

Maldeployment of Celt ACD vascular closure device

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ABSTRACT

Vascular closure devices have become more popular in some clinical settings because they allow for quicker hemostasis and earlier ambulation. Although these devices have several benefits compared with manual compression, errors in deployment can result in a multitude of complications. We have presented two cases in which the Celt arterial closure device was maldeployed and caused significant patient morbidity. (*J Vasc Surg Cases Innov Tech* 2022;8:39-41.)

Keywords: Celt; Closure; Hemostasis

The use of vascular closure devices (VCDs) has increased rapidly in recent years. Compared with manual compression, VCDs can reduce the time required to obtain hemostasis and allow for earlier patient mobilization. However, they carry a risk of complications such as dissection, hematoma, pseudoaneurysm, and arteriovenous fistula.

The Celt arterial closure device (ACD; Vasorum, Dublin, Ireland) is a VCD designed to provide immediate hemostasis and closure of a femoral puncture site. It is composed of biocompatible stainless steel and achieves hemostasis by anchoring both sides of the arterial wall with bendable wings.

In the present report, we have described two cases with failure of deployment of the device, leading to intravascular loss of the Celt device with operative removal in one and advancement of the Celt device into the deep femoral artery (DFA) in the second. Both patients provided written informed consent for the report of their case details and imaging studies.

CASE REPORT

Patient 1. A 74-year-old man had undergone left superficial femoral artery (SFA) atherectomy via retrograde right femoral artery access using a 6F, 45-cm long pinnacle sheath (Terumo Corp, Tokyo, Japan) at an office-based laboratory. Closure of the right femoral artery at the puncture site was performed using a Celt closure device. The patient developed a right femoral pseudoaneurysm and had received a successful thrombin injection the day after the procedure. The patient had subsequently developed symptoms of intermittent claudication of

the right lower extremity when walking 100 yards with an easily palpable right femoral pulse but absent popliteal posterior tibial and dorsalis pedis pulses and an ankle brachial index of 0.6 on the right. An arteriogram of the right lower extremity via a left femoral approach showed the Celt device in the right distal SFA (*Fig 1*) with near occlusion of the artery. Five days after the patient's initial procedure, the patient underwent removal of the Celt device via a longitudinal incision in the lower thigh. At the same procedure, a right SFA endarterectomy was performed because the closure device was intimately adherent to the arterial wall. A bovine pericardial patch repair was performed, with restoration of the distal pulses in the right lower extremity and an ankle brachial index of 1.0.

Patient 2. An 83-year-old woman had undergone coronary intervention for new-onset atrial fibrillation with associated left ventricular dysfunction. Right coronary artery angioplasty and stenting was performed via a right femoral artery approach. A Celt closure device was used at the right femoral access site. However, closure was not successful, and the patient developed a hematoma in the right groin with the Celt device found in the right mid-SFA. Using left femoral artery access and an internal mammary artery catheter, the right common iliac and external iliac arteries were cannulated, followed by passage of a glide wire (0.35 × 180 cm) into the right common femoral artery (CFA; Terumo). A 45-cm-long, 6F pinnacle sheath (Terumo) was inserted, and a 0.014-in., 260-cm-long CHOICE PT guidewire (Boston Scientific, Marlborough, Mass) was used. The guidewire was advanced into the distal SFA beyond the dislodged Celt device. A 5-mm × 2-cm long angioplasty catheter was inflated distal to the embolized Celt device and inflated to bring the device toward the pinnacle sheath and into the distal profunda femoral artery. A small perforation was present near the origin of the SFA, which was controlled by prolonged low pressure balloon inflation with a 7-mm × 2-cm angioplasty catheter. The patient developed a moderate size hematoma in the groin that was not pulsatile. A computed tomography angiogram of the pelvis was obtained (*Fig 2*), which showed a hematoma lateral to the femoral vessels without any evidence of a pseudoaneurysm. The hematoma was managed conservatively. Because the patient did not complain of ischemic symptoms of the right lower extremity (intermittent claudication or rest pain), removal

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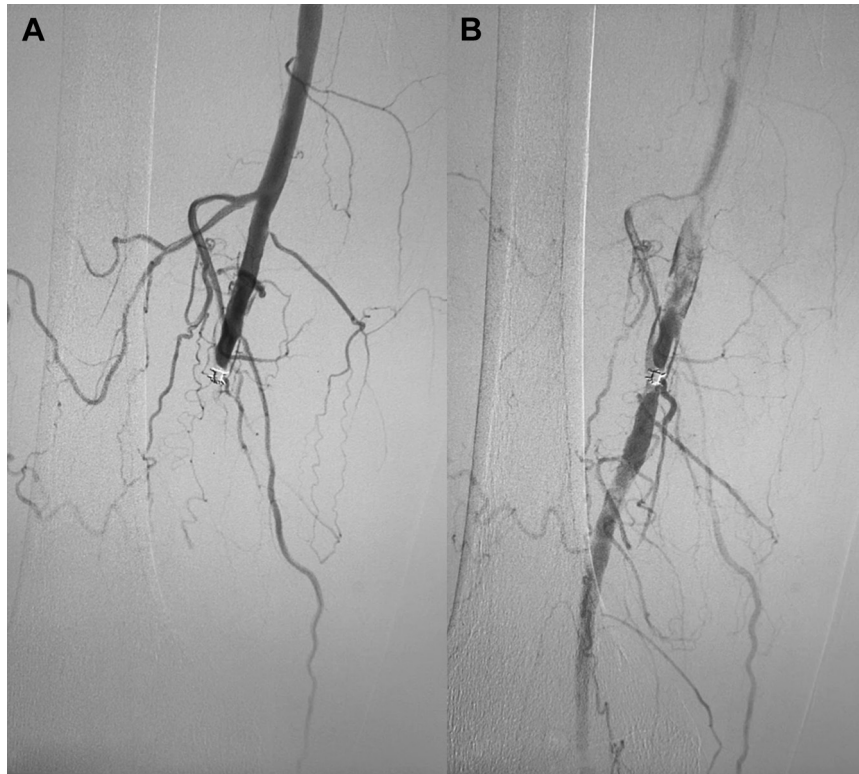


Fig 1. A,B, Angiographic depictions of a maldeployed Celt arterial closure device (ACD) within the right superficial femoral artery (SFA).

