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TECHNICAL NOTE

Catheter-Directed Fenestration for Branch Vessel Reconnection in Aortic Dissection Using a Novel Diamond-Tipped Chronic Total Occlusion Drilling Device: A Technical Report

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Abstract
Purpose Aortic dissection is a complex condition with high morbidity and mortality. Endovascular treatments including percutaneous fenestration can be used to manage branch vessel ischaemia or risk of aortic rupture. A variety of techniques for aortic fenestration have been described. We describe the novel use of the TruePath Chronic Total Occlusion (CTO) device for aortic intimal fenestration to achieve side branch reconnection.
Materials and Methods We present three cases of aortic dissection presenting with symptoms of aortic side branch occlusion and end organ malperfusion, treated with aortic fenestration using the TruePath CTO device via trans-brachial and trans-femoral approaches.
Results Technical success was achieved in all three cases. No complications were encountered. Flow was restored in compromised visceral branches. Branches remained patent on follow-up CT angiography over a minimum 2.5-year follow-up period.
Conclusion Percutaneous aortic fenestration techniques enable a minimally invasive approach to treat visceral branch malperfusion associated with aortic dissection. The TruePath CTO device improves the control of the fenestration procedure with the potential to improve efficacy and safety.

Keywords Aortic dissection · Intimal fenestration · False lumen · True lumen · Endovascular

Introduction

Aortic dissection has an estimated incidence of 3 cases per 100,000 per year [1]. Approximately 30% of patients develop visceral side branch occlusion [2, 3]. Various mechanisms of occlusion have been described and a range of treatments are required to address these [1, 4, 5]. Open surgical treatment of aortic branch compromise is complicated and carries an operative mortality risk up to 26% [2, 6]. Minimally invasive treatment is useful, particularly in patients unsuited to open surgical procedures [2, 7].

Failure to treat branch vessel occlusion can lead to mortality secondary to multi-organ failure. Other causes of death include aortic rupture and secondary cardiac causes [2]. Percutaneous fenestration was first reported in 1990 by Williams et al., who described the process of creating a hole in the dissection flap to decompress the false lumen and allow outflow into the true lumen [7, 8]. It is mainly indicated in complicated dissections involving the descending thoracic and abdominal aorta [2, 4, 7].

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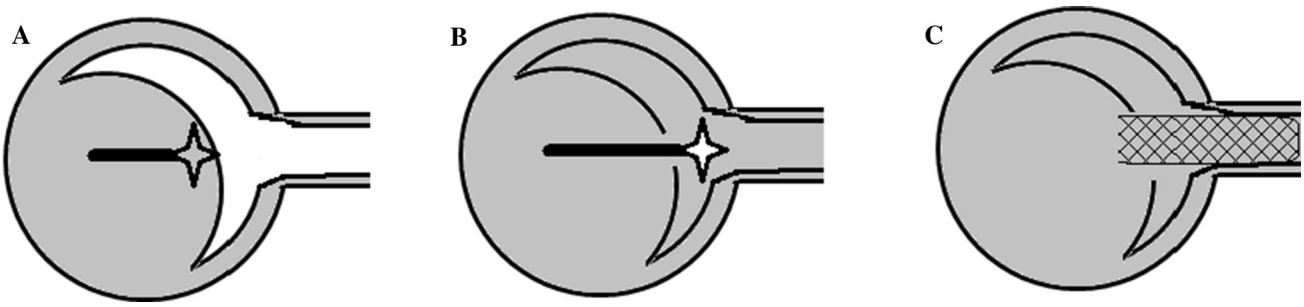

Fig. 1 **A** True lumen in cross section (compressed by false lumen) demonstrates absent flow to side branch (white). TruePath CTO device (starred tip) advanced via false lumen. **B** Controlled tunnelling through intimal flap towards true lumen at level of occluded side branch. Flow re-established (grey). **C** Stent placed across false lumen to maintain patency of flow into side branch

A range of techniques and materials are available [2, 4, 5, 7–10]; however, each procedure should be based on individual anatomy, pathology and clinical presentation. We describe the novel use of the TruePath Chronic Total Occlusion (CTO) device (Boston Scientific Corporation, Natick, MA, USA) in intraluminal aortic fenestration for the management of aortic dissection with malperfusion of abdominal branch vessels.

