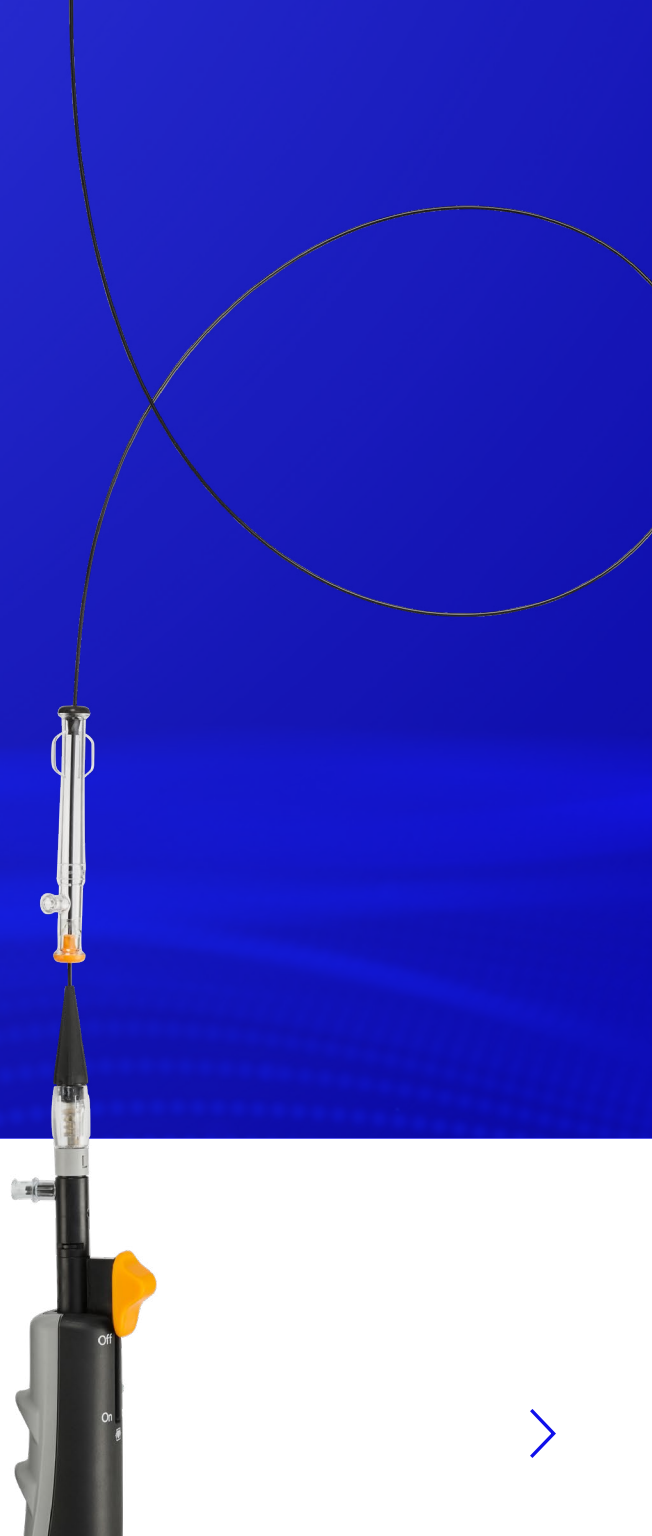
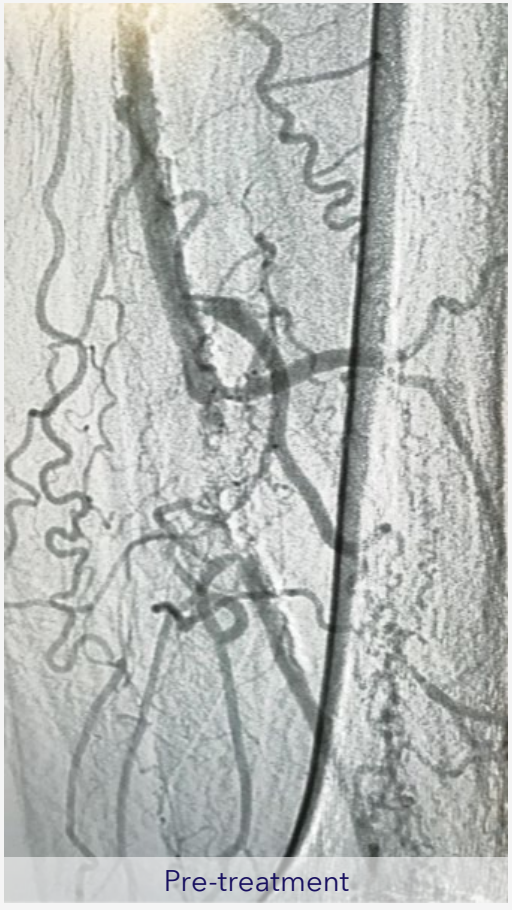
Medtronic

