

Forging a Path

An elegant new catheter provides a winning CTO solution.

**WITH MAHMOOD K. RAZAVI, MD; JOHN R. LAIRD, MD; GARY M. ANSEL, MD;
J.A. MUSTAPHA, MD, FACC, FSCAI; AND NAOTO INOUE, MD**

Over the past 2 decades, endovascular techniques have become the preferred approach in the treatment of peripheral artery disease (PAD). In most cases, delivery of endovascular devices requires passage of a guidewire across or through the lesion. Once the guidewire is in position, various technologies can be used to administer therapy in an effort to restore blood flow to the affected vascular bed. When the vessel lumen is still patent, passage of the guidewire can be achieved in most cases. The more challenging situations are in the case of arterial chronic total occlusions (CTOs), which are frequently encountered during endovascular interventions and reported in up to 40% of patients with symptomatic PAD.¹

As a CTO ages, a hard, fibrous cap can form, making penetration of the occlusion more difficult or, in some cases, impossible. Attempts to cross these lesions with a wire can result in the inability to penetrate the proximal or distal caps. Intraluminal crossing is preferred, but in some cases, the wire will deflect off the cap and enter the subintimal channel.

The traditional approach for treating CTOs has been a support catheter paired with a physician's preferred guidewire. Support catheters work in tandem with the guidewire, providing additional column strength, increasing the "pushability" of the chosen device, and enabling the guidewire/catheter assembly to move through the occlusion.

In approximately 20% of cases, the standard catheter/wire combination is not enough to safely and reliably span the lesion.^{2,3} Several new technologies aim to circumvent this clinical conundrum by focusing on reentry from the subintimal space, engaging or avoiding the CTO, or ablating the tissue occluding the vessel lumen.

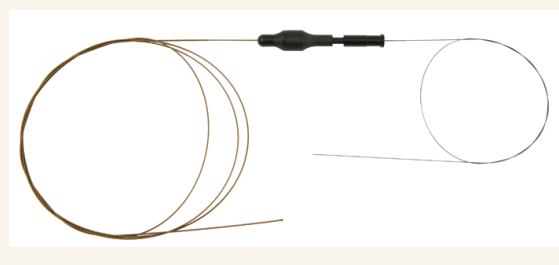
Specialized CTO crossing devices, such as ultrasound-guided vibration angioplasty, blunt microdissection catheters, and reentry catheters have been developed to facilitate the introduction and placement of the guidewire into distal arteries. However, despite the excellent evidence, these devices are not used in routine clinical practice. Devices such as the Crosser (Bard Peripheral Vascular, Inc.), the TruePath (Boston Scientific Corporation), and the Wildcat and Kittykat (Avinger, Inc.)

REFLOW MEDICAL WINGMAN CROSSING CATHETER

Key features

- Braid-reinforced hypotube microcatheter
- Ultra low-profile design available in 0.035-inch and 0.014-inch systems
- Push-and-twist action engages and penetrates
- User-controlled extendable, radiopaque beveled tip
- Broad range of treatment: superficial femoral artery (SFA), iliac, and below the knee

The Wingman Crossing Catheter is designed to simplify the successful crossing of CTOs within the peripheral vasculature. A through-lumen design is compatible with the physician-preferred guidewire and procedural technique, keeping the physician in control of device advancement and activation at all times. A beveled extendable tip engages and penetrates calcified caps or stenotic lesions with a simple push-and-twist action. The Wingman eliminates the need for expensive, complicated energy devices to cross most lesions.



can be very cost prohibitive, making doctors reluctant to pull them off the shelf early in a procedure. In addition, these devices may employ complicated actions that require a learning curve in a situation in which user experience is critical.

THE WINGMAN CATHETER

The Wingman Crossing Catheter (Reflow Medical, Inc.) offers a simple but effective approach to crossing CTOs. The device has a unique, extendable radiopaque tip that is manually controlled to engage with a calcified cap, cre-

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ating a channel for the wire to follow. “The beveled edge is needle-like,” said John Laird, MD, Medical Director of UC Davis Vascular Center, “offering a lot of help to get through a dense proximal cap.”