Technique

The TruePath CTO consists of a tunnelling device and an electronic control unit. The outer shaft is a hollow tube 0.018-inch in diameter with a working length of 165 cm, and a hydrophilic coating. Contained within it is a flexible driveshaft that allows the control unit to rotate the diamond-tipped Active tip, thus tunnelling through an occluded vessel by micro-dissection. The Active tip is radiopaque to allow visualisation and localisation during fluoroscopy [11]. The device is highly flexible, allowing it to be steered by a combination of 5 Fr angiographic catheter and guiding catheter sheath.

True and false aortic lumens are accessed via a transfemoral or trans-brachial approach. A 5 Fr angled Catheter (Dav, Cook, IN, USA) is introduced into one aortic lumen to act as a target. The TruePath CTO device is introduced into the other aortic lumen through a coaxial guiding system consisting of a microcatheter (Direxion, Boston scientific, MA, USA), a 5 Fr catheter (Vanschie 2, Cook, IN, USA), and a guide catheter (7 Fr Vista Brite tip, Cordis, CA, USA). The guiding system is used to direct the TruePath CTO tip towards the catheter within the target vessel. Orientation is confirmed with imaging in orthogonal planes and the device is activated and advanced through the intimal flap towards the target catheter. The microcatheter is advanced over the device, and the device is then removed. Access into the target vessel is confirmed by contrast injection and a guidewire (V18, Boston scientific, Marlborough, MA, USA) is introduced through the microcatheter. The coaxial 5 Fr catheter and 7 Fr guide catheter can then be advanced over the microcatheter, providing track dilatation prior to introduction of a bare or covered stent (V12, Getinge, Gothenburg, Sweden) (Fig. 1).

Table 1 outlines the relevant radiological, technical and long-term clinical outcomes of three patients treated with the TruePath CTO device. Stented branches were widely patent in all patients at follow-up CTA.

Patient 1 (Fig. 2)

A 77-year-old female with a past history of surgically repaired Stanford type A aortic dissection presented with 3 weeks of chest and upper thoracic back pain. CT angiography (CTA) revealed enlargement of the residual descending aortic dissection (Fig. 2A, B). Dissection morphology and luminal status are outlined in Table 1. The patient's preference was to avoid further major surgical intervention. Under general anaesthesia, bilateral brachial artery access was obtained using 8 French introducer sheaths (Terumo Radifocus Introducer II, Terumo, Tokyo, Japan). Selective catheterisation of both true and false lumina was performed. The TruePath CTO device was used to create a fenestration from the true lumen, emerging in the false lumen adjacent to the coeliac trunk origin (Fig. 2C–E). This required traversing a long path through false lumen thrombus. A covered stent (Atrium Advanta V12, Getinge, Gothenburg, Sweden) was deployed into the recanalised coeliac trunk (Fig. 2F, G) to maintain coeliac perfusion, while the subclavian false lumen inflow from the aortic true lumen was occluded with multiple embolisation coils bilaterally.

