Percutaneous Vascular Closure Using an Anchored Collagen Plug Provides Effective Haemostasis Following both Antegrade and Retrograde Femoral Arterial Punctures

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WHAT THIS PAPER ADDS
There is a general perception (with no supporting evidence) that percutaneous closure of antegrade femoral punctures is associated with a disproportionately high rate of deployment failures, resulting in limited usage of vascular closure devices. This paper highlights the difference between antegrade and retrograde modes of vascular closure device deployment, and indicates that though there is indeed a higher deployment failure rate with the Angio-Seal VIP after antegrade punctures, both deployment modes are effective, and this should not discourage clinicians from VCD deployment after antegrade femoral punctures.

Objectives: Small published series suggest a higher failure rate for Angio-Seal vascular closure device (VCD) deployment after antegrade femoral puncture, despite the need for shorter haemostasis times, early discharge, and possibly higher turnover. We seek to compare the deployment efficacy and complications of the Angio-Seal VCD between antegrade and retrograde femoral arterial deployments.

Methods: Radiological data was retrospectively analysed from prospective databases from the hospitals’ Computerised Radiology Information System (CRIS) over 2010—2012. Angio-Seal gauge, Rutherford class (as applicable), puncture mode (used to classify deployment as antegrade/retrograde), sheath sizes, and deployment success/failures were recorded. Numerical/statistical analyses were undertaken using Microsoft Excel 10/SISA software.

Results: A total of 519 Angio-Seal VIP VCDs were deployed in 470 patients over 2010—2012 (13 other patients could not be analysed due to incomplete data). Sheath sizes for antegrade/retrograde femoral puncture were 5F, n = 22/9; 6F, n = 244/223; 7F, n = 1/5; 9F, n = 4/0. 8F Angio-Seal VIPs were used for 9F punctures only, 6F for the remainder. The overall deployment success rate was 93.7%. In total, 247 (91.1%) successful antegrade deployments were undertaken with 24 (8.9%) failures, compared with 229 (96.6%) successful retrograde deployments with eight (3.4%) failures. Antegrade/retrograde failures were classed as failure to deploy, n = 15/5; bleeding despite successful deployment requiring supplementary compression, n = 6/1; haematoma formation, n = 2/1; groin pain, n = 0/1; vessel stenosis, n = 1/0. Higher deployment failures were noted with antegrade deployment (p < .02, chi-square test).

Conclusions: Angio-Seal deployment is successful for both antegrade/retrograde femoral punctures albeit with a higher antegrade failure rate.

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INTRODUCTION
Use of vascular closure devices (VCDs) is now part of the standard armamentarium in achieving groin haemostasis following femoral arterial puncture for peripheral arterial interventions. Smaller series have examined the efficacy of deployment of such devices, typified here by the Angio-Seal VIP (“V-Twist Integrated Platform”; St. Jude Medical, Minnetonka, MN, USA). However, there are limited published data, with heterogeneity of study parameters, comparing it to manual compression,1–4 to other VCDs,5 or simply registries.6 There is also very limited data so far comparing the efficacy of the Angio-Seal (now used to imply the Angio-Seal VIP throughout) VCD between retrograde and antegrade punctures. We therefore seek to compare the deployment efficacy and complications of the Angio-Seal VCD in antegrade and retrograde femoral arterial punctures in a large series.
The Angio-Seal VIP consists of a suture-tethered extra-vascular collagen plug and an anchoring low-profile intra-vascular foot plate which is designed to dissolve in 90 days (Fig. 1A). The anchor allows counter-traction via the thread whilst the plug is pushed into place to cover the arterial puncture. It is easy to use, and consists of a few simple steps: (a) introduction of the dedicated Angio-Seal sheath over a guidewire; (b) adjusting the sheath using the convenient arteriotomy locator provided (blood flow is correspondingly visible on the outside), so that there is only 1.5 cm of its end that is intra-arterial (this prevents over-insertion with its attendant risk of intra-arterial plug deployment, or failure of anchorage); (c) removal of the guidewire and introduction of the anchor and plug delivery system (“carrier tube”); (d) locking the delivery system into the sheath, with intraluminal delivery of the anchor; (e) pullback of the entire system, that is delivery system and sheath, so that the anchor now abuts the intimal aspect, and tamping the collagen plug onto the femoral artery adventitia with the dedicated tamping tube that is provided within the system over the thread. A wait of about 60 seconds in general achieves haemostasis via an “anchor—arteriotomy—collagen plug sandwich” (Fig. 1A). The thread is then cut flush to the skin and the VCD delivery system/sheath removed.

