

Crossing CTOs With the Wildcat Catheter

Experiences using a new option for crossing difficult chronic total occlusions.

BY JOHN P. PIGOTT, MD

An increasing number of vascular specialists are employing a percutaneous intervention-first policy for the treatment of infrainguinal occlusive disease, particularly in patients at high risk for surgical procedures. This approach is based on recent reports of reduced morbidity and mortality with an intraluminal or subintimal endovascular approach.^{1,2} The BASIL trial³ substantiated this preference as well. This multicenter, randomized trial demonstrated essentially no difference in long-term outcomes between percutaneous and surgical revascularization in patients suitable for either form of treatment. Many patients prefer endovascular treatment because of its reduced cost, shorter hospital stay, and reduced procedural morbidity. However, if the patient's arterial occlusion cannot be crossed by percutaneous techniques, the patient will necessarily be relegated to a surgical procedure or, worse, amputation, depending on the arterial anatomy and patient comorbidities.

Crossing chronic total occlusions (CTOs) can be especially challenging if the proximal cap of the occluded arterial segment cannot be engaged or crossed with standard interventional technique. The medical device industry is attempting to address this problem with different types of devices. The corporate rationale behind these efforts is to improve crossing rates that then allow for the delivery of the therapeutic devices (angioplasty balloon, atherectomy catheters, cryoplasty, laser, etc.) to the target lesion.

The recent introduction of the Wildcat (Avinger, Redwood City, CA) as a support catheter has allowed our interventional practice to gain experience with this novel device. To date, 111 cases with the Wildcat (model W-400, 0.035-inch guidewire compatible) have been performed on difficult CTOs at our

institution. The following cases demonstrate the utility of this catheter in clinical practice.

CASE 1

An 84-year-old man presented with severe rest pain of the left foot for the past 3 months. Physical examination revealed a femoral pulse but none distally. Vascular laboratory data demonstrated an ankle-brachial index of 0.3 and markedly attenuated ankle waveforms. A duplex scan revealed a patent superficial femoral artery (SFA) and popliteal artery occlusion.

He harbored diffuse coronary artery disease not amenable to percutaneous intervention. Angiography revealed a patent SFA and proximal popliteal artery. There was a distal popliteal CTO and severe tibial disease (Figure 1).

Attempts to cross the popliteal occlusion were initially unsuccessful. Multiple wire and support catheter combinations were tried. Excellent support and pushability were provided by a long sheath passed down just proximal to the occluded popliteal segment. Nonetheless, all manner of different caliber wires and supports were used to no avail. Subintimal angioplasty was then attempted without being able to penetrate the tough fibrous cap.

Exchange for the Wildcat catheter ultimately allowed for lesion crossing while maintaining the true lumen (Figure 2). A 6-mm SpiderFX embolic protection device (ev3 Inc., Plymouth, MN) was deployed to protect the disadvantaged tibial outflow. Atherectomy of the popliteal segment was performed with a SilverHawk device (ev3 Inc.). Improved tibial imaging at this point revealed occlusions of the anterior and posterior tibial arteries (Figure 3). The peroneal artery was occluded in the



Figure 1. A popliteal artery occlusion and severe infrapopliteal occlusive disease.



Figure 2. Wildcat traversing a popliteal CTO.



Figure 3. Popliteal recanalization with improved distal tibial imaging.



Figure 4. Peroneal runoff to the foot.

midportion. This was recanalized with a 2.5- X 150-mm NanoCross balloon (ev3 Inc.).

There was marked improvement in flow to the foot (Figure 4). The patient experienced immediate on-table resolution of his rest pain. Angio-Seal (St. Jude Medical, St. Paul, MN) closure of the arteriotomy was performed. There was no debris in the embolic protection filter.

The patient was discharged home 2.5 hours after the procedure on an antiplatelet regimen. At 1-week follow-up, his rest pain remained resolved. Color-flow duplex imaging revealed popliteal and peroneal patency. The patient continued to be ambulatory in his assisted living facility.

This case describes the first use of the Wildcat at our institution, allowing for successful limb salvage in a high-risk patient.

