Femoral Hemostasis: When to Avoid a Vascular Closure Device

Morton J. Kern, MD, MSCAI, FACC, FAHA

We have now been a radial-first lab for 15 years, enjoying the benefits of radial access with markedly fewer femoral access cases. Radial access has lived up to its promise, with better patient safety and comfort, and when compared to femoral access, earlier discharge, as well as better patient and nursing satisfaction for post procedure care. For femoral access, we practice best techniques, but still fear the uncommon complications of retroperitoneal hematoma or pseudoaneurysms. With the occasional femoral access case, our fellows (and I at times) experience some anxiety about missing something or encountering one of the well-known access site complications.

We recently had an unusual event with a failure to obtain vascular closure device (VCD) hemostasis with an Angio-Seal (Terumo) VCD, not because of device failure, but rather because of operator technique in a scarred inguinal area. I thought this would be a good case example for a discussion of when it would be best to avoid a vascular closure device and use manual compression.

The Challenging Patient

Our patient was elderly man who had angina 12 years after coronary artery bypass graft (CABG) surgery with a left internal mammary artery (LIMA) graft and 3 saphenous vein grafts (SVGs). His left ventricular ejection fraction (LVEF) had dropped to 35% compared to several years ago. As his body mass index was 35 kg/m^2, and because we are of course a radial-first lab, we chose distal left radial artery access for his coronary angiography, using a 5 French (F) Judkins left (JL) 4 catheter to begin our study. Surprisingly, we encountered significant left subclavian tortuosity and a moderate atherosclerotic stenosis (Figure 1A), which prevented us from completing the angiography from the arm, despite several attempts using different catheters. After imaging the LIMA, we changed to right femoral access to complete the case. Femoral artery access was performed as described[1,2] in a routine manner, but the patient's protuberant abdomen and previous inguinal hernia surgery made access difficult. Using ultrasound guidance and micropuncture technique, we needed to exchange a regular .035-inch J wire for a stiff .035-inch Amplatz wire, and inserted incrementally larger dilators (4, 5, 6, and 7F) before we could insert the 6F sheath. Femoral angiography confirmed good sheath placement in the common femoral artery (Figure 1B). Coronary arteriography of the native vessels and SVGs was performed without problems. For hemostasis, we choose an Angio-Seal VCD anticipating the need for a stiff guidewire and some extra force to place the VCD sheath in the vessel. Both the scarring and angle of entry to the artery made this a challenge. After some struggle, the Angio-Seal vascular marker hole showed blood, indicating proper device position. The VCD was deployed with the usual 2 clicks (1 to expose the foot plug and the second click to deploy the foot in the vessel), followed by withdrawal of the device sheath, looking for the string to push the tamping tube down in order to pack the collagen wrap on the foot plate. But on pulling back the Angio-Seal, the entire device came out (Figure 2A) with no string, tamping tube, or foot plate. We immediately applied manual pressure to obtain hemostasis. At first, we thought the plug was retained, lost in the femoral artery. By reflex, I requested a call to vascular surgery while we tried to figure out where the plug ended up. Could the retention string and plug have been pulled into the artery and carried downstream? This seemed highly unlikely, but anything could have happened. We cut open the Angio-Seal delivery sheath and found the vascular plug intact, with the string still attached (Figure 2B). Our surmise was that although we had blood flow from the marker hole, the sheath was never in far enough to let the plug be deployed. We were very relieved that we had not lost the plug in the vessel.

