Catheterization and Cardiovascular Interventions 83:556–559 (2014)

Fluoroscopy-Guided Snare Retrieval of the Celt ACD® Metallic Vascular Closure Device Following Failed Deployment

Thomas J. Cahill,[1] MA, MBBS, MRCP, Kiyoshi Choji,[2] MD, PhD, FJCR, and Attila Kardos,[1*] MD, PhD, FRCP, FESC

We report a case of endovascular snare retrieval of a new stainless steel vascular closure device (Celt ACD®, Kimal, Middlesex, UK) from the common femoral artery, following device failure after diagnostic coronary angiography. The stainless steel composition of the device aided successful fluoroscopic localization and removal. © 2013 Wiley Periodicals, Inc.

Key words: femoral artery; hemostatic techniques/instrumentation

INTRODUCTION

The use of vascular closure devices (VCDs) has increased dramatically in the last decade, with numerous devices available and a global market approaching $1 billion in 2013[1,2]. Compared with manual compression, VCDs reduce time to hemostasis and mobilization but carry a risk of complications including hematoma, dissection, vascular occlusion, embolization, pseudoaneurysm, infection, and arteriovenous fistula [3,4]. Celt ACD® is a new VCD which achieves hemostasis by delivery of a stainless steel plug, anchored on both sides of the arterial wall by extendable wings. This case illustrates failure of the device leading to an intravascularly lost metallic plug, with an endovascular retrieval strategy.

CASE REPORT

A 68-year-old woman attended for elective coronary angiography. Right common femoral artery (CFA) access was obtained without ultrasound guidance and a 6F sheath inserted. Coronary angiography demonstrated mild plaque in the left anterior descending artery but no obstructive disease. As standard in our centre, a contrast injection through the sheath at the end of the procedure confirmed normal femoral anatomy without significant atherosclerotic disease.

Although previously experienced with Angio-Seal®, following a prospective audit in our centre, our standard practice is now to use Celt ACD® (Kimal, Middlesex, UK) by default. Celt ACD® has been granted CE marking and is under evaluation for FDA approval in the US. A Celt ACD® was chosen by the first operator to seal the arteriotomy, who had previously used the device in 45 patients without complication.

The Celt ACD® is deployed in three steps (Fig. 1). The device is first inserted into the lumen via the existing femoral sheath and the distal wings are extended. The operator then partially retracts the device to appose the distal wings against the luminal wall. At step two, the proximal wings are deployed, to anchor the plug from the extraluminal side. Step three is release of the anchored metal plug from the delivery handle.

In this case, stage one occurred normally, with insertion into the CFA and extension of the luminal, distal wings. As the device was retracted, the metal plug prematurely separated from the delivery mechanism, prior to deployment of the proximal wings which anchor the device to the arterial wall.

The arteriotomy site started bleeding immediately. Manual compression was applied for ten minutes,

[1]Department of Cardiology, Milton Keynes Hospital, NHS Foundation Trust, United Kingdom
[2]Department of Radiology, Milton Keynes Hospital, NHS Foundation Trust, United Kingdom

Conflict of interest: Nothing to report.

*Correspondence to: Attila Kardos, MD, PhD, FRCP, FESC, Department of Cardiology, Milton Keynes Hospital NHS Foundation Trust, 8H Standing Way, Eaglestone, Milton Keynes MK6 5LD, United Kingdom. E-mail: attila.kardos@cardiov.ox.ac.uk

Received 19 August 2013; Revision accepted 30 September 2013

DOI: 10.1002/ccd.25229
Published online 6 October 2013 in Wiley Online Library (wileyonlinelibrary.com)

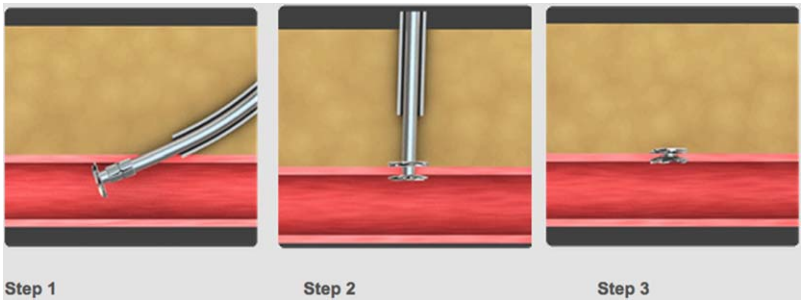

Fig. 1. Three step deployment of the Celt ACD® vascular closure device. The device is inserted into the lumen via the existing femoral sheath and the distal wings are extended (1). The device is then retracted to oppose the distal wings against the luminal wall and the proximal wings are deployed, to anchor the plug from the extraluminal side (2). The anchored stainless steel device is then released from the delivery handle (3). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

