

CME-Certified Article

An Evidence-Based Approach to Femoral Arterial Access and Closure

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Project ID: 5197 ES13

Target Audience

This activity has been designed to meet the educational needs of cardiologists involved in the management of patients who are undergoing invasive cardiac intervention.

Statement of Need

Femoral arterial puncture is essential for the successful execution of diagnostic and interventional catheterization procedures. Although a number of effective closure techniques exist, they cannot be applied to every patient in every situation. The goal of this article is to synthesize the latest research on vascular closure efficacy and provide a balanced discussion of closure devices.

Faculty

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TREATMENT UPDATE

An Evidence-Based Approach to Femoral Arterial Access and Closure

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Percutaneous arterial access is performed in up to 10 million patients worldwide annually. The predominant techniques have been largely unchanged for a half century, but an evolving evidence base over the past several years suggests that major improvements in access and a reduction in complication rates may be accomplished with a better appreciation of anatomy and the use of fluoroscopy or ultrasound guidance. Vascular closure is still predominantly by manual compression; meta-analyses comparing vascular closure techniques have not clearly demonstrated a difference between manual compression and vascular closure device complication rates. Although vascular closure devices are associated with earlier hemostasis and time to ambulation, their cost and potential associated complications limit use to roughly 30% of cases in the United States and single digit percentages in the rest of the world.

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Educational Objectives

After completing this activity, the participant should be better able to:

- Describe the optimum vascular access technique
- Review currently available vascular closure methods
- Cite findings of studies related to vascular closure techniques and technologies
- Describe the relative efficacy of vascular closure techniques

Disclosure

Dr. Turi has received consulting fees and performed contracted research for Abbott Vascular.



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The femoral artery remains the primary access site for invasive cardiac and peripheral diagnosis and intervention. Although this route is used in more than 90% of patients in the United States, radial artery access is common in Europe and has been described as the primary approach in up to 70% of coronary diagnostic procedures in some European countries. Nevertheless, femoral artery access remains predominant because of several advantages: larger size (which enables deployment of a variety of devices sizes 24-French or greater), relatively simple access, and avoidance of anatomic factors that can

limit the radial or brachial approach. Randomized comparisons between radial and femoral approaches have demonstrated generally better success rates with femoral access, albeit with a higher complication rate.¹

The first percutaneous femoral access was described by Seldinger in 1953.² This approach eliminated the need for surgical cutdown and substantially decreased morbidity and mortality associated with intravascular procedures. The initial procedure utilized a through-and-through puncture technique, whereby a hollow needle was passed through the back wall of the artery and then withdrawn until blood spurted through the needle, confirming entry into the true lumen. This technique has subsequently been modified to an anterior wall-only approach. Otherwise, the technique has remained largely unchanged for a half century. Only one other significant advance has occurred: the use of indwelling sheaths to allow multiple catheter exchanges without repeatedly traumatizing the arteriotomy site.³ This approach is thought to have decreased complications associated with fraying of the arterial fenestration from repeat passage of catheters, and to have eliminated collection of debris in the catheter lumen during passage through the skin and subcutaneous tissue. It also allowed monitoring of femoral artery pressure through the sheath sidearm.

Localization of the Puncture Site

A formal evidence base was remarkably absent throughout the first half century of percutaneous vascular access. An exception was a study by Grier and Hartnell in 1990,⁴ which queried 200 radiologists and demonstrated that the most common technique was puncture at the inguinal

crease (40%), without regard to 2 other common landmarks: the point of maximal pulsation and the bony landmarks (an imaginary line drawn from the anterior superior iliac crest to the symphysis pubis, a rough approximation of the location of the inguinal ligament). Puncture at the inguinal crease unfortunately tends to result in low sticks (Figure 1), particularly in obese patients. A common misconception, present in most textbooks that describe the inguinal crease location, places the crease

roughly over the center of the femoral head (FH) and over the common femoral artery. In fact, it is typically below the FH and, on average, 6.1 mm below the bifurcation of the femoral artery.⁴ Puncture below the femoral bifurcation, especially when one of the bifurcation vessels (superficial femoral or profunda femoris arteries) is entered, necessitates manual compression (MC) with the force applied against smooth muscle and fat rather than bone, and increases the risk of pseudoaneurysm formation.⁵

Figure 1. Anatomic landmarks for femoral puncture. Puncture above line A, the bottom of the femoral head, allows enhanced compression against bone rather than muscle and fat, decreasing the risk of pseudoaneurysm formation. The location of the femoral bifurcation is at or below this line in approximately 77% of patients.⁷ Puncture cranial to the centerline of the femoral head, line B, increases the risk of puncture above the inguinal ligament⁹ and thus increases the risk of retroperitoneal hemorrhage.³⁷ Line C, drawn from the anterior superior iliac crest to the symphysis pubis, represents a traditional landmark for puncture site localization (typically 2 finger breadths below this line). Line D is the inguinal ligament off which the inferior epigastric artery reflects as it changes course (point E) to head cranially to merge with the internal mammary artery circulation. The inguinal crease, line F, is most commonly located below the femoral bifurcation as shown,⁴ an average of 6 mm, especially in obese patients. Most texts place the inguinal crease at the center of the femoral head, a common and dangerous misconception. The yellow oval represents an optimal target zone for vascular access. Reprinted with permission from Turi ZG.³⁹

