 doi:10.3400/avd.cr.16-00007

Case Report

Recanalization of a Heavily Calcified Chronic Total Occlusion in a Femoropopliteal Artery Using a Wingman Crossing Catheter

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We present a 77-year-old female with heavily calcified chronic total occlusions (CTO) in a superficial femoral artery treated by endovascular therapy using a Wingman crossing catheter, which is an over-the-wire catheter with a metallic blade, controlled manually. The blade could probe and track the calcified cap of CTO, wherein any hydrophilic guidewires or looped wires could not penetrate. Moreover, the Wingman could proceed through the occlusion and introduce a guidewire into distal intramedial lumen as a support catheter. Finally, wire crossing was achieved using a bi-directional approach. The Wingman can be a simple solution for crossing calcified peripheral CTO.

Keywords: peripheral vascular disease, chronic total occlusion, calcification, new devices

Introduction

Endovascular therapy (EVT) is an established treatment method for peripheral artery disease.[1)] However, the recanalization of peripheral chronic total occlusion (CTO) is technically challenging and time consuming. Especially, recanalization attempts fail in approximately 20% of cases with heavily calcified CTO because of difficulty in safely and reliably crossing the lesion using standard guidewire techniques.[2,3)] Therefore, reentry catheters,[4)] blunt microdissection catheters,[5)] and ultrasound-guided vibration angioplasty[6)] have been developed to facilitate the introduction and placement of guidewires into distal arteries. However, despite excellent evidences, these methods may not be readily available for use in routine clinical practice because of their complexity and cost prohibition.

A Wingman Crossing Catheter (ReFlow Medical, Inc., San Clemente, CA, US) is an over-the-wire extendable-tip crossing catheter with a stainless steel blade. It is a single-use, 0.014- or 0.035-inch non-mechanical device (**Fig. 1A**) and is available in the following three sizes: 65 cm, 90 cm, and 135 cm. Using manual control, the blade can be advanced or retracted through the catheter tip and can be rotated to penetrate solid occlusions in limb arteries (**Figs. 1B** and **1C**). The outer shaft has a 40-cm hydrophilic coating at the tip for advancing smoothly into CTO. A request was submitted to the Food and Drug Administration in August 2013 for approving the Wingman crossing catheter for the treatment of all segments of limb arteries. The previous case report suggested that using the Wingman crossing catheter, true-intimal angioplasty was quickly achieved in a case with a conventional CTO lesion.[7)] However, to date, it is unclear which calcified CTO lesions can be also managed by this device. Currently, the device is not provided as an object of amortization by the national health insurance in Japan. Therefore, the devices were imported privately after approval by the institutional review board at our hospital to use this device in cases with heavily calcified CTO in a superficial femoral artery (SFA) when lesion crossing is not successful using only standard guidewires. Informed consent was obtained from all patients to introduce this new device. We report a case of a calcified occlusion in SFA that was successfully treated using the Wingman crossing catheter.

Case Report

A 77-year-old female with hypertension and on hemodialysis for end-stage renal disease secondary to diabetes was admitted to our hospital with a 2-year history of Rutherford class 4 intractable rest pain in the left lower extremity. The patient's resting ankle-brachial index (ABI) on the left was low at 0.55. Despite maximal medical therapy, she complained of severe lifestyle-limiting claudication. Angiography demonstrated a calcified long-segment CTO in the left SFA from the ostium with collaterals supplying the distal portion of the SFA and tibial arteries (**Fig. 2A**). Because of advanced age and frail condition,[8)] she opted for EVT rather than surgical bypass. A short 6-Fr sheath was placed antegradely via the ipsilateral common femoral artery