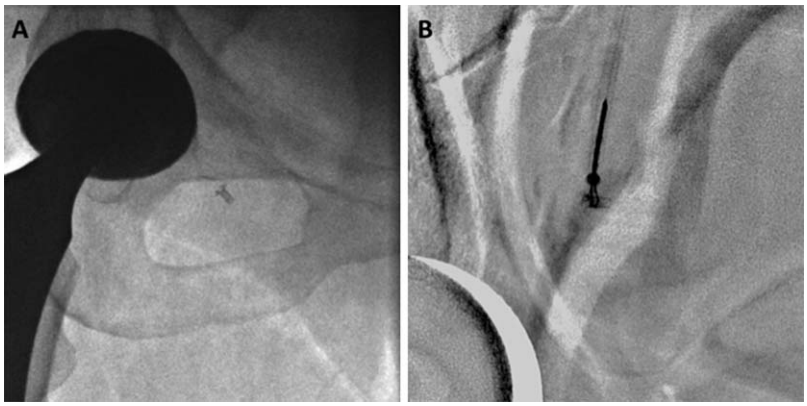

Fig. 2. (A) The semi-deployed Celt ACD® device visualized under fluoroscopy, with the distal wings extended. The device could be seen to pulsate with the femoral artery (online AVI). (B) The Celt ACD® device captured by endovascular snare, as seen under digital subtraction fluoroscopy.

which achieved complete hemostasis. Once hemostasis was ensured, the puncture site was screened under fluoroscopy to allow visualization of the metallic plug, which was pulsating within the CFA. This demonstrated that the distal wings had deployed, but that the anchoring proximal wings were not opened (Fig. 2A). The patient had no symptoms of leg ischemia and had palpable foot pulses.

Due to the risk of distal embolization and vessel occlusion, an urgent endovascular retrieval strategy was proposed, with surgical intervention planned should this fail. The absolute risk of thrombosis formation on the plug was felt to be low in the short timescale awaiting retrieval (<30 min) and no anticoagulation was given. Vascular access was obtained via the left CFA and a 6F sheath inserted. Retrograde access to the right iliac and femoral arteries was obtained, and under subtraction fluoroscopic guidance, a triple-looped EN snare (Merit Medical, South Jordan, UT) used to grab the Celt ACD® plug (Fig. 2B). This was performed in a single pass and was subsequently retracted to the left CFA and removed en bloc through the left groin puncture (Fig. 3). Ultrasound of the right arteriotomy confirmed no new bleeding, possibly because the retained plug was fully within the CFA, rather than in the arterial wall, allowing manual compression to achieve effective hemostasis. The patient was observed overnight and discharged the following day. Given her absence of symptoms at 6-week follow-up, no further imaging of the puncture site by ultrasound or CT was performed.

The Celt ACD® device was returned to the manufacturer (Vasorum, Ireland) for analysis. An internal manufacturers' analysis confirmed primary device failure, rather than mis-deployment or misuse. Following this

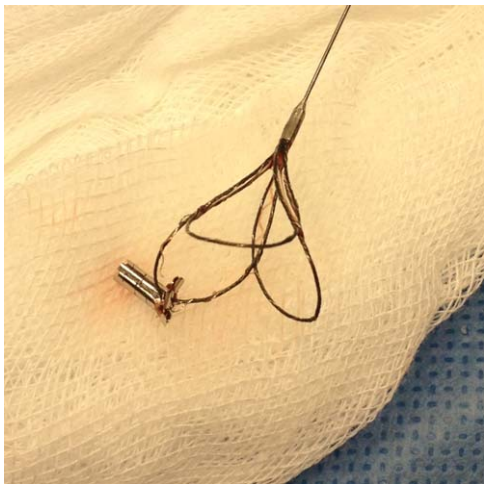

Fig. 3. Celt ACD® device following successful removal. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

critical event the design of the attachment between the metallic plug and the deployment handle is now being re-evaluated.

