

SHORT REPORT

Distal Re-Entry to Treat Lower Limb Chronic Total Occlusions Using a Novel Electrically Guided Re-Entry Catheter

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WHAT THIS PAPER ADDS

With technological advances in endovascular devices, endovascular treatment of complex chronic total occlusions in the peripheral vasculature is becoming more feasible. Re-entering the true vessel lumen after subintimal crossing of heavily calcified lesions remains a limiting factor for successful treatment. The first in human use of an innovative electrically guided re-entry catheter, which has the potential for improving success in these challenging cases, is presented.

Introduction: Endovascular treatment of challenging infra-inguinal peripheral vascular disease is increasingly common because of new techniques and improved tools. The use of a novel electrically guided 5 F re-entry catheter is presented. By emitting a minute electrical field, detected by a target wire inserted from an opposing access, the catheter's orientation is accurately displayed to the operator, allowing precise re-entry without the need for fluoroscopic alignment.

Report: An 84 year old man with tissue loss was treated for a long occlusion of the superficial femoral artery and tibial vessels. Successful subintimal recanalisation was achieved with the help of the ePATH re-entry catheter, restoring inline flow to the foot.

Conclusion: This re-entry catheter benefits from an intuitive alignment method, smaller profile, and operator adjustable needle travel, making it a versatile tool for endovascular cases.

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INTRODUCTION

Since its introduction in 1989, subintimal recanalisation has been performed increasingly during endovascular treatments for peripheral vascular disease.¹ Distal re-entry can be challenging, with failure rates ranging from 8% to 40%.^{2,3} Re-entry catheters may help to achieve technical success but have failure rates of up to 35%.^{4,5} The first in human use of a novel, electrically guided re-entry catheter is described.

REPORT

An 84 year old man presented with tissue loss on the right foot (Rutherford stage 5). Duplex ultrasound (DUS)

identified popliteal artery (POP) occlusion extending to the origin of the infragenicular vessels. The patient underwent endovascular recanalisation under local anaesthesia. Diagnostic angiography confirmed the DUS findings (Fig. 1). The occlusion was initially engaged subintimally, and re-entry was achieved at the level of the tibioperoneal trunk, but recanalisation of the posterior tibial artery was not successful. A retrograde puncture of the proximal anterior tibial artery (ATA) was performed owing to the absence of a stump. The ATA occlusion was crossed intraluminally and wire was progressed to the mid POP, adjacent to the antegrade subintimal flap, but was unable to progress further because of heavy calcification (Fig. 2).

At this point, the use of a re-entry catheter was considered, and given that retrograde access was already secured, the ePATH re-entry catheter (www.pathfindermed.com) was deemed appropriate for the patient's anatomy. This CE marked 5 F re-entry catheter (80 cm working length) is delivered over an 0.014" wire and can be oriented and deployed with radio-opaque markers and a novel electric field based guiding system. The re-entry catheter generates

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Figure 1. (A) Baseline angiography of the right lower limb distal superficial femoral artery (SFA), popliteal artery (POP), and tibial vessels showing an occlusion at the level of the distal SFA–POP artery. (B) Occluded POP with reconstitution at the level of the proximal anterior tibial artery (ATA). The ATA was the single infragenicular vessel runoff to the foot and was found to be occluded several centimetres after its origin. (C) Successful recanalisation of the proximal ATA and mid-distal POP using a 0.018" CXI catheter (COOK, Bloomington, IN, USA) and V18 wire (Boston Scientific, Marlborough, MA, USA). (D) Retrograde wire advanced intraluminally until P1–P2 passage (white arrowhead) and POP subintimal space (re-entry achieved at the level of the tibial peroneal trunk). (E) Final angiograms showing patency of the previously occluded distal SFA/POP/proximal ATA. (F) Single vessel runoff to the foot via the ATA, which reconstitutes the distal peroneal and posterior tibial artery via collaterals.

low power electric dipole fields (imperceptible to the patient), which are fixed in orientation relative to the crossing needle trajectory. The 0.018 ePATH target wire (www.pathfindermed.com), which needs to be inserted from an opposing access, detects this field. Both the re-entry catheter and target wire are connected to the ePATH display (www.pathfindermed.com), which calculates and shows in

real time the angle of alignment of the subintimal crossing needle relative to the target wire in the true lumen (Fig. 2C).⁶ The re-entry catheter was introduced over the antegrade wire and positioned subintimally in the mid POP, while the intraluminal retrograde wire was exchanged for the ePATH target wire (80 cm working length). The re-entry catheter was oriented towards the target wire using the