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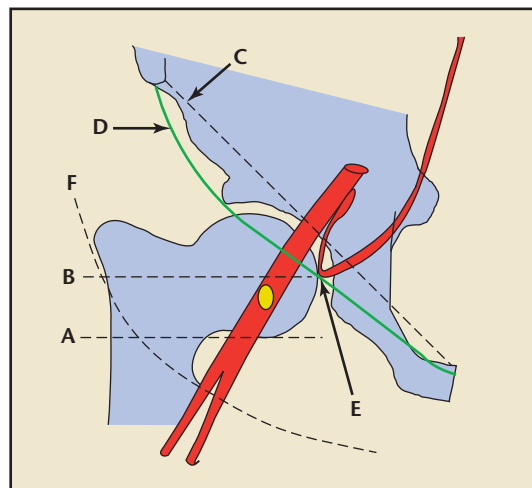
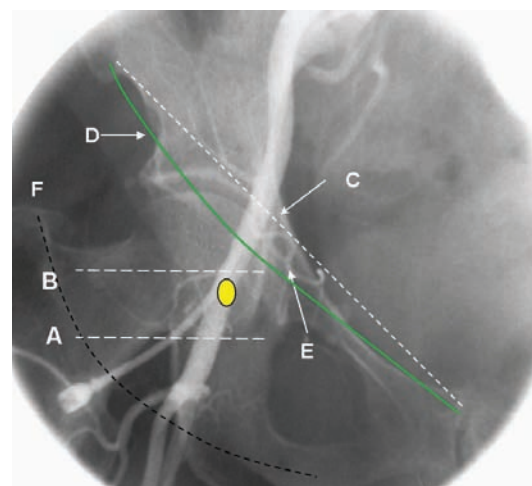


Figure 2. Femoral angiography conforming to the illustration in Figure 1. Note the sheath entry in the target zone. Reprinted with permission from Turi ZG.³⁹

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In contrast, high puncture is particularly dangerous; it is associated with up to a 17:1 odds ratio of retroperitoneal hemorrhage (RPH) in anticoagulated patients.⁶

The ideal puncture location is generally accepted to be over the FH, above the femoral bifurcation, and below the inguinal ligament (Figure 2). We have studied the location of the femoral bifurcation in 200 consecutive patients undergoing coronary angiography.⁷ In 77% of patients, the femoral bifurcation is at or below the FH. Thus, ensuring that the puncture is over the FH decreases the risk of entering the superficial femoral or profunda femoris arteries to 1 in 4. As the needle entry site moves from the bottom of the FH to the centerline, the risk of bifurcation puncture decreases progressively to less than 5%.⁷

An understanding of the anatomy of the inferior epigastric artery (IEA) has allowed for better delineation of the location of the inguinal ligament which, until recently, was incorrectly thought to be near the top of the FH. The IEA originates from the external iliac artery, then swings down to the inguinal ligament but does not cross inferior to it, before turning cranially to join the internal mammary artery feeding epigastric circulation from above (Figure 1). Thus, the inferior-most sweep of the IEA defines the location of the inguinal ligament; punctures below this site are associated with significant decrease in RPH risk.^{6,8} Puncture 5 mm or more below the centerline of the FH results in access below the IEA in 96.6% of patients.⁹

Puncture into the common femoral artery above the bottom of the FH and below the centerline is best accomplished with fluoroscopy. Placement of a hemostat in the surgical field to identify the FH was originally described by Kim and

colleagues.⁵ Iterative fluoroscopy, after the needle has been advanced into the tissue track, to confirm that the needle is over the medial portion of the FH and below the centerline, results in a high proportion (93.6%) of successful femoral punctures below the IEA and above the femoral bifurcation.¹⁰ An alternative technique, utilized primarily by radiologists, is ultrasound-guided access.¹¹ The artery and vein are typically visualized in the cross-sectional view, and the needle can be seen to pass through tissue from the skin surface down to the artery. With fluoroscopic or ultrasound guidance, access to the artery can be substantially faster with a lower probability of inadvertent venous puncture.

Vascular Closure Methods

The most common method of vascular closure remains MC. This technique is used in 60% to 70% of invasive procedures in the United States, and in more than 90% of these procedures throughout the rest of the world. MC hemostasis is highly reliable but dependent on a variety of factors, including appropriate location of compression proximal to the arterial puncture, access located over the FH and below the inguinal ligament, an intact clotting cascade, adequate compression time, and only a single anterior wall puncture of the artery. Data on MC still report a 1.8% vascular complication rate after diagnostic catheterization and a 4% rate after intervention.¹² Although the evidence base is weak, prolonged MC may be responsible for venous stasis, deep vein thrombosis, and, possibly, pulmonary emboli.¹³ Because the safety of MC is thought to depend on normalization of clotting, most laboratories pull sheaths when the activated clotting time falls below 150 or 180 seconds, resulting in prolonged sheath dwell times, a

potential contributor to blood loss and infection.¹⁴ Compression techniques other than manual have been available for decades and consist of various static clamp or bladder compression devices designed to maintain pressure above the arteriotomy until hemostasis occurs. Although these techniques have compared favorably to MC,¹⁵ they are associated with increased pain as well as possibility of tissue necrosis if excess and prolonged pressure is applied to the skin, and significant complications can arise if the devices are incorrectly positioned or left unattended. Generally speaking, compression techniques are effective and safe, although they come at the cost of extended bed rest, extended sheath dwell times if anticoagulation has been used, variably increased pain, and, in some cases, prolonged hospitalization.

