

CASE REPORT

Closure Device Migration: An Unusual Cause of Acute Limb Ischaemia Following a Simple Endovascular Procedure

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Introduction: Acute limb ischaemia resulting from foreign body embolisation is an infrequent yet critical complication associated with vascular closure devices (VCDs). Despite the widespread use of VCDs, rare complications such as fragment emboli pose unique challenges, necessitating heightened clinical awareness. This case report presents a case of acute limb ischaemia caused by a VCD malfunction following an endovascular procedure.

Report: A 70 year old male who was diagnosed with a severe claudication of the lower extremity (Rutherford III) due to right common iliac stenosis, underwent angioplasty using a FemoSeal (Terumo Ltd., Surrey, UK) to close the right femoral artery access. Two weeks later, the patient presented with acute lower limb ischaemia due to a right popliteal–tibial occlusion. Emergency surgical thrombo-embolectomy was successfully performed from a medial popliteal approach, and the thrombus, which contained a polymer disc from the VCD at its distal end, was completely removed.

Discussion: Despite VCDs being proven safe and efficient, rare complications such as fragment emboli can occur, and physicians should be aware of the possible delayed onset of symptoms. Moreover, the radiolucent nature of the polymer disc in a FemoSeal complicates diagnostic imaging. While endovascular approaches exist, open surgery is a safe and effective strategy for retrieving fragments and treating the patient in acute limb ischaemia cases.

Conclusion: Physicians should remain vigilant for embolic risks associated with vascular closure devices, even with suitable anatomy and following guidelines, especially considering the trend toward early ambulation and discharge.

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INTRODUCTION

Vascular closure devices (VCDs) are widely used to close the arterial access at the end of an endovascular diagnostic or interventional procedure. Randomised control trials have proven them to be efficient in reducing time to haemostasis and access site complications when compared with manual compression.¹ The largest studies have reported a complication rate of 6.0–6.9%, including haematomas (major or minor), pseudoaneurysm formation, vessel occlusion, stenosis, dissection, and infection.^{1,2}

This case report describes an unusual ischaemic adverse event that arose with the FemoSeal (Terumo Ltd, Surrey, UK) VCD, which is made of two bioabsorbable polymer discs on both sides of the arterial wall, held together by a bioabsorbable suture with a friction lock. Informed consent was obtained from the patient to include his data in the report.

CASE REPORT

A non-obese, 70 year old male was referred to the clinic with a two year history of right lower extremity claudication. His main cardiovascular risk factors were hypertension, dyslipidaemia, and a history of tobacco use, which had ceased two years before. He had also undergone a lobectomy for a solitary pulmonary nodule without complications.

His walking distance decreased from 400 to 100 m, despite diligently following his exercise therapy. Imaging

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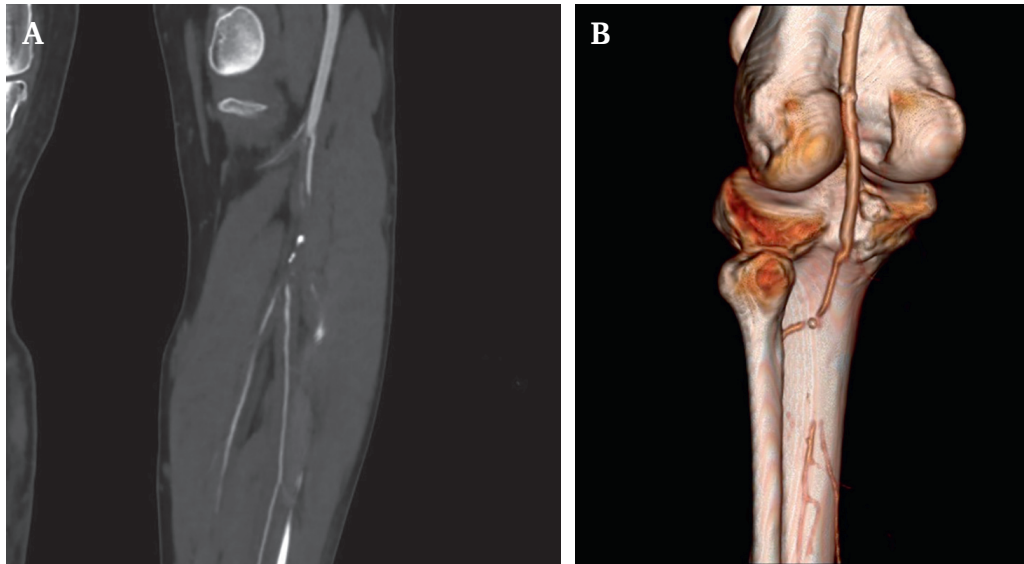


Figure 1. Pre-operative computed tomography angiogram images. (A) Multiplanar reconstruction showing the popliteal artery, tibioperoneal trunk, and posterior tibial artery. (B) Three dimensional reconstruction of the popliteotibial region, indicating incomplete occlusion of the distal popliteal artery and complete occlusion of the tibioperoneal trunk.

investigations found a unique significant calcified stenosis of the right common iliac artery, and he was subsequently scheduled for elective revascularisation.