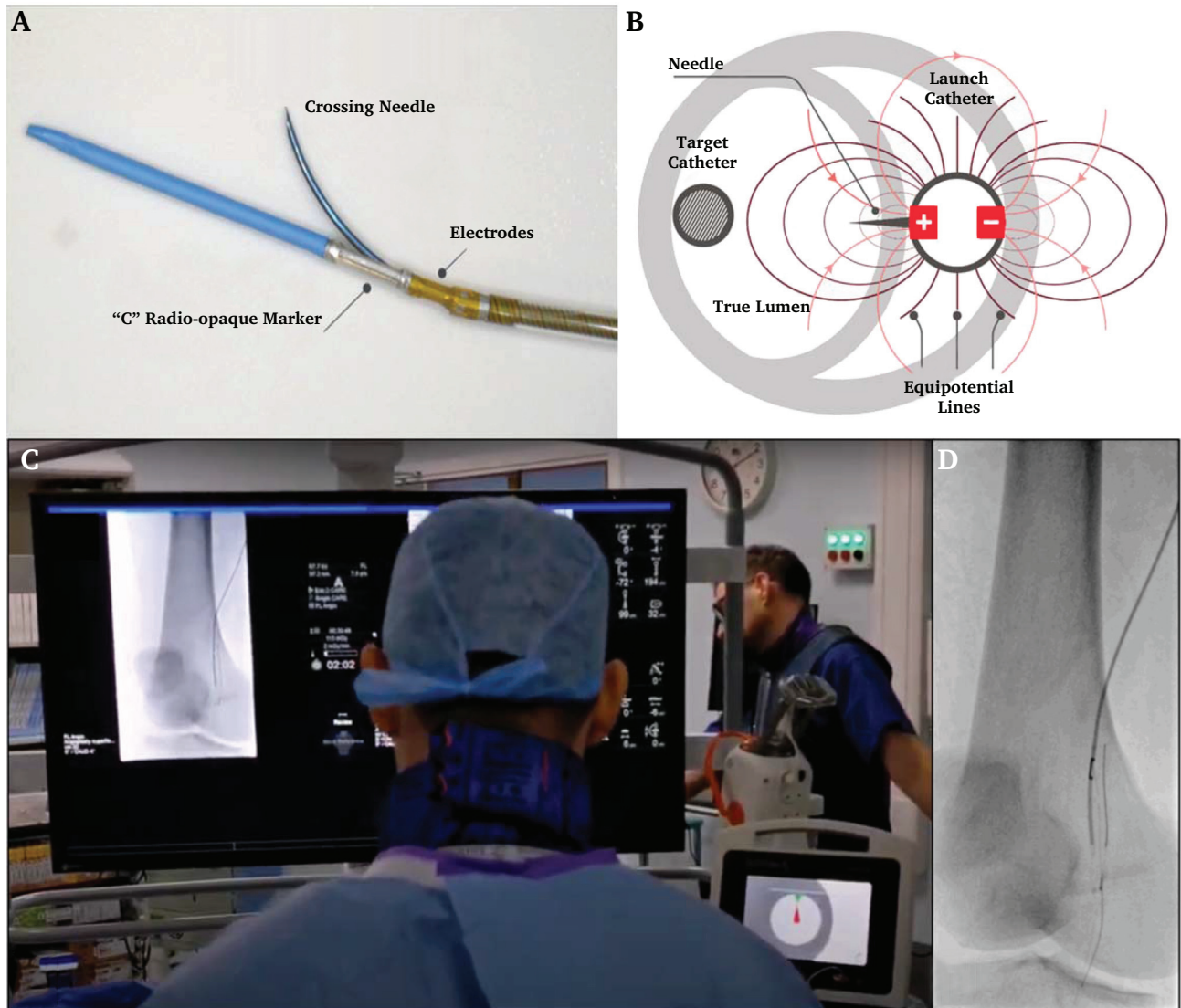


Figure 2. (A) Profile of the ePATH re-entry catheter showing the crossing needle in the part ejected position. (B) Schematic of electronic alignment method showing the electric field being generated by the electrodes (which are fixed in position relative to the needle). This electric field potential is then measured in real time by the target wire to determine the orientation of the needle. The catheter's C shaped radio-opaque markers demonstrate the catheter's orientation under fluoroscopy, as well as the exact exit point of the re-entry needle in the middle of the markers. Device orientation is achieved with a low power, harmless electric field generated by the re-entry catheter, which is then sensed by the target wire.⁹ (C) Electronic alignment between ePATH re-entry catheter and ePATH target wire, achieved using the dedicated ePATH display (bottom right corner) which indicates in real time to the operator when the needle window is facing the target wire without the need for fluoroscopic guided rotational alignment. (D) Fluoroscopic image captured immediately after needle deployment, showing the wire passage into the true lumen of the popliteal artery. The re-entry catheter stands on the left side of the screen and the target wire stands on the right.

ePATH display. The needle was deployed allowing the antegrade wire to advance into the true lumen of the POP on the first attempt (Fig. 2D). Subsequent angioplasty was performed with 7 mm and 6 mm Armada angioplasty balloons (Abbott, Santa Clara, CA, USA) in the distal superficial femoral artery (SFA) and POP, respectively, and deployment of a 6.5 × 100 mm Supera stent (Abbott) and a 3.5 × 38 mm Xience stent (Abbott) was then performed at the level of the SFA—POP and the ATA, respectively. Final angiograms demonstrated brisk inline flow reaching the foot arch via

the ATA (Fig. 1F). Post-operatively, the patient was started on rivaroxaban 2.5 mg taken orally twice daily, in combination with a daily dose of aspirin 75 mg taken orally. Tissue loss was completely healed after 10 weeks with a palpable right dorsalis pedis pulse at the six month follow up.

DISCUSSION

The use of the re-entry catheter in conjunction with the target wire and ePATH display is the true innovation of this new device. It independently and intuitively shows the ideal

orientation of the re-entry catheter without requiring fluoroscopy, thereby reducing radiation dose and contrast load. The electric field is unaffected by calcium and can be detected by the target significantly further away than the needle can reach, thus enabling accurate alignment in heavily diseased vessels, or when the target vessel is directly superimposed (particularly important when considering spiral shaped dissections).

