

Chapter 2

Access Site Hemostasis

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To Close or Not to Close?

The majority of arterial access procedures use the femoral route, with its attendant risks and lengthy periods of immobility. The traditional method for closure is manual compression, either with pressure through the operator's hands or with an external compression device. Multiple vascular closure devices (VCDs) have been developed over the years with the idea of speeding the process of hemostasis and potentially reducing the incidence of vascular complications, which can include hematoma, pseudoaneurysm, AV fistula, retroperitoneal hematoma, need for surgical repair, and infection. VCDs have been successful on multiple fronts, most notably in shortening the time needed to achieve hemostasis and the time to ambulation, and thus can significantly impact patient comfort. The ability to close the access site at the end of a procedure means not only that the patient spends a shorter period of time laying supine, but also that fewer human resources need to be expended in caring for

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patients with arterial sheaths, in manually pulling those sheaths, and in subsequent recovery. The data on complications of these devices when compared with manual compression is mixed and is difficult to interpret. For the most part, VCDs seem to have a comparable safety profile to manual compression, with some notable exceptions (e.g., the Vasoseal device, which appeared in some studies to have an increased rate of complications and has since been removed from the market). This is based on registry data, small studies, and meta-analyses, all of which have significant flaws. At least one large registry, as well as data from the ACUTY trial, has suggested that VCDs actually lower the risk of bleeding. In the end, the decision to use or not use VCDs must be made by each operator based on their own experience and institutional resources, and on the needs and vascular anatomy of each particular patient.

The following is the recommendations of the American Heart Association regarding the use of arteriotomy closure devices (AHA 2010) (see references):

1. Patients considered for deployment of arteriotomy closure devices at the femoral artery site should undergo a femoral angiogram with identification of sheath insertion site and other features (atherosclerosis, calcification, etc.) to ensure anatomical suitability for their use (Class I – Level of Evidence C).
2. Facilities with standard manual compression regimens should aim to achieve the reported low vascular complication rates (<1%), in patients undergoing uncomplicated 5 Fr diagnostic angiography (Class I – Level of Evidence C).
3. Use of arteriotomy closure devices is reasonable following invasive cardiovascular procedures performed via the femoral artery to achieve faster hemostasis, shorter duration of bed rest, and possibly improved patient comfort. The use of these devices should be weighed against the risk of increased complications in certain patient subsets and also take into account body habitus, location of arteriotomy, size and condition of the parent vessel, sheath size, and presence or absence of systemic disease in the patient

(Class IIa – Level of Evidence B). This recommendation is based on a meta-analysis and several small scale trials. However, in these studies there are trends toward higher rates of complications.

4. Arteriotomy closure devices should not be used routinely for the specific purpose of reducing vascular complications in patients undergoing invasive cardiovascular procedures via the femoral artery approach (Class III, Level of Evidence B). This recommendation is based on the aggregate of three meta-analyses, registry data, and moderate-size randomized controlled trials of suboptimal quality. It should be noted that there is significant heterogeneity among the reported effects of the different devices deployed. The writing committee did not feel there was sufficient evidence to warrant a separate recommendation at this time for specific arteriotomy closure devices, or active versus passive closure devices.
5. Complications encountered during or following deployment of arteriotomy closure devices should be collected systematically either as part of local quality efforts or national registries (such as the ACC-NCDR) and systematically reported to the FDA (Class I – Level of Evidence C).

Manual Compression

Manual compression has long been the gold standard for obtaining access site hemostasis. Although compression is straightforward and simple, success requires good preparation and technique.

Preparation

- Have a sphygmomanometer attached to the patient, and take a blood pressure directly prior to sheath removal. In the case of a single operator, set an automatic monitor to take the blood pressure every 2–4 min and make certain that someone is immediately available to assist in case of problems.
- Make sure there is a working peripheral IV, with isotonic fluid (e.g., NS or RL) attached and ready to go if needed.

- Have atropine ready in case of vasovagal episode.
- Although usually not necessary, re-instillation of lidocaine may be useful in case the sheath has been indwelling for a prolonged period.
- Assess the peripheral pulses and examine the access site for hematoma prior to sheath removal.
- Position the patient near to the side of the bed. Set the bed at an appropriate height, such that the operator can extend the arms fully and use upper body weight to apply pressure.