Beginning in the mid 1990s, more than 40 years after Seldinger, vascular closure devices (VCDs) became available. VCDs can be categorized according to whether the device is placed on the skin surface (noninvasive) or in the tissue track (invasive) (Figures 3 and 4).¹⁶ Devices that *actively approximate* the edges of the arteriotomy do so by suturing the fenestration, clipping or stapling it, or creating a sandwich between portions of a device in the inner lumen of the arteriotomy and the outside of the vessel. Devices that close the arteriotomy without active approximation, such as plugs, sealants, and virtually all other approaches, can be considered *passive approximators*. Among devices that provide active approximation, those that suture the arteriotomy or sandwich it and leave a foreign body inside the lumen are classified as *intraluminal*. At least 2 *extraluminal* VCDs actively approximate the arteriotomy but are designed to leave no intraluminal foreign body.

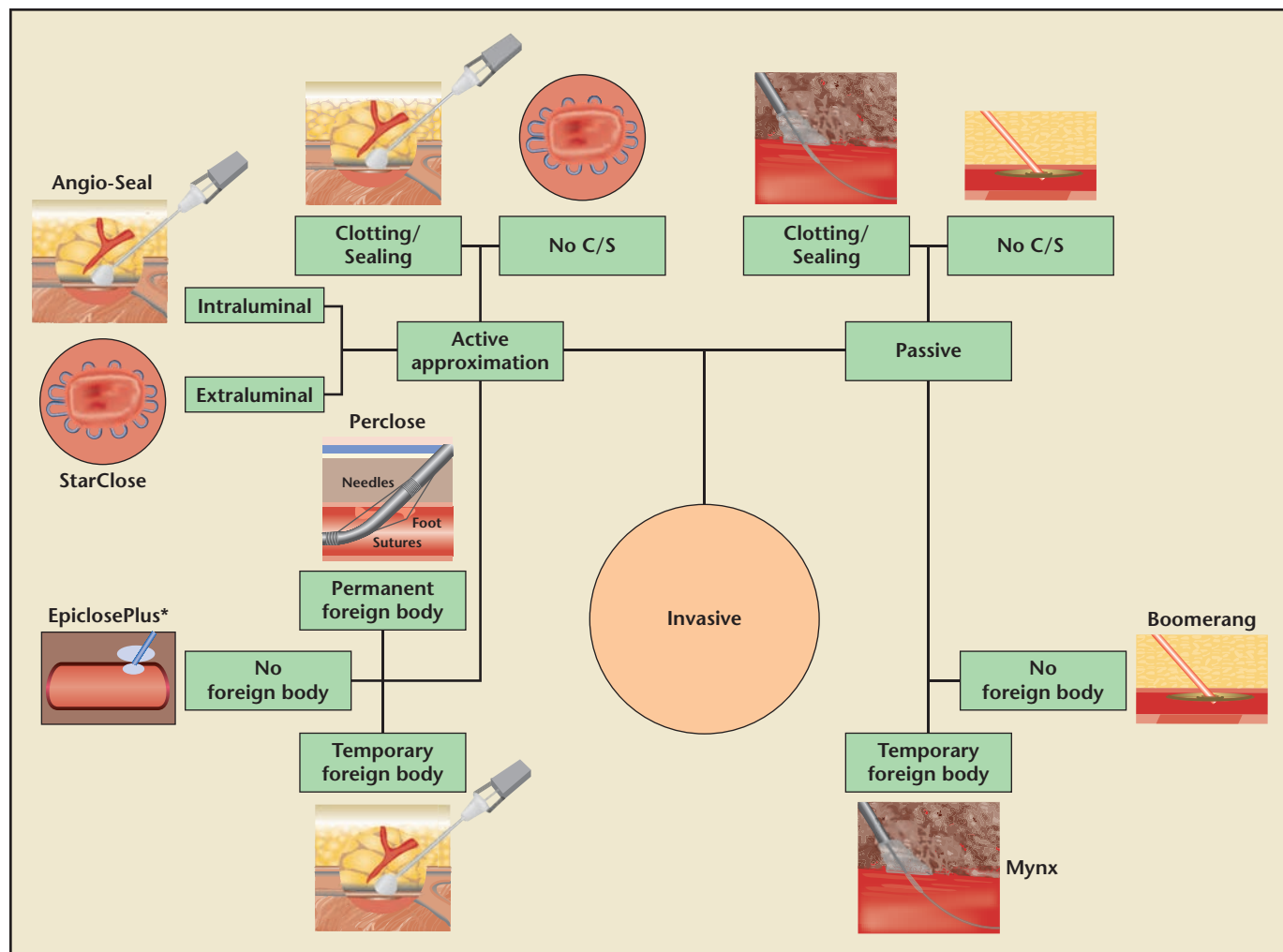


Figure 3. A classification system for vascular closure devices that apply pressure, sutures, clips, staples, thrombosing/sealing agents, or heat inside the tissue track. See Table 1. *Not approved by the Food and Drug Administration. C/S, thrombosing (clotting) or sealing agent. Reprinted with permission from Turi ZG.¹⁶ www.medreviews.com

Additional categories reflect the use of *thrombosing* or *sealing* agents, and whether or not a *temporary* or *permanent* foreign body is left behind (Table 1).