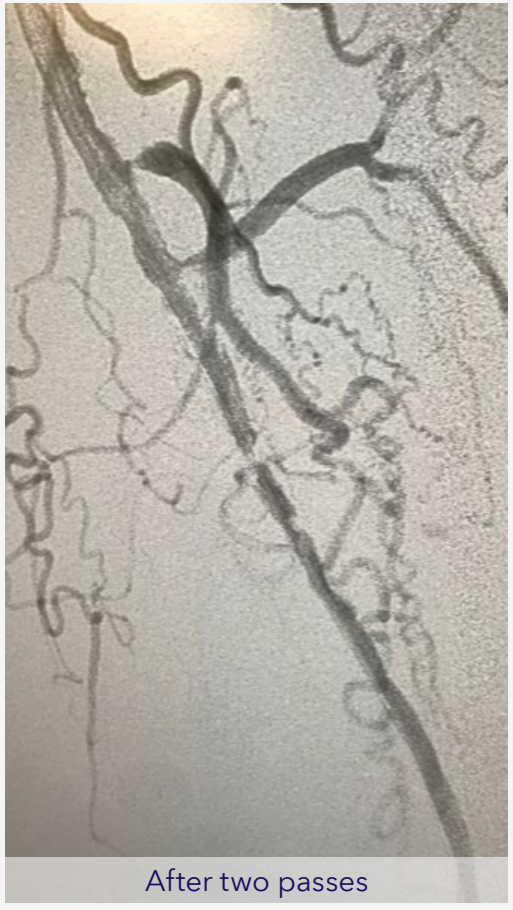
HawkOne™

Directional atherectomy case book

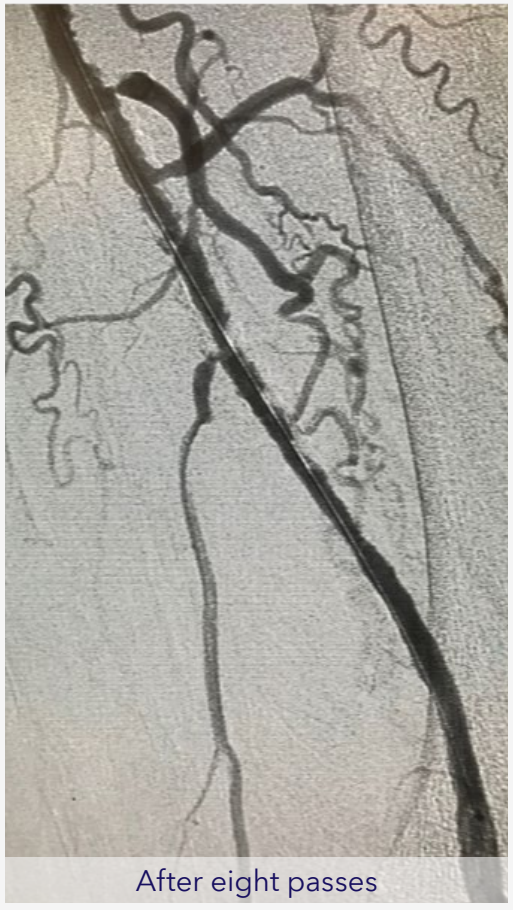




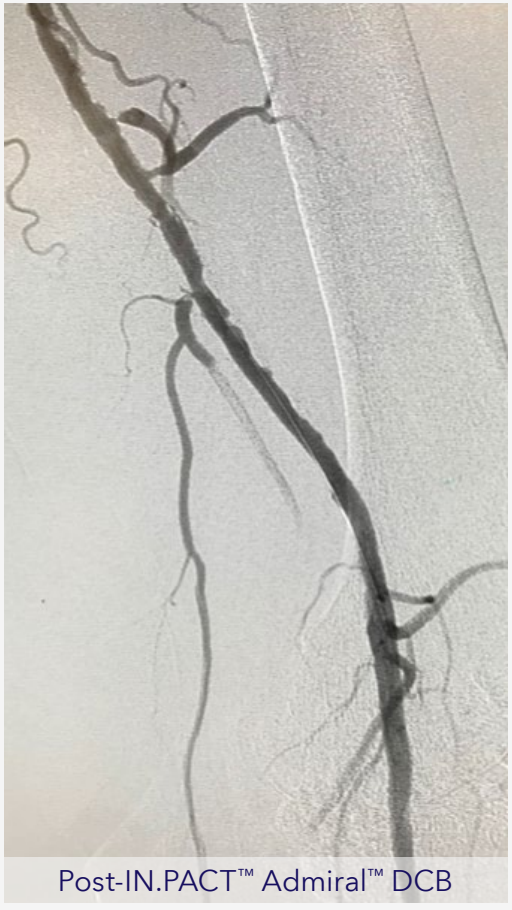
Pre-treatment



After two passes



After eight passes



Post-IN.PACT™ Admiral™ DCB

Images courtesy of Dr. Mohammad Kabir

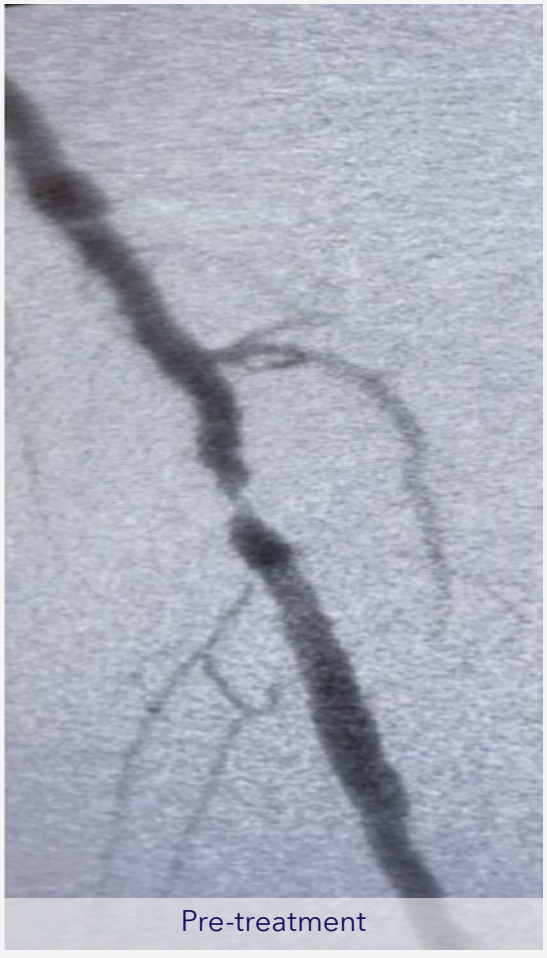
Case notes

HawkOne LS device in the SFA

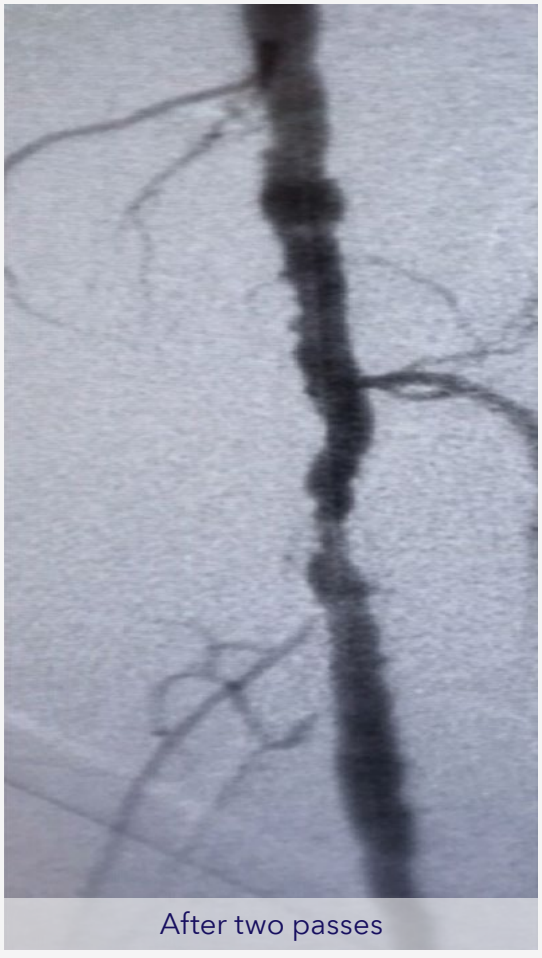
- The lesion was crossed using a Viance™ crossing catheter.
- 6.0 mm SpiderFX™ embolic protection device filter used to protect distal flow during procedure
- 2.5 mm x 60 mm pre-dilatation prior to first HawkOne device pass
- Physician performed eight passes with one insertion
- 5 mm x 80 mm IN.PACT Admiral drug-coated balloon (DCB) used post-HawkOne device

Medtronic

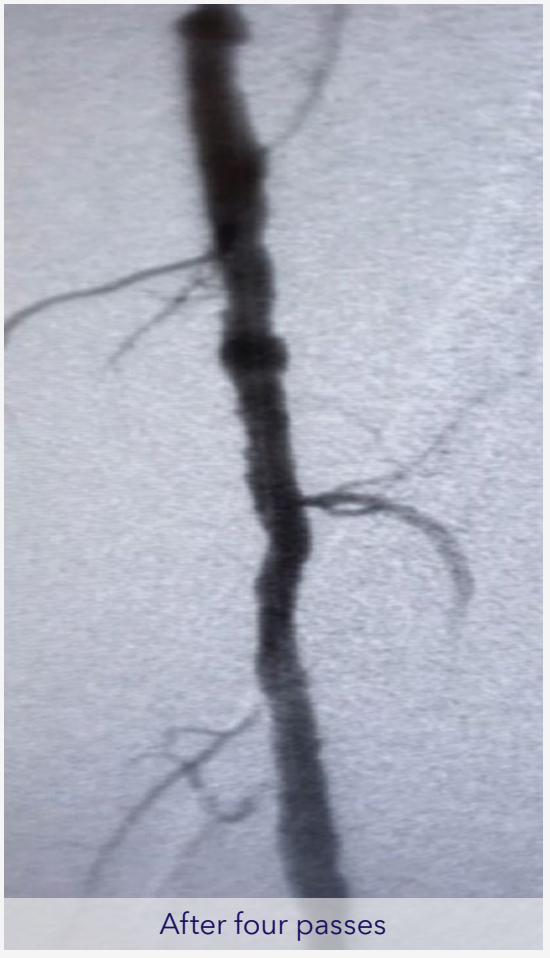
Results may vary given number of passes and lesion characteristics. Use angiographic assessment to determine desired level of debulking.



