

CHAPTER 14

Step-by-Step Guide to Femoral Vascular Access Closure: Devices and Technical Considerations

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Introduction

All transcatheter cardiovascular diagnostic and therapeutic procedures begin with vascular access and end with hemostasis. While the uptake of radial access continues to increase owing to its superior safety profile, there remain populations in whom this access point is unavailable or inappropriate. Operators must, therefore, be equally competent and maintain proficiency in both access and closure at all vascular access sites.

Femoral access

The common femoral artery originates from the external iliac artery as it courses under the inguinal ligament where it gives rise to the inferior epigastric artery which travels superiorly after wrapping around the inguinal ligament. Inferiorly, the common femoral artery bifurcates to provide the superficial and deep femoral arteries. If access is above the common femoral artery, rates of retroperitoneal bleeding increase. If access is below the femoral bifurcation, rates of pseudoaneurysms increase. Without ultrasound guidance, prior femoral angiography or prior computed tomographic imaging, the boundaries of the common femoral artery are impossible to predict prior to access. Bony landmarks can be used to increase the chance of successful cannulation of the common femoral artery; in 95% of cases, the common femoral artery bifurcation is below the middle third of the femoral head. However, at this location, there is an 11% chance of being at or above the level of the inferior epigastric

artery, a finding that is more common in those who are obese.¹ Therefore, the use of a 4 French micropuncture catheter followed by femoral angiography to confirm appropriate arteriotomy site puncture prior to upsizing to a larger sheath is recommended. If access is suboptimal, the sheath can be removed, manual pressure provided for 2 minutes and access can be re-attempted. If the patient is already anticoagulated, or when immediate access is required, the micropuncture sheath can be capped and left as a guide for re-access with another micropuncture kit and removed at the conclusion of the procedure. Ideally, direct ultrasound visualization should be used to obtain vascular access. This measure does not completely eliminate the possibility of a high puncture but can be minimized by locating the bifurcation of the superficial and deep femoral arteries. Every effort should be made to ensure that access is in the common femoral artery as it will facilitate haemostasis with either manual compression or a vascular closure device while limiting the chances of complications.

Femoral angiography

Prior to the use of any femoral closure device, femoral angiography must be performed to confirm suitability for deliverability of a closure device. The image intensifier is brought to a 20-40° oblique angulation ipsilateral to the femoral access site without cranial or caudal angulation. Any excess tissue should be retracted and the sheath or its side arm should be displaced in a medial direction to allow for clear identification of the point of entry into the femoral artery. The entry point should be on the anterior aspect of the common femoral artery, above the bifurcation and below the inferior epigastric artery. There should be enough room for the chosen closure device to be deployed without interaction with another vascular structure. Note should be made of any localized pathology such as atheromatous disease, dissection or any significant calcification, all of which should be considered relative contraindications for the use of femoral closure devices. The femoral angiogram should also be

examined for evidence of posterior wall access, continued bleeding, or the presence of an arteriovenous fistula or pseudoaneurysm.

Vascular closure devices

The ideal vascular closure device would have the following characteristics:

- Capable of providing rapid and complete hemostasis regardless of the French size of the vascular access sheath or the presence of anticoagulation
- Cause minimal patient discomfort or risk
- Easy to use with a minimal learning curve
- Unlikely to fail, and in the event of failure, should allow for alternative closure
- Applicable at multiple vascular access sites
- Should allow for immediate re-access at the same site
- Inexpensive

Unfortunately, no single device has each of these characteristics and therefore, clinicians must become familiar with several closure devices that best meet their patient's needs and is available in their practice location. Details of each device will be discussed following, and are detailed in **Table 1**. Of note, regardless of particular device chosen, sterility must be maintained and staff should be vigilant for both bleeding and ischemic complications. In the event of inability to achieve hemostasis, manual compression should be employed.