Technique

- For a right femoral sheath, place the middle three fingers of the hand such that pressure will be exerted proximally from the sheath site. Remember that the arteriotomy will in most cases be 2–3 cm proximal to the skin entry site.
- If both arterial and venous sheaths were used, remove the arterial sheath first and confirm good hemostasis before proceeding. We generally remove the venous sheath once only 5–10 min are remaining for the arterial site (see below for appropriate “hold times”), and complete the hold with pressure over both sites.
- Remove the sheath slowly at the same angle at which it was inserted.
- Apply firm pressure over the arteriotomy site once the sheath has been removed. Initial pressure should be occlusive, but should be decreased gradually after the first 5 min such that distal pulses can be felt.

What Is the Target ACT for Sheath Removal?

We generally wait until the ACT has fallen below 170 s before removing the sheaths. Recognize, however, that there is little objective evidence supporting the traditional thresholds of 150–180 s. In fact, several recent trials have removed sheaths using a much higher ACT threshold of <250 s, reportedly without a significant increase in bleeding complications. For patients with normal to moderately reduced renal function anticoagulated with bivalirudin, arterial sheaths can be

removed safely 2 h after discontinuation of the medication, without checking the ACT. For patients given bivalirudin with severe renal dysfunction or who are on hemodialysis, we use an ACT threshold of 170 s to guide manual sheath removal.

How Long Do I Need to Hold Pressure?

The easy answer is to hold until hemostasis is attained. Protocols will differ from institution to institution. A good starting place is to hold pressure for approximately 3 min per French size – that is, 15 min for a 5-Fr sheath, 18 min for a 6-Fr sheath, and so on.

How Long Should the Patient Be Immobile After Sheath Removal?

This is another area where very little data exists. Many labs including ours routinely keep patients in bed for 1 h per sheath French size. For example, patients are kept supine for 6 h following removal of a 6-Fr sheath. Raising the head of the bed up to 30° after the first 1–2 h improves patient comfort without appreciably increasing the risk of bleeding.

When Can Anti-coagulation Be Restarted After Sheath Removal?

Anti-coagulation following femoral access site hemostasis is a tricky subject. Of course, coumadin may be restarted immediately after a procedure, since it will not take effect for several days. However, heparin and low molecular weight heparins given soon after femoral arterial sheath removal will significantly increase the risk of rebleeding and of the development of pseudoaneurysm. Just how soon heparin may be restarted is a matter of clinical judgment, balancing the

indication for anticoagulation with the risk of bleeding. In our lab, we wait at least until the end of the bedrest period (6 h for a 6-Fr sheath) before starting heparin, and then do so without a bolus. Because it cannot be readily reversed, LMWH should be given cautiously.

What About Vascular Grafts?

In the PAD population, femoral access adjacent to or even through vascular grafts is sometimes necessary. Manual compression is the method of choice for sheath removal, and should be performed by an experienced operator. Although the technique is similar to that used with native femoral vessels, the risk of graft thrombosis from over-compression must be considered. The principle here is to achieve hemostasis at the site while maintaining flow down the graft by avoiding full occlusive compression. Because of the relatively fine control required, we tend to avoid mechanical devices such as the FemoStop and C-clamp in these patients. Initial holding times are similar to those used for native vessels, but can vary widely. Because of the increased risk of complications, we do not use any of the available arteriotomy closure devices with grafts.



Potential Pitfalls

Effective early control is essential. However, do not start with full pressure until the sheath is removed, so as to avoid stripping off any thrombi. Consider allowing blood to flow for one to two heartbeats to allow any thrombus to be flushed out before applying pressure.

Active Closure Devices

Angio-Seal

The Angio-Seal (St. Jude Medical, St. Paul, MN) device is currently the most widely used VCD, primarily because of its ease of use, short-learning curve, and high initial success rate. The device sandwiches the arteriotomy between a resorbable anchor inside the vessel and a collagen plug outside, with the two joined by a self-tightening suture. The device comes in separate 6 and 8 Fr sizes, and is currently manufactured in three configurations: the STS-Plus, the VIP, and the Evolution. The Evolution is the most recent iteration of the device, and improves on previous versions by including a self-tamping mechanism that standardizes the pressure used to deploy and tamp the collagen plug.

Technique

- Perform an angiogram to confirm that the vessel and sheath placement are suitable for the device. Specifically, the sheath must be in the common femoral artery with a vessel size ≥ 5 mm and less than 40% stenosis near the entry site. This device should not be used if entry point is at or below the femoral bifurcation, or at or above the inferior epigastric artery.
- Flush the procedure sheath, re-prepare and drape the access site, and don new sterile gloves.
- Prepare the Angio-Seal sheath by inserting the arteriotomy locator (the green dilator) into the sheath, confirming that the two snap together firmly.
- Insert the included guidewire into the procedural sheath and remove the sheath, leaving the wire in place in the artery.
- Place the Angio-Seal sheath/arteriotomy locator onto the wire with the arrow on the sheath pointing upward, and advance the sheath into the artery until blood drips from the back of the locator. To avoid over-insertion into the artery, the manufacturer recommends withdrawing the

sheath until blood flow stops, and then slowly re-advancing it until blood again drips from the locator.