Pre-treatment



After two passes



After four passes

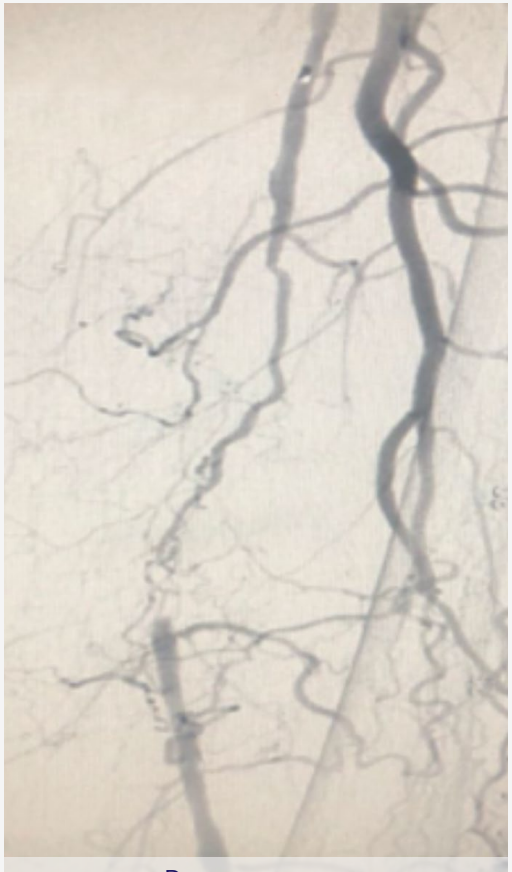
Images courtesy of Dr. Paul Butros

Case notes

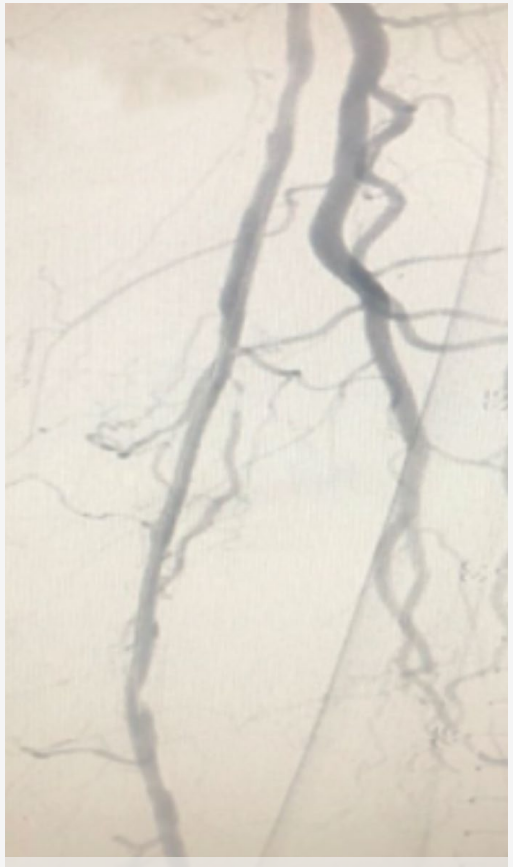
HawkOne M device in the SFA

- No pre-dilatation necessary
- Physician performed four passes with one insertion
- Images demonstrate standalone HawkOne device therapy

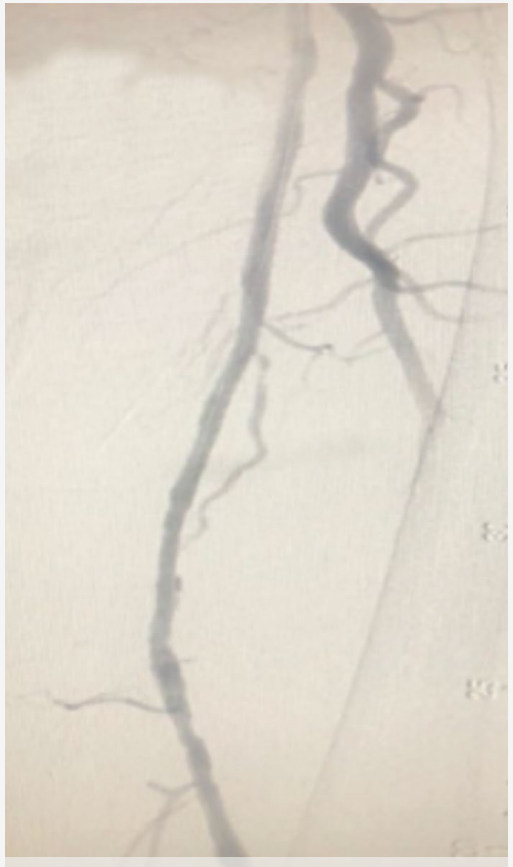
Results may vary given number of passes and lesion characteristics. Use angiographic assessment to determine desired level of debulking.



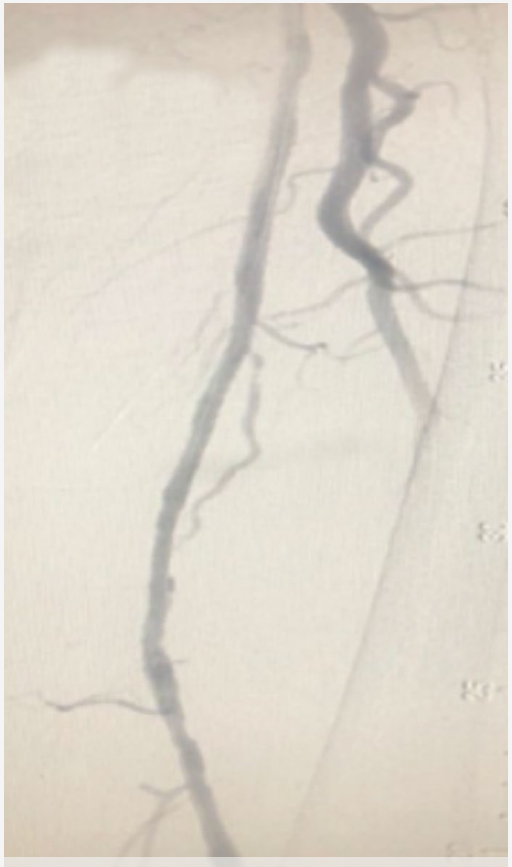
Pre-treatment



After two passes



After four passes



Post-Chocolate™* balloon

Images courtesy of Dr. Lindsay Bools

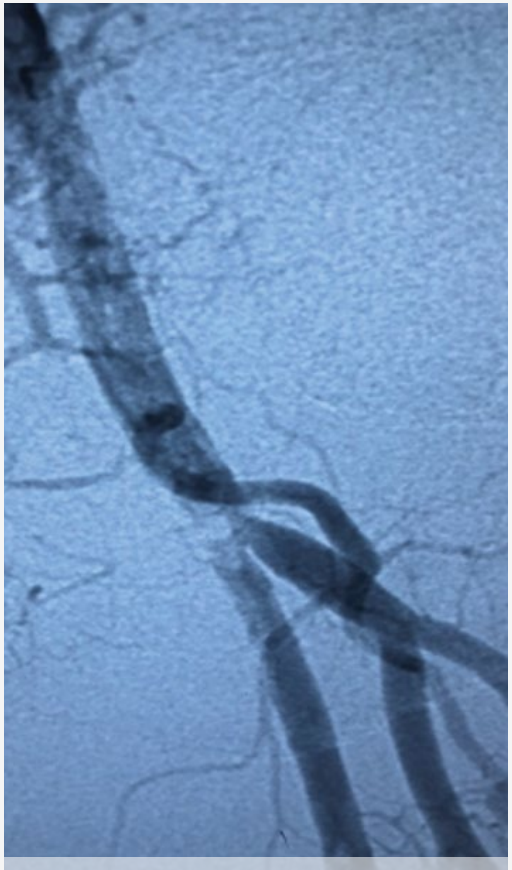
Case notes

HawkOne LX device in the SFA

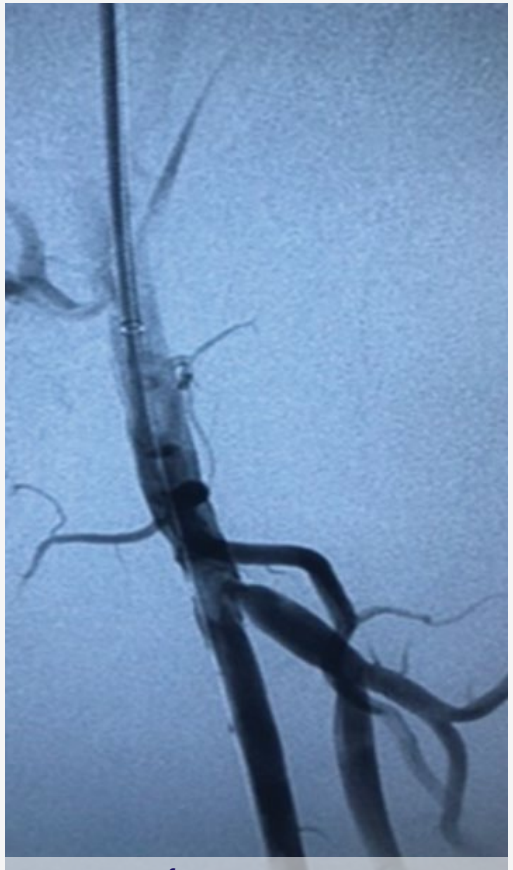
- No pre-dilatation necessary
- Physician performed four passes with one insertion
- Images demonstrate standalone HawkOne device therapy
- 5 mm x 120 mm Chocolate™* balloon used post-HawkOne device
- Physician chose to start conservatively with a medial and lateral pass, shot an angio, then chose to make two more passes

