Treatment of Angioseal-Related Femoral Artery Occlusion Using TurboHawk Directional Atherectomy

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ABSTRACT: Objective: We describe a novel approach for the endovascular treatment of femoral artery occlusion as a result of Angioseal closure device deployment. Background: Angioseal is the most commonly used vascular closure device following percutaneous coronary and peripheral catheterizations worldwide. A rare complication of Angioseal deployment is occlusion of the femoral artery leading to limb ischemia and requiring revascularization. Given its unique ability to cut both plaque and the Angioseal device at operator-directed planes, TurboHawk can be a fast and effective approach to treat Angioseal-associated femoral artery occlusions. Case Series: We report 4 cases of Angioseal-associated femoral artery occlusions that occurred between 3 hours and 12 days after catheterization. These patients were successfully treated with TurboHawk directional atherectomy followed by balloon angioplasty with no complications. During a mean follow-up period of 12.1 months ± 8.6 months, patients remained claudication free with no evidence of obstructive arterial disease of the treated limb on imaging studies. Conclusion: The use of directional atherectomy followed by balloon angioplasty is a quick, safe, and effective endovascular approach to treating Angioseal-associated femoral artery occlusions. It is associated with a high success rate, no complications, and good midterm outcomes.

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The femoral artery is the most widely used vascular access for coronary and peripheral interventions and adequate hemostasis at the end of procedures is required to prevent major bleeding. In the current interventional era, vascular closure devices (VCDs) have become very popular because of their fast rate of hemostasis, which leads to shorter hospital stay and earlier ambulation. However, it is well known that, in rare cases, VCDs may lead to serious vascular complications such as total femoral artery occlusion and acute limb ischemia. Angioseal (St. Jude Medical) is one of the most widely used collagen-plug VCDs for closure of the femoral artery. Depending on the study design, the reported
incidence of total femoral artery occlusion in patients who receive an Angioseal device can be up to 0.06%.\(^3\)\(^-\)\(^5\) Patients with suspected total femoral artery occlusion as a result of VCD use require urgent revascularization.

Directional atherectomy has been successfully used for endovascular excision and removal of atherosclerotic plaque in peripheral arteries for many years. A directional atherectomy device can cut plaque in planes dictated by the operator, making it an effective modality to excise large amounts of plaque. Given the nature of the Angioseal anchor and plaque, we suspected that directional atherectomy followed by balloon angioplasty is a fast and effective approach to treat Angioseal-associated femoral artery occlusions. We describe this novel endovascular approach through a case series of 4 patients who developed this complication.

**CASE 1**

A 53-year-old female with a history of hypertension, hyperlipidemia, coronary artery disease, diabetes, and peripheral vascular disease underwent lower-extremity angiography via right common femoral artery (CFA) access and was found to have chronic total occlusion (CTO) of bilateral superficial femoral arteries (SFA). She then underwent successful percutaneous angioplasty and stenting of the left SFA total occlusion. The right CFA vascular access site had no angiographically significant disease prior to Angioseal deployment (Figure 1A). Hemostasis of the right femoral arteriotomy site was obtained with Angioseal. Four hours following the procedure, she developed right leg numbness and tingling. Physical exam revealed nonpalpable right pedal pulses and weak Doppler signal. The patient was taken back to the catheterization laboratory. Left CFA access was obtained and an iliofemoral angiogram was performed via a pigtail catheter positioned in the distal aorta. It revealed a hazy lesion in the right CFA. A 7 Fr, 45 cm sheath was advanced into the right CFA. Selective angiography of the right leg revealed a new severe and
hazy occlusion at the prior access site in the right CFA (Figure 1B). Because she had a right mid SFA CTO, we advanced a SpiderFX filter (Covidien) into the profunda for embolic protection. Then a TurboHawk LSM atherectomy catheter (Covidien) was advanced to the proximal edge of the lesion and directional atherectomy was performed with 12 passes at operator-directed planes. Finally, the lesion was treated with a 6 mm x 40 mm balloon that was inflated to 4 atm. There was minimal residual haziness with no significant stenosis at the end of procedure (Figure 1C). The patient’s numbness and tingling resolved at the end of the case. Examination of the atherectomy debris from the TurboHawk nosecone and SpiderFX revealed pieces of Angioseal collagen plug, suture material, and atherosclerotic plaque (Figure 1E). Specifically, suture material was found in the SpiderFX, which we assume was introduced into the artery during Angioseal deployment and was cut from the arterial wall by TurboHawk. Nine months later, when she presented for treatment of left SFA restenosis, repeat angiography revealed a patent right CFA with mild stenosis at the site of the previously treated segment (Figure 1D).