Patient 2

A 37-year-old morbidly obese (134 kg) female initially presented with acute type 1 respiratory failure necessitating admission to ICU. The patient subsequently developed

Table 1 Results and demographic details for patients

Patient	Age	Sex	Clinical presentation	Stanford classification	Dissection morphology (luminal status and side branch perfusion)	Complication	Follow-up
1	77	M	Chest pain and dysphagia Previous type A repair	Type A	False lumen inflow via intimal defects within the left and right subclavian arteries False lumen outflow via the coeliac axis and left renal artery True lumen Compressed False lumen Opacified with extensive mural thrombus Branch supply Arising from false lumen Coeliac trunk Left renal artery Arising from true lumen SMA Right renal artery Other findings Atrophic left kidney	N	At 2.5 years Asymptomatic Thrombosis of false lumen Preserved side branch perfusion
2	37	F	Admitted to ICU with Type 1 respiratory failure Developed Acute renal failure with anuria and Ischaemic bowel	Type B	Intimal flap extension into: coeliac trunk and SMA, which are narrowed at origin, extended into bilateral renal arteries True lumen Opacified but markedly narrowed and compressed False lumen Opacified and dilated Branch supply Arising from false lumen Left renal artery: intimal dissection flap extends to mid left renal artery Right renal artery: thrombosed, no perfusion Arising from true lumen Coeliac trunk SMA and IMA Other findings Evidence of ischaemic colitis, hepatitis, splenic infarcts, renal malperfusion MAG3 scan: no perfusion to right kidney (complete cortical infarction). Severe acute tubular necrosis of the left kidney.	N	At 2.5 years Asymptomatic Mild renal impairment Preserved side branch perfusion

Table 1 continued

Patient	Age	Sex	Clinical presentation	Stanford classification	Dissection morphology (luminal status and side branch perfusion)	Complication	Follow-up
3	65	F	Acute abdominal pain and back pain	Type A	Intimal flap prolapses into origins of coeliac trunk and SMA, proximal 10 mm of IMA does not opacify True lumen Collapsed, anteriorly compressed from coeliac axis inferiorly Poorly opacified False lumen Fenestration 3 cm distal to origin Branch supply Arising from false lumen Arising from true lumen Coeliac trunk SMA IMA Other findings Mesenteric ischaemia with diffuse bowel wall thickening Renal infarction	N	At 3 years Asymptomatic Preserved side branch perfusion

severe renal impairment and abdominal pain. CTA revealed an extensive Stanford type B aortic dissection extending from the origin of the left subclavian artery to both common iliac arteries. Dissection morphology and luminal status are outlined in Table 1. These findings were confirmed on digital subtraction angiography. After extensive multidisciplinary discussion, a plan to restore renal artery, coeliac and mesenteric flow using covered stents was made. Reconstitution with stent grafts and stents in the aortic true lumen and branch vessels was rejected because of concerns about obtaining open femoral arterial access in a morbidly obese patient. Under general anaesthesia, bilateral trans-femoral 8 French sheaths were introduced, allowing access into both true and false lumens. The TruePath CTO device was used to create fenestrations from the aortic false lumen through the collapsed true lumen directly into the true lumen of the left and right renal arteries, and superior mesenteric artery (SMA) followed by stent deployment (7 × 19 mm Express SD, 5 × 19 mm Express SD, and 8 × 40 mm EPIC stent graft respectively; Boston Scientific, Marlborough, MA, USA). A good technical result was achieved. The coeliac trunk was not treated as it was adequately reconstituted by retrograde SMA perfusion.

Patient 3 (Figs. 3, 4)

A 65-year-old male presented with acute abdominal and back pain. CTA revealed an acute Stanford type A aortic dissection extending from the sinotubular junction into both the common iliacs and the left femoral arteries. True and false lumen morphology and side branch perfusion are outlined in Table 1 and depicted in Fig. 3. Abdominal pain and an elevated lactate, along with imaging findings suggested mesenteric ischaemia. A plan was made to perform percutaneous revascularisation of aortic branches prior to surgical repair of the ascending aortic dissection. Under general anaesthesia intimal fenestration and revascularisation of branch vessels was performed prior to ascending aortic repair. The coeliac, SMA and right common iliac arteries were connected with the false lumen using the TruePath CTO device to traverse the collapsed true lumen (Fig. 4A–E). Stents were deployed from the false lumen into each of the branches (coeliac stent 10 × 40 mm Astron, Biotronik, Berlin, Germany. SMA stent 9 × 40 mm Astron, Biotronik, Berlin, Germany. Renal arteries, 7 × 15 mm and 7x19 mm Express Vascular SD, Boston Scientific, Marlborough, MA, USA). Rapid flow was evident at the conclusion of the procedure (Fig. 4F).