- Holding the sheath securely with one hand, remove the wire and locator by flexing the base of the arteriotomy locator upward and withdrawing both from the sheath.
- Pick up the Angio-Seal device by grasping it just behind the bypass tube, and insert it into the sheath with the reference indicator facing upward. Advance the device all the way into the sheath until you hear a click. Holding the sheath securely in place, grasp the handle of the device and gently pull back until you hear another click.
- Holding two fingers against the puncture site to provide support pull back on the device handle along the same angle as the sheath tract.
 - For the Evolution device, simply pull back until the green compaction marker is revealed. Then depress the Suture Release button and pull back until the suture is exposed, and cut the suture below the skin surface.
 - For the VIP device, pull back on the handle until the green compaction tube appears and the suture has stopped spooling. Keeping firm backward tension on the device, advance the compaction tube until resistance is felt and (in most cases) the black compaction marker is revealed. Cut the suture to remove the device, and then cut the suture again below the skin surface.

Advantages

- One of the easiest devices to learn and use.
- Has a very high initial success rate.
- The collagen plug in the tract also acts to reduce oozing from the site.
- The retained components of the device are completely resorbed over the course of weeks to months after insertion.

Disadvantages

- The intravascular anchor has the potential to further obstruct a heavily diseased vessel.
- Although extremely rare, embolization of the intravascular anchor is a possibility.

- Repeat access of the same vessel within 90 days of device deployment should be avoided using the same puncture site to avoid disrupting the plug; the manufacturer recommends puncture 1 cm proximal to the initial site. Depending on the location of the initial site, going 1 cm above is not always possible.
- As with all devices with retained components, this device is a potential nidus for infection. Cutting the suture below the skin surface is important for minimizing this risk.

How We Use It

The Angio-Seal is a dependable and easy-to-use device. We tend to employ it in suitably large and relatively disease-free common femoral arteries when the sheath is well clear of the femoral bifurcation and of significant branch vessels. We tend not to use it when we predict possible need for re-access within 3 months, for the reasons stated above.

Starclose

The Starclose (Fig. 2.1; Abbott Vascular, Menlo Park, CA) device employs a nitinol clip that grasps the outside of the vessel to appose the arteriotomy and achieve closure. It is therefore an active (rather than passive) closure device that leaves nothing inside the vessel. The Starclose is approved for closure of 5 and 6 Fr sheaths.

Technique (for the Starclose SE Platform)

- Perform an angiogram to confirm that the vessel and sheath placement are suitable for the device. The device requires a vessel size of 5 mm or greater to allow the vessel locator to be withdrawn to the arteriotomy.
- Make sure that the sheath has a dermatomy of 5–7 mm, and perform blunt dissection to ensure smooth delivery of the clip down to the artery. In our hands, an inadequate tract, leading to inability to fully advance the delivery tube, is the most common reason for device failure. To minimize oozing, consider making the incision and blunt dissection



FIGURE 2.1 Starclose device

at the beginning of the procedure prior to the administration of anticoagulants.

- Flush the procedure sheath, re-prep and drape the access site, and don new sterile gloves.
- Using the supplied guidewire, exchange the procedural sheath for the Starclose sheath.
- Insert the tip of the Starclose device into the sheath and advance the device into the sheath, taking care not to bend the shaft of the device.
- Advance the device until it clicks securely in place in the hub of the sheath (labeled #1 on the device). This usually requires that the sheath be withdrawn slightly from the skin surface.
- Stabilize the device by holding it securely with the left hand by the Stabilizer finger loop. Retract the device 3–4 cm out of the tissue tract (be careful not to retract too far).
- Using the right hand, depress the plunger (labeled #2) fully until a click is heard and the number “2” is fully seen in the number window. This expands the locator wings within the artery and begins the splitting of the sheath, which can be seen above the skin surface.
- Gently retract the device with the right hand along the angle of sheath insertion until resistance is felt, indicating that the vessel locator wings are in contact with the inner surface of the arteriotomy. Again stabilize the finger loop with the left hand.

- Using the right hand, depress the thumb advancer (#3) all the way down, until a click is heard and the number “3” is seen completely within the number window.
- Raise the body of the device to a 70° angle.
- Apply gentle downward pressure on the device to seat the delivery tube against the artery.
- Using the thumb of the right hand, depress the deployment button (#4) until a click is heard. Maintain downward pressure on the device for another 3 s.
- With the left hand providing counter traction, remove the device and apply moderate pressure with the left hand.
- Although not always necessary, we generally apply several minutes of pressure to minimize oozing from the tract.