**CASE 2**

An 83-year-old male with a history of hypertension, hyperlipidemia, and peripheral vascular disease underwent percutaneous laser atherectomy and angioplasty of a right SFA in-stent restenosis via left CFA access, which was angiographically normal prior to Angioseal deployment (Figure 2A). Hemostasis was obtained with Angioseal. Twelve days following the procedure, he developed severe left-leg claudication. Ankle-brachial index (ABI) and pulse volume recording (PVR) testing showed left leg obstructive peripheral artery disease. He was taken to the catheterization laboratory. Nonselective angiography revealed a total occlusion of the left CFA at the site of previous access (Figure 2B).
A 7 Fr sheath was then advanced with the tip positioned in the left external iliac artery, and a 7 mm SpiderFX filter was placed in the distal left SFA for distal protection. Angiography of the left CFA after that showed a small channel through the lesion (Figure 2C). A TurboHawk atherectomy catheter was advanced over a wire (Figure 2D) and atherectomy was performed. Then a 7 mm x 40 mm balloon was advanced across the lesion and inflated to 3 atm. When the SpiderFX was removed, there was a moderate amount of debris in the filter. There was an excellent angiographic result (Figure 2E) at the conclusion of procedure. After the procedure, the patient’s claudication symptoms completely resolved. Twelve months later, the patient was symptom free with a normal ABI and PVR.

CASE 3

A 70-year-old female with a history of hypertension, hyperlipidemia, coronary artery disease, stable angina, and evidence of ischemia on a stress test underwent percutaneous coronary intervention via right femoral access. Prior to Angioseal deployment, the right CFA was angiographically normal (Figure 3A). Hemostasis was obtained with Angioseal. One week following the procedure, she developed right lower-extremity claudication but did not seek medical attention. Seven weeks later, she presented to her cardiologist with chest pain and was referred for urgent coronary angiography to rule out potential stent thrombosis. When she presented to the catheterization laboratory, she reported “new” right-leg claudication symptoms. Left CFA access was obtained and cardiac catheterization was performed, which revealed patent stents with no significant change compared to her prior angiography. Then right lower extremity angiography was performed, which demonstrated a focal obstructive linear lesion at the prior access site (Figure 3B). A 7 mm SpiderFX filter was advanced to the right SFA

**Figure 3.** Patent sheath insertion site (red arrow), prior to Angioseal deployment (A). A new occlusion at the prior sheath insertion site (red arrow) (B). Treatment of occlusion with directional atherectomy catheter (C). Minimal residual stenosis following treatment with directional atherectomy and PTA (D).
A TurboHawk atherectomy catheter was advanced to the proximal edge of the right CFA lesion (Figure 3C). The lesion was initially treated with 5 passes of the atherectomy device. Then a 6 mm x 20 mm balloon was advanced across the lesion and inflated to 8 atm. There was a good angiographic result with small residual plaque remaining at the treatment site (Figure 3D). The patient’s claudication symptoms completely resolved, and she was asymptomatic at follow-up 8 months later.

**CASE 4**

A 77-year-old female with a history of coronary artery disease, myocardial infarction, and angina underwent a diagnostic coronary angiography via right femoral access. Prior to Angioseal deployment, right CFA angiography showed no significant disease (Figure 4A). Hemostasis was obtained with Angioseal. Three hours following the procedure, the patient started experiencing right-leg discomfort and a physical exam was notable for nonpalpable right pedal pulses with absent Doppler signal. The patient was taken back to the catheterization laboratory. Contralateral access was obtained, and angiography of the right leg was performed. It revealed a new severe focal lesion at the prior site of Angioseal deployment (Figure 4B). Balloon angioplasty with Angiosculpt 6 mm x 40 mm balloon (AngioScore) and aspiration thrombectomy with Pronto V3 catheter (Vascular Solutions Inc.) were used without significant improvement of the lesion. Then a 7 mm SpiderFX filter was advanced to the distal right SFA for embolic protection. A TurboHawk atherectomy catheter was advanced to the proximal edge of the lesion and multiple passes with the atherectomy device were performed. Angioseal and suture remnants were removed from the nosecone of the device. No debris was seen in the filter. Finally, a 6 mm x 40 mm balloon was advanced across the lesion and inflated to 2 atm. There was an excellent angiographic result with normalization of the blood flow through the CFA into the SFA (Figure 4C). At follow-up, the patient had no claudication symptoms.