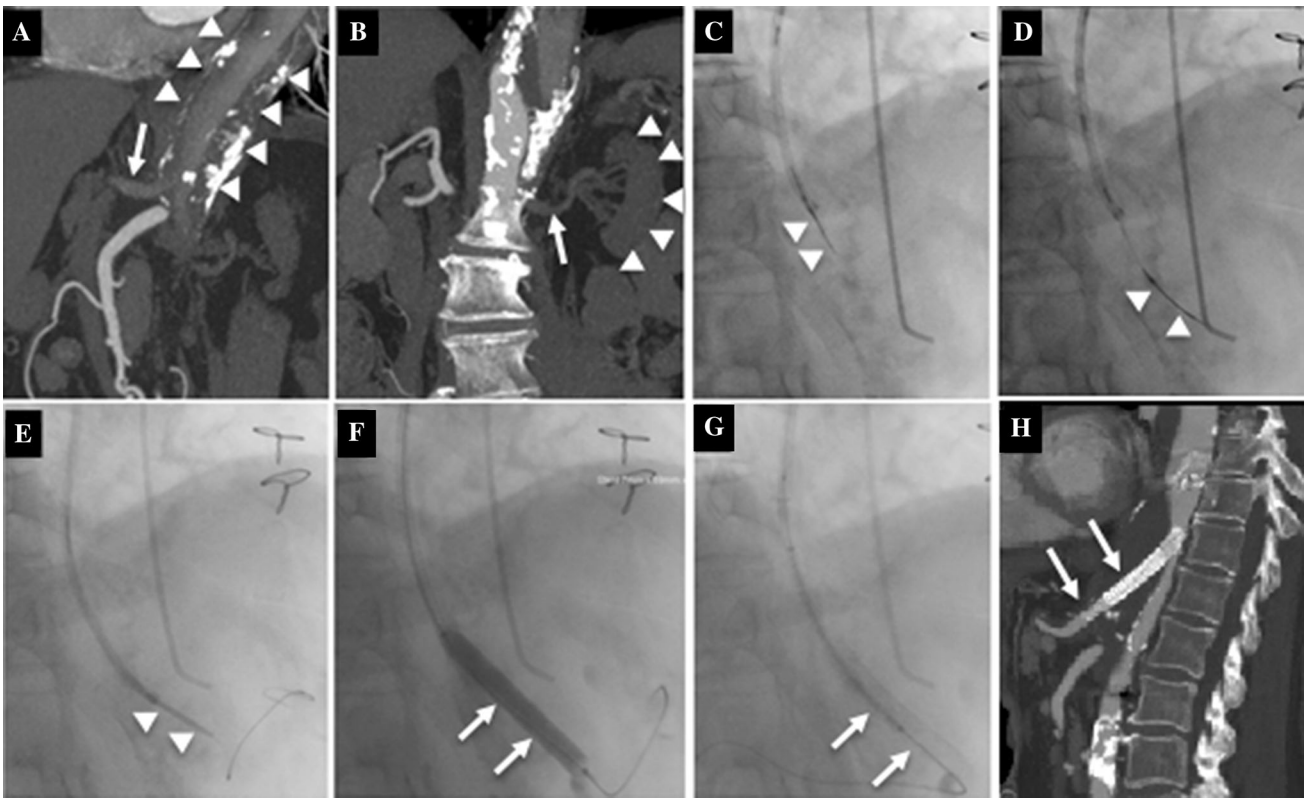

Fig. 2 Images correspond to patient 1. **A** Sagittal maximum intensity projection (MIP) CTA demonstrating poor opacification of the coeliac trunk (arrow) and aortic false lumen (arrow heads) from which it arises and **B** non-opacification and non-perfusion of the left renal artery (arrow) and kidney (arrow heads) arising from the false lumen. Extensive intramural thrombus was present. **C–G** demonstrates stepwise advancement of the TruePath CTO device (arrow heads) through a large volume of intramural thrombus within the false lumen. Balloon angioplasty (arrow) and stenting with an Atrium V12 covered stent (7 mm × 59 mm) (arrows) results in reconstitution of flow from the true lumen into the coeliac axis. **H** Follow-up CTA demonstrates persistent obliteration of the false lumen and excellent opacification of the coeliac axis (arrow)