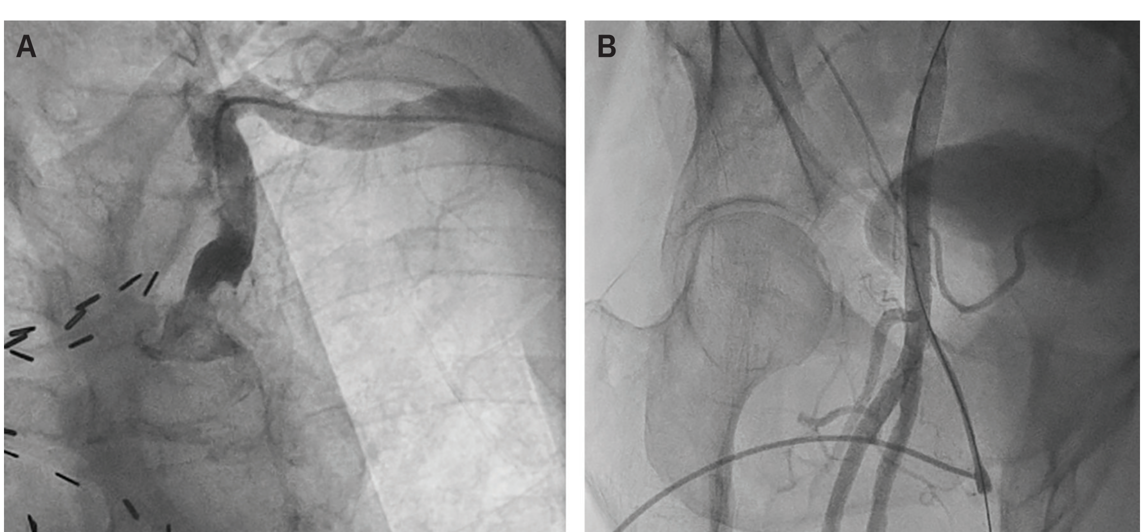


Figure 1. **(Left) Frame from cineangiogram of left subclavian with significant tortuosity and moderately severe stenosis near the aortic junction. The access site was later changed to the right femoral artery (right) with ultrasound imaging and micropuncture technique.**

From this experience, we recognized it may have been a mistake to use a VCD in this type of patient. It is always an easy decision in hindsight. Nonetheless, it does bring up the question of when we should forego using a VCD and go straight to manual compression in even the higher bleeding risk, morbidly obese patients. Before addressing the contraindications and precautions for VCDs, let's review good femoral access and hemostasis practices. A complete discussion of vascular access methods for cardiac cath is provided in *Kern's Catheterization Handbook*, 7th edition.[2]

Good Closure Starts With Good Access: Femoral Artery Puncture Technique

The best entry site for femoral artery access is a puncture in the common femoral artery (CFA), defined as that segment above the femoral artery bifurcation and below the inferior epigastric artery. The CFA target zone is initially located by fluoroscopy,

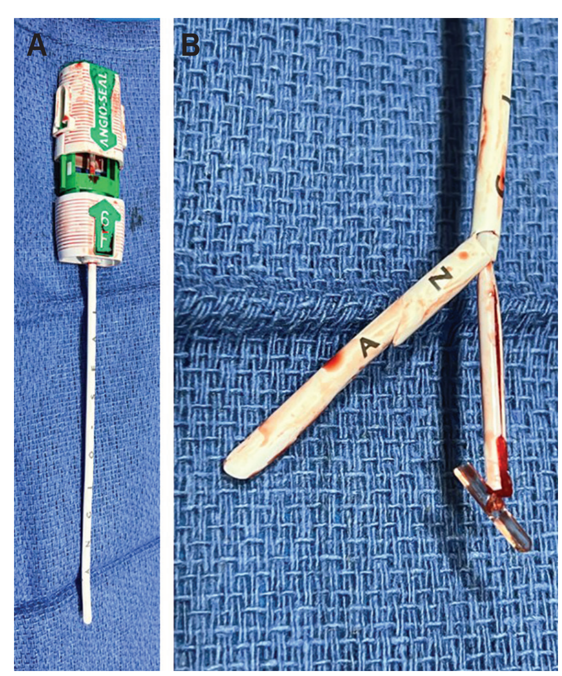


Figure 2. **(Left) The 'deployed' Angio-Seal (Terumo) was pulled entirely out of the vessel. (Right) On opening the Angio-Seal sheath, the foot plate, anchor string, and collagen wrap were intact and had remained inside the sheath. Manual compression was successfully performed.**

