



Brisk Bleeding during Deployment of the Angio-Seal Vascular Closure Device: What the User Manual Doesn't Tell You

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Abstract

Brisk puncture site bleeding during deployment and application of traction to the Angio-Seal footplate indicates that the foot plate is not anchored correctly against the arterial wall. In this situation, the collagen pack should not be deployed. A more vigorous pull should be applied to disengage the mal-positioned footplate, and to bring it to the arteriotomy site. Once the bleeding stops, the collagen plug can be deployed safely. Deploying the collagen plug before the bleeding stops can deliver the plug into the vessel lumen, resulting in arterial thrombosis. We review four patients in our practice that experienced this event.

Introduction

Vascular access closure devices are commonly used to achieve hemostasis following femoral arterial punctures, and to facilitate early ambulation of patients after angiography. The Angio-Seal Vascular Closure Device (St Jude Medical, St Paul, MN) is a widely used such device. It consists (Figure 1) of a footplate or anchor attached to a string that is loaded with a collagen plug. The foot plate is placed inside the artery and pulled by the string against the arterial wall to occlude the arteriotomy site. The collagen plug is then packed by a pusher catheter immediately outside the artery to seal the puncture site and bring about hemostasis. The string is then cut to release the device. The footplate, collagen plug and string are all bio-absorbable. Several authors [1-3] have reported incidents where collagen plugs have been found within the vessel lumen after deployment, leading to lower limb ischemia. The Manufacturer and User Facility Device Experience (MAUDE) database shows over 500 of such incidents. In our practice there were 4 patients in over a 6 year period in whom lower limb ischemia or numbness occurred within several hours after deployment of the 6F STS plus version of Angio-Seal, three of whom required surgical intervention to remove the collagen plug lodged inside the artery. Reports on how this event can be avoided are lacking. The purpose of our report is to elucidate the mechanisms leading to intra-arterial placement of the collagen plug, and steps that can be taken to prevent it. Once aware of this, we were able to avert the complication in a fifth patient. Our institution does not require Research Ethics approval for retrospective case reports.

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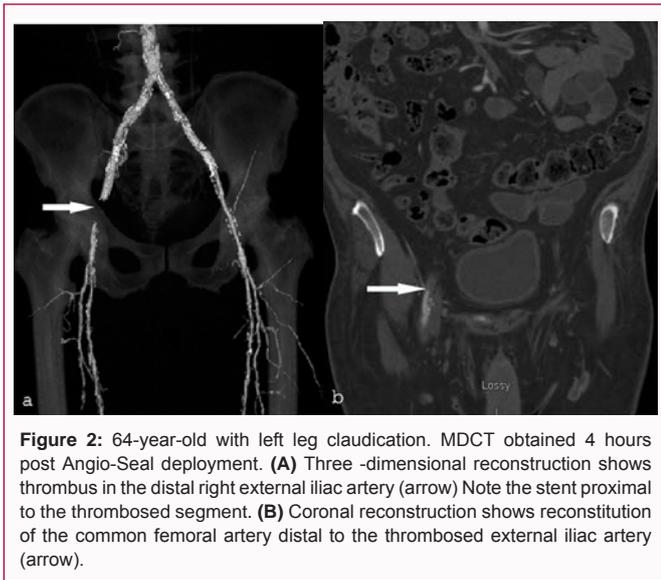
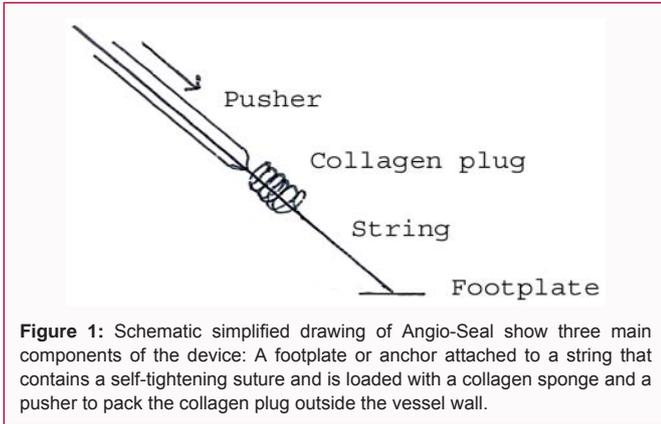
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Case Presentation