Advantages

- The Starclose device deploys on the outside of the artery, leaving nothing in the lumen.
- The external nature of the device means that it may be appropriate for use in situations in which other devices are unsuitable, including vessels with moderate disease at the access site or with the arteriotomy near the femoral bifurcation.
- Note that while the manufacturer advises against using the Starclose when the arteriotomy is below the femoral bifurcation, the device is being used in practice to close the SFA when the vessel is sufficiently large (>5 mm).
- Re-puncture through a deployed Starclose clip may in general be performed safely at any time. Note again that the manufacturer cautions that the safety of repeat puncture and closure has not been fully established, despite two successful bench studies in a porcine aorta model.

Disadvantages

- The ability to deliver the Starclose clip depends on having an adequate dermatomy and a patent tract to allow passage of the relatively bulky delivery system. This generally results in more post-closure oozing from the site compared with other devices.

- Although the device is deployed on the external surface of the artery, remember that the vessel locator portion of the device is inserted into the artery and is drawn back after deploying the wings until it reaches the arteriotomy. This has the potential to disrupt intravascular plaque, similar to other VCDs.
- The Starclose is designed for closure of 5 and 6 Fr arteriotomies only. Although closure of 7 Fr and even 8 Fr sheath sites has been reported, the risk of device failure with these larger sheaths is higher, as is the likelihood of hematoma formation during deployment due to leakage around the 6 Fr Starclose sheath.

How We Use It

The Starclose has become one of the workhorse VCDs in our lab for routine closure of 5 and 6 Fr sheaths. It allows secure closure of vessels that were previously un-closeable, including relatively diseased vessels and arteriotomies near the femoral bifurcation. We routinely re-puncture and re-close the same access site using this device.

Perclose

The Perclose (Abbott Vascular, Menlo Park, CA) is the prototype of the suture-based VCD, and has gone through several iterations since its inception. Since the first Perclose device was introduced in 1994, several advances have made the device simpler to use. The precursor of the currently available devices, the Closer, delivered polyester suture to the vessel. The knots were hand-tied and advanced to the arteriotomy to effect closure. In 2002, Abbott Vascular (which acquired the Perclose company in 1999) introduced the Perclose A-T (auto-tie), which greatly simplified the procedure through use of a pre-tied knot, allowing faster deployment with a single operator. Although the A-T is still available, most labs have adopted the more recent Proglide version (Fig. 2.2), which replaced the braided polyester suture



FIGURE 2.2 ProGlide device

with a polypropylene monofilament for easier knot advancement, and added a suture-cutting mechanism on the device. The Proglide is approved for closure with sheath sizes between 5 and 8 Fr.

Technique (for Closure at the End of a Procedure)

- Perform an angiogram to confirm that the vessel and sheath placement are suitable for the device. The Proglide requires a vessel size of >5 mm, and should not be used if the puncture site is at or below the femoral bifurcation.
- Flush the marker lumen of the device with saline to confirm lumen patency.
- Flush the procedural sheath, place a 0.035 or 0.038 in. guidewire into the artery, and remove the sheath. Note that the device does not come packaged with a guidewire. Any standard 0.035 or 0.038 in. guidewire can be used.

We generally clean and save the J wire used to deploy the sheath at the beginning of the case.

- Backload the Proglide device onto the guidewire, and advance it into the artery until the guidewire port reaches the skin surface. Remove the guidewire.
- Continue to advance the device into the artery until a continuous flow of blood is seen through the marker lumen.
- Deploy the foot process inside the vessel by lifting the level marked #1.
- Gently retract the device until resistance is felt, positioning the foot process against the inside of the vessel wall. Blood flow through the marker lumen should be reduced or stopped altogether.
- Push firmly on the plunger marker in the direction marked #2 to deploy the needles.
- Stabilizing the device firmly with the left hand, remove the plunger and needles by pulling back on the plunger in the direction marked #3. The plunger should be attached to one suture limb. Pull gently until the suture is taut.
- Cut the suture, either by using the Quickcut mechanism on the body of the device or using a scissors or scalpel.
- Push the lever (marked #4) down.
- Stabilizing the access site with the left hand, withdraw the Proglide device until the guidewire port (marked on each side by a white arrow) is visible above the skin.
- Harvest the sutures by pulling the suture ends from the device. You should have one blue (rail) suture end and one white (non-rail, knot-tightening) suture end.
- If you wish to retain wire access, then re-insert the guidewire through the wire lumen.
- Load the blue rail limb of the suture onto the snared knot pusher, and wrap the end around the index finger of your left hand. Keep the white non-rail limb out of the way by weighting it down with wet sterile gauze.
- Remove the Proglide device, and advance the knot to the arteriotomy by pulling gently on the blue rail limb.
- If the site is hemostatic, then remove the guidewire and proceed with advancement and tightening of the knot as

described below. (If no hemostasis was achieved, then a sheath may be advanced over the guidewire to re-secure the access site.)