Medtronic

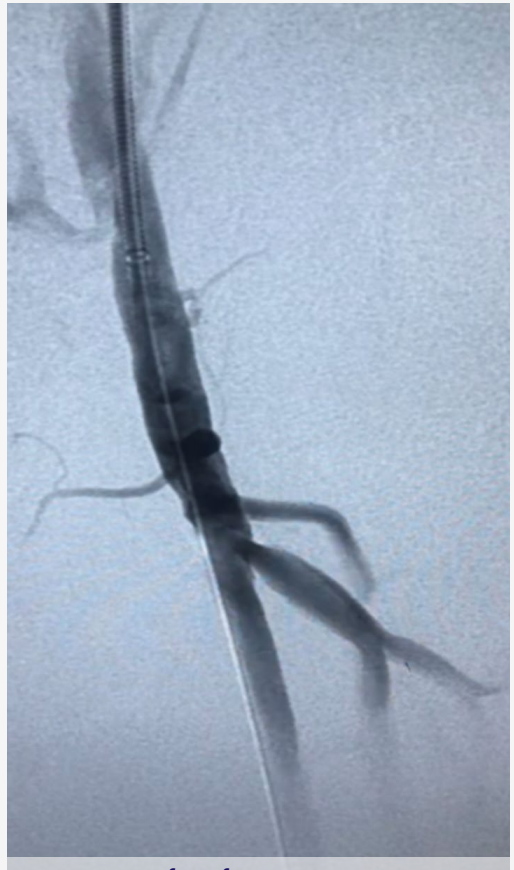
Results may vary given number of passes and lesion characteristics. Use angiographic assessment to determine desired level of debulking.



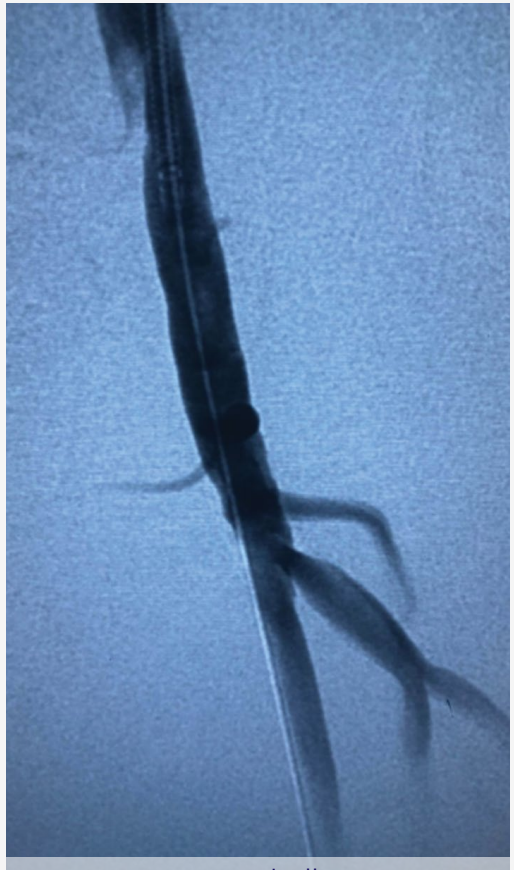
Pre-treatment



After two passes



After four passes



Post-PTA balloon

Images courtesy of Dr. Jasrai Gill

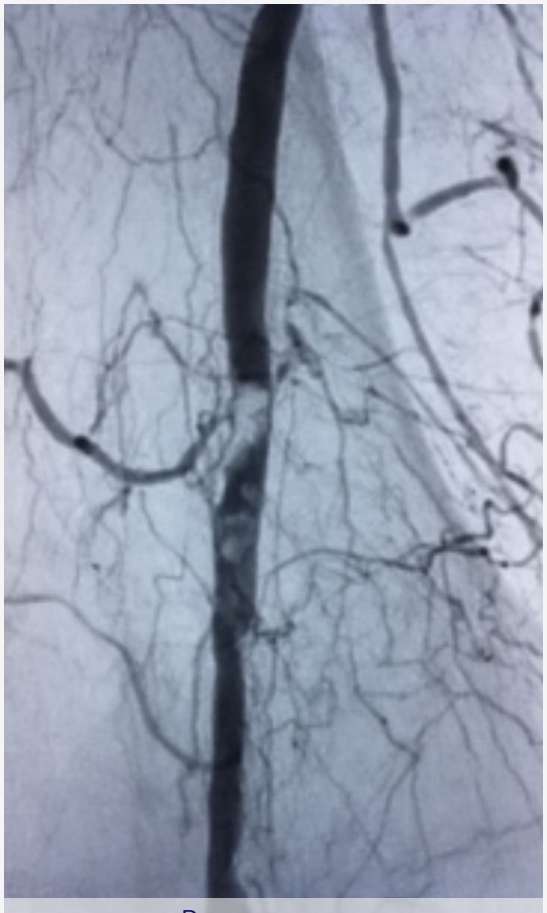
Case notes

HawkOne M device in the CFA

- No pre-dilatation necessary
- Physician performed four passes with one insertion
- Images demonstrate standalone HawkOne device therapy
- 6 mm x 40 mm PTA balloon used post-HawkOne device

Medtronic

Results may vary given number of passes and lesion characteristics. Use angiographic assessment to determine desired level of debulking.



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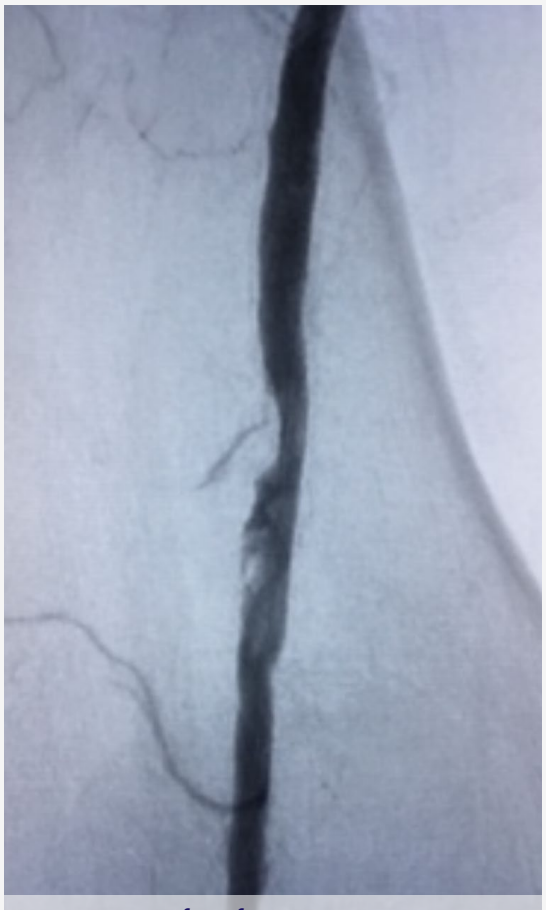
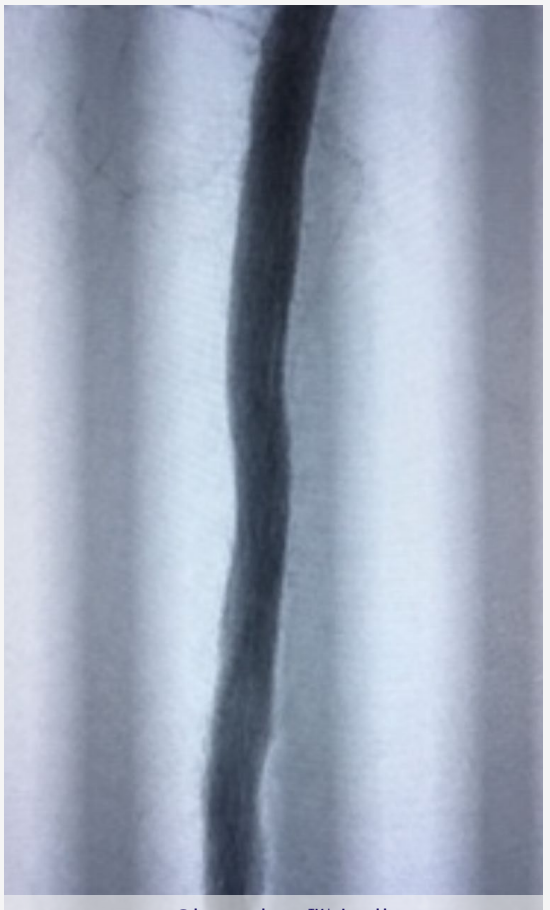