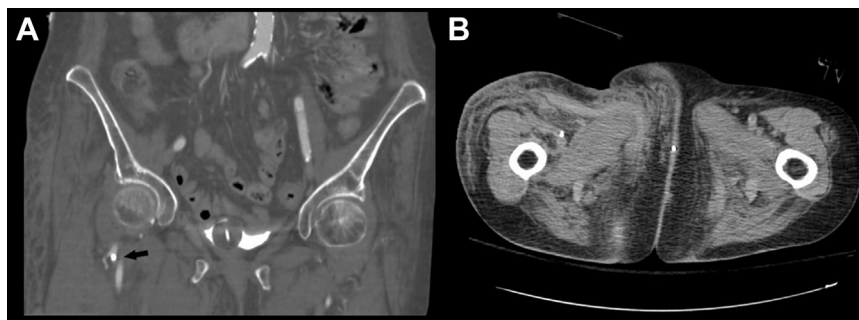


Fig 2. A,B, Views of computed tomography angiogram of the maldeployed Celt arterial closure device (ACD) in the distal profunda femoral artery.

of the Celt device from the DFA was not recommended because of her poor cardiac and overall medical condition.

DISCUSSION

Vascular closure devices can be classified into three main categories according to their mechanism of obtaining hemostasis:

1. Vascular plug (Angio-Seal, Terumo; VasoSeal, Data-scoped Corp, Mahwah, NJ; EXOSEAL, Cordis Corp, Baar, Switzerland)
2. Vascular clips (StarClose, Abbott Vascular, Chicago, Ill; Angiolink EVS [expanding vascular system], Angiolink Corp, Taunton, Mass) and the Celt ACD (Terumo)

3. Suture closure (Perclose, Abbott Vascular; SuperStitch Vascular Suturing Device, Sutura, Inc, Como, Italy)

Immediate or early repuncture of the femoral artery is relatively contraindicated with the use of collagen plug devices such as Angio-Seal (Terumo) owing to the potential for local infection and the time required for collagen biodegradation over the arterial puncture site to occur.

The Celt ACD is deployed in three steps. The device is inserted into the lumen via the existing femoral sheath, and the distal wings are extended. The device is then retracted to oppose the distal wings against the luminal



Fig 3. Celt arterial closure device (ACD).

wall, and the proximal wings are deployed to anchor the plug (Fig 3). The anchored stainless steel device is then released from the delivery handle. In addition to scarring and tissue reactions, VCDs such as the Celt ACD can cause potential difficulties for future arterial access. Extraluminal vascular devices are safer for patients with arterial occlusive disease; however, stenosis or occlusion of the access artery and femoral neuralgia are more common. Jan et al,¹ in a prospective, nonrandomized study of the Celt device in 49 patients, observed significant decreases in the time required for hemostasis. They reported mechanical failure of the delivery system with deployment intra-arterially, retrieval of the implant under radiological guidance, and subsequent operative closure of the puncture site. Cahil et al² reported endovascular snare retrieval of the Celt ACD from the CFA. Other studies have demonstrated the effectiveness of novel vascular closure devices. Wong et al³ demonstrated the superiority of the Celt ACD with a decreased time required for hemostasis in fully anticoagulated patients and a similar 30-day rate of vascular complications compared with manual compression. Although the Celt ACD does have an increasing body of data supporting its use, at present, the available literature for the Celt ACD is less than that for other more well-known closure devices.

VCDs have been most often used after retrograde access of the CFA. Recently, VCDs have been used after antegrade puncture of the femoral artery. The Celt ACD device has been approved for obtaining hemostasis of both antegrade and retrograde punctures. Data have demonstrated the use of antegrade closure with the device to be safe; however, recent studies have suggested an increased risk of access site hematoma formation.^{4,5}

In our first patient, the distal wings were deployed but the anchoring proximal wings had not opened. The

maldeployment was likely a combination of atherosclerosis and technical error, because the puncture site was in the proximal SFA. The combination of the small diameter of the SFA and the associated plaque likely resulted in the improper deployment of the wings. In our second patient, the operator was able to retrieve the maldeployed ACD by placing the Celt ACD into the sheath and subsequently deploying it into the distal branches of the DFA. Deployment of the device into the DFA was decided at an office-based laboratory before the vascular surgery consultation and is not the optimal management of a maldeployed device. Once the vascular team was involved, no surgical intervention was performed owing to the patient's poor medical condition, including cardiomyopathy with a decreased ejection fraction. At the last follow-up, the patient had not experienced any ischemic symptoms of the right lower extremity. These two cases emphasize the potential maldeployment of the Celt ACD device, which can lead to significant morbidity and an increased length of stay.

CONCLUSIONS

In the present report, we have highlighted the unique complications that can occur with the Celt ACD and the strategies and bailout options available to treat maldeployment.

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