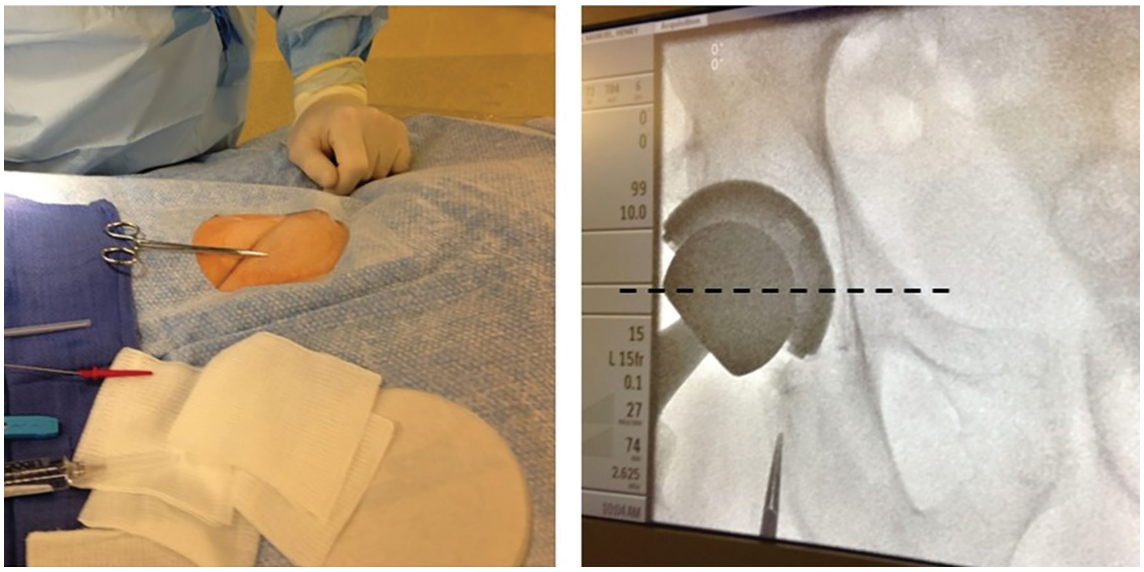


Figure 3A. For illustration purposes, Initial visualization of the femoral access area by surface landmarks (left) and then by fluoroscopy (right).

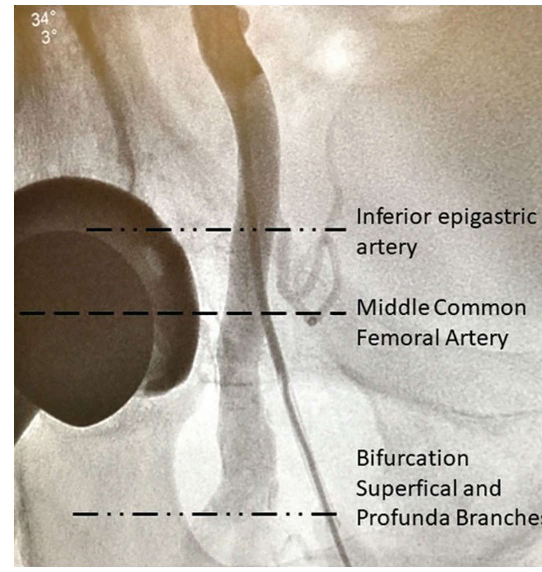


Figure 3B. Defining the common femoral artery, which lies between the inferior epigastric artery and the bifurcation of the superficial and profunda femoral artery branches.