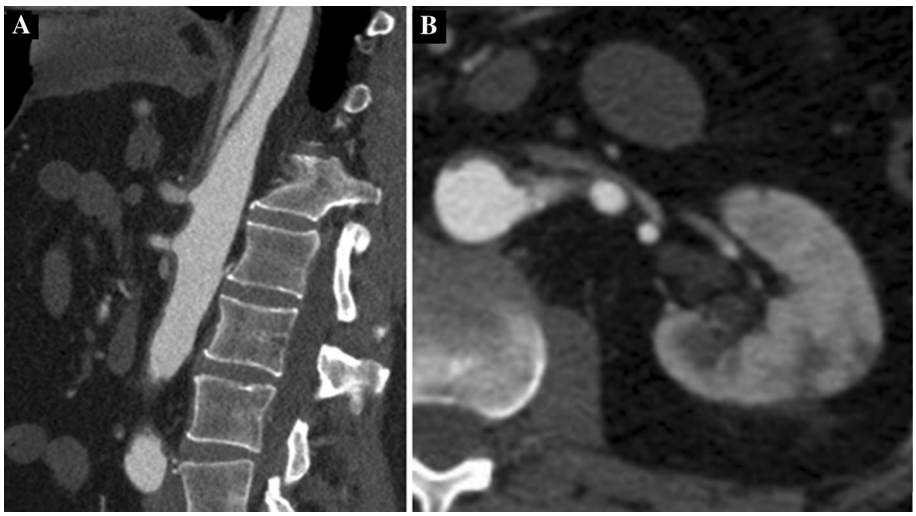

Fig. 3 Images correspond to patient 3. CT angiography demonstrates **A** Extensive type B aortic dissection with marked anterior compression of the true lumen which prolapses into the ostium of the coeliac and superior mesenteric arteries resulting in malperfusion **B** intimal flap extension into the left renal artery with resultant malperfusion and an acute renal infarct

Discussion

Endovascular techniques are increasingly important in the management of aortic dissection, particularly in the presence of branch occlusion. Percutaneous aortic fenestration techniques have significantly reduced the operative mortality of patients undergoing treatment of aortic dissection with branch vessel occlusion (operative mortality of 35.1% pre-1990, compared with 14.8% post-1990) [2, 4, 5, 12]. These observed improvements in mortality are a major