- Keeping tension on the blue end, advance the knot pusher to complete advancement of the knot. Make sure that the knot pusher is going all the way to the arteriotomy, and is not getting caught up in the tissue tract.
- Keeping the knot pusher in place, pull on the white limb of the suture to tighten the knot.
- Remove the knot pusher from the tract. Hemostasis may be checked at this point by asking the patient to cough or bend the leg. Continued bleeding should be managed by further knot advancement, followed again by again securing the knot through tension on the white non-rail suture end.
- Once hemostasis has been achieved, remove the knot pusher completely.
- Load both ends of the suture onto the suture trimmer device and advance down to the arteriotomy. Pull back on the red trimming level to cut the sutures, and remove the device and suture ends from the wound.
- Hold gentle pressure until oozing is controlled.

Advantages

- Guidewire access is maintained until at least partial hemostasis is confirmed. This advantage is important in situations where device failure may have serious consequences.
- May be used to “preclose” the vessel (see discussion below) for procedures requiring very large sheaths.
- Effective use results in effective closure with only suture in the wall of the vessel, with no bulky or thrombogenic material in the lumen.
- A single device closes arteriotomies in the 5–8 Fr range.
- Re-access of the vessel has no restrictions.
- The device needles enter the artery from above (in contrast to the Prostar devices), thus minimizing the risk of getting the needles stuck if the device fails.

Disadvantages

- Somewhat more difficult to learn than some of the other devices.
- Difficult to use in calcified vessels, as the needles may fail to penetrate the arterial wall, causing the device to fail.

How We Use It

I prefer the Perclose Proglide in appropriate vessels when I cannot afford to have the device fail, since access with a guidewire can be maintained until at least partial success is confirmed. We use the Proglide preferentially for the preclose technique. We avoid the Proglide in very heavily calcified vessels or with sheath entry in the superficial femoral artery or profunda, as the foot process can catch on the femoral bifurcation and result in inappropriate deployment of the suture.

Prostar XL

The Prostar (Fig. 2.3; Abbott Vascular, Menlo Park, CA) is one of the original suture-based devices. It results in the deployment of two sutures at right angles to one another, via four suture needles. Of the several Prostar devices that have been manufactured over the years, only the Prostar XL 10 Fr device is still sold in the US. The suture is polyester and requires manual knot tying, and is therefore more challenging to use compared with the Perclose Proglide. Also in contrast to the Perclose Proglide and A-T, the Prostar needles are deployed from the inside of the vessel outward. This brings up the possibility of getting the device stuck in the event of improper use. For these reasons the Prostar is labeled by Abbott as a Percutaneous Vascular Surgical device (as opposed to the Suture Mediated Closure label applied to the Proglide) and is marketed primarily to vascular surgeons.

Advantages

- Deploys two sutures with a single device, making it a natural device for use in “preclosure” of large access sites.
- No restrictions on re-access of the vessel.



FIGURE 2.3 ProStar XL device

Disadvantages

- Relatively difficult to learn and use.

Passive Closure Devices

Mynx

The Mynx (Fig. 2.4; AccessClosure, Inc., Mountainview, CA) is a more recent device that effects closure by depositing a polyethylene glycol (PEG) sealant in the tissue tract, through the procedural sheath. Because it does not anchor to the artery itself, it is often referred to as a passive, rather than an active, closure device. The device is manufactured in a 5 Fr version and a separate 6Fr/7 Fr version.

Advantages

- Because it is placed directly through the procedural sheath and uses a synthetic sealing agent, the Mynx theoretically has low infection potential.
- Causes very little discomfort during deployment, in comparison to other devices.