Other variants of the Angio-Seal include the newer Angio-Seal Evolution and the older Angio-Seal STS (Self-Tightening Suture)-Plus, both of which also come in 6F and 8F configurations. The former has an internal geared system that automatically tamps the collagen plug down whilst the device is being withdrawn. The Angio-Seal VIP (Fig. 1B) is similar to the Angio-Seal STS but with a larger footprint for the collagen plug, which is relevant to “downsizing” as discussed below.

MATERIALS AND METHODS

Data was retrospectively analysed from prospective databases from the hospitals’ Computerised Radiology Information System (CRIS) over 2010—2012. Angio-Seal gauges were identified from procedure reports, whilst Rutherford class (where interventions were undertaken for peripheral arterial disease) was also identified from the report and cross checked from the request form. Location of the optimal puncture point was undertaken using immediate pre/intra-procedure duplex ultrasound scan (DUS), which also allows avoidance of anterior calcifications as far as possible; magnetic resonance angiography (MRA) is our preferred modality for arterial imaging,6 with computed tomographic angiography (CTA) used usually in urgent cases.

Figure 1. (A) Schematic of the Angio-Seal VIP outlining the “anchor—arteriotomy—collagen plug sandwich”. (B) Indicating the appearance of the Angio-Seal VIP with the “carrier tube” element locked into the sheath (a = carrier tube element; b = sheath element; c = protruding foot plate in line with the device prior to deployment, extent of elements arrowed). Used with permission (Angio-Seal and St. Jude Medical are trademarks of St. Jude Medical Inc. or related companies. Reprinted with permission of St. Jude Medical, ©2013 All rights reserved).
or in those patients in whom MRA cannot be undertaken, and a DUS-only approach in those who are suitable for none of the previous. We have no specific protocol for sizing the artery as such and work simply on how the artery is visualised pre- and intra-procedure.

Puncture mode (used to classify deployment as antegrade/retrograde) was determined from the type of procedure, as also sheath sizes and deployment success/failures which were recorded. Failure was taken to include (a) failure of deployment, and also (b) bleeding despite successful deployment requiring supplementary compression, (c) haematoma formation after perceived successful deployment, (d) groin pain, and (e) vessel stenosis.

Patients were typically asked to rest for 2 hours (though we acknowledge this can be less) after successful deployment, with observations in the recovery ward, and then discharged, with the majority of cases undertaken on a day case basis. Groins were not reassessed immediately afterwards using DUS as a routine.

Numerical and statistical analyses were undertaken using Microsoft Excel 10 and SISA statistical software respectively. Two-group two-sample non-parametric data analyses were undertaken using chi-square tests in 2 x 2 table format, modified to the Fisher exact test when a parameter frequency was <5.

RESULTS

A total of 519 Angio-Seals were deployed in 470 patients (305 male, 165 female) from March 2010 to October 2012. Thirteen other patients could not be analysed due to incomplete data. 8F Angio-Seals were used for 9F punctures only, 6F for the rest.

Specifically there were 282 antegrade (including 11 other deployments excluded from the comparative analysis; 7 “turnarounds” [i.e. procedures where a catheter had been turned around from the abdominal aorta after an iliac procedure and then redirected to the femoropopliteal segment]; 2 double deployments in the same groin — deep femoral (DFA)/common femoral arteries (CFAs), and CFA twice) and 237 retrograde punctures. Closure success was therefore compared between 271 true antegrade punctures and 237 retrograde punctures, totalling 508 deployments available for analysis.

Indications (designated here in terms of Angio-Seals deployed) for antegrade punctures were mostly for femoropopliteal/crural occlusive disease (n = 246) and also for popliteal endovascular aneurysm repair (n = 4). This was more diverse for the retrograde group (typically interventions for iliac occlusive disease), including, for example, subclavian angioplasty (n = 1), uterine fibroid embolisation (n = 3), diagnostic angiography for a hand arteriovenous malformation (AVM; n = 1), renal embolisation (n = 2), AV fistuloplasty (n = 1), pre-EVAR internal iliac interventions (n = 2), internal iliac angioplasty for erectile dysfunction (n = 2).

A total of 247 (91.1%) successful antegrade deployments were undertaken with 24 (8.9%) failures, and 229 (96.6%) successful retrograde deployments with eight (3.4%) failures. There was a significantly higher failure rate with antegrade deployment (p < .02, chi-square test). This held true when comparing pure deployment failures alone as well (p = .02, Fisher exact test).