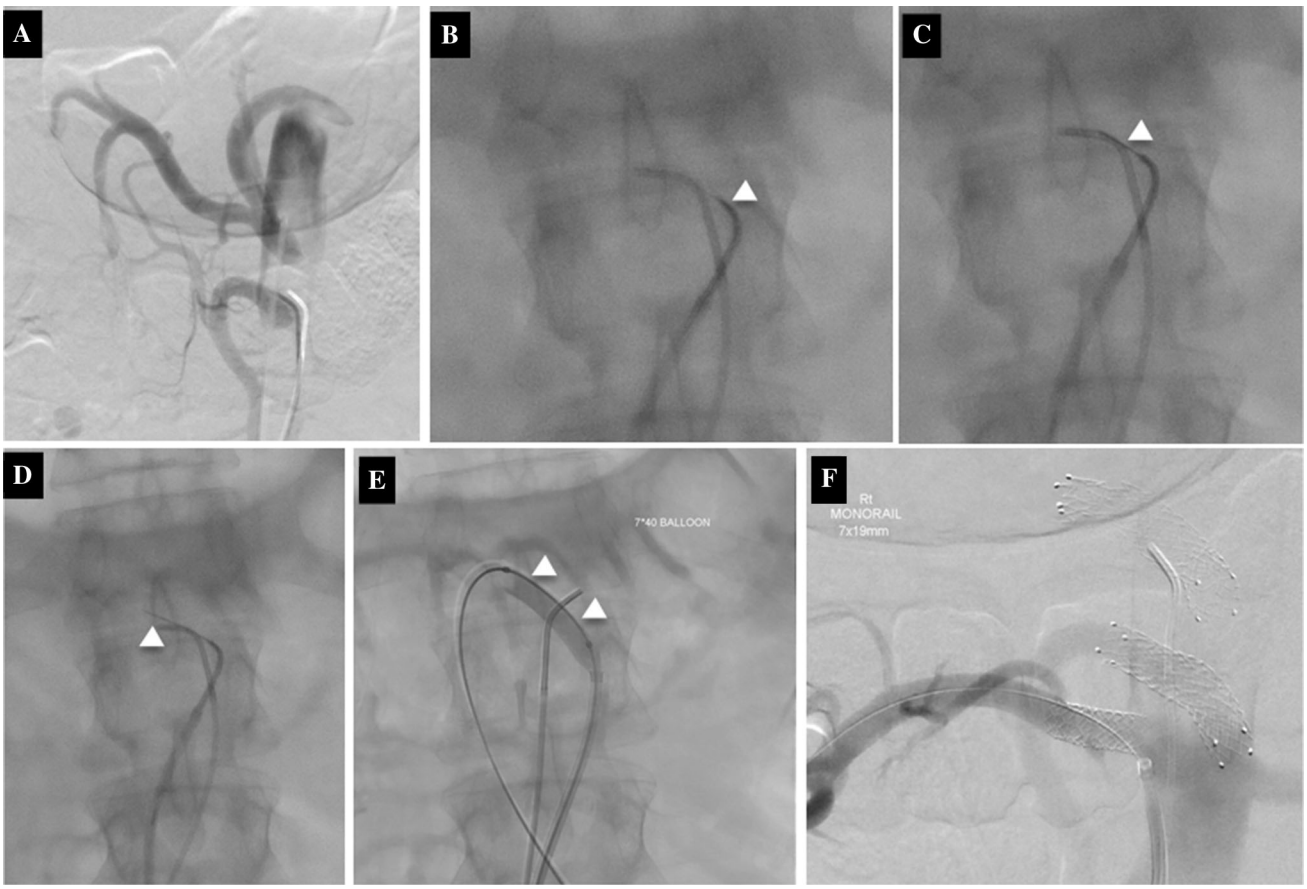

Fig. 4 Images correspond to patient 3. **A** The floating mesenteric vessels are compatible with the known type A aortic dissection with side branch origin from the malperfused true lumen. **B–E** demonstrates stepwise advancement of the TruePath CTO device (arrow heads) from the false lumen through the aortic intimal flap and into the malperfused coeliac trunk. **F** The device was used to reconstitute flow to the remaining mesenteric and right renal arteries. The coeliac and superior mesenteric arteries were subsequently stented with nitinol metal stents (Biotronik SE, Biotronik) measuring 10 × 40 mm and 9 × 40 mm, respectively. The right renal artery was stented with a 7 × 19 mm bare metal stent (Express Vascular SD, Boston Scientific)

drive for ongoing novel approaches and research into optimum aortic fenestration techniques [2].