After four passes



Post-Chocolate™* balloon

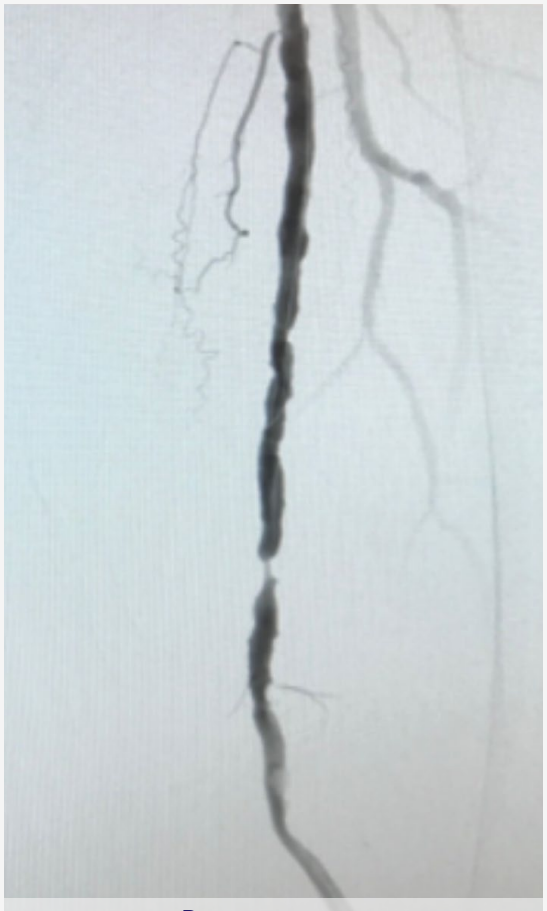
Images courtesy of Dr. Sai Sajja

Case notes

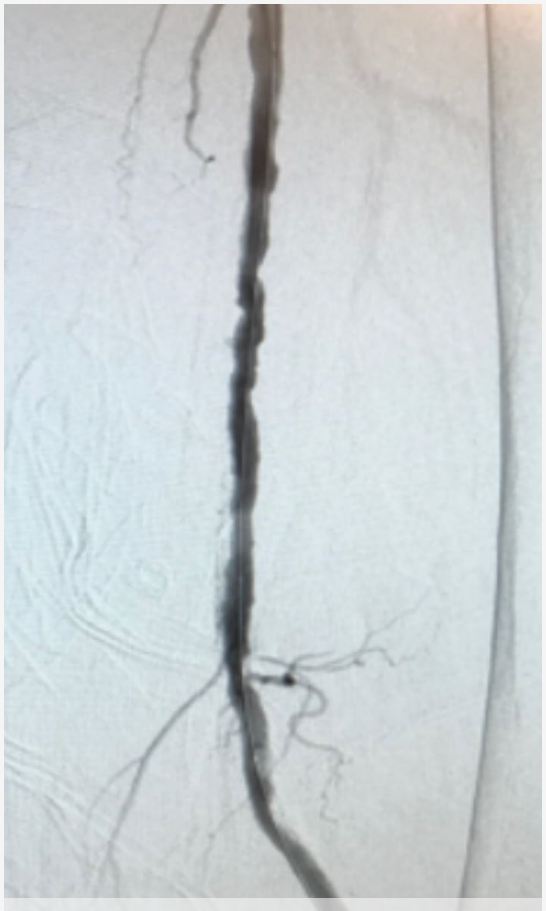
HawkOne M device in the SFA

- Distal flow protected with a 6 mm SpiderFX filter
- No pre-dilatation necessary
- Physician performed four passes with one insertion
- 5 mm x 80 mm Chocolate™* balloon and a 6 mm x 100 mm EverFlex™ self-expanding stent used post-HawkOne device

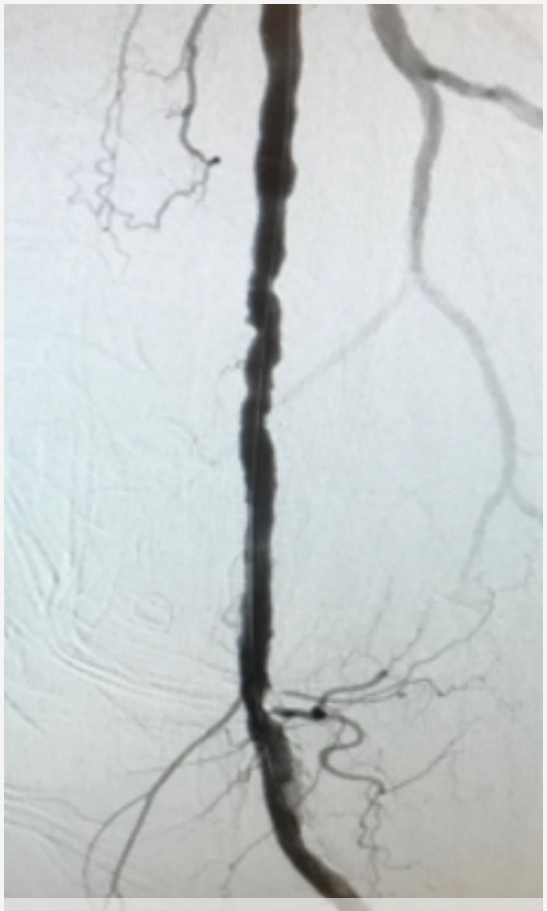
Results may vary given number of passes and lesion characteristics. Use angiographic assessment to determine desired level of debulking.



Pre-treatment



After six passes



Post-Chocolate™* balloon

Images courtesy of Dr. Zachary Bland

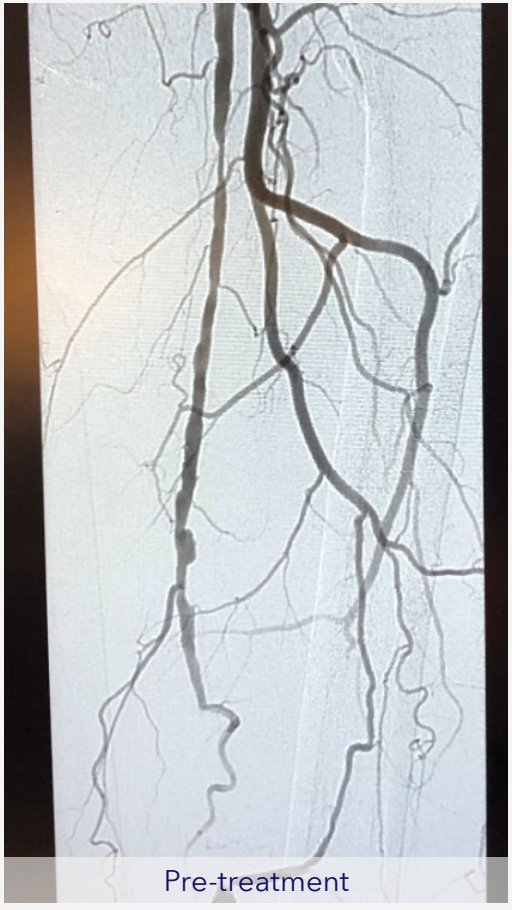
Case notes

HawkOne M device in the SFA

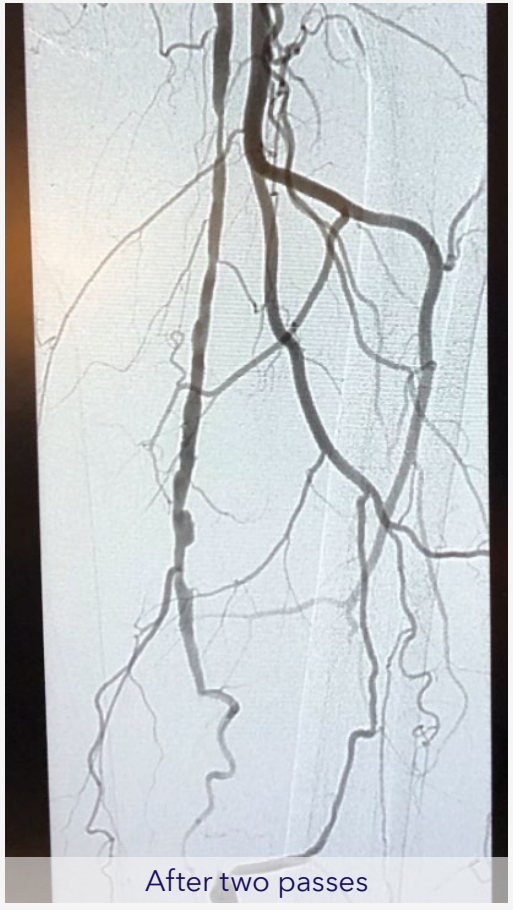
- No pre-dilatation necessary
- Physician performed four passes with one insertion
- 5 mm x 40 mm Chocolate™* balloon used post-HawkOne device