This catheter may have important benefits over existing re-entry catheters. The Outback Elite (Cordis, Santa Clara, FL, USA) is an established device. Although a proven and useful tool, its functionality is limited by the fixed needle travel length on deployment, and reliance on orthogonal fluoroscopy alone to achieve orientation.⁷ An inability to track the 6 F catheter (with a bulkier profile) over an 0.014" wire is a common issue, especially via a contralateral approach or through calcified lesions.⁴ The Pioneer Plus (Philips NV, Eindhoven, The Netherlands) is another 6 F profile re-entry catheter with integrated intravascular ultrasound (IVUS). The main downside, together with having a high unit price, is that IVUS images require interpretation and their quality is affected by highly calcified lesions and poor flow into the distal re-entry site, both common findings in chronic total occlusions.⁸ The smaller and smoother profile of the ePATH catheter compared with the two aforementioned catheters potentially improves manoeuvrability in tibial vessels and subintimal spaces, increasing the likelihood of crossing highly calcified lesions, and reducing the required size of access when potentially advanced from a retrograde access.⁹ As with the Pioneer Plus, the maximum travel length of the ePATH re-entry needle (up to 8 mm) is operator adjustable, to improve the precision of deployment.

A potential downside of the ePATH catheter is that two different approaches are required for the re-entry catheter and the 0.018" target wire for deployment. Positioning wires and catheters from a retrograde access requires fluoroscopy, which could offset some of the reduction in radiation dose. The re-entry catheter can also be used without the ePATH target wire or display, as a lower profile alternative to the Outback re-entry catheter with user adjustable needle travel. In this situation, it is operated in the same way as the Outback catheter, using the C shaped, radio-opaque markers under fluoroscopic imaging, without electrical alignment functionality.

CONCLUSION

The ePATH re-entry catheter enabled safe and effective re-entry to the true lumen in this complex infra-inguinal arterial recanalisation. This electrically guided re-entry catheter may prove to be useful in different clinical

scenarios, including re-entry in iliac or aortic chronic total occlusions, percutaneous femoropopliteal bypass, and endovascular creation of arteriovenous fistula for dialysis.

CONFLICTS OF INTEREST

Sorin Popa and Robert Dickinson own shares in Pathfinder Medical Ltd. Lorenzo Patrone is a consultant to Pathfinder Medical Ltd.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.ejvsf.2021.04.002>.

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