A basic push-and-twist motion anchors the tip into the cap and allows for penetration of the CTO (Figure 1). The tip can be retracted and then redeployed when the operator encounters stenoses or other areas of calcification. When the tip is retracted, the catheter is tracked and follows the wire as a support catheter. “This is a very useful device for breaking through caps; the extendable tip makes all the difference,” said Mahmood Razavi, MD, Research Director at St. Joseph Vascular Institute in Orange, California. “The extendable tip is one of the unique features of this device.”

The Wingman is compatible with the physician-preferred guidewire and currently comes in 0.035-inch and 0.014-inch options. The through-lumen of the device also provides a conduit for the delivery of saline solutions or diagnostic and therapeutic agents. More than 200 cases by over 40 physicians in nine countries have been performed utilizing the Wingman catheter; the following is a brief overview of some of the clinical experiences to date.

EXPERIENCE WITH WINGMAN CATHETER

Calcifications are problematic; wires that cannot readily penetrate these blockages will be deflected or redirected. “The ability to get through calcified lesions is better than I ever expected,” said Gary Ansel, MD, System Medical Chief of Vascular Services at OhioHealth/Riverside Methodist Hospital in Columbus, Ohio. “[With] this device, you can basically burr your way through the calcifications.”

CTOs can occur in a variety of arteries, making it difficult to adopt a universal approach. “The Wingman provides options for addressing the multiple and variable

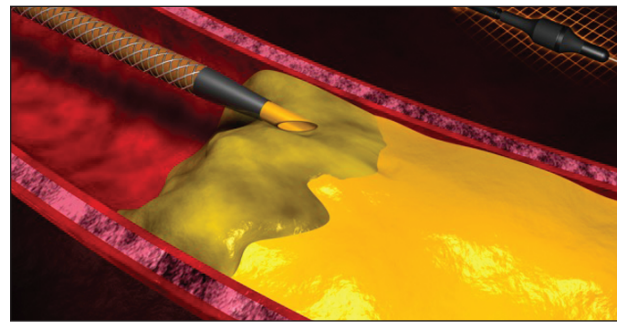


Figure 1. The Wingman Crossing Catheter is an over-the-wire catheter with an extendable radiopaque tip that is manually controlled to engage with the lesion. A basic push-and-twist motion allows penetration of the tip into the cap for further advancement of the wire into the CTO.

CTOs that can span from the SFA to the popliteal and tibial arteries,” said J.A. Mustapha, MD, FACC, FSCAI, Director of Cardiovascular Catheterization Laboratories at MetroHealth Hospital in Wyoming, Michigan. “This device has a significant advantage with its 0.014-inch and 0.035-inch systems, giving it a range of therapy from the groin to the feet.”

When a traditional guidewire and catheter fail to cross a CTO, routine procedures must often be abandoned, and the clock starts ticking. “We have been able to observe the Wingman under both fluoroscopy and ultrasound, providing us with direct visualization and confirmation of the device’s position,” said Dr. Mustapha. “This direct visualization gives us full confidence to cross the most complex lesions in a very short period of time.” Dr. Ansel agrees that rapidity is a key advantage. “For something to be economically and procedurally viable, it cannot add much more time to a case. Procedure time is always related to complications.”

CASE STUDIES

CTO Treatment for Claudication

Naoto Inoue, MD

Sendai Kousei Hospital, Japan

The Wingman has recently been used in the first Japanese cases by Dr. Inoue and colleagues at Sendai Kousei Hospital in Sendai, Miyagi. The Crosser is currently the only approved CTO device in Japan, but Dr. Inoue notes that most practitioners opt for Japanese stiff-wire technology to manage CTOs.

“Even in patients with noncalcified CTOs, intraluminal crossing is not easily achieved,” said Dr. Inoue. “New devices are not readily available in many countries because of the high cost and complexity.