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Received: January 19, 2016; Accepted: April 26, 2016
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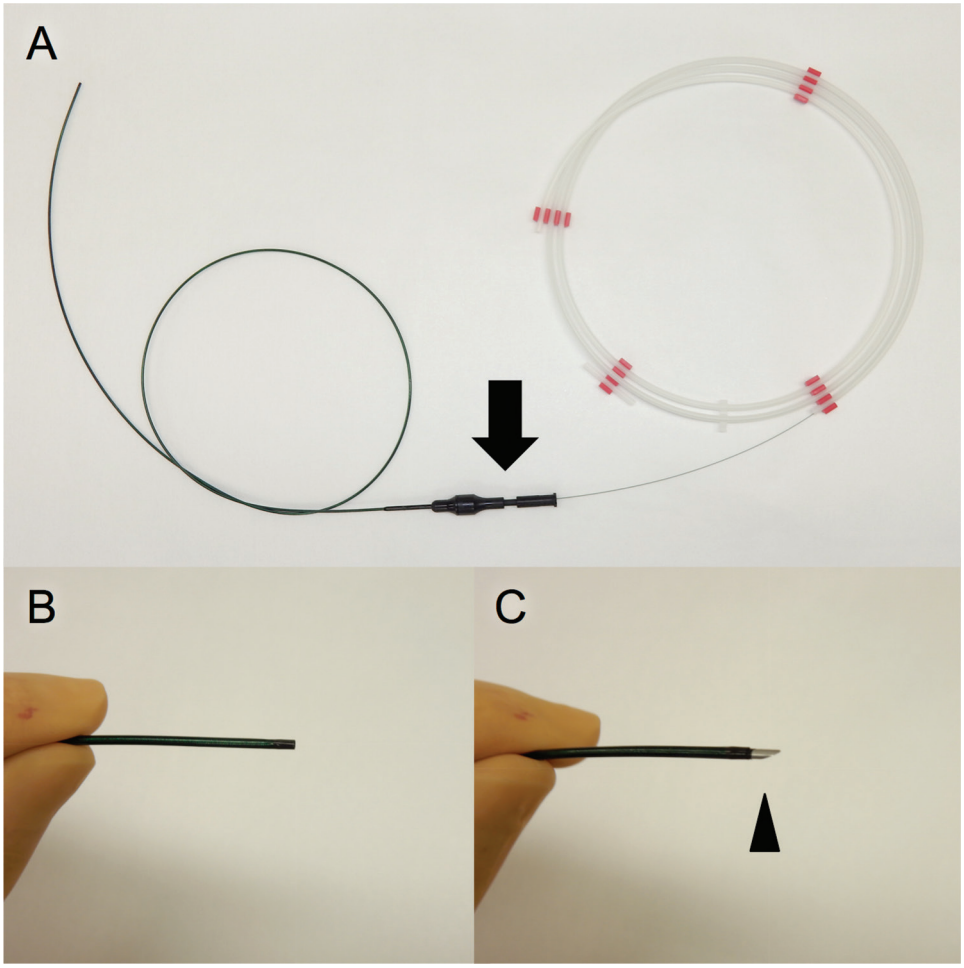

Fig. 1 (**A**) A Wingman crossing catheter is a single-use, over-the-wire, 0.014- or 0.035-inch guidewire-compatible catheter with a metallic blade and a manual control device (black arrow). (**B** and **C**) The blade can be advanced or retracted through the catheter tip and can be freely rotated.

(CFA), and manipulation was attempted using a 0.014-inch Chevalier Tapered 30 guidewire (Cordis, Fremont, CA, US), 0.018-inch Astato guidewire (Asahi Intecc, Aichi, Japan), and a 0.035-inch 1.5J guidewire. However, a calcified ostium of CTO could not be penetrated. A Wingman14 catheter was introduced into the proximal cap using the 0.014-inch Chevalier Tapered 30 guidewire. After the catheter preceded the guidewire, the calcified plaque in the proximal cap was carefully probed and tracked by the rotated blade (**Fig. 2B**). A small entry was created and the Wingman14 could advance into the proximal portion of CTO. However, even after tracking the cap, no guidewires could proceed forward into the body of CTO. Then, subintimal tracking was performed using the Wingman14 crossing catheter. After the Wingman catheter was directed to the arterial lumen by manipulation of the guidewire, the blade could get through the subintima along the artery and move forward slowly without arterial perforation (**Fig. 2C**). And then, the 0.014-inch Chevalier Tapered 30 guidewire was introduced in the distal subintimal space in the reentry site at the end of the occlusion using the Wingman14 as a support catheter. Intravascular ultrasound revealed that the guidewire passed through intramedia but did not penetrate the adventitia (**Figs. 2D** and **2E**). The ipsilateral popliteal artery was punctured retrogradely under angiography, and a 0.014-inch Cruise guidewire (Asahi Intecc, Aichi, Japan) with a microcatheter was introduced into the distal lumen of CTO. The Cruise guidewire was replaced for a 0.014-inch Astato XS 9–12 guidewire (Asahi Intecc, Aichi, Japan), and wire crossing was successfully achieved using a controlled antegrade and retrograde subintimal tracking technique with antegrade 4.0-mm balloon dilatation (**Fig. 2F**). Two bare self-expandable stents were implanted in the SFA with no periprocedural complications (**Fig. 2G**). Contrast-enhanced computed tomography demonstrated optimal stent expansion 2 days after EVT (**Fig. 3**). The patient's ABI increased to 0.90 and her rest pain was resolved.