Passive Closure

The use of collagen for hemostasis was well established prior to the introduction of VCDs¹⁷; collagen acts by inducing platelet adhesion and activation.¹⁸ The first alternative to compression, VasoSeal® (Datascope, Montvale, NJ), incorporates a collagen plug in the tissue track on the surface of the arteriotomy. Thus,

VasoSeal is considered *invasive*, since it is placed beneath the skin surface; *thrombosing*, since collagen is used; and a *temporary foreign body*, since it resorbs in approximately 4 to 6 weeks. Most importantly, VasoSeal is considered a *passive* closure device, since it is deposited on the surface of the arteriotomy, but it does not actively approximate the arteriotomy edges. Although the device was generally effective, there was a significant failure rate, commonly reported to be in the 15% range, particularly in fully anticoagulated patients. When compared with MC, VasoSeal was

associated with a higher complication rate.^{19,20}

Other passive closure devices include the Duett™ (Vascular Solutions, Minneapolis, MN), which has a thrombin collagen procoagulant solution that is placed in the tissue track. This solution was associated with occasional intra-arterial deposition (as was VasoSeal), and resulted in a number of cases that required thrombolysis and embolectomy, and rare cases of limb loss.²¹ Because of rapid resorption of the material, the Duett has been associated with a low infection rate. The Duett, like

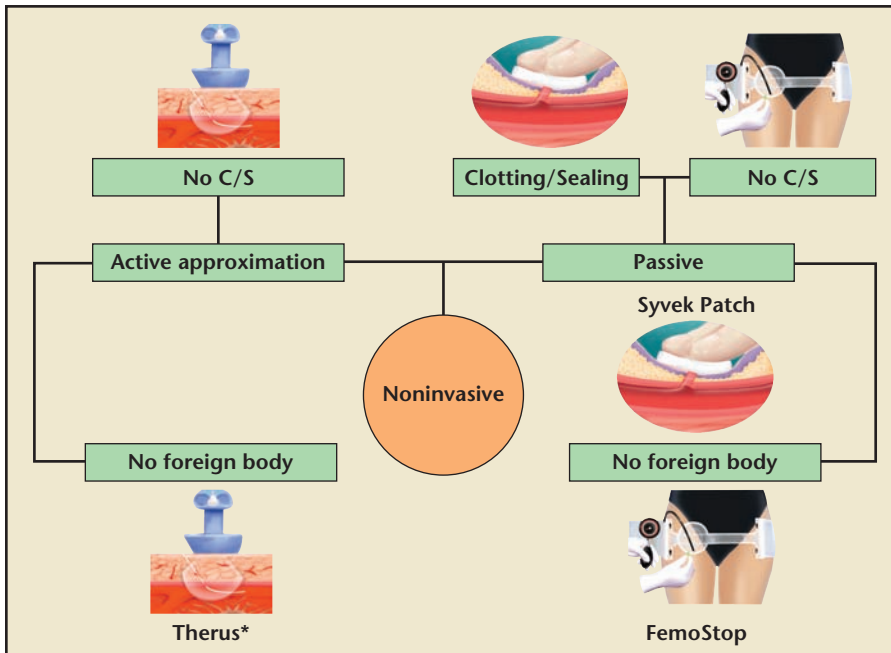


Figure 4. Classification system for closure devices that apply pressure, thrombosing/sealing agents, or heat from the skin surface. *Not approved by the Food and Drug Administration. C/S, thrombosing (clotting) or sealing agent. Reprinted with permission from Turi ZG.¹⁶ www.medreviews.com

VasoSeal, is no longer actively marketed. Two devices with sealing rather than thrombosing agents are the Mynx[®] (a polyethylene glycol plug, AccessClosure, Mountain View, CA) and ExoSeal[™] (a polyglycolic acid-based plug, Johnson and Johnson, New Brunswick, NJ), the latter not yet approved by the Food and Drug Administration (FDA). A novel passive closure technology is the Boomerang[™] ClosureWire (Cardiva Medical, Mountain View, CA). This device provides traction from the inside of the blood vessels with a nitinol disk; after a clot forms on the arterial surface, the disk is collapsed and pulled through the fenestration with additional MC, and no foreign body is left behind. The Mynx, ExoSeal, and ClosureWire are all deployed through the same sheath used for the catheterization; this is a theoretical advantage over many VCDs since it avoids potential upsizing of the tissue track or introduction

of a new device through the skin at the end of the procedure, when contamination of the cath environment may be more prevalent. In general, because none of these devices provide active approximation, their success rates in fully anticoagulated interventional patients remain to be demonstrated in large clinical series. Finally, a variety of topical patches are available, which deploy various coagulant agents on the skin surface at the site of the tissue track. The mechanism of action of these devices, in particular their ability to promote clotting remote from the skin surface at the arteriotomy site, remains to be demonstrated; nevertheless, patches have grown to about 20% of the VCD market.