Medtronic

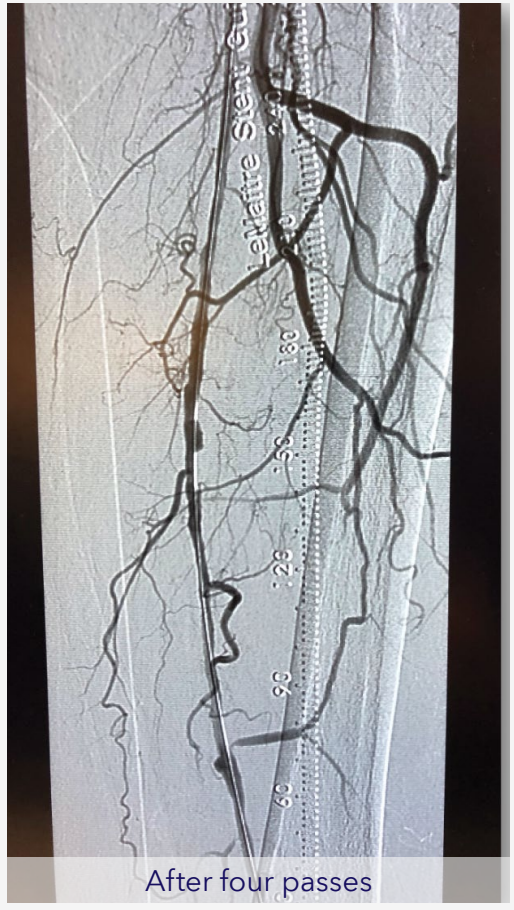
Results may vary given number of passes and lesion characteristics. Use angiographic assessment to determine desired level of debulking.



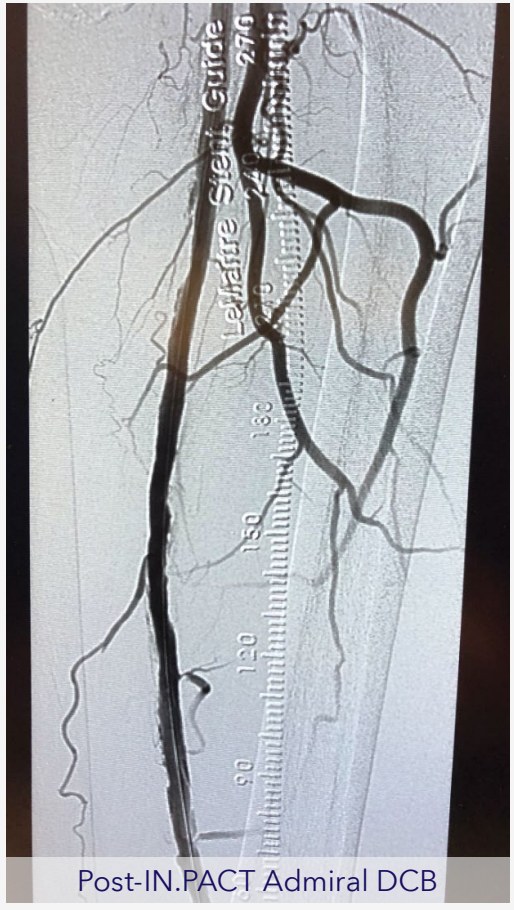
Pre-treatment



After two passes



After four passes



Post-IN.PACT Admiral DCB

Images courtesy of Dr. Sharat Koul

Case notes

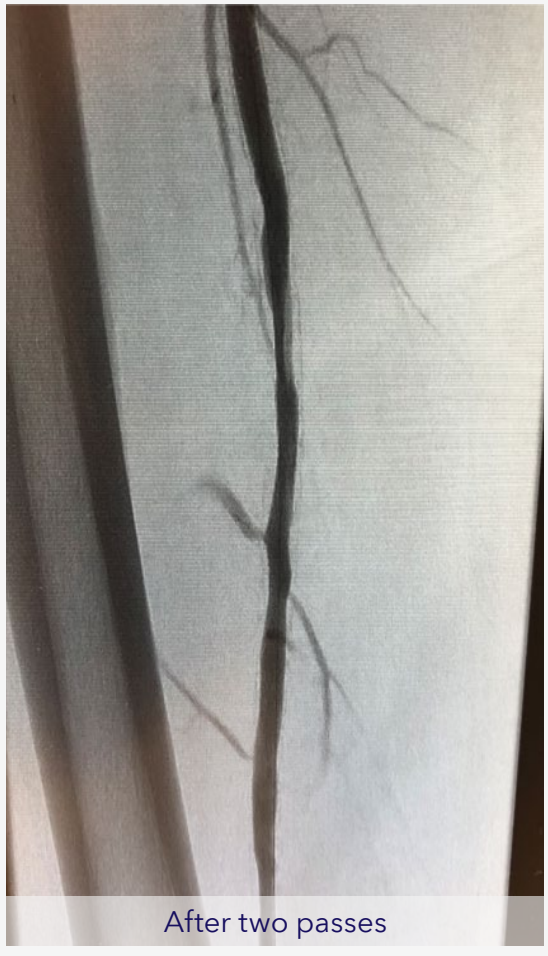
HawkOne M device in the SFA

- No pre-dilatation necessary
- Physician performed four passes with one insertion
- 5 mm x 250 mm IN.PACT Admiral DCB used post-HawkOne device

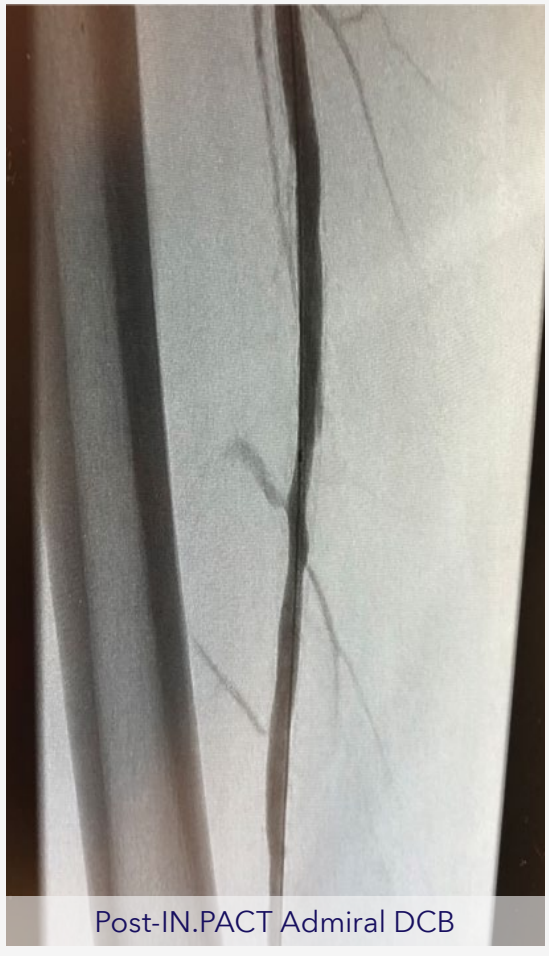
Medtronic

Results may vary given number of passes and lesion characteristics. Use angiographic assessment to determine desired level of debulking.