CASE 2

An 82-year-old man presented with progressive claudication in his left lower extremity. He had been followed for the past 2 years for stable claudication. Recently, his ambulation distance fell to 50 to 75 feet, and his foot became numb if he walked farther. Noninvasive vascular laboratory examination revealed an ankle-brachial index of 0.55, and an SFA occlusion was demonstrated by duplex exam. He had a strongly palpable femoral pulse but no pulse distally.



Figure 5. A proximal SFA CTO.



Figure 6. An SFA occlusion with above-the-knee popliteal reconstitution.

Angiography documented an SFA occlusion (Figures 5 and 6). There was three-vessel tibial runoff. A Wildcat catheter was used to engage the CTO and subsequently cross through the true lumen (Figures 7 and 8). Atherectomy was accomplished with the TurboHawk device (ev3 Inc.) using the SpiderFX for embolic protection (Figure 9). The majority of patients with critical limb ischemia undergoing intervention at our institution have a filter placed prophylactically to prevent potential distal emboli and fully preserve distal runoff vessels. No debris capture was noted



Figure 7. Wildcat with wedges out (white arrow) traversing the femoral CTO. Note the collaterals (black arrows).

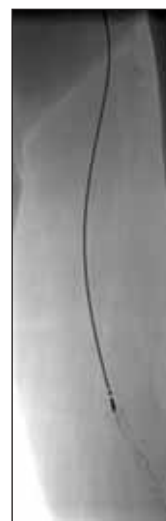


Figure 8. The Wildcat catheter ready to reenter the lumen distally.



Figure 9. Recanalized SFA.

in this case. The procedure restored palpable pulses and resolved his disabling claudication.

DISCUSSION

The Wildcat was originally manufactured as a support catheter in a 0.035-inch caliber system. The catheter is hydrophilic coated and has excellent pushability and trackability. It is approved for use as a standard support catheter. In addition, it has a rotatable tip that is manually activated by turning the device handle to which it is connected (Figure 10). The tip has both passive and active configurations

(Figures 11 and 12). The active configuration is a more aggressive tip profile that occurs when the “wedges” are exposed out of the catheter tip by sliding the hand control to advance them. If standard interventional technique does not allow for wire and support passage, the Wildcat tip is delivered to the proximal CTO cap. It is then used (with the crossing wire retracted a short distance into the tip) to initiate channeling through the proximal cap and CTO.

The tip is rotated in the passive mode first, and if the cap is not traversed, the active wedge mode is configured. The tip can be rotated clockwise, counterclockwise, or a combination of the two until the proximal cap is traversed and channeling is initiated.

At our institution, there has been no increase in the vessel complication rate with use of the Wildcat. The author has had no cases of perforation or embolization. It is recommended, however, that if the Wildcat is felt to be in a subintimal plane, the wedges should be in the retracted position (remain in “passive mode”). This should prevent engaging of the thin outer medial/adventitial layer, thereby preventing potential perforation.

Crossing times have been noticeably reduced in difficult CTOs with the Wildcat; however, the lesions most difficult to treat continue to be those that are highly calcified. The “active mode” configuration (with wedges out) seems especially suited to calcified lesions and can allow for channeling through densely calcified sections.

Another advantage of the Wildcat is that the stiffer catheter design and tip deflection allow for directing of the catheter away from large collaterals just proximal or at the

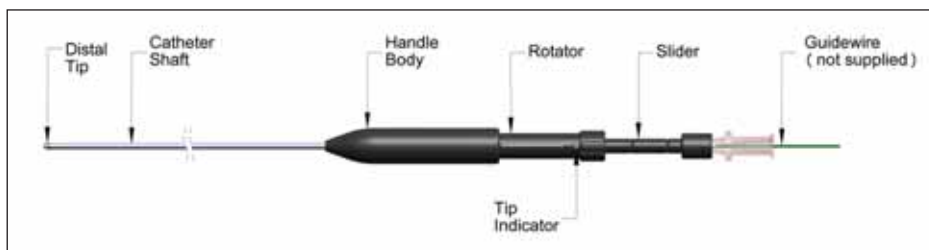


Figure 10. The Wildcat catheter.



Figure 11. The Wildcat catheter tip in passive mode.