The Wingman is easy to use compared with mechanical crossing devices. Now, there is some possibility of successful crossing of previously challenging lesions with only a single wire simply and quickly using the Wingman.”

A 64-year-old man with a history of hypertension, diabetes, and a prior smoking history presented with Rutherford stage 3 intermittent claudication in the left lower leg and a resting ankle-brachial index (ABI) of 0.57. Angiography showed a long-segment CTO in the left SFA. A short 6-F sheath was placed in an antegrade fashion via the ipsilateral common femoral artery. A

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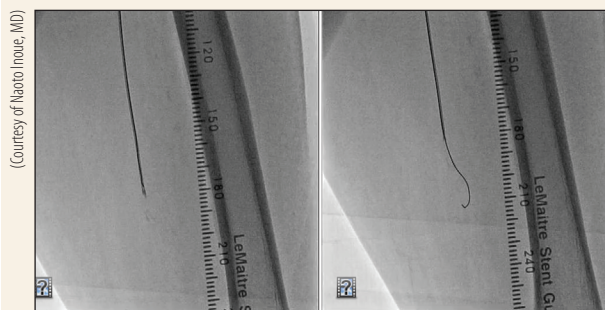


Figure 2. When a Treasure wire could not proceed, deployment of the Wingman device achieved penetration of the CTO. Repeating this procedure, successful crossing was achieved in 8 minutes.

0.018-inch Treasure guidewire (Asahi Intecc) was introduced, supported by a 0.035-inch Wingman device. The wire was able to penetrate the CTO but could not proceed through the occlusion. The Wingman tip was extended, and the blade was rotated. The guidewire was once again able to proceed, and crossing was achieved in 8 minutes (Figure 2). Intravascular

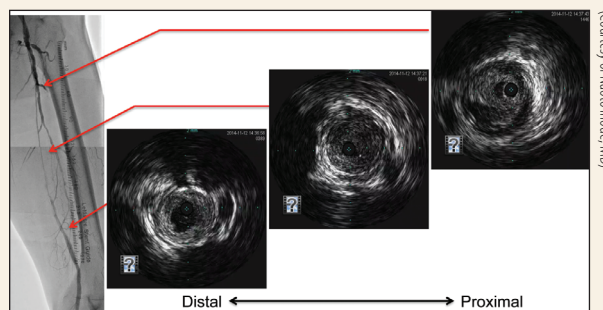


Figure 3. Intravascular ultrasound revealed true lumen crossing through the CTO after penetration using the Wingman.

ultrasound showed true lumen crossing for the entire length of the CTO (Figure 3). A balloon was deployed, and two bare self-expandable stents were implanted in the SFA, leading to successful revascularization in a total of 40 minutes with no evidence of embolization or periprocedural complications. The left ABI increased to 0.88, and the patient's ischemic symptoms resolved.

SFA CTO With a Severely Calcified Cap

J. A. Mustapha, MD, FACC, FSCAI

Metro Health Hospital, Wyoming, Michigan

Dr. Mustapha and his team at Metro Health Hospital in Wyoming, Michigan, have been utilizing the Wingman over the past few months.

"Initially, it was the device to use after all other devices had failed, which equates to more time, cost, contrast, radiation, etc," said Dr. Mustapha. "We learned quickly that the Wingman brings qualities that no other CTO device can provide, including direct needle penetration of CTO caps with high-plaque, calcified burdens. I go to Wingman in complex CTOs, especially straight-segment CTO caps. Anatomic locations vary all the time, hence the need for variable CTO devices. The Wingman absolutely plays a crucial role in our team's CTO therapy."

A 72-year-old man presented with Rutherford stage 3 severe claudication of the right lower extremity, with marked limitation of ordinary physical activities. The patient had a long-standing history of tobacco use, hypertension, hyperlipidemia, and obesity, along with a remote history of endovascular stent grafting for abdominal aortic aneurysm and a left femoral/popliteal bypass.



