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Technical Report

Endovascular treatment for Angio-Seal-related complications: long-term outcome

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Introduction

Vascular closure devices (VCD) are used commonly in interventional radiology and cardiology practice to enable more rapid mobilisation after percutaneous femoral artery access. Although meta-analyses have shown no significant difference in bleeding complications from VCDs compared with manual compression,[1] there is a trend towards fewer complications,[2] and patients are able to ambulate quicker.[3]

At our institution, the Angio-Seal vascular closure device (St Jude Medical, St Paul, MN, USA) is routinely used following common femoral artery access. The Angio-Seal closes the arteriotomy by percutaneous access through a dedicated sheath. It consists of a bio-absorbable intravascular polymer anchor and a collagen plug positioned extravascularly, and a suture securing the two components. Haemostasis is achieved by sandwiching the arteriotomy between the intravascular anchor and the extravascular collagen plug.[4]

There have been reported thromboembolic complications related to the intravascular component of the Angio-Seal device. This has resulted in acute limb ischaemia due to arterial occlusion both at the common femoral artery access site[5–10] and popliteal artery.[11] Surgical management has been the mainstay of treatment,[10] with Steinkamp *et al.*[12] having used excimer laser angioplasty with success in small numbers. Rekik *et al.*[13] have utilised a combination of angioplasty and primary stenting.

The present report describes the authors' experience of treating complications of arterial stenoses and occlusions resulting from use of the Angio-Seal device with angioplasty alone or a combination of angioplasty and thrombolysis.

Technique

Patients were considered for endovascular treatment if they had common femoral artery (CFA) occlusions secondary to Angio-Seal malfunction less than 10-days old, or stenoses of any age. Pre-procedure imaging was performed if there was a delay in presentation or doubt as to the aetiology of the new symptoms. Informed consent was obtained from patients.

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Endovascular treatment was performed with access from the contralateral common femoral artery with a 6 F Destination sheath (Terumo, Tokyo, Japan) over the aortic bifurcation. An angiogram was performed to confirm the location of the stenosis or occlusion (Fig 1). In occlusions, >1 cm in length, intra-arterial Alteplase (Actilyse, Boehringer Ingelheim, Biberach an der Riss, Germany) was administered as a 10 mg bolus for thrombolysis, because of the risk of thrombus associated with Angio-Seal endplate migration into the CFA. The patient was then removed from the interventional radiology room for 1–2 hours, after which repeat angiography was performed to assess response. Thrombolysis was not used for patients with CFA stenosis or short occlusions (≤1 cm). Five thousand international units of intra-arterial heparin was used in all patients. A curved tip 0.035 inch hydrophilic guide wire (Terumo) was manipulated through the stenosis/occlusion and angioplasty was performed with over-the-wire balloon catheters (5–7 mm diameter balloons; Fig 2). The end point was restoration of flow with no residual stenosis >30% with prolonged balloon inflation performed as required to achieve this end point (Fig 3). Patients remained on intravenous heparin for 24 hours after the procedure and received aspirin 75 mg daily indefinitely and clopidogrel 75 mg daily for 3 months.

Results

In the 53-month period reviewed, there were 12 patients with Angio-Seal dysfunction (Table 1). In all cases, a retrograde approach was used during the initial procedure. Nine patients underwent endovascular management and three patients with occlusion of >10 days had surgical repair. Two patients with CFA occlusions >1 cm received 10 mg intra-arterial Alteplase prior to angioplasty. In both cases the thrombus had resolved 1 hour later without the need for prolonged thrombolysis. One patient had a balloon expandable stent placed to the external iliac artery (EIA) because of a concurrent EIA and CFA occlusion. The mean time to angioplasty in the endovascular group was 15.2 days (range 0–77 days).