Figure 12. The Wildcat catheter tip in active mode (wedges out).

CTO and back toward the occluded true lumen. This is in contradistinction to what typically occurs with catheter/guidewire combinations that routinely deflect into these proximal collateral vessels away from the intended target.

Generally, the Wildcat remains in an intraluminal rather than a subintimal plane with easier reentry into the true lumen distally. Although comparative data between intraluminal and subintimal lesion crossing are limited, there are theoretical advantages to remaining within the true lumen. These include improved crossing success rates, easier reentry at the distal extent of the lesion, decrease in procedural complications, and improved procedural patency.

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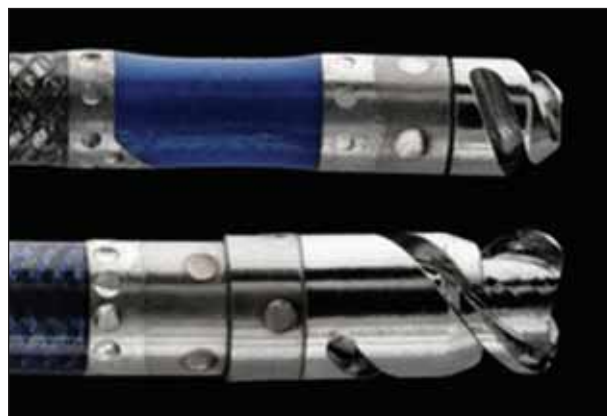


Figure 13. The 0.014-inch Wildcat catheter tip (top) versus the 0.035-inch tip (bottom).

(Figures 10 through 13 courtesy of Avinger.)

Critical Decision Making in Carotid Embolic Protection

Carotid stenting in a patient with stenosis of the left external and internal carotid arteries.

BY JENNIFER FRANKE, MD; MARIUS HORNING; NINA WUNDERLICH, MD;
AND HORST SIEVERT, MD, FESC, FACC, FSCAI

In September 2010, a 72-year-old man was admitted to the neurological department of his nearest hospital due to a transient ischemic attack with sudden weakness of the right arm and leg that continued for approximately 10 minutes. Cranial magnetic resonance imaging ruled out cerebral lesions. His risk factors included hypertension (adequately treated), hyperlipidemia, and peripheral arterial occlusive disease. Initial examinations included a duplex scan of the supra-aortic arteries, a transcranial Doppler examination, transthoracic and transesophageal echocardiography, and a 24-hour electrocardiogram. Diagnostics revealed a high-grade eccentric stenosis of the left internal carotid artery (ICA) and the left external carotid artery (ECA).

After informing the patient about different treatment modalities, clopidogrel and statins were added to his medication, and he was referred to our center for carotid stenting of the symptomatic left ICA. Angiography demonstrated a short, eccentric, high-grade stenosis of the left ICA, an ostial subtotal occlusion of the left ECA with slow flow, and a comparably large-lumen superior thyroid artery. As measured by angiography, the common carotid artery (CCA) measured 7 mm in diameter, and the ICA was 5 mm in diameter. The intracranial runs revealed adequate flow in both the anterior and middle cerebral artery.

DECISION POINT 1

Considering the patient suffered a transient ischemic attack 1 week before, would a proximal embolic protection device or a distal filter device be best in this situation?

Because the procedure was performed shortly after a cerebrovascular event, embolic complications were more likely to occur due to vulnerable plaques.¹⁻³ By providing complete

“In general, correct selection of embolic protection based on clinical aspects as well as on radiological features of the lesion is essential . . .”

protection through retrograde flow before lesion manipulation, the chance of microembolization of very small particles (< 80 µm in diameter) can theoretically be reduced by using a proximal occlusion device. These systems consist of a long introducer sheath with a balloon that is inflated in the CCA. A second balloon inflated in the ECA ensures the total blockade of the antegrade blood flow in the ICA. The proximal protection systems facilitate the cerebral vascular connections of the circle of Willis. After the occlusion of the CCA and ECA, the collateral flow through the circle of Willis creates so-called back pressure, which prevents antegrade flow in the ICA.