The overall combined deployment success rate was 93.7%, when combining both groups. When analysing the failures in themselves, the total complication rate despite successful deployment was 12 of 32 (37.5%), whilst true deployment failures numbered 20 of 32 (72.5%) failures overall.

All patients with failed deployments and bleeding complications were observed overnight, counselled for bruising and possible need for further intervention; they needed no further intervention and were problem-free at routine follow-up at the vascular surgical outpatient clinic. Simple failure to deploy with no bleeding complications was successfully managed with manual pressure. The patient with groin pain was managed conservatively with adequate symptom relief. One patient presenting with femoral arterial stenosis manifested as recurrent right leg claudication at about 8 weeks; CTA indicated a stenosis at the puncture site (Fig. 2), which was corroborated at open femoral artery exploration as due to a fibrotic nodule arising from the intima (specimen not examined histologically). The common femoral artery was endarterectomised and closed with a prosthetic patch, with symptom resolution.

These results are summarised in Table 1.

DISCUSSION

Use of the Angio-Seal VIP is widespread in interventional radiology and interventional cardiology, with benefits
including reduced stay and possibly increased turnover. It is primarily aimed for punctures smaller than 8F, given that is manufactured in 6F and 8F configurations, and is ideally deployed in vessels >5 mm in diameter. However, given the size of the plug, it is possible to downsize for larger holes, as is our experience. In fact, recently, synchronous dual deployments in single large calibre arterial defects employing a “double-Angio-Seal” technique have also been described. As per the Instructions for Use, there are no contraindications as such, especially relating to antegrade punctures.

Possible adverse effects as described by the manufacturers include bleeding or haematoma, AV fistula or pseudoaneurysm, infection, allergic reaction, foreign body reaction, inflammation, or oedema. The last one may be responsible for groin pain and vessel stenosis, as noted in our series. However, inappropriate deployment has been associated with ischaemic problems, from intra-arterial plug deployment, embolisation, to delayed occlusive-ischaemic complications that often necessitate open surgical reconstruction at the common femoral bifurcation. The incidence of complications does not seem to have changed with emerging generations of devices, with a reassuringly high success rate in terms of deployment. Correspondingly, we do not feel there is a need to undertake immediate post-procedure DUS, which is reflective of real-world practice; this is not what centres undertake, and would unnecessarily add to the turnover time in our view, which is precisely what we seek to reduce. In general, given the known efficacy and early time to hemostasis as indicated in the IFU (100% hemostasis by 10 minutes using both the 6F and 8F devices), as also early ambulation times, post-procedure DUS may be counter-productive and probably only pick up insignificant haematomas that would occur as a default of the puncture, whereas it is our view that larger ones would be clearly clinically apparent within the 2-hour observation period, which is well within the timeframe described even in older, more conservative papers.

Strategies, though, are required to deal with failed deployments such as those noted in this series. Failed deployments without active bleeding can be simply managed by manual pressure alone, much as when no VCD is used, with an extended period of post-procedure observation, as outlined. Failed deployments with bleeding complications may require prolonged pressure (thereby also requiring a protracted period of observation, including admission), and even use of adjuncts such as the FemStop (RADI Medical Systems, Uppsala, Sweden) or haemostatic pads such as the QuikClot Interventional Hemostatic Bandage (Z-Medica Corporation, Wallingford, CT, USA); we did not need these in this series. Patients should be counselled regarding the expected bruising in the genitofemoral region, the need for further investigations including DUS and CTA, and also further interventions including surgery. It would also be prudent in our view to check clotting parameters such as activated partial thromboplastin time (APTT) in those with prolonged bleeding despite successful deployment, and in cases of patients who are hyper-responsive to heparin. Abnormally high APTT levels can be successfully reversed with protamine. Groin pain may respond to simple analgesic measures or may need a referral to a chronic pain specialist. Further investigations including DUS and CTA, and also further interventions including surgery. It would also be prudent in our view to check clotting parameters such as activated partial thromboplastin time (APTT) in those with prolonged bleeding despite successful deployment, and in cases of patients who are hyper-responsive to heparin. Abnormally high APTT levels can be successfully reversed with protamine. Groin pain may respond to simple analgesic measures or may need a referral to a chronic pain specialist.

