascular lumen surface, pathologic
tissue morphology, disease distribution patterns, and stent strut
positioning. Accordingly, interventionalists treating ISR us-
ing OCT may appreciate disease proximal and distal to scaffold
edges, disease-free in-stent regions, strut malapposition, overall
thrombus burden, and vulnerable plaque including thin-capped
fibroatheromas. X-ray fluoroscopy does not provide plaque mor-
phology insight and requires multiple angles with added contrast
for accurate assessment of plaque distribution at lesion edges.
Furthermore, a major advantage of OCT-guided therapies is the
significant radiation and contrast reduction for lower-extremity
revascularizations.

Until recently, IVUS-guided and OCT-guided diagnostic
catheters were independent from therapeutic catheters, adding
time to procedures and ultimately limiting the benefit of direct
visualization for real-time therapeutic guidance. The Pantheris
catheter (Avinger) is the first device to incorporate real-time OCT for intravascular imaging. OCT provides visualization without the
need for contrast or x-ray radiation. This case demonstrates the successful recanalization of a complex superficial femoral
artery ISR chronic total occlusion utilizing the Pantheris catheter.

**ABSTRACT:** The treatment and management of patients with in-stent restenosis (ISR) remains an important clinical
challenge. ISR cases involving the superficial femoral and popliteal arteries are complex due to the potential for multi-
variable complications, including severe neointimal proliferation, stent fracture, and increased restenosis lesion length.
We present a challenging superficial femoral artery ISR chronic total occlusion in a 66-year-old female with a history of
severe vascular disease. She presented with rest pain and computed tomography angiographic evidence of moderate
calcification surrounding a re-occluded drug-eluting stent. The ISR disease morphology and distribution were visualized
and removed using optical coherence tomography (OCT)-guided directional atherectomy. Avinger’s Pantheris catheter is
the first therapeutic device to incorporate real-time OCT for intravascular imaging. OCT provides visualization without the
need for contrast or x-ray radiation. This case demonstrates the successful recanalization of a complex superficial femoral
artery ISR chronic total occlusion utilizing the Pantheris catheter.

**Key words:** peripheral arterial disease, chronic total occlusion, in-stent restenosis, peripheral intervention,
optical coherence tomography

**Figure 1.** Design of the Pantheris catheter and real-time optical coherence tomographic visualization while revascularizing an
in-stent restenosis case (used with permission from Avinger).
CASE REPORT

A 66-year-old female presenting with left lower extremity rest pain was referred with Rutherford category 3 intermittent claudication. Previous treatment of the target lesion included balloon angioplasty and drug-eluting stent (DES) implantation. Diagnostic angiography revealed an ISR-CTO of the left SFA extending into the P1 segment.

Contralateral access was gained with a 7 Fr sheath placed into the left common femoral artery. A 0.035″ Trailblazer (Medtronic) and soft-angled Glidewire (Terumo) were used to cross the 400 mm SFA-CTO. After crossing, a 3 mm Spider filter (Medtronic) was deployed into the peroneal artery.

Using OCT guidance, directional atherectomy of the left SFA was successfully performed with the Pantheris catheter. Atherectomy required two catheter insertions, with a total of seven cutting passes through the ISR region. OCT revealed dense disease 5 cm above the proximal stent edge extending to 6 cm below the distal stent edge. The neointima was most dense at the stent edges, with approximately 100 mm of intermittent intrastent disease-free segments. A large, mixed morphology thrombus burden was also noted within the ISR. The nose cone was cleaned following each insertion, with a large volume of plaque specimen removed each time. Angiography revealed post-Pantheris residual stenosis of <20%.

Following OCT-guided atherectomy, the filter wire was removed with minor thrombotic debris noted. However, given the risk for distal embolization when treating ISR, routine use of filter wire is advised. A MiracleBros 12 gauge guidewire (Abbott Vascular) was placed into the left SFA and In.Pact drug-coated balloons (DCBs; Medtronic) were placed in the distal SFA (6.0 x 120 mm), mid SFA (6.0 x 120 mm), proximal SFA (6.0 x 120 mm), and ostial SFA (6.0 x 80 mm). Subsequent angiography demonstrated excellent results with <10% residual stenosis. Total therapy time was measured at 23 minutes.