Active Approximation

Angio-Seal[™] (St. Jude Medical, St. Paul, MN), the second VCD released, added an anchor inside the artery to a collagen plug on the arterial surface,

with suture material tethering the 2 elements together. This device remains the most commonly used VCD. The anchor, suture material, and collagen are temporary foreign bodies that resorb in approximately 30 to 90 days. Because Angio-Seal is both an active approximator and uses a thrombosing agent in the tissue track, it can be considered a “belts and suspenders” device, the only such VCD to date. Its 97% success rate at achieving hemostasis²² is likely related to this dual mechanism of action.

The next device released, Perclose[®] (Abbott Vascular, Santa Clara, CA), moved away from thrombosing agents, and introduced percutaneous suture closure of the arteriotomy. An active approximator, it differs from Angio-Seal because it lacks a thrombosing agent, and the suture material used is a permanent foreign body. It does more closely approximate the techniques used by vascular surgeons who rely primarily on stitch closure of vessels, and the foreign body footprint, both inside the vessel and in the tissue track, is substantially smaller than Angio-Seal's. Both Angio-Seal and Perclose have demonstrated overall safety comparable with MC.^{19,20} Although Angio-Seal and Perclose are the 2 most widely used devices in vascular closure, there are no significantly sized randomized comparisons. A large non-randomized series compared success rates with earlier generations of both devices, finding a slight advantage for Angio-Seal.²²

Percutaneous Metallic Arterial Closure

Two FDA-approved devices fall into the percutaneous metallic arterial closure (PMAC) category: StarClose[®] (Abbott Vascular, Santa Clara, CA) and AngioLink (Medtronic, Santa Rosa, CA). The former is a nitinol

Table 1
Classification of Vascular Closure Devices

	Invasive/ Noninvasive	Active/Passive Approximation	Intraluminal/ Extraluminal	Thrombosing/ Sealing	Temporary or Permanent Foreign Body
AngioLink	Invasive	Active	Extraluminal	No	Permanent
Angio-Seal	Invasive	Active	Intraluminal	Thrombosing	Temporary
Arstasis*†	Invasive	Active	Intraluminal	No	No
EpiClose Plus**	Invasive	Active	Extraluminal	No	No
FISH†	Invasive	Active	Intraluminal	Sealing	Temporary
Perclose	Invasive	Active	Intraluminal	No	Permanent
StarClose	Invasive	Active	Extraluminal	No	Permanent
SuperStitch§	Invasive	Active	Intraluminal	No	Permanent
Boomerang	Invasive	Passive		No	No
Duett	Invasive	Passive		Thrombosing	Temporary
ExoSeal*	Invasive	Passive		Sealing	Temporary
Mynx	Invasive	Passive		Sealing	Temporary
VasoSeal	Invasive	Passive		Thrombosing	Temporary
Therus*‡	Noninvasive	Active	Extraluminal	No	No
Patches	Noninvasive	Passive		Thrombosing	No

*This device is not approved by the Food and Drug Administration.

†The Arstasis (Modesitt, San Carlos, CA) and FISH™ (Morris Innovative Research, Bloomington, IN) devices are designed to address closure during initial access, the former by creating a dissection plane that leads to closure with sheath withdrawal, and the latter using small intestinal submucosa wrapped around the access sheath that plugs the arteriotomy and then resorbs.

‡The EpiClose™ Plus (CardioDex, Tirat-Hacarmel, Israel) and Therus® (Therus, Seattle, WA) devices are designed to apply heat to the arteriotomy site to seal the arteriotomy with endogenous denatured collagen in the vessel wall; the former applies heat from the skin surface using ultrasound, and the latter applies heat locally in the tissue track.

§The SuperStitch® (Sutura, Fountain Valley, CA) is conceptually similar to Perclose.

||A thrombosing agent is exposed in the tissue track during device deployment.

clip, and the latter is a titanium staple. AngioLink is not available despite FDA approval in 2004. The differences in design between the 2 technologies may be meaningful, although no direct comparison has been performed. AngioLink is a staple, which means that the equivalent of a temporary anvil is placed inside the arteriotomy to stabilize the deposition of the titanium. The arteriotomy is upsized to 10-French. StarClose uses nitinol, a memory metal, thus no anvil is required inside the artery. As such, it does not upsize the arteriotomy, although it does upsize the tissue track to 12-French. The theoretical benefits of the PMACs relate to the active approximation of

the vessel wall, the deposition of the devices on the surface of the artery penetrating only to the arterial media, and the avoidance of leaving a bulk of foreign material in the tissue track or suture material from the arterial surface to the skin surface.²³ The avoidance of leaving a foreign body inside the arterial lumen may have potential advantages for vessel healing. Core laboratory ultrasound examination of 71 patients closed with StarClose in the Clip Closure In Percutaneous Procedures (CLIP) trial²⁴ demonstrated lack of soft tissue reaction or inflammatory response and minimal scar formation,²⁵ potential advantages of devices that have a small extraluminal footprint

only and do not incorporate bioactive agents.

Similarly, these devices may have advantages in patients with peripheral vascular disease (PVD), although the extent of PVD in which it is appropriate to use these devices is unknown. The fact that there is no suture material extending to the skin surface avoids the potential wicking effect that theoretically may enhance the infection rate associated with Angio-Seal. The absence of a collagen sponge soaked with clot, which is an excellent culture medium, could theoretically lead to a lower infection rate as well, but there are no published data to support a clinical difference between these technologies.

