Intravascular ultrasound findings of the protrusion of the EXOSEAL plug that caused acute limb ischemia

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ABSTRACT

Vascular closure devices have become popular for rapid hemostasis and early ambulation. However, there are a few reports of complications. We presented a case with acute limb ischemia caused by the protrusion of the EXOSEAL plug into the vessel. Intravascular ultrasound imaging helped determine the plug that caused the occlusion. (J Vasc Surg Cases Innov Tech 2023;9:1-5.)

Keywords: EXOSEAL; Acute limb ischemia; Endovascular; IVUS

Vascular closure devices (VCDs) are useful to achieve rapid hemostasis and shorten the patient's rest time. Among them, EXOSEAL (Cordis) is a device that deploys a bioabsorbable polyglycolic acid plug to close the subcutaneous puncture route. This device reduces the risk of anchor-related lumen narrowing and occlusion because it leaves nothing inside the vessel. Lower limb ischemia related to the VCD is a rare complication; however, we encountered a case of acute puncture site occlusion after using the EXOSEAL. Intravascular ultrasound (IVUS) imaging showed the protrusion of the plug into the vessel, so we could find the cause of the acute occlusion.

CASE PRESENTATION

An 87-year-old woman with rest pain underwent the leg angiogram using a contralateral approach. We found a chronic total occlusion from her right femoropopliteal artery to the below-the-knee lesion (Fig 1, *A*). The contralateral approach was not suitable for the below-the-knee intervention because of the less torque performance. We therefore switched the approach site to the ipsilateral approach through a 6F sheath. We checked that there was no stenosis in the common femoral artery (CFA) lesion (Fig 1, *B*) and performed the puncture by palpation while confirming the puncture height fluoroscopically. There was no problem to insert the sheath to the mid of the superficial femoral artery (SFA). We succeeded in opening the chronic total occlusion of the femoropopliteal artery and peroneal artery (Fig 1, *C*). We used a 6F EXOSEAL for hemostasis. After using EXOSEAL, we confirmed hemostasis and finished the procedure. The next day, she complained of paleness and rest pain in her right leg. Her right popliteal artery was not palpable, and her ankle-brachial pressure index could not be measured on her right leg. We suspected the reocclusion of the SFA and performed an emergency angiography. The angiography showed an occlusion from the ostium of the right SFA, which had not been treated in the intervention 1 day before (Fig 1, *D*). We retried endovascular therapy (EVT) using a 6F guiding catheter by the contralateral approach. The guidewire was advanced smoothly; then we checked IVUS imaging. The IVUS imaging demonstrated that a high-density structure was crossing the wall of the ostium of the SFA into the vessel (Fig 2). This narrowed the lumen of the SFA. From there to the distal SFA, it was filled with thrombus. From this IVUS imaging, the EXOSEAL plug protruded into the vessel, which might have facilitated thrombus formation, resulting in flow limit and occlusion. In addition, we found that the puncture site on the previous day was the SFA not CFA. We performed thrombus aspiration and balloon dilatation. After that, IVUS imaging showed that the plug was compressed on the wall and the SFA lumen became larger than before at that site (Fig 3, *A* and *B*). However, the thrombus was poorly controlled, and dissections occurred in the proximal SFA (Fig 3, *C*). We deployed two self-expandable Eluvia stents to seal the plug, thrombus, and dissection. The final angiography and IVUS imaging showed revascularization of the SFA (Fig 4, *A* and *B*) and good expansion of the stent at the site of the plug (Fig 4, *C*). After the procedure, her symptoms disappeared and the value of the brachial pressure index was normalized. The ultrasound images at the 1-year follow-up showed that Eluvia stents put at the protrusion site were patent.