The single case of intravascular footplate embolisation to the popliteal artery occurred in a young woman who underwent renal artery angioplasty for fibromuscular dysplasia. She reported intermittent claudication at her 6-week check-up. Imaging with Duplex and magnetic

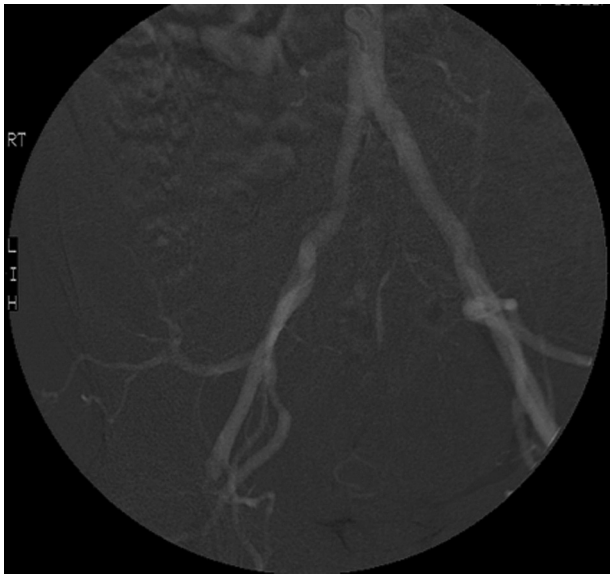

Figure 1 Angiographic image showing occlusion of the right CFA.

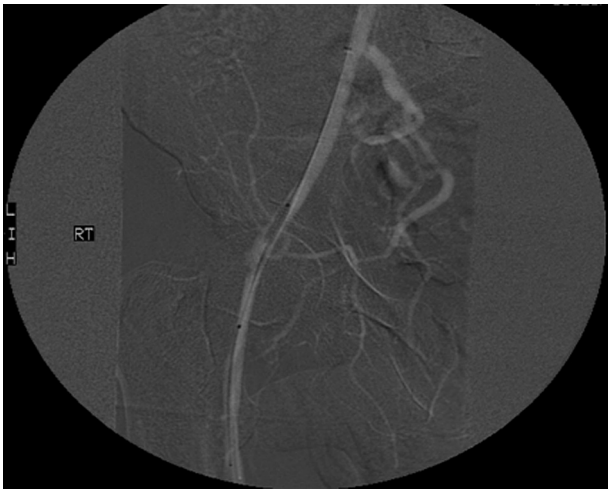

Figure 2 Roadmap image showing angioplasty balloon across previous occlusion.

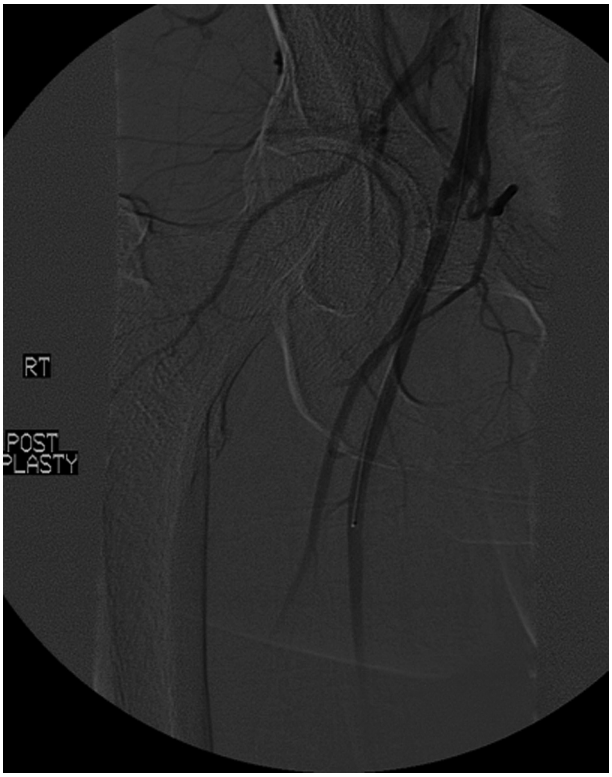

Figure 3 Post-angioplasty with non-flow-limiting mild residual stenosis of the right CFA.