Theoretical disadvantages of StarClose include upsizing of the tissue track; the lack of a thrombosing agent, which results in more post-closure oozing from the tissue track in fully anticoagulated patients; and the deposition of a permanent foreign body, which has not been shown to have any deleterious effects but is a potential drawback of this class of devices.

Special Considerations

With Vascular Closure Devices

A number of features of VCDs are important, including reaccess to the artery after initial puncture, "preclosure," and operator learning curves. Re-access was an issue starting with the initial closure devices, with a concern that the needle used for vascular access might displace collagen into the tissue track. Subsequent small series have not demonstrated such displacement,²⁶ but it remains a theoretical risk, as does disruption of the resorbable intra-arterial anchor and suture material. Both Perclose and StarClose lend themselves well to immediate repuncture, although there is only a modest evidence base without specific FDA approval.

"Preclosure" is a technique for placing sutures around the arteriotomy at the beginning of an intervention without bringing the knots down to the arterial surface. This step is done prior to the placement of large bore sheaths; at the end of the case, the large sheaths are withdrawn and the knots are advanced to the arteriotomy. There is now substantial experience with placement of 1 to 2 Perclose 6-French devices with subsequent percutaneous insertion of abdominal aortic stent grafts, percutaneous heart valves, and temporary left ventricular assist devices; a recent 258-patient series described a 93.8% success rate with sheaths up to 24-French.²⁷

The learning curves for VCDs are both institutional and individual. Furthermore, individual learning curves reflect both generic understanding of the use and limitations of VCDs, as well as specific knowledge of the nuances of implanting each individual device. Balzer and colleagues²⁸ described an 8.8% failure rate in their institution in the first 50 cases using Perclose, a rate that declined to 3.1% as they approached 1000 cases. Warren and coworkers²⁹ described a 14% failure rate with Angio-Seal in their first 50 cases, which declined to 3.5% during their subsequent 200-patient experience.

Complications of Vascular Closure

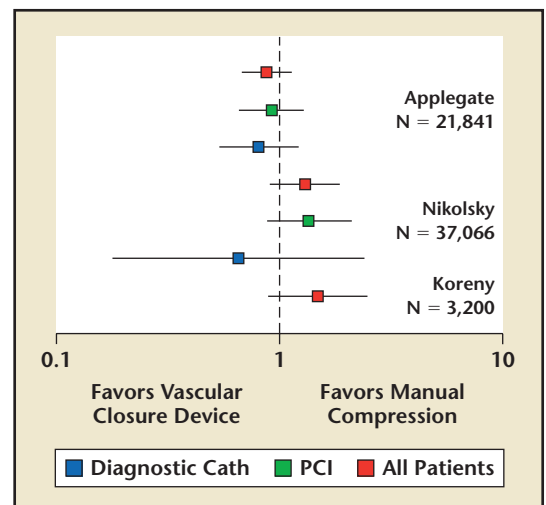
Complications of vascular closure (whether MC- or VCD-related) remain among the most vexing problems in invasive medicine. The complication rate is generally thought to be in the single-digit percentage range, but because of assessment and reporting methodology variations, and the generally poor quality of the vascular closure literature,^{30,31} comparison between various modalities is difficult. Nevertheless, vascular closure represents the source of the

majority of complications in invasive vascular procedures in most studies. The complication rates associated with intervention are approximately twice those seen after diagnostic procedures.^{12,20} The reasons for this are multiple, but the most important relates to the anticoagulation given during intervention. The risk factors for vascular complication include age, female sex, diabetes, low body surface area (the obesity paradox), large sheath size, small vessel size, level of anticoagulation and antiplatelet therapy, puncture technique (high or low stick, multiple or back wall punctures), prior instrumentation, presence of vascular disease at the puncture site, and operator learning curve.^{20,29,32} In general, the vascular complication rates have declined steadily, both with MC³³ and closure devices.³⁴ The reasons for the decline are multiple, including shift to lower overall and weight-adjusted heparin dosing, use of smaller sheaths, and avoidance of postprocedure anticoagulation.³³

Compared with MC, the complication rates for VCDs have been reported to be lower,^{20,35} higher,³⁰ or the same^{19,36} (Figure 5), with meta-analyses and propensity scoring

Figure 5. Results of 3 studies comparing manual compression versus vascular closure devices. The studies straddle the null hypotheses, and in general the meta-analyses by both Koreny and colleagues³⁰ and Nikolsky and coworkers¹⁹ are handicapped by the poor quality of most of the underlying studies analyzed. The study by Applegate and colleagues³⁶ analyzed the cumulative experience of a single high-volume site using propensity analysis. PCI, percutaneous coronary intervention.

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techniques attempting to compensate for the poor quality of the evidence base. The clinical trials incorporated in the meta-analyses lack blinding and include selection bias, cohort mismatch, and learning curves. In addition, they lack information on the level of anticoagulation, the state of the femoral anatomy pre-closure, and the uniform definition of important endpoints, such as hematomas. The complications of VCDs can be considered both generic to all VCDs and specific to each closure device. An excellent source for reviewing the latter is to be found in the FDA Manufacturer and User Facility Device Experience (MAUDE) database: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm>.