Case 1

A 64 year old man presented with a chronically infected wound site following left tarso-metatarsal amputation. Because of increasing ischemia and necrosis, he was referred for possible percutaneous revascularization. The procedure was performed from a right common femoral arterial approach. Self-expanding metallic stents were noted in the right common iliac artery and bilateral distal external iliac arteries. Angioplasty of the distal left superficial femoral artery, tibio-peroneal trunk, proximal peroneal artery and anterior tibial artery were performed. At the end of the procedure, a 6 F Angio-Seal device was deployed, following which there was brisk bleeding from the puncture site. This was attributed to device failure, and manual compression was applied for 10 minutes to obtain hemostasis. Three hours later the patient developed features of acute right lower limb ischemia, for which a MDCT was done, revealing a short segment of occlusion immediately distal to the external iliac stent and reconstitution of flow in the common femoral artery through the collaterals (Figure 2). This was suspected to be due to the collagen plug of the Angio-Seal, and the patient was transferred to the operating room. At surgery the Angio-Seal device was found lodged



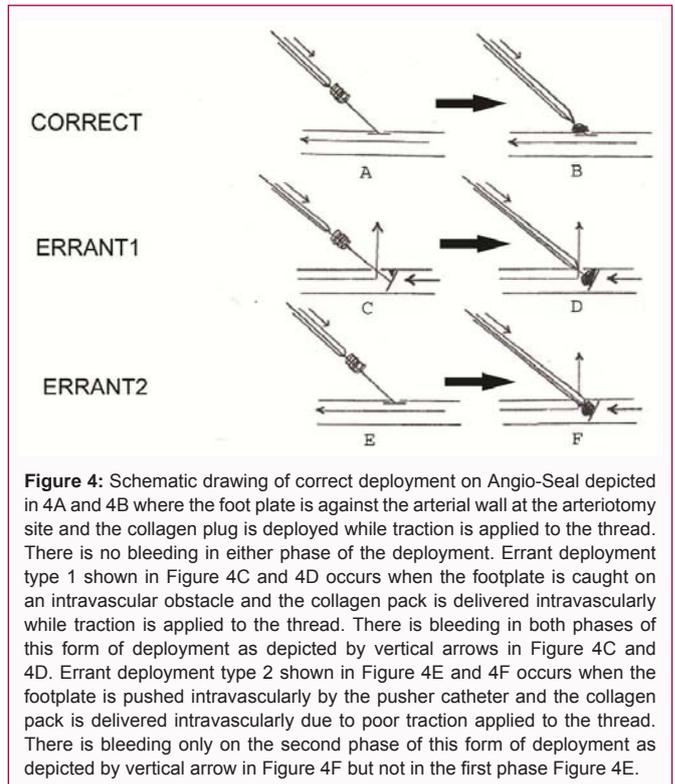
at the distal end of the external iliac artery stent. Following removal of the device there good arterial flow was restored.

Case 2

A 72 year old man with a past history of left external iliac artery stenting presented with painful left buttock claudication. Via a Left common femoral arterial approach, angioplasty of the left external iliac artery and stenting of the left common iliac – proximal external iliac artery were performed. At the end of the procedure, 6 F Angio-Seal was deployed, following which the patient had significant brisk bleeding at the puncture site. Hemostasis was achieved by 15 minutes of manual compression. Four hours later the patient developed left lower limb ischemia and he was operated upon. The Angio-Seal was found inside the proximal common femoral artery and there was complete occlusion of distal external iliac artery. Several atheromatous plaques were seen in both vessels, for which endarterectomy was performed. Good arterial flow was obtained following device removal and endarterectomy.

Case 3

A 58 year old woman presented with claudication of the right leg. An MDCT revealed a severe stenosis in the right distal superficial femoral artery for which the patient underwent a successful angioplasty from an antegrade right femoral approach. Following the deployment of the footplate of a 6F Angio-Seal severe bleeding was encountered which did not stop after deployment of the collagen plug. Manual



groin compression was applied for 15 minutes and hemostasis was obtained. Shortly after the deployment of Angio-Seal the patient developed discoloration right foot and this was attributed to vascular spasm. But symptoms worsened over the following two hours and she complained of numbness in her foot. An angiogram from the contra lateral femoral artery showed occlusion of the right femoral artery which was not present on a diagnostic arteriogram 2 months earlier (Figure 3A and B). This necessitated surgical exploration disclosing the collagen plug within the common femoral arterial lumen. After removal of the plug and thrombectomy the circulation in the right leg improved and the ischemia resolved.

Case 4

A 45 year old woman presented with cervical bleeding due to cancer of cervix. Urgent embolization of the anterior trunk of both internal iliac arteries with Gelfoam torpedoes was performed from a right femoral approach. A 6 F Angio-Seal was used for hemostasis. The footplate was deployed, stopping bleeding at the puncture site. However the patient was severely cachectic and lacking in subcutaneous fat, such that when the collagen plug was packed under the skin, it was inadvertently pushed intravascularly. A brisk non-pulsatile hemorrhage ensued which was controlled by manual compression. Several hours later, the patient complained of numbness of the right foot, and MDCT confirmed isolated right common femoral artery occlusion. Since the symptoms were relatively mild and the patient's life expectancy was limited, the attending physician decided to treat this conservatively.