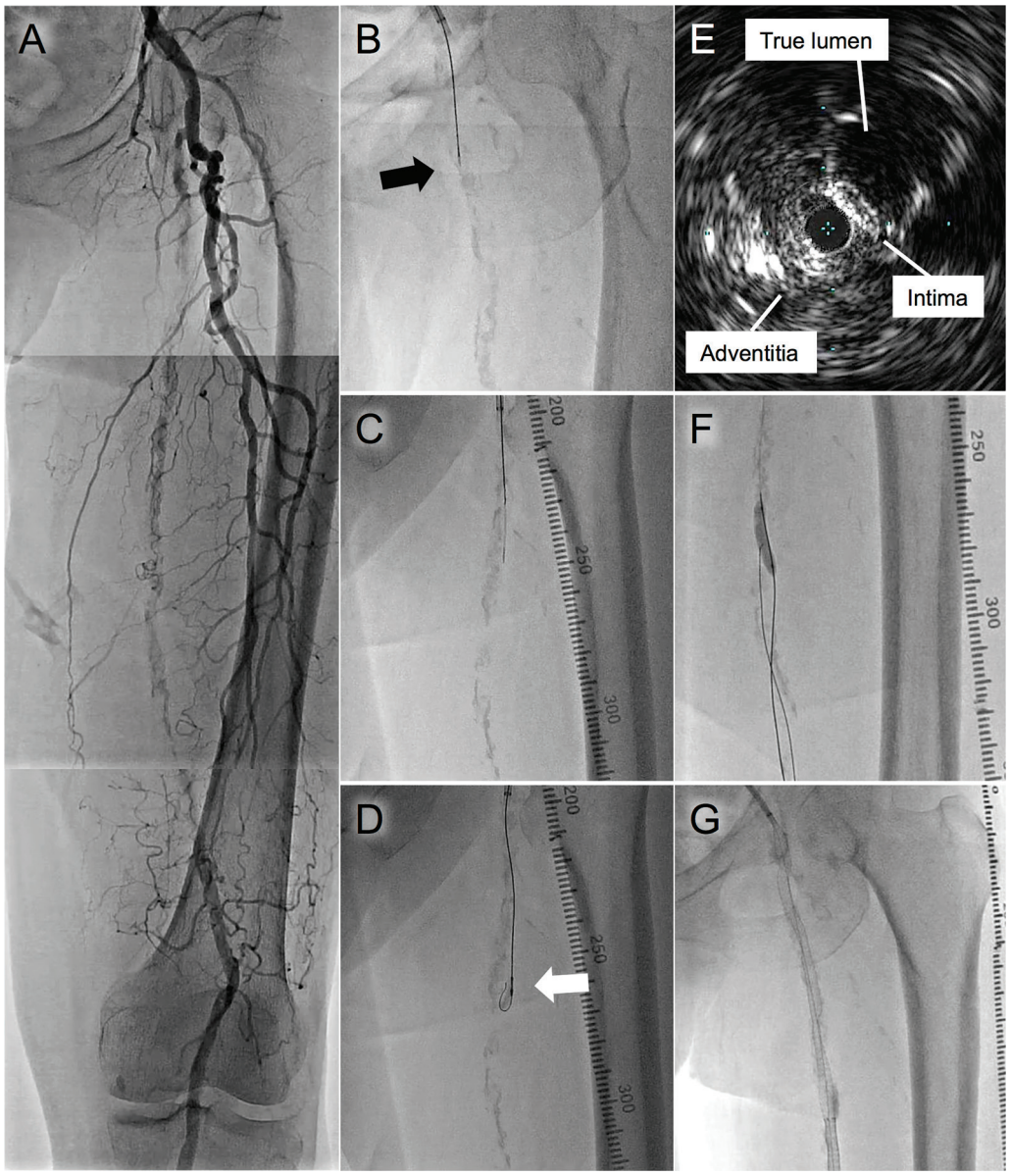

Fig. 2 (**A**) Angiography revealed a CTO with heavy calcification in the left SFA from the ostium onward and filling of the distal portion of the SFA by collaterals. (**B**) A small entry was created using a Wingman14 crossing catheter (black arrow) in the proximal cap of CTO, wherein no stiff guidewires could advance. (**C**) Subintimal tracking was performed using the Wingman14 catheter. (**D** and **E**) Intravascular ultrasound (white arrow) revealed that the guidewire passed between a media and adventitita in the mid portion of CTO. (**F**) Successful wire crossing was achieved by controlled antegrade and retrograde subintimal tracking technique. (**G**) Two bare self-expandable stents were implanted from the ostium to the distal SFA. CTO: chronic total occlusion; SFA: superficial femoral artery

Discussion

The management of symptomatic occlusive disease in a peripheral artery has been greatly improved by EVT, compared with surgical bypass.[9] However, a densely calcified occlusion is associated with a higher procedural complication rate and is a predictor of failed wire crossing.[3] Severe calcification presents a particular challenge; it appears to be almost impossible to achieve true lumen crossing through dense calcium using hydrophilic and stiff guidewires or even mechanical crossing devices. This situation may require the operator to pass a guidewire through subintimal space and to lead it to a distal true lumen. However, subintimal crossing is not always successful in patients with heavily calcified arteries because dense calcification usually presents in a media as well as an intima.[10] As described in our case

Fig. 3 Contrast-enhanced computed tomography scan demonstrated optimal stent expansion 2 days after EVT. EVT: endovascular therapy

report, the Wingman crossing catheter could penetrate the calcified proximal cap of CTO and provide greater penetration force in a linear direction for sharp recanalization compared with the conventional stiff guidewires.