In general, the most serious complications have been RPH, vascular occlusion, and infection. Retroperitoneal bleeding has increased to nearly 1% in the interventional era,^{6,8,37} and is apparently exacerbated by the deployment of VCDs in fully anticoagulated patients, with an odds ratio of 2.8:1 for anticoagulated patients receiving Angio-Seal.⁶ This factor is particularly an issue with punctures above the IEA; in practice, the transversus abdominus muscle lies between the skin and the external iliac artery, and may prevent a collagen plug from penetrating through the tissue track to the arterial surface.⁶ The mortality from RPH in anticoagulated patients is high, in the range of 4% to 6%.^{6,37} Vascular occlusion has been described in less than 0.2% of cases and, if related to VCD use, is the result of deposition of a thrombosing agent in the vessel, the approximation of the front and back walls by suture or clip/staple devices, or a localized reaction to or migration of the Angio-Seal anchor. Finally, infection is a dreaded complication of VCD use, reported to

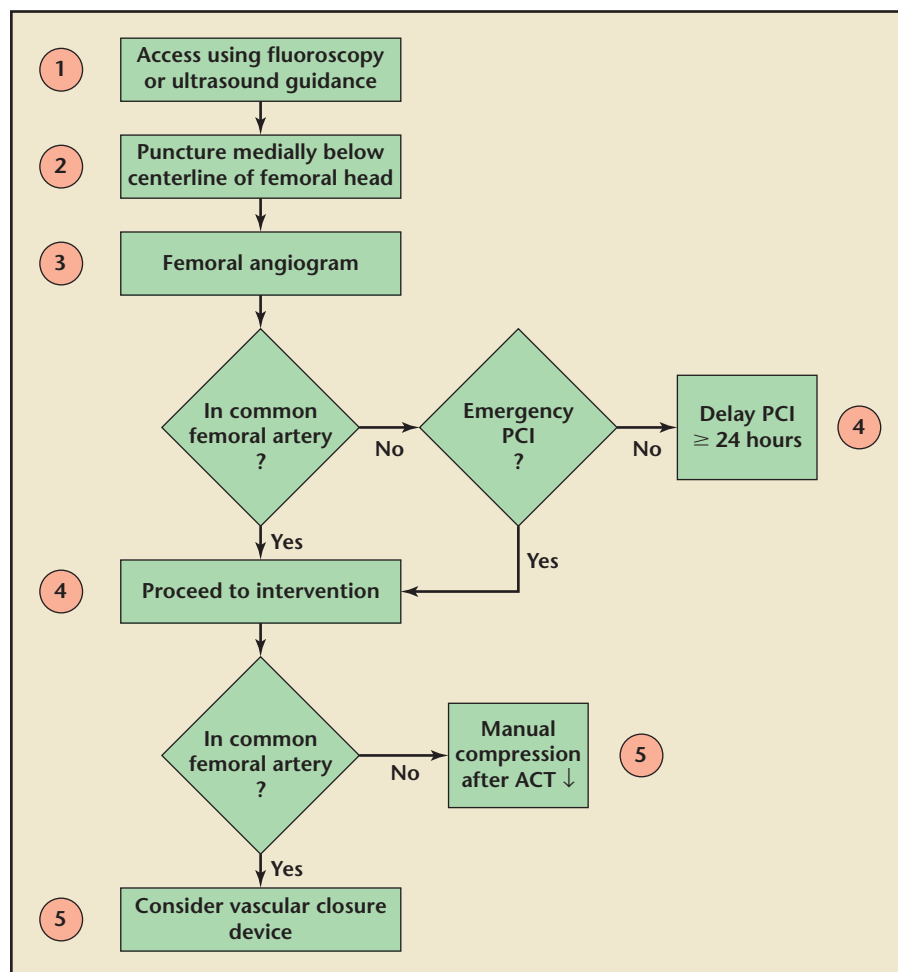
be less than 0.3%, with a 6% associated mortality as well as occasional limb loss.³⁸ Infections are primarily seen in diabetics, at a median interval of 8 days after the procedure; nearly half of affected patients (42%) develop a mycotic pseudoaneurysm (which invariably requires surgical intervention), and 86% have positive blood cultures, predominantly *Staphylococcus aureus*.

Ideal Femoral Access Management

An algorithm for vascular access is shown in Figure 6. As described, vascular access using fluoroscopy or

ultrasound will improve the ability to puncture at a level approximately 5 mm to 14 mm below the centerline of the FH, a target zone that will limit the likelihood of puncture above the IEA or into the femoral bifurcation vessels. Femoral angiography in every case (whether or not VCD use is intended)³² is necessary to identify puncture location, size of the artery, and presence of PVD, as well as occasional dissection or perforation. Without angiography, the invasive cardiologist is operating blind, and if a VCD is used, the patient may be unnecessarily exposed to development of complications. If

Figure 6. An algorithm for vascular access and closure in patients undergoing PCI. Steps 4 and 5 are dependent on the location of the puncture and the emergent/elective nature of the procedure. PCI, percutaneous coronary intervention; ACT, activated clotting time. www.medreviews.com



the location of the femoral puncture is outside the common femoral artery, avoidance of anticoagulation will decrease the risk of post-procedure complications, especially if the puncture is high; in the case of the latter, unless the intervention is an emergency, we advocate waiting 24 hours and repuncturing to avoid potential RPH. The key to management lies in avoiding high puncture, avoiding anticoagulation when a high puncture has taken place, and avoiding VCDs in anticoagulated patients with high punctures. If the puncture location is in the target zone, with the femoral artery of adequate diameter and free of significant disease, VCD use will enhance patient comfort and convenience, and eliminate the need for prolonged bed rest and sheath dwell times.