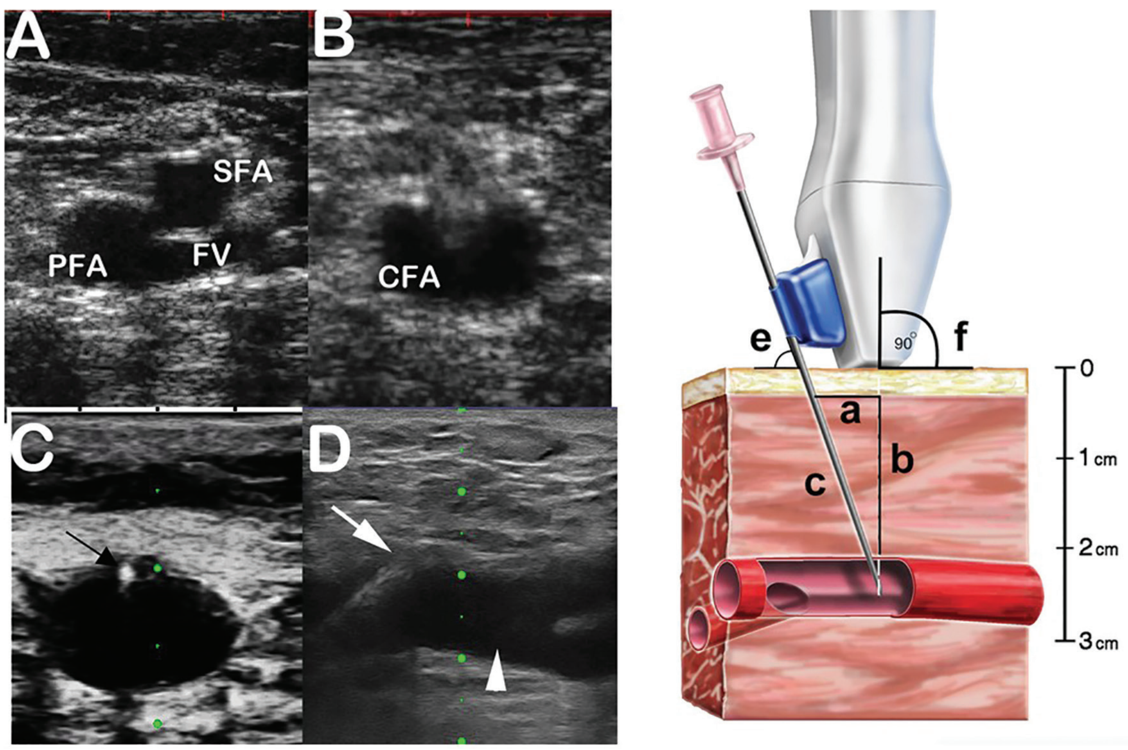


Figure 4. (Left) Axial ultrasound of common femoral artery (CFA). (A) The right common femoral bifurcation is imaged, demonstrating the profunda femoral and superficial femoral arteries. Compression is used to differentiate arteries from the femoral vein. (B) The probe is angled superiorly to the CFA. During needle advancement, the anterior wall of the vessel is indented by the needle tip. (C) The guidewire insertion point (arrow) can be imaged in the axial plane after cannulation to confirm that the insertion is above the CFA bifurcation. (D) Longitudinal view shows the guidewire entry (arrow) is superior to the CFA bifurcation (arrowhead).
(Right) Axial technique of ultrasound-guided access. The probe is aligned perpendicular (f) to the vessel, creating a circular image of the vessel. (A) Without a needle guide, the needle is inserted at an angle (e) and at a distance (a) from beneath the center of the probe. The needle is not visible until it crosses the imaging plane of the probe at a depth (b). Changes to (a), (b), (e), and (f) are interrelated, such that the success of this technique depends on experience, repeated jabbing motions of the needle, and adjustment to probe angle (f) to visualize the course of the needle. (B) With a needle guide selected based on the depth (b) of the vessel, the needle angle (e) is fixed to intersect the ultrasound plane at the set distance below the ultrasound plane, guaranteeing needle puncture at the location imaged. The probe angle (f) can and should be adjusted to allow for a shallower entry of the needle.