DISCUSSION

Hemostatic VCDs fall into three main classes based on their mechanism of action: those deploying a vascular plug (e.g., Angio-Seal®, VasoSeal®, ExoSeal®, Celt-ACD®), those using clips (e.g., StarClose®, Angiolink EVS®) and those which perform suture closure (e.g., Perclose®, SuperStitch®) at the arteriotomy site [5].

Each type of VCD has distinct advantages, disadvantages, and potential complications. Immediate or early re-puncture is relatively contraindicated with collagen plug VCDs such as Angio-Seal® due to possible increased risk of local infection and the required time to allow collagen biodegradation over the arteriotomy site. Furthermore, tissue reaction, scar formation, or long-term plug persistence (in the case of Celt ACD®) can potentially hinder future surgical access. In contrast, suture-based devices allow early and repeated access.

VCDs also differ on whether an intraluminal component remains following deployment, which may increase the incidence of late complications. For example, Angio-Seal® and Celt ACD® both leave an intraluminal plug, compared with the suture devices and some plug devices (e.g., VasoSeal®, ExoSeal®) which are fully extraluminal. Extraluminal VCDs have the advantage of being safe in patients with peripheral vascular disease. The pattern of complications is influenced by the type of VCD: stenosis or occlusion at the puncture site and femoral neuralgic syndrome have been described more frequently with the suture closure devices, and late femoral artery thrombosis and embolization is more common with plug devices [5].

The proposed benefits of the Celt ACD® include reduced incidence of subcutaneous tissue reaction, use of the existing sheath without further arterial dilatation, reduced patient discomfort, and the ability to visualize the device under fluoroscopy to allow early re-puncture away from the plug. Like other intraluminal devices, these must be weighed up against the potential for device failure with distal embolization, as occurred in this case. A potential disadvantage of the metallic design is the potential risk of thrombus formation on the retained intraluminal metallic wings, prior to endothelialization, although to our knowledge this has not been reported in early trials.

The Celt ACD® is unique in its high-visibility on fluoroscopy, and while intended to permit remote re-puncture, this aided endovascular retrieval in this case. There are previous reports of endovascular removal of Angio-Seal® VCDs, but these attempts have been complicated by difficult direct visualization, with partial retrieval or distal embolization following manipulation [6,7]. Previous endovascular strategies have employed use of the Simpson atherectomy device, gooseneck catheter, and Fogarty balloon retrieval. Snare retrieval of an Angio-Seal® arteriotomy device has also been reported, but was again complicated by difficult visualization of the foreign body under fluoroscopy [8].

CONCLUSION

In this case of vascular closure device malfunction, fluoroscopic visualization of the stainless steel Celt ACD® allowed immediate and straightforward endovascular retrieval without the need for surgical intervention.

LITERATURE CITED

1. Bechara CF, Annambhotla S, Lin PH. Access site management with vascular closure devices for percutaneous transarterial procedures. J Vasc Surg 2010;52:1682–1696.
2. Dauerman HL, Applegate RJ, Cohen DJ. Vascular closure devices: The second decade. J Am Coll Cardiol 2007;50:1617–1626.
3. Das R, Ahmed K, Athanasiou T, Morgan R, Belli A-M. Arterial closure devices versus manual compression for femoral haemostasis in interventional radiological procedures: A systematic review and meta-analysis. Cardiovasc Interv Radiol 2011;34:723–738.

4. Carey D, Martin JR, Moore CA, Valentine MC, Nygaard TW. Complications of femoral artery closure devices. Catheter Cardiovasc Interv 2001;52:3–7.
5. Hon LQ, Ganeshan A, Thomas SM, Warakaulle D, Jagdish J, Uberoi R. An overview of vascular closure devices: What every radiologist should know. Eur J Radiol 2010;73:181–190.
6. Goyen M, Manz S, Kröger K, Massalha K, Haude M, Rudofsky G. Interventional therapy of vascular complications caused by the hemostatic puncture closure device Angio-Seal. Catheter Cardiovasc Interv 2000;49:142–147.
7. Rafeh NA, Saiful FB, Khoueiry G, Zgheib M, Arain S. Successful endovascular extraction of newer generation Angio-Seal collagen plug and anchor after acute embolization. Vascular 2013:1–4.
8. Garg N, Rajpurohit N, Webel R. AngioSeal device malfunction: A case report of dilator tip fracture and successful endovascular retrieval. EJVES Extra 2011;22:e49–e51.