Fenestration involves creating a hole in the intimal flap separating the true and false lumen, at a point near to side branch vessels, often by first accessing the false lumen and directing the puncture towards the true lumen with a requirement of a minimum diameter of true lumen in order to reduce the risk of aortic perforation [7]. Various techniques, often requiring concurrent use of endovascular ultrasound for localisation, have been described with varying results and success of up to 90% in relieving ischaemia [1, 4, 5, 10, 12]. These involve using a sharp device such as a trans-septal, Colopinto or Chiba needle to puncture from one lumen to another. While these approaches give some control over the location of the fenestration, the stiffness of these devices limits their use through tortuous access vessels. They are also less steerable than standard angiographic catheters, and the forceful manoeuvre required to puncture the septum is associated with a risk of missing the planned site of fenestration or extending the puncture through the aortic adventitia. Additionally, the intimal flap can become mobile and occlude nearby side branches in balloon fenestration procedures [4, 5, 7, 8]. Other risks include failure of the technique due to thrombosis around the access artery sheath and long-term enlargement of the descending thoracic aorta [3]. While it is clear that minimally invasive aortic fenestration carries less operative risk than open procedures to relieve distal ischaemia, no reference standard approach to intimal fenestration exists [4, 5, 12]. Furthermore, there is limited data outlining novel techniques for fenestration such as use of the Outback LTD single lumen re-entry catheter system [2, 9].

The use of the TruePath CTO device for subintimal fenestration provides a novel approach to the management of chronic aortic dissection. The TruePath CTO device has

been validated as a technically reliable and safe method of crossing chronic total occlusions in the iliac arteries [13]. Although its use in aortic dissection is 'off-label', the technical advantage it offers makes it a suitable device to consider in intimal flap fenestration.

Aortic intimal fenestration can prove technically challenging. Fluoroscopic guidance, even with the use of intravascular ultrasound can be difficult, particularly in complex and tortuous vasculature and in the presence of intimal flap calcification leading to traumatic fenestration [9, 10]. Furthermore, prolonged procedure times and increasing radiation exposure are highly dependent on operator expertise. Additionally, the flexibility of the Active Tip and its ability to be manoeuvred by standard angiographic guiding catheters, enables operators to overcome at least some of these technical difficulties potentially leading to greater rates of technical success. In particular, the TruePath CTO device can be introduced through tortuous anatomy and the site of fenestration accurately targeted to align with branch vessels. The powerful microdissection capabilities of the device allow fenestration through calcified intimal flaps, avoiding the risk of puncturing the opposing aortic wall by undue force. Similar impressions were made by use of the TruePath device in iliac vessel disease in the Re-Open trial [13].

In two of the cases presented, we chose to connect branch vessels with the false lumen. We do not advocate this as a general principle, as it would preclude subsequent aortic stenting. Also, false lumen thrombosis could result in loss of branch vessel perfusion. This method was chosen because of individual circumstances relating to the cases. Even though this has resulted in good intermediate-term outcome for the two cases described, in general we would advocate a true lumen-based approach whenever possible.

Limitations in the use of the TruePath CTO device include risk of significant advancement beyond the edge of the aorta leading to aortic rupture. However, as this is the first description of the use of this tunnelling device for this purpose, there is no data on the incidence of this complication. In our case studies, no such complication arose; however, perforations using other fenestration procedures have been reported as high as 30%. Biplanar imaging or concurrent intravascular ultrasound guidance to improve device localisation as well as repeat angiograms to assess for leaks would likely ameliorate the likelihood of perforation during fenestration.

Conclusion

The TruePath CTO device is a useful alternative to existing fenestration techniques. It has several advantages over existing intimal fenestration methods and has the potential to improve technical and long-term outcomes in patients with complex aortic dissections. Further case series or prospective studies may validate the use of the device for aortic intimal fenestration.

Compliance with Ethical Standards

Conflict of interest We declare that we have no conflict of interest.

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