Retrograde access from the right common femoral artery was performed, a long 7F sheath was inserted, and a 9 mm balloon expandable stent graft (BeGraft, Bentley, Hechingen, Germany) was deployed at the stenosis level. After the final angiogram, the arterial access was closed by an experienced surgeon using a FemoSeal device, with immediate technical success and without the need for additional manual compression. After an observation period of four hours in a decubitus position followed by one hour of mobilisation, no complications occurred and a pedal pulse was palpable. The patient was discharged home on the same day of the procedure, as planned.

Fifteen days later, the patient presented to the emergency department exhibiting signs and symptoms of acute right lower limb ischaemia, which had occurred suddenly on the same day. Motor function in the leg was preserved, despite pain and pallor of the right foot, and minimal sensory loss was observed, accounting for a Rutherford's stage IIa. Duplex and computed tomography angiography confirmed subtotal occlusion of the distal popliteal artery followed by complete occlusion of the tibioperoneal trunk and the ostia of the peroneal, and anterior, and posterior tibial arteries (Fig. 1A and B). The aorto–iliofemoral axis was patent without potential embolic lesion and electrocardiogram showed no sign of dysrhythmia. An intravenous heparin infusion was started and the patient was consented for open thrombo-embolctomy.

Under general anaesthesia, a medial approach to the below knee popliteal artery was performed. After the arteries were controlled and clamped, a transverse arteriotomy was made in the distal popliteal artery to retrieve the

thrombus. A fresh thrombus combined with a polymer disc attached to its suture rope was found (Fig. 2). Additional embolectomy was performed proximally and distally using Fogarty catheters, followed by the flushing and closure of



Figure 2. Peri-operative photograph demonstrating the polymer disc and suture removed during thrombo-embolctomy.

the arteriotomy site. Both posterior tibial and pedal pulses were present at the end of the intervention. Clinical improvement occurred immediately after the surgery and the patient was discharged home three days later without any complications.

DISCUSSION

This case report presents a case of delayed acute limb ischaemia following a technically successful vascular closure device (VCD) deployment. The most frequent adverse events regarding the use of this type of VCD are haemorrhagic. Ischaemic complications are rare and usually secondary to arterial narrowing at the puncture site.² In the ISAR-CLOSURE randomised trial, including >1 500 patients who underwent coronary angiography by femoral access followed by closure with a FemoSeal VCD, no limb ischaemia was reported.¹ Likewise, a Cochrane database review, including 52 studies, analysing the outcomes of VCD at femoral arterial puncture sites (19 192 participants) did not report any fragment migration.³

In the literature, FemoSeal is a widely used and safe intravascular closure device that has one of the lowest complication rates.⁴ Despite a theoretical risk of distal embolisation associated with any intravascular closure devices, it is believed that no such incident has been reported for the FemoSeal device. However, fragment migration has previously been described with extravascular closure devices using clips (StarClose SE, Abbot Laboratories, USA)⁵ or collagen (MynxGrip, Cordis, USA).⁶

Therefore, this case differs from what has previously been reported. When they occur, VCD complications usually happen instantaneously after deployment and, more specifically, fragment migration has mostly been reported in the immediate setting of the device implantation.^{6–8} In the current case, the patient's symptoms started 15 days after the initial intervention, suggesting either delayed thrombosis or late fragment dislocation. A similar occurrence of ischaemia caused by fragment emboli has been documented with the Angio-Seal device (St-Jude Medical, Saint-Paul, MN, USA), which features a bioabsorbable anchor within the vessel secured to an extravascular collagen plug.⁹ When the patient presented to the emergency department, the mechanism of the ischaemia was unclear; although the contrast media sudden cut off and absence of significant atherosclerotic disease in the femoropopliteal arteries were suggestive of an embolic mechanism. Notably, as the polymer discs used in the FemoSeal are radiolucent, the computed tomography angiogram could not determine the iatrogenic origin of the lesion.

For the treatment of VCD fragment migration, endovascular approaches using a snare device have been described.⁸ In the current case, an open surgical approach was preferred in the setting of acute limb ischaemia caused by a long popliteal embolus of unknown origin. As other case reports suggest, open surgery seems to be the most reliable and effective option to treat acute limb ischaemia in this specific setting.^{5,10}

This case highlights the fact that fragment migration can occur when using VCDs, and physicians should consider this complication when facing delayed ischaemia following recent use of these devices. Awareness of this rare complication might be important to determine the best management strategy. In this kind of case, open surgery seems to be a safe and effective way to treat the patient and retrieve the fragment.

Conclusion

Physicians should always consider the embolic risk of vascular closure devices, even with suitable anatomy, retrograde access, and following instructions for use, especially considering the trend toward early ambulation and discharge.

CONFLICTS OF INTEREST

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