Modified from Seto AH, Abu-Fadel MS, Sparling JM, et al. Real-time ultrasound guidance facilitates femoral arterial access and reduces vascular complications: FAUST (Femoral Arterial Access with Ultrasound Trial). JACC Cardiovasc Interv. 2010; 3:751-758, with permission.

visualizing the head of the femur with a metal marker (eg, hemostat, Figure 3). The ultrasound probe is then placed over this area, visualizing the bifurcation of the superficial and profunda arteries, then moving up to the CFA (Figure 4). Remember that skin landmarks, specifically the inguinal crease, should not be relied on for vessel insertion. Using ultrasound to visualize the 21g micropuncture needle, a single front-wall puncture is best for two reasons: (1) reduced chance of bleeding from multiple punctures and (2) reduced bleeding after successful vascular closure device placement, since a back wall puncture might not be easily controlled.

Fluoroscopy of the femoral artery after micropuncture access has the potential to improve the safety and accuracy of femoral access, particularly useful for large-bore sheath placement. The key elements of fluoroscopic guidance include: (1) identification of the mid-third of the femoral head and ultrasound-guided femoral artery puncture; (2) wire navigation with fluoroscopy; (3) contrast angiographic confirmation of the arterial entry site through the 4F dilator of the micropuncture set. If the operator is not satisfied with the position of entry, the small catheter can be removed, and access reattempted after 5 minutes of manual compression. The micropuncture needle also has a lower crossing profile, which can be helpful in highly resistant (calcified) arteries. After documenting the CFA in the ipsilateral oblique view by angiography, the inner dilator is removed and a standard .035-inch guidewire is inserted to facilitate 6F or larger sheath placement.

Ultrasound Imaging for Femoral Access

Ultrasound image-guided access is part of the best practice for vascular access in anesthesia, critical care medicine, vascular surgery, and interventional radiology, and for the last decade, invasive cardi-