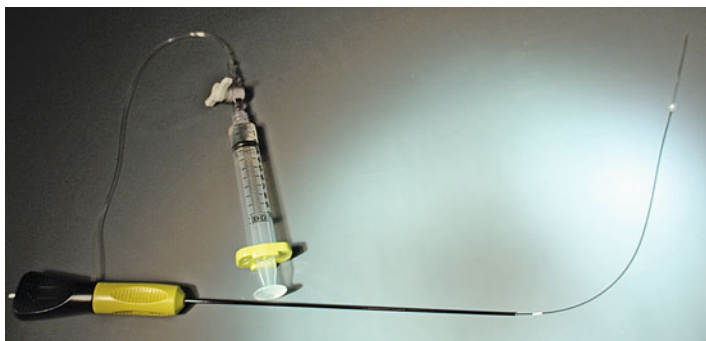


FIGURE 2.4 Mynx

- The device places the sealant entirely external to the artery, and therefore does not compromise the lumen.
- Use of multiple Mynx devices to close larger-bore access sites has been reported.

Disadvantages

- Because this is a passive device, closure is potentially less secure than with active devices. Testing the device (by having the patient cough or lift the leg) is actually contraindicated.

Technique

- Remove the Mynx device from its tray.
- Fill the locking syringe with 3 mL of saline.
- Attach the syringe to the stopcock on the device, and draw vacuum to prep the balloon.
- Inflate the balloon until the black mark on the inflation indicator is visible.
- Deflate the balloon completely and leave the syringe neutral. Submerge the tip of the shuttle tube in sterile saline for 5 s.
- Insert the device into the sheath and advance until it reaches the white marker. Inflate the balloon until the black inflation mark is visible, and turn the stopcock.
- Holding the device by the handle, draw back at an angle parallel to sheath insertion. Resistance will first be felt

when the balloon abuts the tip of the sheath. Continue withdrawing until the balloon reaches the arteriotomy.

- Confirm that the balloon is against the arteriotomy by opening the stopcock on the procedural sheath. Brisk flow of blood would indicate that the balloon is not adequately against the arteriotomy and needs to be repositioned.
- While maintaining light backward pressure on the handle with the right hand, grasp the shuttle with the left hand and advance down through the procedural sheath until resistance against the balloon is felt. A quiet “click” should be heard.
- Now grasp the procedural sheath and withdraw it until the sheath, shuttle, and handle all come together.
- While continuing to maintain backward tension on the handle, grasp the advancer tube at skin level and advance two markers.
- Lay the device down and allow at least 10 s for the device to swell in the tract. Wait longer (at least 60 s) for anti-coagulated patients.
- With the left hand, grasp the advancer tube at the skin to stabilize it. Pull back on the syringe until it locks, and open the stopcock to deflate the balloon. Wait until all fluid and air bubbles have stopped moving through the tubing to be certain that the balloon is completely deflated.
- Maintaining light forward pressure on the advancer tube, slowly withdraw the balloon catheter through the advancer tube lumen.
- Remove the advancer tube and apply light pressure for 2 min.

Tips of the Trade

In situations where it may be more difficult to determine by feel whether the balloon is all the way back against the arteriotomy (e.g., iliac tortuosity or disease, scar tissue at the access site), fill the syringe with a 50:50 contrast/saline mix and use fluoroscopy to guide.

In patients with iliac tortuosity that prevents tracking of the device up the iliac, first placing a 0.035-in. wire as a “buddy” can facilitate the initial device insertion.

How We Use It

Because of its essentially painless deployment process, the Mynx is my go-to device for patients who are sensitive to groin pressure or who may have a vagal response to full manual pressure. It is a good alternative as a completely external-to-the-artery device when a passive device is suitable.

Cardiva Catalyst

The Cardiva Catalyst (Cardiva Medical, Sunnyvale, CA) device is the successor to the Boomerang Wire. These devices are intended to assist with arteriotomy closure while leaving nothing behind either in the artery or the tract. The concept is simple: replace the 5, 6, or 7 Fr sheath with a wire that has a collapsible biconcave disc near the distal end that can be retracted against the inner surface of the arteriotomy to achieve temporary hemostasis. During a dwell time of between 15 min and several hours, the natural recoil of the vessel wall around the arteriotomy results in a smaller arterial defect and more efficient manual closure. The Catalyst II device improves on the earlier Boomerang by incorporating a biocompatible coating (containing kaolin and chitosan) that aids hemostasis. The Catalyst III is intended for use in heparinized patients, and incorporates protamine sulfate into the coating to locally neutralize heparin.

Advantages

- The Catalyst leaves no foreign body behind in the vessel. Theoretically, this should translate into a lower risk for infection and lower potential for adverse reactions.
- Because nothing is left in the artery, vascular disease at the access site has less effect on the ability to use the device.

- Manual compression time is significantly shorter than without the device.
- With anti-coagulated patients, the time to hemostasis is significantly shorter than when using manual compression without the device.

Disadvantages

- Manual compression is still required.



Potential Pitfalls – Common to All Closure Devices...