Figure 4. A diagnostic angiogram showed a CTO of the right SFA from its origin, reconstituting distally by the collateral arteries, with moderately severe calcification and multiple areas of severe focal stenosis.

The patient's baseline ABI was 1.3 on the left and 0.71 on the right. A diagnostic angiogram showed a CTO of the right SFA from its origin, reconstituting distally in the collateral arteries, with moderately severe calcification and multiple areas of severe focal stenosis (Figure 4).

Ultrasound-guided access of the right posterior tibial artery was obtained. A 4-F Pinnacle Precision (Terumo Interventional Systems) sheath was placed and flushed, and nitroglycerin was followed by heparin. A Regalia (Asahi Intecc) 0.014-inch guidewire was advanced into the posterior tibial artery and maneuvered into the popliteal artery and SFA but was stopped at the mid-SFA, which appeared to

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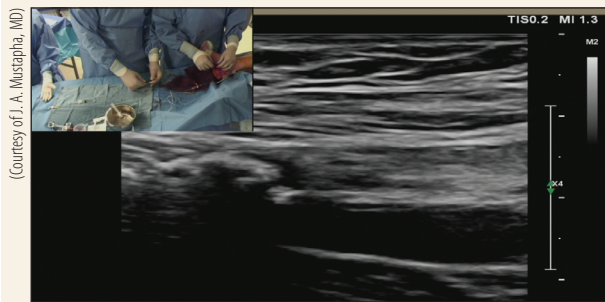


Figure 5. The Wingman device was deployed and penetrated the cap with no difficulty.

be totally occluded. A NaviCross catheter (Terumo Interventional Systems) was advanced in a retrograde fashion into the CTO segment.

Via ultrasound, the proximal SFA segment showed about 20 mm of severely calcified CTO cap with antegrade complex morphology and a retrograde concave morphology. The Wingman device was deployed and penetrated the cap with no difficulty (Figure 5). The guidewire was advanced into the iliac system, and the Wingman device was removed. The NaviCross catheter was advanced into the common femoral artery. The Regalia wire was exchanged for a ViperWire (Cardiovascular Systems, Inc.). A 1.25-mm microcrown Diamondback 360 (Cardiovascular

Systems, Inc.) was utilized in the popliteal artery and SFA at low, medium, and high speeds. Balloon angioplasty followed, using a 5- x 100-mm Saber balloon (Cordis Corporation) in the SFA and popliteal artery. Repeat angiogram showed residual stenosis at the ostium of the SFA, which was retreated with a 6- x 40-mm Saber balloon with prolonged inflation.

This tibiopedal arterial minimally invasive retrograde revascularization technique with atherectomy and balloon angioplasty achieved successful true lumen CTO crossing using the Wingman device. A final angiogram with a catheter placed in the right common femoral artery from the right retrograde posterior tibial artery showed excellent flow and resolution of the stenosis of the SFA and popliteal artery, from 100% to less than 20% with brisk flow into the tibial vessels. No access or procedural complications were appreciated.

The patient was discharged home the same day and seen for routine 30-day postprocedure follow-up with no complications reported at that time. Right ABI at follow-up was 0.96. Duplex ultrasound reported multiphasic Doppler signals throughout with three-vessel runoff. The patient reports full resolution of claudication and is walking 1 mile every other day for exercise.

CONCLUSION

CTOs continue to provide clinical challenges. Many CTO devices, while specialized, can interrupt the flow of a procedure and introduce the potential for complications. During an interventional treatment, the ability to maintain routine as much as possible saves time and money, while increasing patient safety and improving outcomes. The Wingman's rapid and routine approach to lesion crossing largely sidesteps concerns about cost or complicated techniques by providing the best of both worlds: the function and simplicity of a support catheter combined with the benefits of a specialized CTO device. Look for Wingman Crossing Catheter options in the coronary arena soon. ■

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This article was written by Joely Johnson Mork, MS, with the assistance of ReFlow Medical, Inc.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

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