Angio-Seal

Description

The Angio-Seal (Terumo Corporation, Tokyo, Japan) closure device is approved for use at the femoral access site for sheath sizes of up to 8Fr using the 8Fr Angio-Seal or up to 6Fr using the 6Fr

Angio-Seal. The closure device achieves hemostasis by delivery of a bioresorbable polymer within the femoral artery, a collagen plug on the outside of the artery and a self-tightening suture. This forms a fully bioresorbable structure that sandwiches the femoral artery access site.

Technique

1. A 0.035'' wire is introduced into the existing sheath. The authors prefer to use the standard guidewire, instead of the kit's 70 cm wire. This provides an additional level of protection against inadvertent wire removal, especially important when longer sheaths are used.
2. While maintaining hemostasis, the sheath is removed and a specially designed 6Fr or 8Fr sheath with an arteriotomy locator is delivered and advanced 1 cm into the vessel lumen beyond when blood ceases to flow from the drip hole. The guidewire and the arteriotomy locator are removed while firmly holding the sheath in place.
3. The Angio-Seal device is inserted into the sheath until it snaps in place.
4. The anchor is deployed and pulled against the arterial wall. Further retraction of the device delivers the collagen plug just outside the arterial wall.
5. Tension is maintained and a tamping tube is used to ensure the collagen plug is sutured directly outside the vessel wall.
6. The device is then cut below skin level.

Special Considerations

One strategy that can be used to prevent device failure is to use the 'double-wire' technique. In this technique, two 0.035'' wires are introduced to the sheath at the conclusion of the procedure. A single Angio-Seal device is deployed in the standard fashion while maintaining wire position with the second 0.035'' wire. If this results in hemostasis, the second wire is removed while maintaining pressure

on the collagen plug with the tamping tube. If hemostasis does not occur with the first device, a second device is delivered in the standard fashion over the remaining 0.035'' wire and then both sutures are cut. This strategy, with the use of 8Fr Angio-Seal devices has been successful in closure of arteriotomies up to 12 Fr in size.²

Pitfalls

Given the structure of the device, if there is incomplete apposition against the vessel lumen, such as in the case of an irregular lumen profile with peripheral vascular disease, hemostasis may not be achieved. When the femoral artery is very superficial, the collagen plug may be visible at the tissue entry site, which should be avoided. The plug should not be trimmed as the suture may be disrupted causing bleeding and/or device embolization. Furthermore, ischemic complications may occur if the collagen plug becomes intravascular. This can occur if in obtaining access, the needle first passes through a vascular structure prior to definitive entry. Hence, femoral angiography is necessary to rule out this possibility.

If the sheath is advanced while removing the arteriotomy locator, the anchor could be delivered against the posterior wall and the plug within the vessel. Therefore, sheath position must be maintained and the anchor must catch the anterior wall of the vessel. If the sheath is retracted when removing the arteriotomy locator, the device will not be delivered intra-lumenally and hemostasis will not occur. Furthermore, if tension is not maintained during device delivery, the device will not correctly sandwich and tamponade the arteriotomy site.

While the device is fully bioresorbable, this process takes between 60-90 days. Hence, if re-access is required at the same site prior to 90 days, access should be obtained 1 cm proximal to the previous location to prevent disruption of the previously delivered Angio-Seal. If this were to result in unsuitable access, an alternative access site should be used.

Mynx

Description

The Mynx (Cardinal Health, Dublin, OH) vascular closure device features a pliable and resorbable polyethylene glycol sealant that deploys outside the artery while a balloon acts as a footplate within the artery to ensure correct delivery. This device can be used to seal up to 7Fr arteriotomy sites.

Technique

1. The device is advanced through the sheath and a small, semicompliant balloon is filled with contrast (for visualization) or sterile saline and is inflated within the artery and retracted against the arteriotomy site to obtain transient hemostasis.
2. A shuttle is advanced to the artery bringing the polyethylene glycol plug to the site.
3. While maintaining continued tension on the system, the procedural sheath is then retracted and the polyethylene glycol plug is advanced towards the arteriotomy by advancing the delivery system. Forward pressure is maintained on the sealant using the advancer tube.
4. The polyethylene glycol expands and after 30 seconds, the device can be laid flat for an additional 90 seconds of curing.
5. The balloon is then deflated and retracted in the same plane as the tissue tract.
6. Manual pressure is applied to the access site for an additional 30 seconds until hemostasis occurs.