DISCUSSION

The VCDs become very useful for the interventionists to achieve rapid hemostasis at the puncture site. The EXOSEAL is a VCD that delivers a bioabsorbable polyglycolic acid plug between outside the vessel and inside the fascia of the neurovascular bundle (Fig 5, *A-C*). The EXOSEAL is different from other VCDs in that it does not leave

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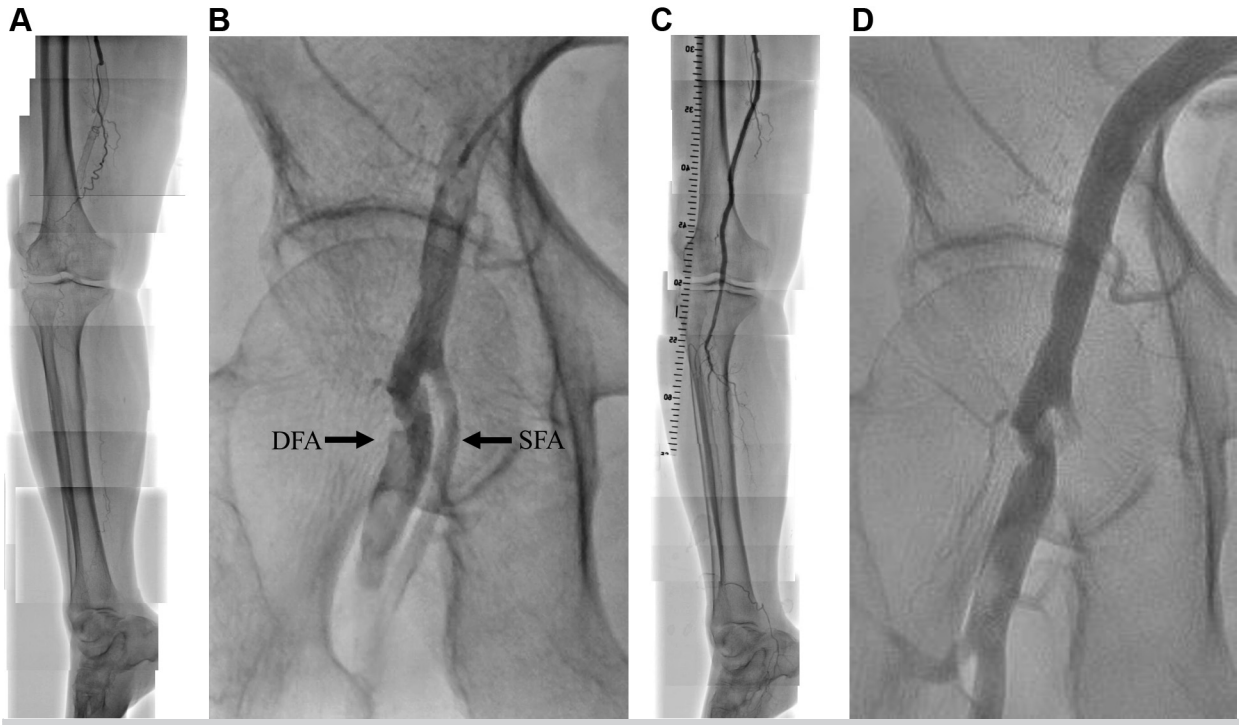

Fig 1. A, Angiography before the initial intervention showed the total occlusion from the middle aspect of the superficial femoral artery (*SFA*) to the below-the-knee lesion. **B,** Angiography before the intervention at the groin. The common femoral artery and the deep femoral artery (DFA) and SFA were patent. **C,** Final angiography of the initial intervention. The lumen from the SFA to the peroneal artery was open. **D,** Angiography of the acute limb ischemia. The SFA was occluded.