Pre-treatment



After two passes



Post-IN.PACT Admiral DCB

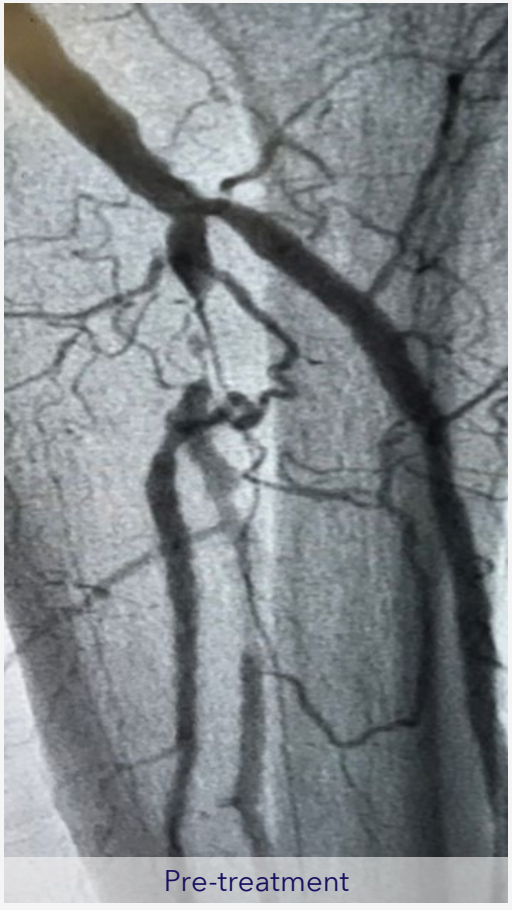
Images courtesy of Dr. Roy Miler

Case notes

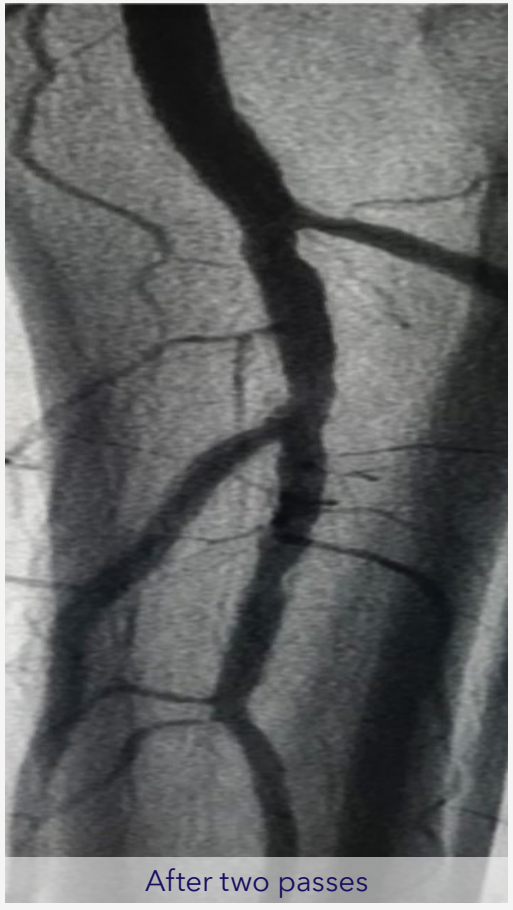
HawkOne M device in the SFA

- No pre-dilatation necessary
- Physician performed four passes with one insertion
- 6 mm x 40 mm IN.PACT Admiral DCB used post-HawkOne device

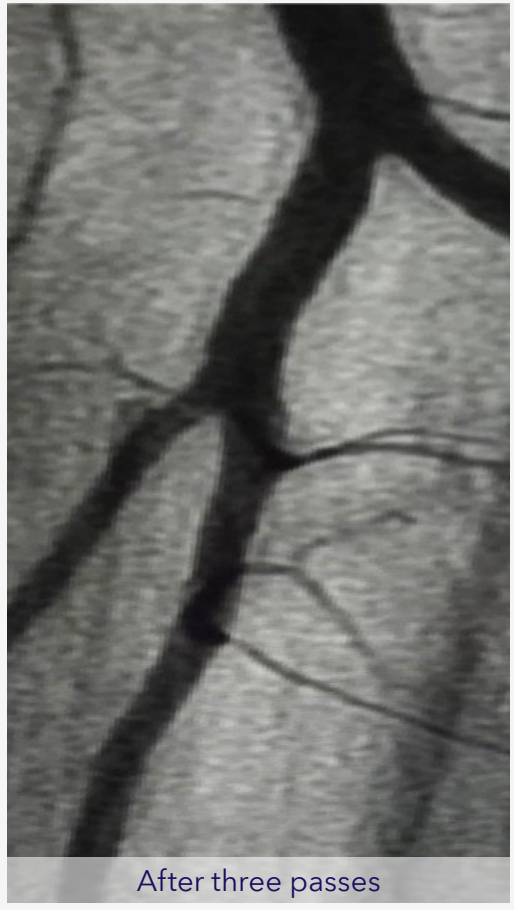
Results may vary given number of passes and lesion characteristics. Use angiographic assessment to determine desired level of debulking.



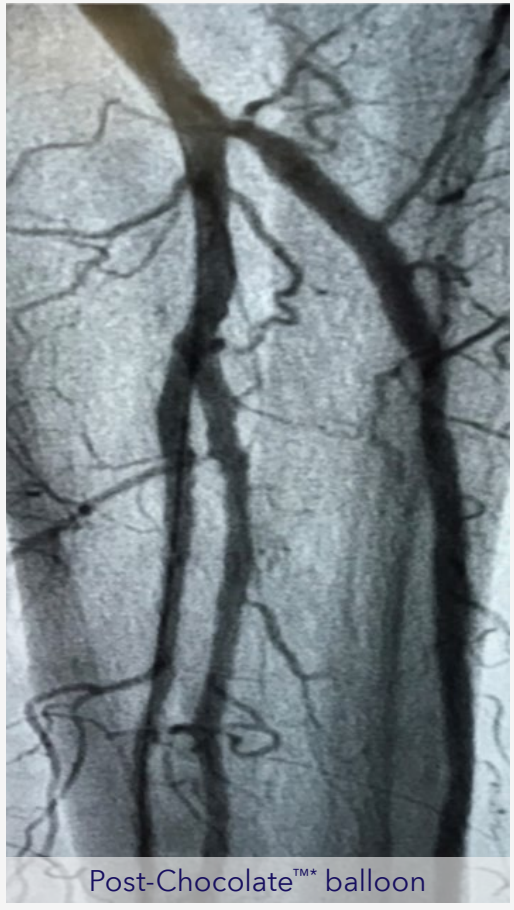
Pre-treatment



After two passes



After three passes



Post-Chocolate™* balloon

Images courtesy of Dr. Jeremiah Havins

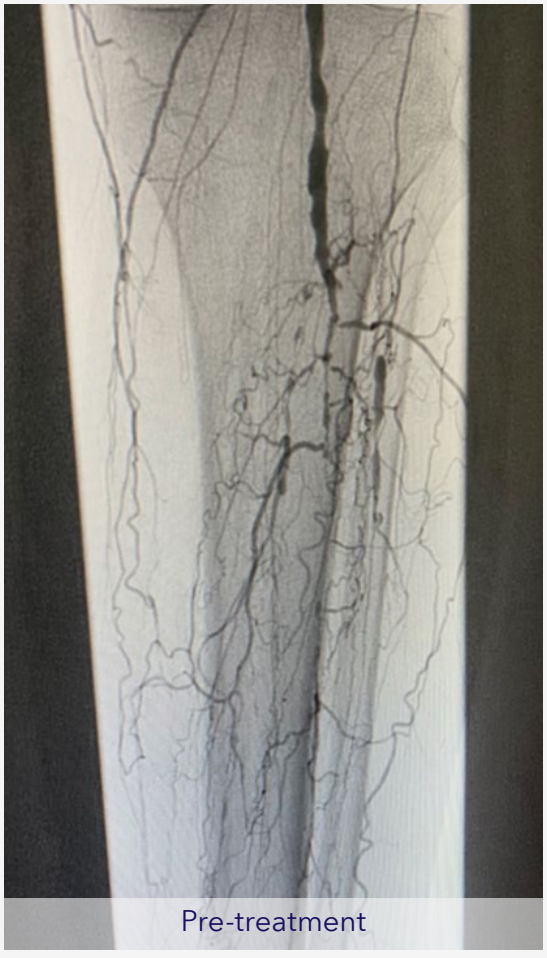
Case notes

HawkOne S device in the anterior peroneal artery

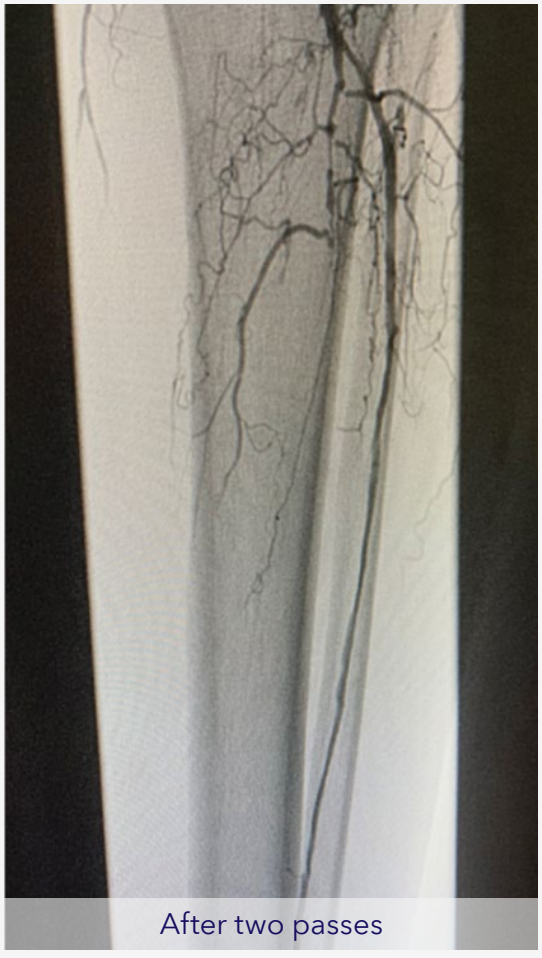
- No pre-dilatation necessary
- Physician performed three passes with one insertion
- 3 mm x 120 mm Chocolate™* balloon used post-HawkOne device