DISCUSSION

Endovascular intervention of ISR has evolved significantly over the last decade. The introduction of DCBs, DESs, and atherectomy (directional, orbital, and laser) has yielded significantly improved short-term results, yet these lesions are still characterized by a relatively high incidence of restenosis. Atherectomy along with cryoplasty shows poor overall patency in non-randomized trials, including 25% at 12 months and 43% at 6 months. Results from randomized DCB trials, such as PACUBA and FAIR, add to the growing body of evidence for the treatment of SFA-ISR. PACUBA reports 74 patients with claudication, randomized to DCB vs standard angioplasty treatment, with 12-month target-lesion revascularization (TLR) rates of 51% vs 78%, respectively. The FAIR trial included lesions half the length of the PACUBA trial, and reported TLR rates that were significantly improved for DCB vs angioplasty (9% and 47%, respectively). Lastly, the paclitaxel-eluting stent (Cook Medical) showed favorable results for SFA-ISR cases in a non-randomized study, with primary patency of 78.8% at 12 months. The wide variability in lesion sizes studied and long-term patency results across therapies suggests that there remains a lack of evidence to support a single solution. Accordingly, given the considerable population of patients with peripheral stents, innovative technologies and long-term datasets must continue to define an algorithmic approach to ISR therapy.

Adverse events associated with ISR revascularization include the inability to accurately characterize proximal and distal disease with angiography, risk of catching stent struts, and appreciation of hibernating thrombus burden. In fact, secondary to commercial safety complaints, x-ray-guided directional atherectomy (Silverhawk; Medtronic) received a post-market contraindication for ISR therapy. The role of intravascular imaging may improve both safety and efficacy when treating ISR. For example, IVUS and OCT have been shown to detect the presence and depth of neointimal hyperplasia, strut malapposition, and scaffold-edge disturbances, which have the potential to provide the operator with valuable insights on vessel sizing for optimal therapy. In contrast to alternative devices such as the excimer laser, which utilizes light energy to vaporize matter and to modify the plaque, directional atherectomy removes the plaque mechanically, and thus has the advantage of achieving a larger luminal gain. It has been shown...
that achieving ≤30% residual stenosis improves long-term patency following revascularization. The visualization of the distinct arterial wall composition and the embedded stent struts during OCT-guided atherectomy allows maximal luminal gain.

Moreover, recent studies have shown that when treating ISR in the femoropopliteal region, a combination treatment of atherectomy and DCB is superior to stand-alone DCB. The results were significant in the retrospective single-center DEBATE-ISR study, with a reported 12-month freedom from restenosis rate of 84.7% for atherectomy + DCB vs 70.5% for DCB alone. Given these results, current studies looking at Pantheris + DCB will need to be monitored for their effectiveness in delivering improved long-term patency.

This case report demonstrates a challenging SFA-ISR, with heavy disease burden extending from the proximal SFA to the P1 segment. In this case, because of the length and complexity of ISR disease, we decided to treat using Pantheris’s real-time OCT capabilities. Our results demonstrate how intravascular OCT visualizes proximal and distal disease, stent struts, and thrombus burden (Figure 3). This is the first report of OCT-guided atherectomy successfully treating ISR. In this case, the visualization provided by the Pantheris catheter assisted the operators to safely and effectively revascularize a complex ISR lesion.

**CONCLUSION**

The proper treatment algorithm for femoral ISR is complex and represents an important challenge for peripheral interventionists. We present a complex SFA-ISR–CTO where OCT-guided atherectomy enabled identification of lesion extension beyond stent boundaries, thrombus burden within ISR, acute strut malposition, and disease burden assessment, all without the need for contrast or fluoroscopy. OCT diagnostic visualization during therapy was safe, effective, and time efficient.

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**Figure 3.** Optical coherence tomography of the superficial femoral artery through the Avinger Pantheris system. All three images are in different regions of the treatment region. (A) Proximal stent: minimal neo-intima along the stent strut and laminar surface. (B) Mid stent: catheter cutter approaches the strut showing preserved native media and external elastic lamina (EEL) behind the stent edge. (C) Distal stent: approaching chronic total occlusion distal cap, evidence of full thickness, intimal hyperplasia. (D) Distal stent: superior and lateral troughs debulked at distal cap, cutter engaging inferior portion of plaque burden.
REFERENCES