We have to discuss about potential pitfalls of this device. In order to exert the penetration force in cases with CTO in SFA, the crossover approach via the contralateral CFA should be avoided, because we believed that the bending of the catheter might reduce its pushability and make it difficult to sufficiently rotate the blade. Moreover, the outer shaft of this catheter has hydrophilic coating to smoothly proceed into CTO; however, sometimes the catheter body slips backwards when the blade is tracking solid plaques. Therefore, when the blade is tracking solid materials, the Wingman catheter has to be firmly held by operators for preventing it from slipping.

It should be noted strongly that use of the Wingman catheter might increase the risk of vessel perforation. The penetration force of this device appears to work in a linear direction and it might be difficult to control the direction of its blade at will. We emphasized that use of the Wingman should be limited in the straight and solid occlusions which standard guidewires could not penetrate. We believed that revascularization might not be successful without the Wingman crossing catheter in this case, although the device proceeded between arterial media and adventitia, not true lumen. In order to reduce the risk of perforation, real-time external echo-guidance might be a great help to cross true lumen.[11] Moreover, tortuous iliac artery lesions may have the more risk of vessel perforation caused by this crossing catheter. Although this device has some pitfalls, the Wingman crossing catheter can be economically viable and makes it possible to cross the complex peripheral CTO if it is used appropriately.

Conclusion

To the best of our knowledge, this is the first case report with a heavily calcified peripheral CTO treated by EVT using the Wingman crossing catheter. This crossing device facilitated subintimal tracking in a heavily calcified occlusion, even when several stiff guidewires could not. The safety and efficacy of this device still remains a concern; therefore, a further investigation is required to clarify the role of this device for the treatment of patients with peripheral CTO.

Disclosure Statement

All authors do not have any conflicts of interest to declare with respect to the research, authorship and/or publication of this article.

Author Contributions

Study conception: NI
Data collection: KH, AT
Analysis: KH
Investigation: KH, AT
Writing: KH
Critical review and revision: all authors
Final approval of the article: all authors
Accountability for all aspects of the work: all authors

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