Although large, randomized studies comparing the clinical benefit of the different approaches are pending, it is conceivable that a proximal occlusion device could be beneficial in vulnerable lesions with fresh thrombus compared to a device that is placed distally and therefore requires unprotected crossing of the lesion. With the Mo.Ma system (Medtronic Invatec, Frauenfeld, Switzerland), the occlusion balloons of the ECA and CCA are mounted on the guiding catheter in a fixed distance. Therefore, in patients with significant stenosis of the ECA, positioning of the distal balloon is either cumbersome or, in some cases, not possible.⁴⁻⁵ In the situation of a total occlusion of the ECA, the sole occlusion of the CCA balloon may not establish complete blockage of

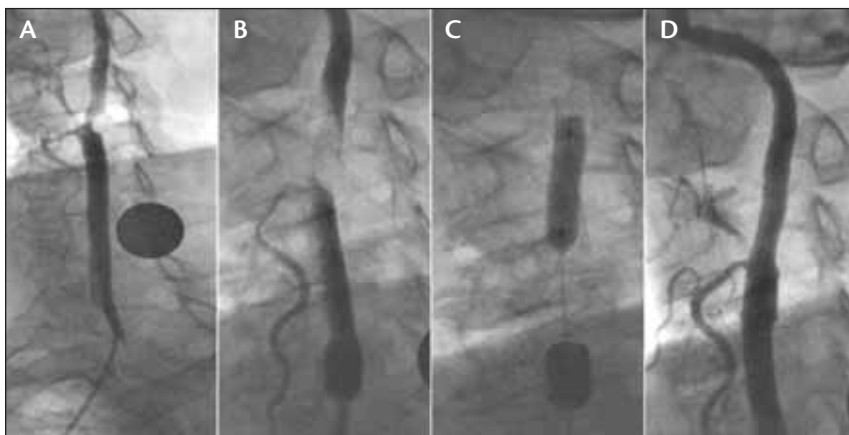


Figure 1. Angiography revealed an eccentric, high-grade stenosis of the left ICA and a subtotal occlusion of the left ECA. The superior thyroid artery originated from the CCA below the carotid bifurcation (A). After inflation of the proximal balloon in the CCA, a column of contrast remained in the CCA, and the contrast located in the ICA was washed out slowly. Forward flow to the intracranial arteries was still maintained via the superior thyroid artery and partially contributed to by the subtotally occluded ECA (B). Postdilation of the carotid stent while a distal filter and proximal protection device are in place (C). Final angiogram showed adequate flow in the ICA and no residual stenosis (D).

antegrade flow. The total occlusion may lie distal to the ostium of the most proximal branches of the ECA—the superior thyroid artery and lingual artery.

In our patient, the ECA was subtotally occluded at its ostium, with only slow flow through the external carotid lesion shown in angiographic imaging. In addition, the patient had an anatomical variation—the superior thyroid artery originated from the CCA below the carotid bifurcation and not as a side branch of the ECA distal to the subtotal lesion (Figure 1A). In this quite specific anatomy, the use of the Mo.Ma system was limited due to the previously mentioned specifications of the device. Unlike with the Mo.Ma device, the proximal and distal balloons of the Gore Flow Reversal system (Gore & Associates, Flagstaff, AZ) are mounted on two separate components. The distal balloon is mounted on the balloon wire, and the proximal balloon is located at the distal end of the introducer sheath. On the basis of these small advantages, the Gore Flow Reversal system was a viable alternative in our patient's anatomy because it allowed the operator to position the proximal occlusion balloon at any distance to the bifurcation. However, after positioning the proximal protection device and occluding the balloon in the CCA, a column of contrast remained in the CCA, and the contrast located in the ICA was washed out slowly. In this situation, forward flow to the intracranial arteries was still maintained via the superior thyroid artery, partially contributed to by the subtotally occluded ECA. Thus, ade-

quate cerebral protection was not achieved (Figure 1B).

DECISION POINT 2

What should you do when antegrade flow cannot be adequately blocked by proximal occlusion?