Case 5

A 75 year old woman presented with severe left lower limb claudication. After a diagnostic arteriogram via left femoral artery access, left common iliac artery angioplasty and stenting were performed. Post procedure, a 6F Angio-Seal was deployed in the left common femoral artery. Brisk puncture site bleeding was noted post traction, but prior to packing of the collagen plug. We exposed the left foot and found it to be cold and discolored. Because of our earlier experiences we suspected this was the result of inadvertent entrapment of the footplate by a plaque, causing the obstruction of the vessel lumen. As the string had not yet been cut, we were able to pull back the footplate more forcibly, stopping the hemorrhage and confirming that the foot plate was now in correct position against the arterial wall. The collagen plug was then deployed and packed. Foot color returned to normal promptly.

Discussion

When the Angio-Seal device is deployed correctly, a mechanical seal is created between the anchored footplate on the intimal surface and the collagen plug on the adventitial surface of the artery (Figure 4A and B), securing hemostasis. If the footplate is not positioned correctly, the collagen plug can be injected inadvertently into the vessel lumen.

Dregelid et al. [2] reported that it was not advisable to use an Angio-Seal if the superficial femoral artery was punctured, as this could result in intraluminal lodging of the device. However they did not elaborate upon its mechanism or how this complication might be anticipated or steps that can be taken to prevent it.

We propose that there are two general situations leading to vessel occlusion from the mal-positioned closure device. The first mechanism is deployment of the Angio-Seal in the presence of an intra-arterial narrowing due to a nearby arterial division, stenotic plaque, metallic stent, or simple arterial spasm. Each of these situations can singly or in common, lead to errant lodging of the foot plate, and subsequent intraluminal lodging of the collagen plug.

With the footplate caught somewhere other than the arteriotomy site, the arteriotomy access will remain open as shown in Figure 4C, resulting in non pulsatile back-bleeding from the artery distal to the arteriotomy site. Many interventional radiologists would intuitively rush to deploy the collagen pack to stop the bleeding, and would then cut the device string. However in doing so they will in fact deploy the collagen plug inside the vessel as shown in Figure 4D. Since the intra-

arterial plug does not close the arteriotomy site the back-bleeding will continue and would require several minutes of manual pressure until the bleeding stops. The partial thrombosis will then progress to a complete thrombosis over the following few hours, causing ischemic symptoms similar to those that occurred in our first three patients.

A second mechanism which could lead to intra-arterial lodging of the Angio-Seal plug when the interventional radiologist does not hold adequate traction on the string during the packing of the collagen. This permits the footplate to migrate further in the vessel under pressure from the pusher catheter and the collagen enters the lumen during the packing stage (Figure 4E and F). This condition, which was seen in our case 4 and a few other cases reported in the literature [5] occurs mainly in patients with no atherosclerotic plaques or in situ stents and in patients with common femoral artery punctures. It differs from Errant deployment type 1 in that there is no bleeding at the time of the footplate traction against the arteriotomy site, but rather the bleeding commences immediately after packing the collagen. Many of the patients in the latter group may be asymptomatic or mildly symptomatic for several days to weeks because blood flows around the plug and the incomplete occlusion. It appears that over time fibrotic reaction to the existing intraluminal collagen could result in a complete occlusion or the partial degradation of the collagen plug may lead to symptoms arising from distal embolization of the parts of the plug down into the popliteal artery and runoff vessels [4-6].

If the footplate is pulled correctly against the arteriotomy site there should be no bleeding. It follows that if there is a brisk bleeding following deployment of the footplate this indicates that the foot plate is not against the arterial wall (type 1 errant deployment), and therefore the collagen pack should not be deployed. More vigorous traction should be applied to the string attached to the footplate in order to disengage it from the plaque and to bring it to the arteriotomy site. This maneuver should cause the bleeding to stop as in our patient described in case 5. The collagen plug can then be safely deployed. If the bleeding cannot be stopped with the application of due force to the string, the collagen plug should not be deployed and hemostasis should be obtained by manual compression. If there are no distal ischemic symptoms then the string could be cut subcutaneously. The string should be left accessible to allow easier extraction of the footplate intraoperatively should the patient subsequently develop symptoms of ischemia in the affected limb. If there are no ischemic symptoms in the foot then the string could be subcutaneously cut. It is logical to cut the string subcutaneously only after confirmation of a palpable foot pulse or adequate perfusion to the affected foot. Likewise it is important to keep the traction taught during light packing of the collagen plug to avoid Type 2 errant deployment.

Conclusion

We would like to stress on the importance of obtaining complete hemostasis before packing the Collagen plug with Angio-Seal to avoid complications. Brisk bleeding following deployment and traction of the Angio-Seal footplate should be given due significance and if needed the footplate has to be pulled harder so that it opposes the arteriotomy site with resultant decrease or stop in the bleeding before packing the collagen plug.

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