Medtronic

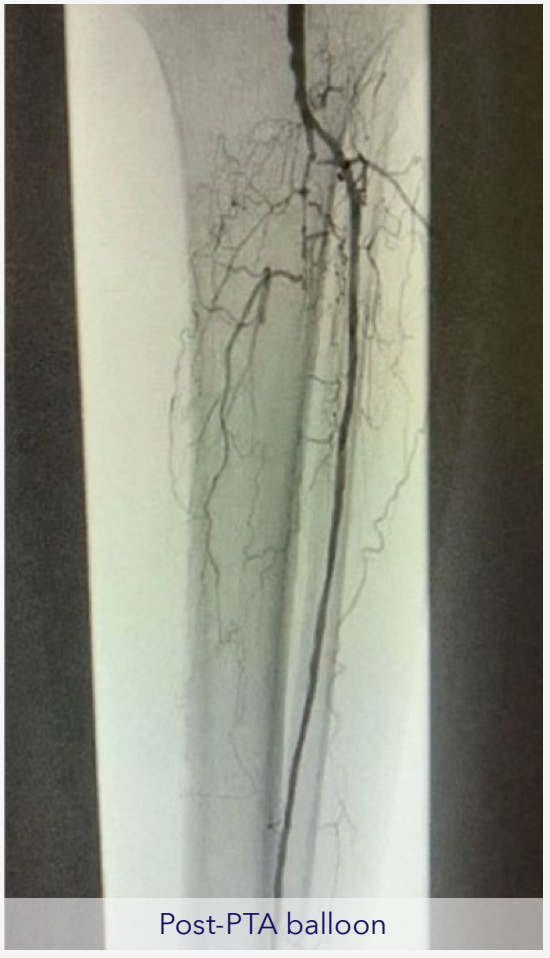
Results may vary given number of passes and lesion characteristics. Use angiographic assessment to determine desired level of debulking.



Pre-treatment



After two passes



Post-PTA balloon

Images courtesy of Dr. Matthew Langenberg

Case notes

HawkOne S device in the anterior tibial artery

- No pre-dilatation necessary
- Physician performed two passes with one insertion
- 3 mm x 150 mm PTA balloon used for post-dilatation after HawkOne device

Results may vary given number of passes and lesion characteristics. Use angiographic assessment to determine desired level of debulking.

Brief statements

HawkOne™ Directional Atherectomy System
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.
Indications for Use: The HawkOne™ peripheral directional atherectomy system is intended for use in atherectomy of the peripheral vasculature. The HawkOne catheter is indicated for use in conjunction with the SpiderFX™ embolic protection device in the treatment of severely calcified lesions. The HawkOne catheter is NOT intended for use in the coronary, carotid, iliac orrenal vasculature.
Caution: Federal (USA) law restricts this product for sale by or on the order of a physician.

Chocolate™* PTA Balloon Catheter
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device.
Indications for Use: The Chocolate™* PTA balloon catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries.
Caution: Federal (USA) law restricts this product for sale by or on the order of a physician.

EverFlex™ Self-expanding Peripheral Stent System
Indication: The EverFlex™ self-expanding peripheral stent system is intended to improve luminal diameter in the treatment of symptamotic *de novo* or restenotic lesions up to 180 mm in length in the native superficial femoral artery and/or proximal popliteal arteries with reference vessel diameters ranging from 4.5 mm – 7.5 mm.
The EverFlex self-expanding peripheral stent system is indicated for improving luminal diameter in patients with atherosclerotic disease of the common and/or external iliac arteries up to and including 100 mm in length, with a reference vessel diameter of 4.5 mm - 7.5 mm.The Protégé™ EverFlex self-expanding biliary stent system is intended as a palliative treatment of malignant neoplasms in the biliary tree.
Contraindications: Use of the EverFlex self-expanding peripheral stent system is contraindicated in patients with known hypersensitivity to nickel titanium and in patients contraindicated for anticoagulant and/or antiplatelet therapy, patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.
Potential Adverse Events: Potential adverse events which may be associated with the use of a stent in the SFA and proximal popliteal arteries include, but are not limited to: Allergic reaction, Amputation, Artery perforation or rupture, Bleeding requiring transfusion, Infection, Pseudoaneurysm, Restenosis, Stent collapse or fracture, Stent migration, Surgical or endovascular intervention, Thrombosis/ occlusion of the stent. See the Instructions for Use provided with the product for a complete list of warnings, precautions, adverse events and device information.
CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.

SpiderFX™ Embolic Protection Device
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.
Indications for Use:
Lower Extremity (LE) Interventions
The SpiderFX™ Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk™ Peripheral Plaque Excision System, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities. The vessel diameter at the filter basket placement site should be between 3.0 mm and 6.0 mm.
Carotid Interventions
The SpiderFX Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 7.0mm.
Saphenous Vein Graft (SVG) Interventions
The SpiderFX Embolic Protection Device is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/debris). The device also acts as the guidewire while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.0mm to 6.0mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral vasculature.

IN.PACT™ Admiral™ drug-coated balloon
Indications for Use:
The IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of *de novo*, restenotic, or in-stent restenotic lesions with lengths up to 360 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.
Contraindications: The IN.PACT Admiral DCB is contraindicated for use in:
- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure.

Warnings:
- A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients.
- Use the product prior to the Use-by Date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT Admiral DCB.
- Do not exceed the rated burst pressure (RBP). The RBP is 14 atm (1419 kPa) for all balloons except the 200 and 250 mm balloons. For the 200 and 250 mm balloons the RBP is 11 atm (1115 kPa). The RBP is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety and effectiveness of using multiple IN.PACT Admiral DCBs with a total drug dosage exceeding 34,854 µg of paclitaxel in a patient has not been clinically evaluated.

Precautions:
- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents.
- The safety and effectiveness of the IN.PACT Admiral DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure or following treatment failure has not been evaluated.
- The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the Instructions for Use (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events
- Vessel preparation using only pre-dilatation was studied in the clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT Admiral DCB.
- This product is not intended for the expansion or delivery of a stent.

Potential Adverse Effects:
The potential adverse effects (e.g. complications) associated with the use of the device are: abrupt vessel closure; access site pain; allergic reaction to contrast medium, antiplatelet therapy, or catheter system components (materials, drugs, and excipients); amputation/loss of limb; arrhythmias; arterial aneurysm; arterial thrombosis; arteriovenous (AV) fistula; death; dissection; embolization; fever; hematoma; hemorrhage; hypotension/hypertension; inflammation; ischemia or infarction of tissue/organ; local infection at access site; local or distal embolic events; perforation or rupture of the artery; pseudoaneurysm; renal insufficiency or failure; restenosis of the dilated artery; sepsis or systemic infection; shock; stroke; systemic embolization; vessel spasms or recoil; vessel trauma which requires surgical repair.
Potential complications of peripheral balloon catheterization include, but are not limited to the following: balloon rupture; detachment of a component of the balloon and/or catheter system; failure of the balloon to perform as intended; failure to cross the lesion.

Although systemic effects are not anticipated, potential adverse events that may be unique to the paclitaxel drug coating include, but are not limited to: allergic/immunologic reaction; alopecia; anemia; gastrointestinal symptoms; hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia); hepatic enzyme changes; histologic changes in vessel wall, including inflammation, cellular damage, or necrosis; myalgia/arthralgia; myelosuppression; peripheral neuropathy.
Refer to the Physician's Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time.

Viance™ Catheter
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.
Indications for Use: The Viance™ catheter is intended for use with a guidewire to access discrete regions of the peripheral vasculature. When used as part of the peripheral system, the Viance catheter is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.
Caution: Federal (USA) law restricts this product for sale by or on the order of a physician.

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