- Risk of infection. Caution in certain groins, with long-dwelling sheaths, etc. Consider antibiotics in certain cases.
- Always perform an angiogram prior to insertion. Look for problems including calcification or tortuosity, severe luminal disease.
- Do not deploy devices with intravascular components at or below the femoral bifurcation.
- If the sheath is at or above the inguinal ligament, use caution! The vessel turns posteriorly here, and most devices will not deploy properly. Unrecognized device failure can lead to severe retroperitoneal hemorrhage.

Mechanical Devices That Assist with Manual Compression

FemoStop

The FemoStop device (Fig. 2.5; St. Jude Medical) consists of a rigid frame that holds a clear pneumatic dome that can be inflated to provide pressure over the femoral artery. The frame is held in place by a wide adjustable belt that is placed under the patient's hips. The dome pressure is controlled



FIGURE 2.5 FemoStop device

precisely by way of a pump with a manometer, very similar to that used with blood pressure cuffs.

- The FemoStop can be used to replace manual compression, by placing the device before sheath removal. For this indication, pressurize the device to 60–80 mmHg for sheath removal, then increase the pressure to just above the systolic pressure for approximately 3 min. Then reduced the pressure in the dome to just above the diastolic blood pressure and confirm return of distal pulses. Retain the device at this pressure for at least 15 min. Then reduce the pressure by 10–20 mmHg every few minutes until all the pressure is released.
- Another option is to remove the sheath manually, and then apply to FemoStop device. When this is the intention, be sure to place the belt in good position under the patient's hips BEFORE removing the sheath, so that the device is ready to apply.
- The FemoStop can be a good option for manual compression when very long compression times are anticipated, or when a hematoma has developed prior to sheath removal, making compression with the hands challenging.

- The FemoStop device may remain in place at low pressure (30 mmHg or less) during bedrest. This is especially useful for patients on gpIIb/IIIa inhibitors or for whom re-bleeding is otherwise considered likely.

Clinical Pointers

- The FemoStop can be an effective device for treating a femoral pseudoaneurysm, and is formally indicated for this purpose.
- Compression of a pseudoaneurysm can be uncomfortable. Consider giving local anesthesia and systemic pain medication prior to starting.
- Examine the site by duplex ultrasound in order to locate the artery, vein, pseudoaneurysm, and tract. Mark the skin over the site to be compressed with an “X.”
- Position the FemoStop over the marked site and inflate. Do not keep at occlusive pressure for more than 3 min. Maintain a constant pressure for 20 min, making sure that distal pulses are palpable during compression.
- Release pressure and repeat ultrasound, looking for flow in the pseudoaneurysm and tract.
- If abnormal flow persists, then repeat 20 min of compression.
- Bedrest with low-pressure (30 mmHg or less) compression. Repeat ultrasound to confirm resolution.

C-Clamp

Several “c-clamp” devices are manufactured, marketed as the CompressAR (Advanced Vascular Dynamics) and ClampEase (ClampEase, Portland, OR). These devices are comprised of a stand with an arm that applies direct pressure to a disc situated over the artery. In skilled hands, these devices can be very effective for applying manual compression. They are not meant to be used unmonitored, however. Once placed, they

need to be evaluated frequently for bleeding, misalignment, or excessive pressure leading to limb ischemia.

Safeguard

The Safeguard device (Maquet Cardiac Assist, Mahwah, NJ) is a large sterile dressing with an integrated inflatable bulb that adheres over the access site and assists with pre- and post-hemostasis management.

- When placed prior to sheath removal (the “manual assist” technique), the Safeguard reduces active compression time. Because pressure is exerted through the bulb of the device, the application of pressure can be more comfortable than using the hands alone.
- As a post-hemostasis management device, the Safeguard can be applied once hemostasis is achieved to stabilize the site. This can decrease the rate of recurrent post-procedure bleeding, especially with patients who are heavily anticoagulated or who are non-compliant with the restrictions on mobility post-procedure.
- The clear window on the device allows monitoring of the site while it is in place. This offers an advantage to the traditional “pressure dressing” made of tape and gauze, which usually obscures the site.
- The device relies on adhesive to hold it in place. In our experience the Safeguard can be expected to fit poorly on certain patients, such as those with a large abdominal pannus.



Potential Pitfalls

- Each of the mechanical compression devices needs to be placed by a trained operator, and must be monitored closely.

- Minimize the amount of time that full occlusive pressure is applied. Full occlusive pressure does not speed hemostasis, can be painful, and can cause complications.
- The FemoStop and C-clamp devices can be very uncomfortable for the patient. Beware of vagal episodes when using these.
- Be aware that use of these devices generally compresses the adjacent vein as well as the artery, and therefore carries a small risk of deep venous thrombosis. Make sure that the device does not stay in place longer than is necessary.