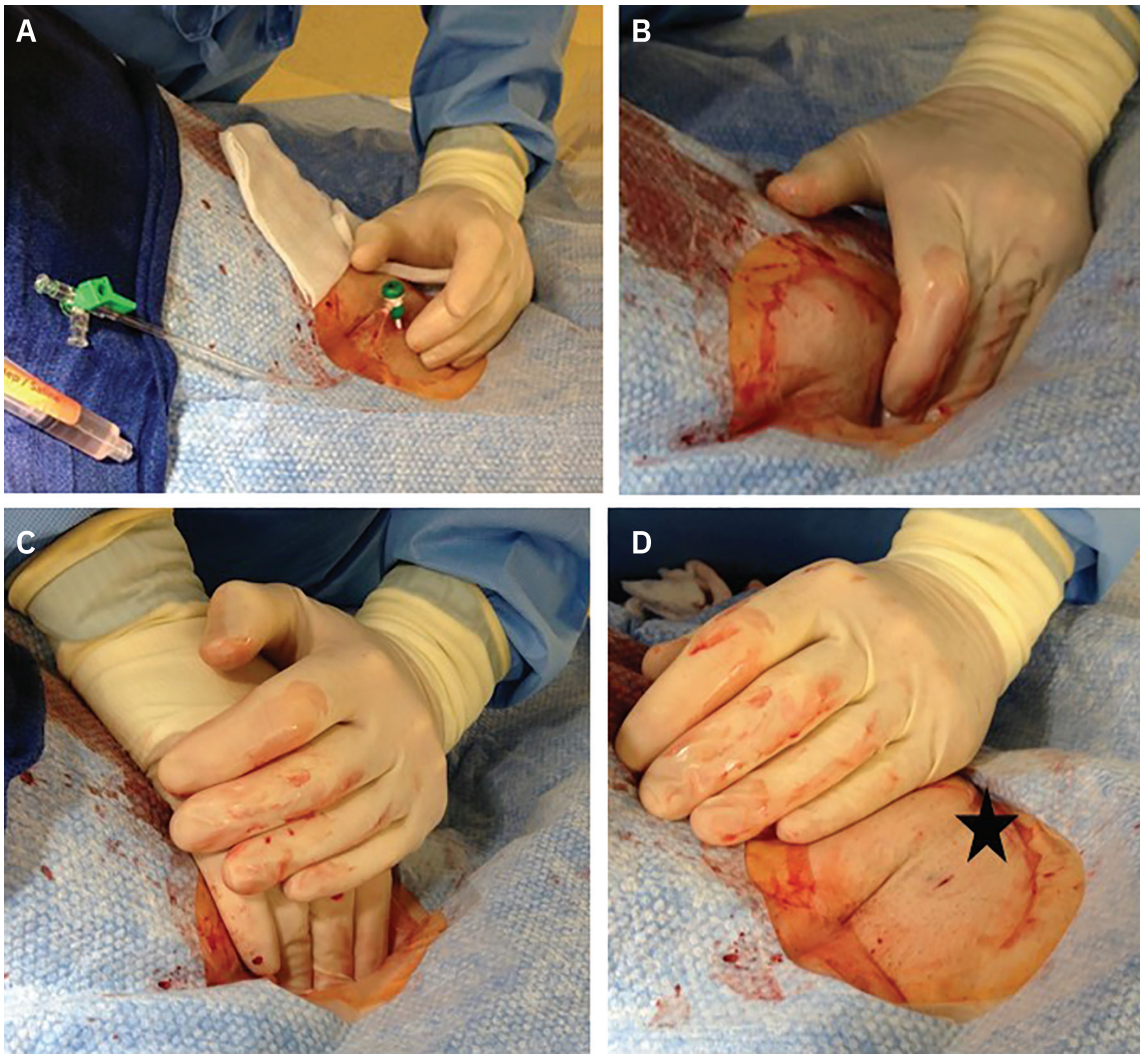


Figure 5. Method of manual compression. Top left, the operator places hand over femoral artery above the puncture site but directly over artery entry site. Top right, firm pressure is applied. Bottom right, the operator may switch hands or have an assistant complete compression maintaining pressure over the puncture site. Bottom right, at end of procedure, the puncture site is without bleeding and no induration beneath it of a hematoma (star is next to puncture site).

Reprinted with permission from Kern M. Back to basics: femoral artery access and hemostasis. Cath Lab Digest. 2013 Oct; 21(10): 4-10. Copyright 2013 HMP Global.

Ultrasound imaging can help avoid puncturing locations that are heavily calcified to ensure successful access and closure. Support for the use of ultrasound-guided access was published by Seto et al in the Femoral Arterial Access with Ultrasound Trial (FAUST).[3]

ology. Ultrasound imaging can identify the CFA bifurcation consistently and ensure the access is located above it. In the longitudinal view, ultrasound can also identify the femoral head, the posterior course of the external iliac artery, and the soft-tissue inguinal ligament (which appears as an echodense triangle). These structures may protect against an overly superior insertion. One should avoid tilting the probe cranially, as it results in a higher puncture artery puncture site.

Ultrasound images can also guard against an overly low or inferior cannulation. Some operators use a needle guide attached to the transducer and preload the needle into the guide. The needle angle is fixed to intersect the ultrasound plane as a specified depth. This provides superior control, such that the needle is guaranteed to be inserted at a specified depth (Figure 4). Ultrasound imaging can help avoid puncturing locations that are heavily calcified to ensure successful access and closure.