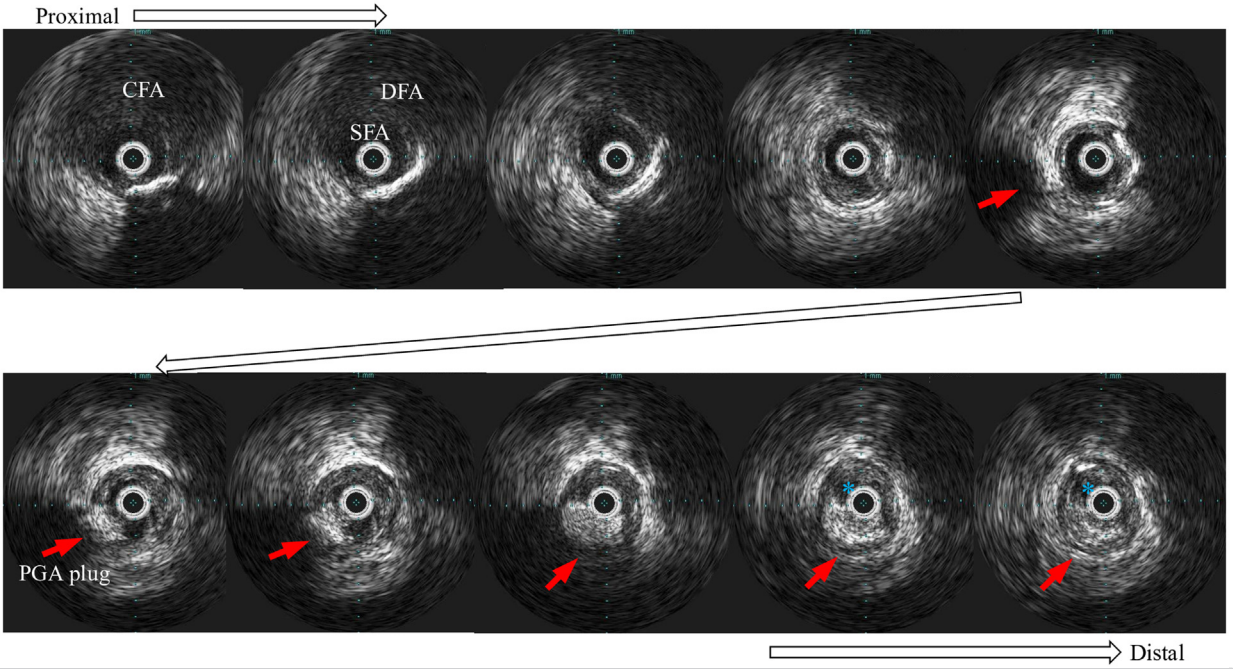

Fig 2. Intravascular ultrasound (IVUS) images. The high-density structure was crossing into the vessel (*red arrows*). This was the plug of EXOSEAL and narrowed the lumen of the proximal superficial femoral artery (*SFA*) (*blue asterisk*). *CFA*, Common femoral artery; *DFA*, Deep femoral artery; *PGA*, polyglycolic acid.