Topical Hemostasis Aids

A variety of topical patches, pads, bandages, and powders is available for use to assist with hemostasis with manual compression. The idea is that these devices accelerate the clotting process and thus accelerate hemostasis, potentially allowing for shorter compression times and lower incidence of re-bleeding. Approximately 10 such products are currently approved by the FDA for use.

- Most of these agents have been approved based on studies showing that they improve time to hemostasis and time to ambulation, versus unassisted manual compression.
- Topical agents leave no foreign body behind, and act by accelerating natural hemostasis.
- Topical agents still require manual compression.

The Preclose Technique

The suture-based devices, Perclose Proglide and Prostar XL, rule in the arena of closure of large-bore access sites. That is because these devices may be used to place sutures in the arteriotomy at the beginning of a case with small-bore access (5–8 Fr with the Proglide, or 10 Fr with the Prostar) and lay

the suture ends aside. The arteriotomy may then be dilated up to the desired size, up to 25 Fr in some series. At the end of the procedure, the large sheath is removed, and the sutures are tightened down to effect hemostasis. The technique is known as Preclose because the devices are deployed at the beginning rather than at the end of the case. If the Proglide is used, two devices are deployed resulting in two separate sutures at the puncture site. The Prostar only requires a single device, since it is designed to place two sutures at right angles to one another.

How I Do It

- Safe closure starts with good access. Use fluoroscopy and a 4-Fr micropuncture kit to access the common femoral artery. Confirm appropriate positioning by a contrast injection before proceeding.
- Dilate the puncture site with a 6 Fr sheath. Remove the sheath, leaving a 0.035-in. guidewire in the artery.
- Place a Proglide over the wire and advance into the vessel. Rotate the device counterclockwise to the 10 o'clock position, and deploy.
- Harvest the suture ends from this first device, tag them with a small hemostat, and lay them aside. Maintain guidewire access.
- Insert a second Proglide device, rotate clockwise to the 2 o'clock position, and deploy.
- Harvest the suture ends from the second device and tag them with another small hemostat. Again replace the guidewire before removing the device.
- Make sure to save the knot pusher and suture trimmer for later.
- Now serially dilate the access site over a stiff guidewire and place the procedural sheath. Proceed with the planned intervention.
- Once the procedure is complete, replace the stiff 0.035-in. guidewire and slowly remove the large sheath while applying manual pressure to the site.
- Use the knot pusher to cinch down both of the previously placed sutures. Release manual pressure to assess the site.

If hemostasis has been achieved, then remove the guide-wire and further tighten and lock the knots.

Tips of the Trade

- If pulsatile flow is still seen after both sutures are secured, a third Proglide device can sometimes be deployed successfully. If this does not work, then reinsert an appropriate-size sheath to regain hemostasis and consider surgical repair of the artery.

Radial Access Closure

Radial access for interventional vascular procedures continues to gain traction due to its overall excellent safety profile. Multiple hemostasis devices are now on the market, each essentially providing local pressure over the access site. The simplest of these is the Hemoband (HemoBand Corporation, Portland, OR), which is essentially an adjustable plastic compression strap. The RadAR device (Advanced Vascular Dynamics, Portland, OR) is similar, but adds an adjustable screw for more fine control of wrist pressure. Vascular Solutions manufactures a version that incorporates its D-stat hemostasis pad into a compression band. The TR band (Terumo Medical Corp., Somerset, NJ) uses dual compression balloons, inflated with air by a syringe, to accomplish hemostasis. The RadiStop (St. Jude Medical) incorporates a compression pad and straps onto a support plate that holds the hand, wrist, and forearm.

How hemostasis is achieved can have a significant impact on the rate of subsequent radial artery occlusion.

- The hemostasis device should not remain in place too long. On average, the device should be able to be removed after 2–3 h.
- Use the “patent hemostasis” approach:
 - Place the compression device with the least pressure necessary to achieve hemostasis.

- Place a pulse oximetry probe on the thumb or index finger of the involved hand.
- Occlude the ipsilateral ulnar artery with manual compression. If oximeter signal is present, then the radial artery is patent and you have achieved “patent hemostasis.”
- If no signal is present, gradually loosen the compression device until either signal returns or bleeding occurs. Note that we are not able to achieve patent hemostasis in every patient.
- Devices allowing for more fine control over radial artery pressure, such as the TR band and RadAR device, are somewhat easier to use for this purpose.

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