For now, VCD use remains largely in the realm of patient and physician preference. As the evidence base and VCD technology develop, it is hoped that there will be a compelling risk/benefit and cost argument for the expanding use of these devices. ■

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Main Points

- Utilization of improved techniques for vascular access will substantially increase the probability of a safe location of femoral puncture.
- A target zone located below the centerline of the femoral head will maximize the probability of puncture into the common femoral artery.
- Routine femoral angiography, whether or not vascular closure devices are used, will enhance the safety of cardiac and peripheral catheterization.
- Vascular closure devices improve patient comfort and convenience, allow for faster hemostasis and ambulation, and ensure that patients will not be sent out of the laboratory with vascular sheaths still in place.
- Vascular closure devices have not been demonstrated to reduce complication rates. Early diagnosis and aggressive management of possible retroperitoneal hemorrhage and of possible infections at the vascular access site are important adjuncts to the management of patients undergoing catheterization.

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SELF-ASSESSMENT POST-TEST

An Evidence-Based Approach to Femoral Arterial Access and Closure

1. Which of the following is true of placement of the femoral puncture site?
 - a. Puncture below the femoral bifurcation necessitates manual compression and increases the risk of pseudoaneurysm formation
 - b. A high puncture increases the risk of retroperitoneal hemorrhage
 - c. The most favorable location is generally accepted to be over the femoral head, above the femoral bifurcation, and below the inguinal ligament
 - d. All of the above
2. Puncture into the common femoral artery above the bottom of the femoral head is best accomplished with:
 - a. palpation and knowledge of anatomical landmarks
 - b. fluoroscopy
 - c. supervised clinical experience
 - d. specially designed access devices
3. Effective vascular closure using manual compression is dependent on which of the following factors?
 - a. Appropriate location of compression
 - b. An intact clotting cascade
 - c. Adequate compression time
 - d. A single anterior wall puncture of the artery
 - e. All of the above
4. Risk factors for complications of vascular closure post-procedure include which of the following?
 - a. Older patients
 - b. Patients with diabetes
 - c. Low body surface area
 - d. Presence of vascular disease
 - e. All of the above
5. The most serious complications related to use of vascular closure devices have been found to be retroperitoneal hemorrhage, vascular occlusion, and infection.
 - a. True
 - b. False



EVALUATION FORM

An Evidence-Based Approach to Femoral Arterial Access and Closure

Project ID: 5197 ES13

To assist us in evaluating the effectiveness of this activity and to make recommendations for future educational offerings, please take a few minutes to complete this evaluation form. ***You must complete this evaluation form to receive acknowledgment for completing this activity.***

Please answer the following questions by circling the appropriate rating:

1 = Strongly Disagree 2 = Disagree 3 = Neutral 4 = Agree 5 = Strongly Agree

EXTENT TO WHICH PROGRAM ACTIVITIES MET THE IDENTIFIED OBJECTIVES

After completing this activity, I am now better able to:

- | | | | | | |
|--|---|---|---|---|---|
| • Describe the optimum vascular access technique | 1 | 2 | 3 | 4 | 5 |
| • Review currently available vascular closure methods | 1 | 2 | 3 | 4 | 5 |
| • Cite findings of studies related to vascular closure techniques and technologies | 1 | 2 | 3 | 4 | 5 |
| • Describe the relative efficacy of vascular closure techniques | 1 | 2 | 3 | 4 | 5 |

OVERALL EFFECTIVENESS OF THE ACTIVITY

The content presented:

- | | | | | | |
|---|---|---|---|---|---|
| • Was timely and will influence how I practice | 1 | 2 | 3 | 4 | 5 |
| • Enhanced my current knowledge base | 1 | 2 | 3 | 4 | 5 |
| • Addressed my most pressing questions | 1 | 2 | 3 | 4 | 5 |
| • Provided new ideas or information I expect to use | 1 | 2 | 3 | 4 | 5 |
| • Addressed competencies identified by my specialty | 1 | 2 | 3 | 4 | 5 |
| • Avoided commercial bias or influence | 1 | 2 | 3 | 4 | 5 |

IMPACT OF THE ACTIVITY

Name one thing you intend to change in your practice as a result of completing this activity: _____

Please list any topics you would like to see addressed in future educational activities: _____

Additional comments about this activity: _____

FOLLOW-UP

As part of our continuous quality improvement effort, we conduct postactivity follow-up surveys to assess the impact of our educational interventions on professional practice. Please indicate if you would be willing to participate in such a survey:

- ☐ Yes, I would be interested in participating in a follow-up survey.
- ☐ No, I am not interested in participating in a follow-up survey.

POST-TEST ANSWER KEY

1 _____ 2 _____ 3 _____ 4 _____ 5 _____

If you wish to receive acknowledgment for completing this activity, please complete the post-test by selecting the best answer to each question, complete this evaluation verification of participation, and fax to: 303-790-4876.

Request for Credit

Name _____	Degree _____
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FOR PHYSICIANS ONLY

I certify my actual time spent to complete this educational activity to be:

- ☐ I participated in the entire activity and claim 1.0 credits.
- ☐ I participated in only part of the activity and claim _____ credits.

Signature _____ Date Completed _____