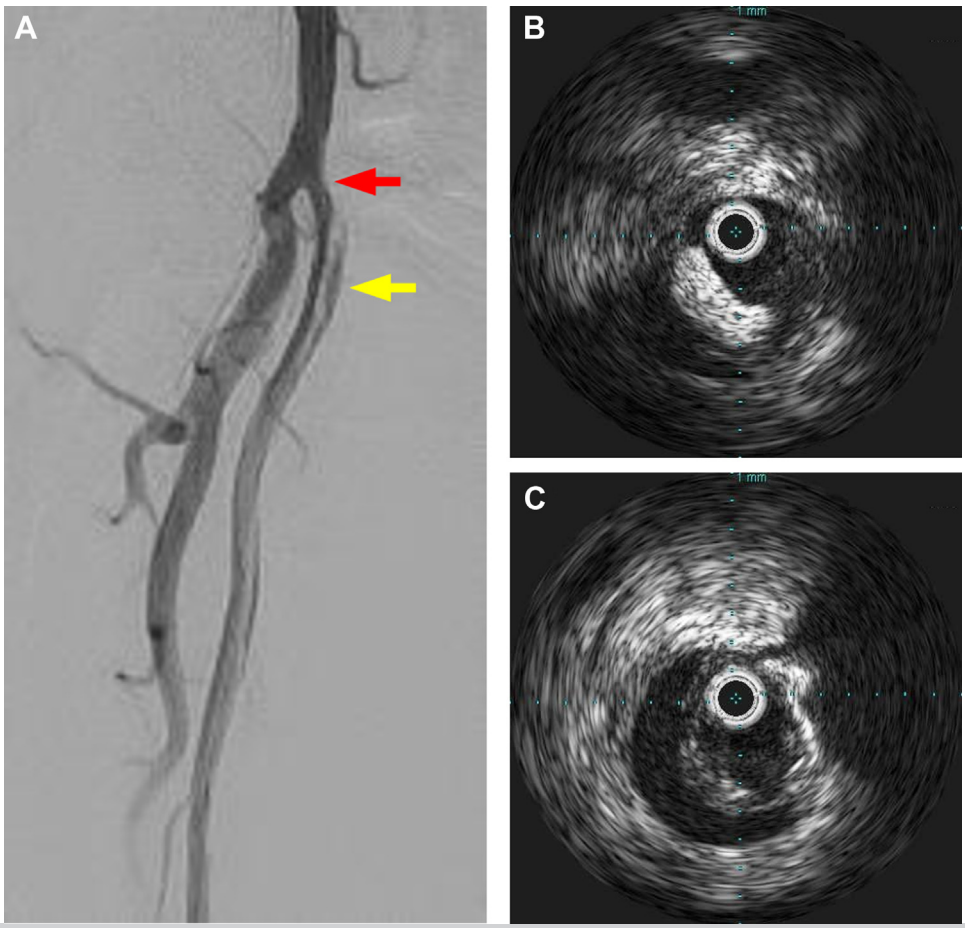

Fig 3. A, Angiography after balloon dilatation. The point of the *red arrow* was the site of the protrusion. Below that point, there were some dissections (*yellow arrow*). **B,** Intravascular ultrasound (IVUS) image at the *red arrow* **(A)**. The high-density structure was compressed, and the area of the superficial femoral artery (SFA) becomes larger. **C,** IVUS image at the *yellow arrow* **(A)**. It showed the major dissections.

foreign objects such as anchors inside the vessels, which reduces the risks of stenosis, occlusion, and distal embolisms.

There were some reports about the efficacy and safety of antegrade femoral access using the EXOSEAL.[1,2] Another report demonstrated that the EXOSEAL can be safely used for antegrade direct puncture of the patent SFA with ultrasound or fluoroscopic guidance.[3] Recently, Kawasaki et al[4] reported the use of the EXOSEAL for the occluded SFA, which required confirmation of the extravascular position of the indicator wire by fluoroscopy at the plug deployment. In our case, we accessed the femoral artery by palpation-guided puncture, and we did not notice the unintentional puncture of the proximal SFA. We intended to use the EXOSEAL for healthy CFA, but actually, we used it for the slightly calcified and stenosis SFA (Fig 1, *A*). It might happen that the indicator wire of the EXOSEAL got entangled in the calcified SFA and the visual indicator window changed to all black as if it exited the vessel wall, thereby deploying the EXOSEAL plug at the internal surface of the vessel (Fig 5, *D-F*). To avoid such complications, we recommend an ultrasound- or fluoroscopy-guided puncture to confirm the puncture site.

It was reported that some of the risk factors for acute thrombotic occlusion (ATO) after EVT were the lesion involving the popliteal artery and poor runoff.[5,6] These were observed in this case. Therefore, this case was at risk of ATO after EVT regardless of EXOSEAL use. However, the plug of EXOSEAL remarkably protruded into the SFA and narrowed the lumen of the vessel, so we considered that plug protrusion and ATO were related.

There were some case reports of acute limb ischemia related to the EXOSEAL.[7-9] All of them reported that the plug completely fell into the vessel, that is, embolism below the puncture site. In contrast, in this case, the plug