Some options are available to prevent antegrade flow in this situation. One basic concept is to increase the amount of back pressure applied to the cerebral circulation. By opening the proximal stopcock of the arterial sheath and letting it bleed back, or alternatively, by attaching the external filter of the device and connecting the system to a sheath placed in a femoral vein (producing an arteriovenous shunt), retrograde flow can be enhanced. Due to the patient's specific anatomical situation with the superior thyroid artery originating from the CCA below the carotid

bifurcation, blockage of the superior thyroid artery with a balloon would prevent antegrade flow via this route, yet would not eliminate the chance of distal embolization via the ECA. Performing manual aspirations with a syringe between the steps of the procedure would additionally prevent distal embolization but would not sufficiently eliminate antegrade flow in between aspirations.

A further option would be to place a filter embolic protection device in the distal ICA and therefore achieve additional distal protection by filtering the remaining antegrade blood flow. In this particular patient, as complete retrograde flow could not be established even after connecting the system to the femoral vein, the operator decided to place a Gore Embolic Filter device (Gore & Associates) adjunctive to the proximal protection device (Figure 2). A feature of the Gore Embolic Filter is its comparably long circumferential frame at the proximal end of the filter, which provides improved alignment of the filter basket to the vessel wall. As a result of filter placement, embolic protection was additionally given through the filtration of blood that continued to flow distally despite proximal protection.

DECISION POINT 3

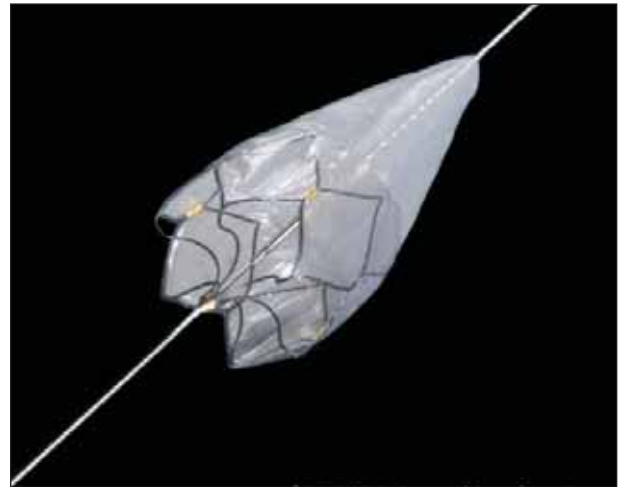
Which stent design is preferred in symptomatic carotid lesions?

The clinical impact of open-cell design versus closed-cell design, or perhaps more importantly the impact of cell size and pore size, is still unclear. Insufficient wall coverage of a

stent may lead to protruding atherosclerotic debris through the stent struts. Therefore, in lesions with high emboligenic potential, as presumed in this patient, closed-cell stents may provide better scaffolding.⁶⁻⁸ Additionally, choosing a carotid stent that is slightly larger than the vessel diameter itself (oversizing), creates an artificially smaller pore size between the stent struts. In this case, an 8-mm X 3-cm Xact stent (Abbott Vascular, Santa Clara, CA) was implanted and postdilated with a 5-mm balloon. Angiographic results were satisfactory (Figure 1C and 1D). Throughout the procedure and during the postprocedural period, the patient showed no neurological symptoms or hemodynamic complications. He was discharged 2 days after the procedure.

CONCLUSION

When using the Gore Flow Reversal system, it is mandatory to verify complete blockage of antegrade flow in the vessel and the achievement of blood flow reversal in the ICA before continuing with the next step of the intervention. If blood flow in the ICA merely stagnates, cerebral protection is not sufficient. In this situation, a short interruption of back pressure during the procedure could allow debris accrued in this area to flow cranially and possibly cause a



(Courtesy of Gore & Associates)

Figure 2. The Gore Embolic Filter has a long circumferential frame at the proximal end of the filter, providing improved alignment of the filter basket to the vessel wall.

severe stroke. In the case of the Mo.Ma device, the operator needs to verify that there is no flow in the ICA after inflation of the clamping balloons in the ECA and CCA. Furthermore,

What's Now.

