A ‘post-close’ Technique for Femoral Hemostasis After Percutaneous EVAR Using an Ultra-low-profile Endoprosthesis System

A. Chaudhuri

Bedfordshire — Milton Keynes Vascular Centre, Bedford Hospital NHS Trust, Kempston Road, Bedford MK42 9DJ, United Kingdom

**Introduction:** We present a ‘post-close’ technique using the Angio-Seal VIP vascular closure device (VCD) after percutaneous endovascular aneurysm repair (p-EVAR) using an ultra-low-profile (ULP) device.

**Technique:** Following percutaneous using an ULP device (here the Ovation Prime system, Trivascular, Eysins, Switzerland), contralateral femoral hemostasis is achieved by using an ‘undersized’ application of an 8F Angio-Seal VIP vascular closure device (VCD) for all punctures wherein upto 12F sheaths have been applied for access. On the ipsilateral side, following ‘double-wire’ preparation, synchronous deployment of an 8F and 6F Angio-Seal VIP VCDs achieves hemostasis. Procedural heparin is reversed as an adjunct, pressure dressings are applied and the patient kept flat for 2 hours.

**Discussion:** Double-wire VCD deployments, and ‘post-close’ techniques have not been described in the context of femoral hemostasis after p-EVAR. This technique is easy to apply and saves time (and potentially cost) used to set up ‘pre-close’ devices, as is typically used these days.

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**INTRODUCTION**

Percutaneous femoral access for endovascular aneurysm repair (EVAR) is increasingly becoming the norm, with femoral arterial defects now typically closed using vascular closure devices (VCDs). Such minimally invasive access has the perceived advantage of minimising groin trauma, with reduced operating time, reduced pain, early discharge and reduction of post-surgical complications, with early return to activity. We describe, along with a technical video, the use of a plug-based vascular closure device, namely the Angio-Seal VIP (St. Jude Medical, Minnetonka, MN, USA; hereafter referred to as the Angio-Seal), in effecting ‘post-close’ femoral hemostasis after percutaneous EVAR (p-EVAR).

**TECHNIQUE**

Following p-EVAR typically using an ultra-low-profile (ULP) device such as the Ovation Prime (Trivascular, Eysins, Switzerland), the sheath of the contralateral limb is left in after deployment if 12F; if a 14F profile contralateral limb is used this is removed and the femoral defect ‘downsized’ using a 12F sheath. The ipsilateral sheath (device body) is removed and replaced with a 14F Dry-Seal sheath (WL Gore & Associates, Inc., Medical Products Division, Flagstaff, AZ, USA) to facilitate passage of 14F ipsilateral limbs and minimise sheath exchanges. A second wire, typically a Bentson (Merit Medical, Jordan, Utah, USA) or Glidewire Advantage (Terumo Medical Corp., Somerset, NJ, USA), is then para-axially introduced alongside the procedural Lunderquist wire in the ipsilateral 14F sheath [Video 1].

Supplementary video [Video 1] related to this article can be found at http://dx.doi.org/10.1016/j.ejvssr.2015.10.001.

Firstly, for all contralateral punctures, an 8F Angio-Seal is deployed over the procedural Lunderquist wire left in [Video 1]. Supplementary post-deployment manual compression is required for at least 1 minute as per the IFU, and the author suggests even a little longer as these are large holes in heparinised patients compared to those made in the more typical scenario e.g. lower limb angioplasty; even though there is visible hemostasis at 1—2 minutes, 100% hemostasis time is up to 10 minutes. Next, for double VCD deployments on the ipsilateral side, an 8F Angio-Seal is first deployed over the Lunderquist wire, and then a 6F Angio-Seal over the para-axial wire [Video 1]. The key to avoiding dislodgement of the first ipsilateral VCD is to maintain traction on the foot plate of the 8F Angioseal and continued tamping of the collagen plug (which can be undertaken by an assistant) whilst the 6F Angio-Seal is being deployed. Furthermore the lower profile and gradual taper of the tip allows the 6F device to be introduced alongside the previous device with no dislodgement of the 8F Angioseal in either the footplate or plug component.

