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## **Percutaneous Femoral Access and Vascular Closure Devices**

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### Executive Summary

Percutaneous femoral access for cardiac catheterization has become one of the most widely utilized procedures in the United States. Still, the rate of complications with vascular access and closure remains high. Vascular closure devices have undergone scrutiny since their debut in the early 1990s, but are considered to be a safe and efficacious alternative to manual compression in certain circumstances. In particular, they provide improved patient comfort and decreased time to ambulation and hospital discharge. Newer devices may expand the population in which devices can be used to include those currently considered high risk, such as patients with small caliber vessels and peripheral arterial disease. The following chapter begins with a strategic approach to vascular access in attempts to minimize patient risk, and then gives a review of the major vascular closure devices, with an emphasis on emerging studies and their future role in arteriotomy closure.

# Introduction

Femoral arterial access is the most common method of vascular access for coronary angiography and percutaneous coronary intervention (PCI) in the United States. The gold standard of manual compression for femoral access hemostasis has evolved since the introduction of devices for arteriotomy closure in the 1990s. A number of vascular closure devices (VCDs) have been developed as an alternative to manual compression to improve patient comfort, decrease time to hemostasis, ambulation, and hospital discharge, and to limit time constraints on staff. VCDs have over a 90% success rate in several meta-analyses, however, they are not without their limitations. Device failure, bleeding, infection, and the need for vascular surgery can occur in a minority of cases with a relative risk comparable to manual compression alone (1-4). There are also concerns with excess vascular inflammation and scarring associated with VCDs. With strategic evaluation of the patient on an individual basis, complications from femoral vascular access and VCDs can be minimized and patient care improved.

## Common Femoral Artery Vascular Access

### Complications

The most common complications associated with femoral arteriotomy include bleeding (from minor bleeding (hematoma) to major bleeding (retroperitoneal hemorrhage)), infection, arterio-venous (A-V) fistulas, pseudoaneurysms, and occlusive or thromboembolic events requiring vascular surgery (1-4). In recent years, the aggressive use of concomitant pharmacology (thrombolytics, triple antiplatelet therapy, and anticoagulation) in the catheterization laboratory has led to an increasing risk of major and minor bleeding, with reported rates as high as 11% in interventional procedures (6% in diagnostic procedures), however the procedure-related mortality rate remains low at 0.5% (1-6). While VCDs have not been shown to lower complication rates, they have proven to be a safe and efficacious alternative to manual closure, even in patients receiving thrombolytics (1-4,7).

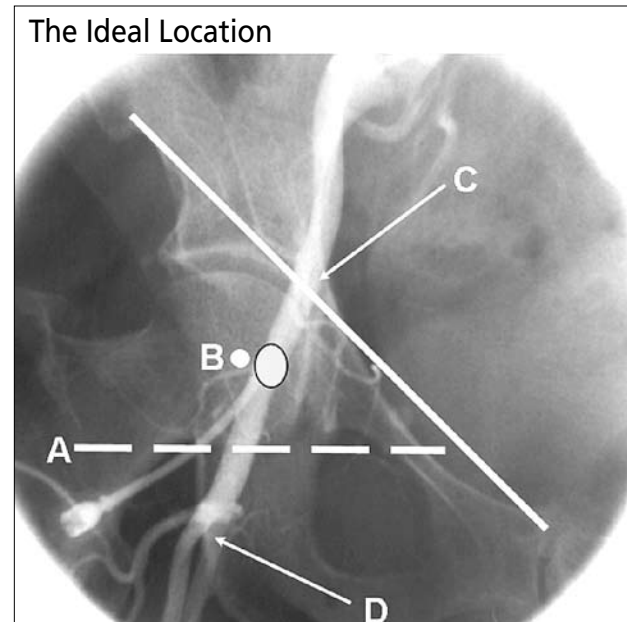
### Obtaining Access

With the development of a strategic approach to common femoral artery (CFA) access (Table 1), complications may be minimized. There are three contemporary approaches to identifying the optimal location for femoral artery access, which is in the CFA just inferior to the midline medial border of the femoral head

**Table 1 Approach to Femoral Access and Closure**

- Define the bony landmarks and palpate the common femoral artery
- Fluoroscopy to identify the medial half of the femoral head just inferior to the midline
- Confirm needle location prior to femoral artery entry using fluoroscopy
- Femoral angiography (RAO/LAO 30-40 degrees) to determine sheath entry site in relation to the femoral head, the inferior epigastric artery, and the CFA bifurcation
- Choose manual vs. VCD based on the size of the vessel, location of the arteriotomy, vessel calcification, PAD, and patient comorbidities, including risk of infection

(Figure 1). The first approach is anatomical, locating the bony landmarks of the anterior superior iliac spine and pubic symphysis to identify the level of the inguinal ligament, and then puncturing approximately 2 cm below the inguinal ligament at the level of the CFA. The second approach is fluoroscopic, placing a hemostat tip at the inferior border of the femoral head under fluoroscopy and puncturing the CFA approximately 1 cm above the location of the hemostat tip. Some will also use fluoroscopy to visualize the location of the