Pitfalls

This device can only be used for sheaths of up to 7 French. Problems with hemostasis may arise owing to the fact that the balloon is brought through the tissue tract after delivery of the gel. Care must be taken to ensure the balloon is completely deflated prior to removal. Furthermore, if the gel is not delivered adjacent to the artery, hemostasis may not result. Alternatively, if there is localized

calcification or localized disease, or if there is overzealous forward pressure on the advancer tube, the gel may be delivered intraluminally. This device is associated with higher rates of vascular complications than other closure devices, especially in those with diabetes, those ≥ 70 years of age and women.³ Resorption occurs over 60 days and there is no contraindication to re-access prior to this time.

Perclose

Description

The Perclose (Abbott Vascular Inc., Redwood City, CA) closure device is a polypropylene suture mediated closure device that can be used to close arterial access sizes of 5 - 21 Fr though it has been reportedly used in sheaths of up to 26Fr.⁴ For sheaths 5-8 Fr, a single device can be deployed at the conclusion of the procedure. For sheaths >8F, the pre-close technique with two Perclose devices is generally employed. There is no contraindication to re-access at the same site when a Perclose has been used.

Technique

For devices of up to 8Fr:

1. A 0.035" wire is inserted into the sheath and the sheath is removed while maintaining hemostasis.
2. The hydrophilic device is placed over the guidewire using wet gauze to assist with gripping and loading the device. The device is gently delivered to the exit port of the guidewire and the guidewire removed.
3. The device is advanced until blood return occurs indicating that the anchor is within the arterial lumen.

4. A lever (#1) is pulled deploying the anchor within the lumen and the device pulled back until resistance is met, positioning the device against the anterior wall of the vessel.
5. A plunger (#2) is depressed sending two needles to the anchor creating a suture loop.
6. The plunger device is then removed (#3) and the suture cut on the Perclose handle.
7. The anchor is retracted back into the device (#4) and the device is partially removed, thus exposing the suture limbs. The dark blue limb is the suture rail and the white-tipped suture is only manipulated when the knot is to be locked in place.
8. With the suture limbs out of the way and the guidewire exit site visible, the device is re-wired with a 0.035" wire to maintain vessel access. The device is then removed while maintaining wire position.
9. The pre-tied knot is advanced to the outer vessel wall over the suture rail (dark blue) using the knot pusher/cutting device. If hemostasis is achieved, the guidewire is removed while maintaining tension on the suture rail.
10. The knot is then locked in place by pulling on the white-tipped with the knot pusher/cutting device to the outer vessel wall and finally, the sutures are cut.

For devices >8 French in size, two devices must be deployed prior to increasing the sheath size >6Fr. The first device is deployed at the 10 o'clock position. The guidewire is repositioned through the first Perclose device as above and a second Perclose is delivered at the 2 o'clock position. This will allow for two sutures to be delivered in a 90 degree angle with an 'X' formation of the sutures over the arteriotomy site. The knots must not be advanced to the outer vessel wall until the conclusion of the procedure, and therefore, the sutures are secured with clamps or wet gauze in an orientation that will allow for their identification and retrieval at the end of the procedure. At the conclusion of the procedure, the sheath is removed with a guidewire in position.

By leaving the guidewire in position, if preclose fails to achieve complete hemostasis, the interventionalist has the following options:

1. A smaller sheath can be placed to allow for immediate hemostasis. Manual compression can be performed when safe to do so, or alternative access and balloon tamponade (+/- covered stent placement) can be pursued as appropriate.
2. Attempt to deploy a third perclose device. Additional devices beyond a third device are unlikely to be successful.
3. If hemostasis can be achieved with a 6-8Fr sheath, an alternative closure device can be used to achieve hemostasis.^{5,6}
4. Manual compression.