Support for the use of ultrasound-guided access was published by Seto et al in the Femoral Arterial Access with Ultrasound Trial (FAUST).[3] Ultrasound guidance reduced the number of attempts required to successfully cannulate the femoral artery (1.3 vs 3.0; *P*<.001), increased the first-pass success rate (82.7% vs 46.4%; *P*<.001), and reduced the risk of accidental venipuncture (2.4% vs 15.8%; *P*<.001). As a result, the incidence of any vascular complications was reduced with ultrasound (1.4% vs 3.4%; *P*=.041). The average time to access was reduced with ultrasound guidance from 213 to 185 seconds (*P*=.016). In the trial, ultrasound guidance was associated with a learning curve, requiring approximately 10 procedures before proficiency was achieved.

Hemostasis After Femoral Procedures: Manual Compression or Vascular Closure Device

Manual compression and several vascular closure devices (see below) are the most common ways to obtain hemostasis after femoral artery puncture. The technique of manual sheath removal and hemostasis has changed little since its inception 40 years ago. Best practices for good manual sheath removal begins with the patient and operator setup. Some helpful hints to remember:

- Adjust bed height or use a footstool to comfortably exert downward pressure over the puncture site.
- Ensure good intravenous access.
- Have pain medication and atropine available (for analgesia or vagal response treatment). Many operators give local anesthetic (10 to 20 mL of 1% lidocaine) to the skin around the sheath.
- Before removing the sheath, check that the activated clotting time (ACT) is <150 seconds, vital signs are stable, no chest pain is present, and there are no plans for immediate re-catheterization.
- If prolonged pressure application is needed (eg, after removal of a large sheath, intra-aortic balloon pump catheter, or cardiopulmonary support cannula), a compression device (eg, FemoStop [Abbott] or CompressAR [Semler Technologies]) can provide a constant stable pressure, relative patient/operator comfort, and easy adjustment of the degree of pressure applied. Compression devices are not intended for unsupervised use. The duration of pressure application should be kept to a minimum to decrease complications such as skin necrosis, nerve compression, or venous thrombosis.

Vascular Closure Devices

Vascular closure devices (VCDs) were developed both to obtain quick, safe hemostasis and to improve patient comfort by decreasing the time patients lie flat after the procedure. The safety of VCDs has been demonstrated in diagnostic catheterization and interventions. Most catheterization laboratories report high success rates for various closure devices used after percutaneous coronary intervention in fully anticoagulated patients receiving antithrombins, heparin, or glycoprotein receptor blockers. Four commonly used VCDs are shown in Table 1.

Table 1. Vascular Closure Devices.

Device	On the Market	Mechanism	Advantages	Disadvantages	Sheath Sizes	Ipsilateral Access <90 Days
Angio-Seal (Terumo)	1997 to present	Collagen and suture mediated	Secure closure, long track record	Intra-arterial component, possible thromboembolic complications, infection related to suture serving as a wick	6 and 8F	1 cm higher
Perclose (Abbott Vascular)	1997 to present	Suture mediated	Secure closure	Intra-arterial component, steep learning curve, device failure may require surgical repair	5 to 8F	No restrictions
StarClose (Abbott Vascular)	2005 to present	Nitinol clip	No intra-arterial component	Adequate skin tract needed to prevent device failure	5 to 6F	Not fully established
Mynx (Cordis Corporation)	2007 to present	PEG hydrogel plug	No intra-arterial component, potential use in PVD	Possible intra-arterial injection of sealant, failure rate	5 to 7F	No restrictions

F = French; PVD = peripheral vascular disease; PEG = poly(ethylene glycol)
Modified from Lim M, Sorraja P, Kern MJ, eds. Chapter 2. Vascular Access. In: Kern's Cardiac Catheterization Handbook, 7th edition, 2019.

Table 2. Contraindications and Relative Contraindications for Vascular Closure Devices.