For the purpose of the study we have included both technical and non-technical complications under the “device failure” umbrella, as this is the true reflection of the efficacy of the device. Our total success rate of 93.7%, as

### Table 1. Overview of Angio-Seal deployments and analysis.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Antegrade</th>
<th>Retrograde</th>
<th>Other (incl. double deployments)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>286</td>
<td>175</td>
<td>9</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>175/91</td>
<td>121/54</td>
<td>7/2</td>
</tr>
<tr>
<td>Mean age (SD)</td>
<td>73.1 (11.3)</td>
<td>66.7 (12.3)</td>
<td>66.0 (12.3)</td>
</tr>
<tr>
<td>Rutherford class</td>
<td>2</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>109</td>
<td>168</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>5</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>90</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>35</td>
<td>1</td>
</tr>
<tr>
<td>Unrecorded</td>
<td>22</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>NA</td>
<td>3</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>Sheath sizes</td>
<td>5</td>
<td>22</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>244</td>
<td>223</td>
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<tr>
<td></td>
<td>7</td>
<td>1</td>
<td>5</td>
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<tr>
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<td>8</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Deployed numbers</td>
<td>271</td>
<td>237</td>
<td>11</td>
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<tr>
<td>Angio-Seal size</td>
<td>6F</td>
<td>267</td>
<td>237</td>
</tr>
<tr>
<td></td>
<td>8F</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Haemostasis</td>
<td>Success (%)</td>
<td>247 (91.1)</td>
<td>229 (96.6)</td>
</tr>
<tr>
<td></td>
<td>Failure (%)</td>
<td>24 (8.9)</td>
<td>8 (3.4)</td>
</tr>
<tr>
<td>Failure specifics (%)</td>
<td>Failed to deploy</td>
<td>15 (5.5)</td>
<td>5 (2.2)</td>
</tr>
<tr>
<td></td>
<td>Bleeding</td>
<td>6 (2.2)</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td></td>
<td>Haematoma</td>
<td>2 (0.73)</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td></td>
<td>Groin pain</td>
<td>0</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td></td>
<td>Vessel stenosis</td>
<td>1 (0.37)</td>
<td>0</td>
</tr>
</tbody>
</table>

NA = not applicable.
per the criteria we have employed, is therefore slightly lower than the 96–97% success rates quoted in the literature which, however, only measures the technical deployment success rate. Sub-analysis of our technical deployment success (96.1%, including all successful deployments) matches published rates, though. Complications described in the literature but not encountered in our series include vessel occlusion/thrombosis, groin haematoma requiring transfusion, retroperitoneal haematoma, pseudoaneurysm formation, AV fistula, plug embolisation, distal ischaemia, and infection.

This study indicates that the Angio-Seal is effective, with a high deployment success rate matching that in the literature. There is a significantly higher device failure with antegrade punctures, which correlates to published figures. Our series has shown an overall low complication rate, comprising only minor complications, thus supporting the concept Angio-Seal is a safe VCD. In our hands, concern about the turnaround technique may also be alleviated: in such cases, flush angiography is undertaken with a 4F catheter, and the turnaround undertaken using a Side-winder catheter with its tip pointing caudally. This does not increase the arteriotomy size till a 6F sheath is then introduced as per standard for the antegrade procedure, which can be conveniently closed with a 6F Angio-Seal, and as is the case with this series, there were no failed deployments in this scenario.

The significant difference between antegrade and retrograde deployment rates is probably multifactorial, and not addressing all such factors may be a limitation of this study, which we have tried to address. So far, only obesity has been reported as an independent risk factor for deployment failure in antegrade punctures. In contrast though, other papers examining this issue in the context of percutaneous EVAR have suggested that BMI is not relevant to VCD deployment success rates, though of course punctures in such cases are by default retrograde. It is certainly our experience that traversing through a fatty/deep groin in an antegrade fashion can create a right angle kinking the Angio-Seal sheath, which may contribute to deployment difficulty and failure. However, BMI was not specifically included as a parameter within this study, and is a possible limitation. Similarly, we lack long-term follow-up, but, again, this is a reflection of real-world practice with such cases. Angio-Seal deployment is recorded routinely in all procedural reports, which eliminates recall bias. Antiplatelet agents were not stopped in any of the patients, and angioplasties were not undertaken if the patients’ INR exceeded 1.5. Furthermore, whilst the puncture method may be an issue, the fact that a VCD is being used negates whether the puncture was US guided (as is our practice) or fluoroscopy guided using the femoral head, as these aspects are no longer relevant to achievement of haemostasis with successful deployment.

In conclusion, this large series suggests that Angio-Seal VIP deployment is successful for both antegrade/retrograde femoral punctures, albeit with a higher antegrade failure rate.

**FUNDING**

None.

**CONFLICT OF INTEREST**

None.

**REFERENCES**