Special Considerations

A modified version of the pre-close technique has been described in patients requiring Impella for mechanical circulatory support.⁷ In this technique, the suture is delivered and secured with hemostats and wrapped in sterile dressing and secured against the patient's body with a sterile bandage. Delayed closure was performed up to 17 days after insertion when Impella support was deemed unnecessary. Access is obtained on the contralateral side, a peripheral balloon delivered to the ipsilateral iliac and inflated to low pressure (2-4 atmospheres) until there is loss of pressure waveform on the Impella sheath. This ensures a bloodless field for delivery of the Perclose sutures. After closure and prior to deflation of the occlusive iliac balloon, contrast is injected through the guidewire port of the iliac balloon to ensure that hemostasis is achieved prior to balloon deflation. As an added safety measure, a guidewire can be placed in the large bore sheath prior to its removal; this allows for the above four steps to be employed in the event of failure to achieve hemostasis. If a guidewire is not

placed, manual pressure, prolonged ipsilateral iliac balloon inflation or covered stent delivery from the contralateral access is still possible.

Pitfalls

Complications are more likely in those with peripheral vascular disease, women and smaller vessels of <5 mm in diameter. Infection is possible, though this risk has been reduced by the change from a braided suture to a monofilament design. If the risk of infection is of concern (e.g. diabetic status), pre-emptive antibiotics can be administered to prevent this complication.

Calcification can cause deflection of the needles, resulting in failure of the suture and the anchor to mate. This will be apparent with removal of the plunger; no suture will be tracked through the vessel. If this occurs, an additional Perclose can be attempted in a slightly different orientation. If the second Perclose also fails, a third device is unlikely to be successful. If a vessel bifurcation is within reach of the anchor, the device may also be inadvertently tethered posteriorly, which may result in femoral artery occlusion.⁸

In the obese patient, it may be possible that the device does not reach the femoral artery. If this is the case despite manual retraction of pannus tissue, the device cannot be used. Furthermore, particularly in the obese patient, the fascia overlying the femoral sheath can be mistaken for the vessel wall. If the knot is secured at this location, bleeding will occur. To avoid this, blunt dissection may be necessary to allow the knot pusher to reach the vessel wall. If the knot has not been locked in place (by manipulating the white suture string), re-advancement of knot over the rail with the knot pusher should be possible. If these strategies fail, and presuming the guidewire remains in place, another device can be delivered.

Ambulation post closure device

Factors, such as the use of anticoagulants and overall health status, must be considered when making bed rest recommendations. However, in general, patients may ambulate within 2 hours if access and vascular closure are uneventful.

Alternative Uses

While these devices were originally developed for use in the femoral artery, they can potentially be safely used in other arterial locations using the same principles. In large bore venous access, or in venous access with anticoagulation, the use of closure devices is appealing to expedite hemostasis and for patient comfort. To facilitate identification of the venous entry point, the patient can either Valsalva, or manual pressure applied proximal to the entry point. This results in venous return from the blood hole, allowing for identification of when the device is intraluminal and allowing delivery of these devices.^{9,10} Additionally, use of the Angio-Seal closure device in the setting of iatrogenic right ventricular perforation has been described.^{11,12}

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Table 1: Common Vascular Closure Devices

Device Name	Manufacturer	Puncture Size (Fr)	Comments
Angio-seal	Terumo Corporation	5/6, 7/8 8-12*	Passive approximator, absorbable. Composed of intraluminal anchor, suture & collagen plug to anchor collagen plug in arteriotomy site. Absorbed over thirty days, re-access prior to this time must be above/below the anchor. *Two 8F devices have been used to close up to 12F arteriotomy sites.
Mynx	Cardinal Health	5-7	Sealant based, absorbable. Composed of balloon and delivery system to deliver polyethylene glycol outside the artery. Absorbed over thirty days.
Perclose ProGlide	Abbott Vascular	5-7 8-26**	Suture based, absorbable. Percutaneous deployment of a polypropylene suture. **For greater than 8F, two devices and preclose technique required.

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