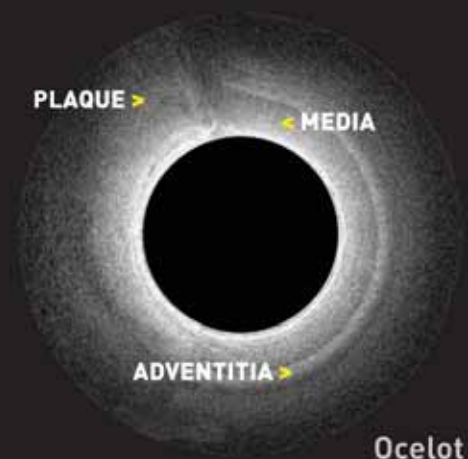


W400 WildCat



W500 KittyCat

What's Next.



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The Wildcat Guidewire Support Catheter is intended to be used to support steerable guidewires in accessing discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. It may also be used to deliver saline or contrast. The Wildcat is not cleared by the FDA for use in crossing chronic total occlusions. Avinger is conducting the CONNECT study to secure FDA clearance for an indication specific to crossing chronic total occlusions.

performing the intervention stepwise and aspirating in between the procedural steps may provide additional safety. In general, correct selection of embolic protection based on clinical aspects as well as on radiological features of the lesion is essential and greatly influences the outcome of carotid stenting. Particularly in challenging anatomical situations, such as in the case presented here, specific knowledge of device-related advantages and potential drawbacks of different concepts of embolic protection is required to provide patients with the optimal treatment modality. ■

Jennifer Franke, MD, is a fellow in cardiology and performed her doctorate thesis at the CardioVascular Center Frankfurt, Germany. She has disclosed that she holds no financial interest in any product or manufacturer mentioned herein.

Marius Hornung, is a doctoral candidate at the CardioVascular Center Frankfurt in Frankfurt, Germany. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

Nina Wunderlich, MD, is Codirector of the CardioVascular Center Frankfurt in Frankfurt, Germany. She has disclosed that she holds no financial interest in any product or manufacturer mentioned herein.

Horst Sievert, MD, FESC, FACC, FSCAI, is Director of the CardioVascular Center Frankfurt in Frankfurt, Germany. He has disclosed that he has received consulting fees, travel expenses, or honoraria for clinical trials from Abbott Vascular, Boston Scientific Corporation, Cordis Corporation, EndoTex Interventional Systems, ev3, Inc., Gore & Associates, Guidant Corporation, Lumen Biomedical, and Medtronic Invatec. Dr. Sievert may be reached at horstsievertmd@aol.com.

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FUTURE PROSPECTS

More recently, a 0.014-inch Wildcat catheter system has been introduced. This low-profile device appears to have applicability in CTOs in tibial vessels as well as those in the SFA with a tight luminal or subintimal space. Unlike the 110-cm catheter length on the 0.035-inch system, the 0.014-inch catheter length is 140 cm to allow for access of the distal tibial arteries from a contralateral femoral approach. In addition, the wedges on the 0.014-inch system are not retractable, remaining fixed and exposed (Figure 13). A handheld motor drive unit will be an optional attachment in the near future; design platforms are currently undergoing testing.

The catheter has also been combined with optical coherence tomography visualization, which employs near-infrared light to obtain high-resolution (< 10 μ m) images. The first-in-man imaging occurred recently in Europe and was successful in demonstrating intraluminal and subintimal catheter positions. Improved vessel-wall imaging may allow for more precise therapeutic device delivery and successful interventions in the future.

Although currently approved as a procedural support catheter, the CONNECT (Chronic Total Occlusion Crossing With the Wildcat Catheter) trial is assessing the safety and efficacy of crossing superficial femoral and popliteal artery occlusions. This company-sponsored trial began in late 2010, and its current enrollment is already greater than 50% of the completion target.

CONCLUSION

Early experience with the Wildcat catheter reveals utility in crossing difficult arterial occlusions. Further refinements in crossing catheters throughout the industry continue to address the need for crossing difficult CTOs. ■

John P. Pigott, MD, is the Associate Director of Endovascular Surgery at Jobst Vascular Institute in Toledo, Ohio. He has disclosed that he is a paid consultant to and receives grant/research funding from ev3 Inc. and Covidien, and that he is an owner of or shareholder in Avinger. Dr. Pigott may be reached at (419) 291-2080; marilyn.gravett@promedica.org.

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