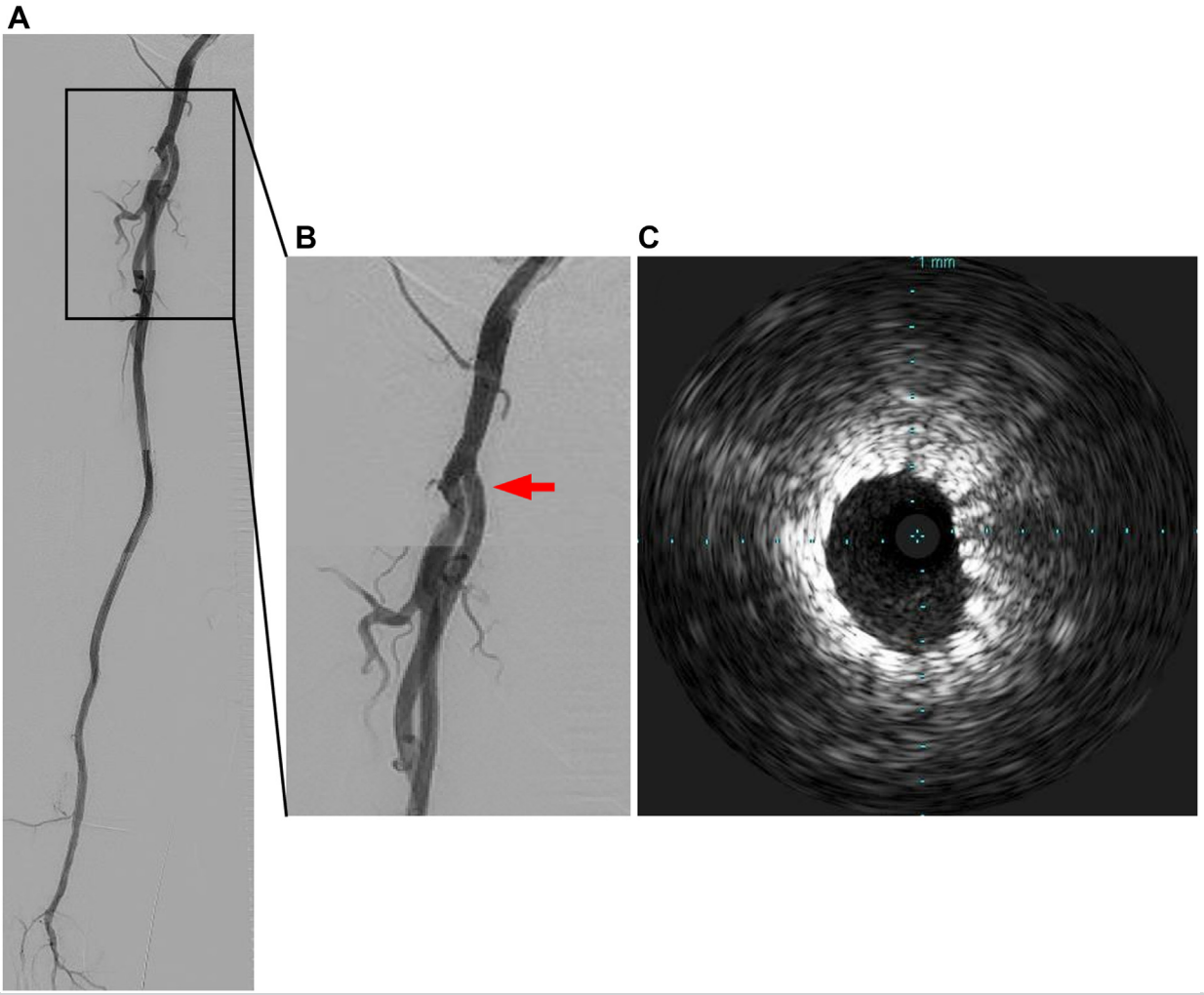

Fig 4. A, Final angiography showed a favorable flow in the superficial femoral artery (SFA). **B,** Angiography at the site of the plug protrusion (*red arrow*). It remained no stenosis. **C,** Intravascular ultrasound (IVUS) image at the *red arrow* **(B)**. The stent was expanded enough.

protruded but achieved successful hemostasis. With IVUS imaging, we could find out the protrusion of the EXOSEAL plug, which had high density and was easily distinguishable from the surrounding tissue. It is rare to look at the IVUS image of the plug because the plug is absorbed within 3 months.

We consider that a slight protrusion of the plug into the vessel may occur asymptomatically and without notice. Nakamura[10] reported a case of the deployment into the vessel wall that caused lumen narrowing. In that report, the patient was asymptomatic and was followed up with the expectations of EXOSEAL absorption, the plug was completely absorbed, and the lumen narrowing disappeared 3 months later.[10] We recommend checking whether there is any stenosis at the puncture site by ultrasound imaging after using EXOSEAL. As spontaneous healing could occur, whether or not to perform the intervention would depend on the severity of the symptoms.