**DISCUSSION**

Angioseal is the one of the most widely used collagen-plug VCDs and carries a very low complication rate. Angioseal deployment is indicated only in puncture sites of femoral arteries, and is contraindicated in puncture sites above the inguinal ligament, below the femoral artery bifurcation, in diseased access arteries, and in small access arteries. The structure of Angioseal consists of a suture that connects a bovine collagen plug and a polymer anchor made of polylactic acid.
and polyglycolic acid.\(^1\)\(^8\) During Angioseal deployment, the polymer anchor is positioned in the intravascular space, and the collagen plug is positioned in the extravascular space. After Angioseal deployment, femoral artery occlusion can occur as a result of anchor deployment into a small vessel, anchor deployment into a diseased vessel, or inadvertent collagen plug deployment into the intravascular space.\(^1\)\(^6\)\(^7\) Femoral artery occlusion may potentially lead to severe limb ischemia and, if not addressed urgently, limb amputation. To minimize vascular complications, the American Heart Association provides a Class I recommendation on obtaining a femoral angiogram, identifying the sheath insertion site, and identifying any vessel disease prior to VCD deployment.\(^2\)

Historically, this complication has been treated successfully using an open surgical approach.\(^6\) However, we felt that the use of directional atherectomy could be used successfully in treatment of this complication given the ability of the TurboHawk device to excise both the Angioseal structure and the large amount of associated plaque. The TurboHawk device contains a rotating cutter that can be directed at different planes dictated by the operator. This unique feature of the TurboHawk device allows it to cut not only large amounts of plaque, but also the Angioseal collagen plug and the Angioseal polymer anchor in an efficient and effective manner. Distal to the cutter, there is a nosecone reservoir that collects debris. There is no general consensus on the deployment of an embolic protection device distally prior to atherectomy. Given that the Angioseal-associated occlusion most likely contains the Angioseal polymer anchor, the Angioseal collagen plug, and a large amount of thrombus, we felt that prevention of the potential distal embolization using distal embolic protection device would be reasonable. In this case series, a SpiderFx filter device was always deployed distally for embolic protection prior to TurboHawk deployment. In 2 of the cases, we observed debris in the filter.

In this case series, 4 patients underwent elective percutaneous peripheral or coronary interventions via femoral access followed by deployment of an Angioseal device for hemostasis. None of them had contraindications for Angioseal use. However, within 3 hours to 12 days, they developed symptoms of claudication or rest pain in the limb that was used for access. Angioseal complications most commonly occur within a few hours post procedure. However, it may occur as late as 3 months after device deployment.\(^9\) In a case report, Wille et al describe a patient who developed leg ischemia 37 days after Angioseal deployment.\(^6\) The patient underwent surgical exploration which revealed an excessive fibrotic reaction from the anchor absorption that led to obstruction of the femoral artery.\(^6\) Based on these reports, we believe that the second and third cases most likely had a delayed clinical presentation due to the same mechanism.

In all 4 patients, selective femoral angiography revealed severe stenosis or occlusion at the prior access site. The lesions were treated with TurboHawk directional atherectomy followed by percutaneous transluminal angioplasty. All patients were successfully treated with no complications and a mean procedure time of 59.7 minutes ± 21.4 minutes. All patients were discharged within 24 hours and received follow-up after their procedures in the cardiovascular clinic. During a mean follow-up period of 12.1 ± 8.6 months, patients remained free from claudication with no evi-
idence of obstructive arterial disease of the treated limb on imaging studies.

**CONCLUSION**

Angioseal-related complications may present immediately after the procedure or even as late as several weeks after. Given the nature of the Angioseal anchor and plaque, we propose that directional atherectomy followed by balloon angioplasty is a fast and effective approach to treat Angioseal-associated femoral artery occlusions. We also suggest using a distal embolic protection device especially in patients with abnormal outflow. In 4 patients, this approach has shown to be associated with a high success rate, good midterm outcomes, and no complications. In the laboratories with insufficient expertise of directional atherectomy use, surgery should be considered as a primary treatment option.

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**REFERENCES**