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* Tel.: +44 1234 355122.
E-mail address: a.chaudhuri@ntlworld.com (A. Chaudhuri).
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DISCUSSION

The Angio-Seal consists of a suture-tethered extravascular collagen plug and an anchoring LP intravascular footplate which is designed to dissolve in 90 days. The plug is pushed into place to cover the arterial puncture with counter-traction at the anchor via the thread, creating an “anchor-arteriotomy-collagen plug sandwich”. It is easy to use, and the deployment technique has been previously described. We have extensive experience with use of the Angio-Seal device, including using it in ‘undersized’ scenarios i.e. where the labelled VCD profile is smaller than the profile of the endovascular device used prior. Our own experience and prior description of the ‘double-wire’ technique was the background in applying this ‘post-close’ technique. In the current scenario we see no real limitations to using it as such, as the foot plate clearly locks onto the intimal surface of the femoral artery, allowing tamping of the collagen plug into place. An 8F Angio-Seal will therefore easily seal a 12F defect, and it is standard practice in our peripheral interventional experience to close such femoral punctures with the 8F Angio-Seal. Operators will be aware that it is clearly notable at open access that the defect in a pliable artery shrinks down once the endograft body/sheath has been removed, and no doubt this is what allows the Angio-Seal anchor to ‘hold’ from within the arterial lumen, and this is the key to successful deployment in this scenario. We would also reiterate that such deployments are off-label.

Other techniques include a ‘pre-close’ approach using a suture mediated closure device (SMCD) such as the Perclose ProGlide Suture-Mediated Closure System (Abbott Vascular, Abbott Park, Illinois, USA; hereafter referred to as the ProGlide). Typically, for a pre-closed p-EVAR, 4 ProGlides are deployed (2 per groin, as per the IFU for ‘large hole’ access), costing £506.50; comparatively, two 8F and one 6F Angio-Seal cost £368.70 in total, resulting in a cost saving of £13 780 per 100 patients. An additional advantage is the procedural time gained in not having to set up as for pre-close devices. Post-closure techniques that preclude use of a VCD include the fascial stitch technique which is limited by contraindications such as the need to increase incision size, the unacceptably high rates of complications including pseudoaneurysm formation, and contraindications such as high bifurcation, previous surgery, and inadvertent high puncture that limit its application. In this context, as long as there is wire access the author would advocate Angio-Seal deployment is feasible even in a high puncture. The author’s femoral punctures are all ultrasound-located so this should really not happen but is not felt to be a major issue if it does. As for previously operated groins, access through a scarred groin is of course an issue but once achieved we do not have problems deploying an Angio-Seal. This is potentially due to the fact the Angio-Seal is deployed along the track already created and does not need to be rotated within a fibrotic field as would be required for the 10 o’clock and 2 o’clock positioning needed for double ProGlide deployment. The ProGlide needs to traverse arterial and likely scar tissue for needle passage and suture delivery which is not required with the Angio-Seal. It is precisely in such a scenario that the Angio-Seal has been used as a bail-out post-close adjunct for incomplete hemostasis after use of ProGlides.

Similar technical and indication-related considerations arise in the obese patient. Firstly, obesity is not a contraindication in this scenario, and was reported only as a factor affecting antegrade deployments. Secondly, an issue that seems to cause failed deployments in obese patients is to do with the lack of stiffness of the Angio-Seal sheath which tends to buckle once the introducer is removed if the device is maintained at a right angle, which then results in the inability to introduce the plug delivery system. Therefore, if the delivery/sheath angle is made more shallow while introducing the plug delivery system, sheath buckling can be minimised (an assistant can support the device as indicated in video 1) allowing for successful deployment, and we have indeed done undertaken successful deployment with patient BMI of 40. This is an aspect that needs particular attention especially in the contralateral groin where just one 8F Angioseal is deployed with no fallback options (unless a double wire is also established there for safety, which would then add to procedural time).

A post-close technique using an anchored collagen plug-based VCD, namely the Angio-Seal VIP, is entirely feasible for femoral arterial haemostasis, including synchronous ‘double-wire’ deployments following p-EVAR using an ULP device. This is now my default technique in this scenario.

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REFERENCES