The IVUS imaging showed that a lumen of the SFA was dilated at the protrusion point after the balloon. If there was no thrombus and dissection, it might have been enough only with the balloon dilatation with the expectations of the EXOSEAL plug absorption. However, we put the stents because of controlling the thrombus and dissection. The expansion of the stent at the site of the plug was effective in terms of its sealing and alleviation of the thrombus and dissection (Fig 4).

CONCLUSIONS

EXOSEAL has a rare complication of acute limb ischemia. IVUS imaging is effective to find out whether the plug is the cause of acute limb ischemia. Thus, in acute limb ischemia after using EXOSEAL, IVUS imaging is a useful method to decide the strategy of the intervention.

We obtained the patient's consent to present the case and to provide vascular images.

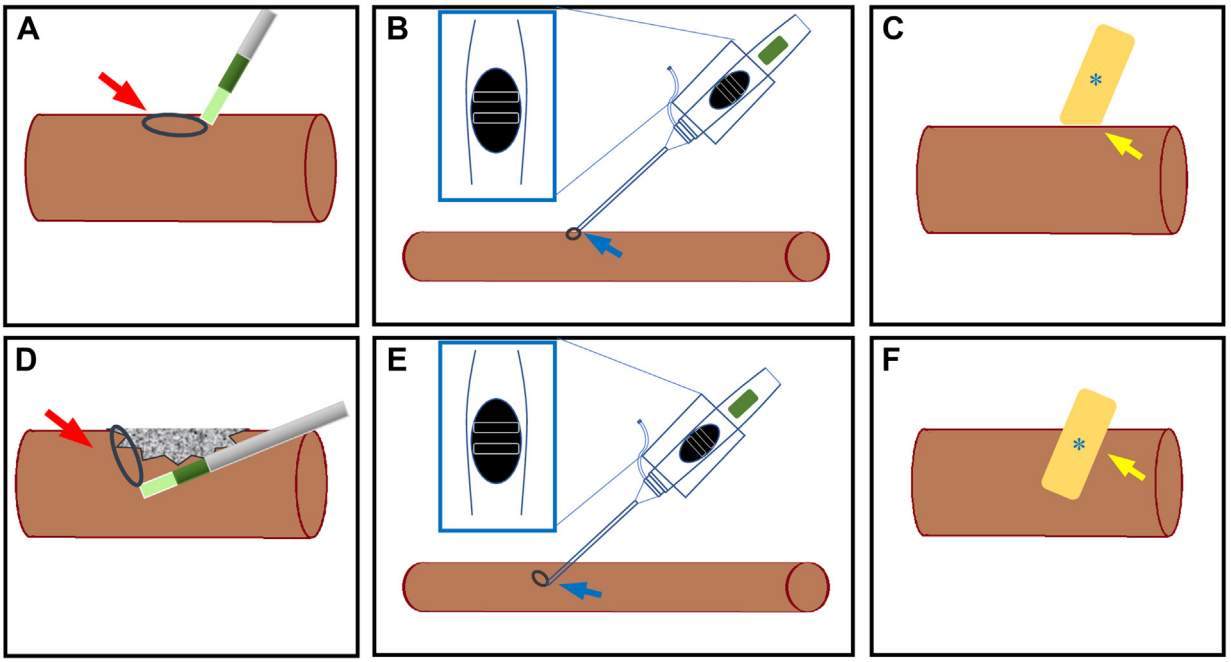

Fig 5. A, In a normal situation, the indicator wire (*red arrow*) is stretched by the vessel wall. **B,** The visual indicator changes to all black when the indicator wire is stretched (inside the *blue box*). That means the tip of EXOSEAL is outside of the vessel (*blue arrow*). **C,** The plug (*blue asterisk*) is deployed between outside the vessel and inside the fascia of the neurovascular bundle and closes the subcutaneous puncture route (*yellow arrow*). **D,** In this case, the indicator wire got entangled in the narrow and calcified superficial femoral artery (SFA) (*red arrow*) and was stretched. **E,** The visual indicator changed to all black despite the tip of EXOSEAL still inside the vessel (*blue arrow*). **F,** The plug (*blue asterisk*) was deployed into the vessel (*yellow arrow*).

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