Contraindications
• Access obtained above the inguinal ligament
• Access obtained through the superficial or deep femoral arteries
• Access obtained from the lateral surface of the artery wall
• Multiple puncture attempts
• Bacterial infection
• Heavy calcification in the access site
Relative Contraindications
• Anticoagulation with warfarin
• Thrombolysis
• Bleeding diathesis
• Peripheral vascular disease
• Scarring in groin
• Prior radiation treatment
Modified from Lim M, Sorraja P, Kern MJ, eds. Chapter 2. Vascular Access. In: Kern's Cardiac Catheterization Handbook, 7th edition, 2019.

In Which Patients Will the Operator Have Trouble With a VCD?

VCDs require a suitable pathway through the skin and deeper tissues to the femoral artery. In most patients, this path is direct and easily negotiated. In others, such as morbidly obese patients, or those with inguinal scarring, multiple prior interventional procedures, aorto-femoral bypass grafts or extensive hernia surgery, mechanical circulatory support device explant, or radiation therapy, a VCD may not be suitable (Table 2). For these patients and for many other reasons, radial access has become a favored access route worldwide).

Special considerations are needed to obtain femoral access in obese patients due to the steep angle of entry and possible kinking of the sheath system as the operator attempts to enter the artery. The sheath may not pass into the artery due to buckling or kinking of the wire in the subcutaneous adipose tissue. A stiff .035-inch guidewire will be helpful. Similarly, access through a severely fibrotic, scarred groin or through a femoral bypass graft may require a stiff guidewire and successive dilations with 5, 6, 7, and 8F dilators before inserting a vascular sheath one size smaller than the largest dilator. It is worth remembering that the Perclose and Starclose closure devices (Abbott Vascular) have difficulty penetrating calcified or fibrotic arteries, and should be used with caution, if at all.

In patients with previously placed VCD, most device manufacturers indicate that re-access can be performed without a problem, if the device has no internal artery fixation component. Caution should be used when re-accessing all VCD sites, but especially in those closed with Angio-Seal, although no reports of Angio-Seal anchor dislodgement during re-access have been reported. Although considered safe after 2 to 4 weeks, the contralateral femoral artery should be used in most cases for patient (and operator) comfort. Table 2 lists the potential contraindications to use of VCDs.

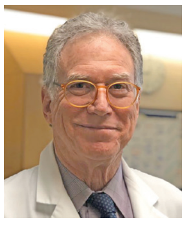
The Bottom Line

Every catheterization case is a learning experience. I thought I'd seen everything that could happen with an Angio-Seal, but I was wrong. Fortunately, this 'failure to deploy' caused no harm. It's worth remembering the old saying, "As the stick goes, so goes the case". A difficult stick portends trouble. The best results stem from a meticulous arterial puncture technique coupled with careful sheath placement and safe hemostasis. ■

References

1. Kern M. Back to basics: femoral artery access and hemostasis. *Cath Lab Digest*. 2013 Oct; 21(10): 4-10. Accessed April 15, 2022. https://www.hmpglobal-learningnetwork.com/site/cathlab/articles/back-basics-femoral-artery-access-hemostasis
2. Modified from Lim M, Sorraja P, Kern MJ, eds. Chapter 2. Vascular Access. In: *Kern's Cardiac Catheterization Handbook, 7th edition*, 2019.
3. Seto AH, Abu-Fadel MS, Sparling JM, et al. Real-time ultrasound guidance facilitates femoral arterial access and reduces vascular complications: FAUST (Femoral Arterial Access with Ultrasound Trial). *JACC Cardiovasc Interv*. 2010; 3: 751-758.

Morton J. Kern, MD, MSCAI, FACC, FAHA
Clinical Editor; Chief of Cardiology, Long Beach VA Medical Center, Long Beach, California; Professor of Medicine, University of California, Irvine Medical Center, Orange, California



Disclosures: Dr. Morton Kern reports he is a consultant for Abiomed, Abbott Vascular, Philips Volcano, ACIST Medical, and Opsens Inc.

Dr. Kern can be contacted at mortonkern2007@gmail.com
On Twitter @drmortkern