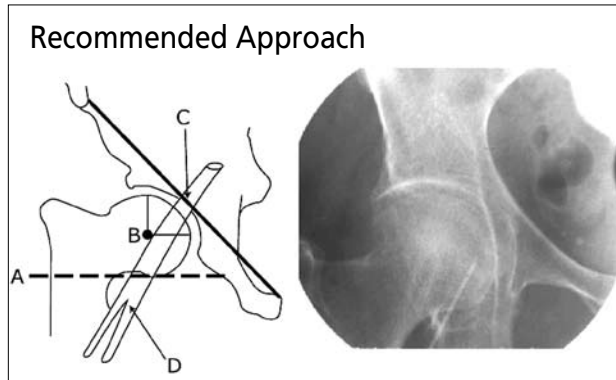


**Figure 1 Optimal Location for Femoral Artery Access**

The outlined dot marks the sheath entry site into the CFA at the medial aspect of the femoral head in the midline. (A) Inferior border of the femoral head. (C) Line demarcating inguinal ligament running from the anterior superior iliac spine to the pubic symphysis. (D) Bifurcation of CFA into superficial femoral artery and profunda.

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needle just prior to entry into the CFA (Figure 2). The third approach is manual, puncturing the artery at its point of maximal intensity. No approach is foolproof, so using a combination may optimize access. The traditional approach of using the inguinal skin crease can be misleading and is considered outdated (8).



**Figure 2 Using Fluoroscopy as an Adjunct in Gaining Femoral Artery Access**

Puncture needle can be seen entering the CFA at the optimal location in the medial portion of the midline of the femoral head.

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### Femoral Angiography

Angiographic imaging of the artery should occur either at the beginning or end of the case. The advantage to performing angiography at the beginning of the case is that a decision to defer intervention, in the case of a high stick for example, can be determined ahead of time (9). Femoral angiography can be performed in the RAO and/or LAO 30-40 degree view. The ipsilateral (same side as arterial puncture) view has the advantage of laying out the femoral bifurcation and the level of the inferior epigastric artery (IEA), but obscures the sheath entry site. On the other hand, the contralateral (opposite side as the arterial puncture) view will display the sheath entry site, but the bifurcation will be obscured (Figure 3).

### High Femoral Arteriotomy

The most serious access site complication is retroperitoneal hemorrhage (RPH). It is associated with a mortality rate of up to 10%. Independent predictors of a retroperitoneal hemorrhage include female sex, low body surface area (BSA < 1.73m<sup>2</sup>), glycoprotein IIb/IIIa antagonist use, and a high femoral arteriotomy. There are currently three definitions of a high femoral arteriotomy including 1) above the proximal third of the femoral head (10), 2) above the origin of the IEA (11), and 3) above the inferior most border of the IEA (12). All definitions have been associated with RPH, but which is the best predictor of RPH remains to be de-



**Figure 3 Femoral Angiography**

For a right femoral arteriotomy, the RAO 30/40 degree view (left) nicely lays out the femoral bifurcation and the level of the inferior epigastric artery (arrow), but obscures the sheath entry site. The LAO 30/40 degree view (right) displays the sheath entry site, but the bifurcation is obscured.

termined. Low femoral arteriotomy, cannulation below the CFA bifurcation into the superficial femoral artery (SFA) or the profunda artery, has been associated with A-V fistulas and pseudoaneurysms (12).

### Vascular Closure Devices

There are several VCDs currently available that can be categorized based on the method of closure and whether they have an intravascular or extravascular arteriotomy closure. Table 2 compares the advantages and disadvantages of the most widely used VCDs along with manual compression alone. All VCDs have demonstrated rapid hemostasis and a decreased time to ambulation when compared to manual compression (1-4). Vasoseal™ has been associated with the highest risk of infection, while Angiolink™ and Starclose™ are felt to have the lowest risk (1-4). Angioseal™ theoretically has a higher risk of thromboembolic events due to the intravascular collagen anchor. The suture-mediated devices utilize primary healing (end to end anastomosis at the arteriotomy site), but are the most complex technically and have the highest rate of device and operator failure.

### Collagen and Procoagulants

The Vasoseal™ closure device (Datascope Corp., Montvale, NJ) was introduced in 1995 (revised in 1999 and 2002) and utilizes an extravascular Type-1 collagen produced from bovine tendons. When deployed at the arteriotomy site the collagen initiates coagulation by activating platelets (secondary healing). Vasoseal™ is FDA approved for both diagnostic and interventional procedures, with a single device used for 5-8 French sheath sizes. The Angio-Seal™ device (St. Jude Medical, St. Paul, MN) achieves hemostasis by sandwiching the puncture site between an intravascular bio-absorbable (over 8-12 weeks) anchor and an extravascular bovine

**Table 2 Device Characteristics**

	Manual	VasoSeal	AngioSeal	Suture-mediated	Clip/Staple
Delayed Hemostasis	+++	+	+	+	+
Delayed time to ambulation	+++	+	+	+	+
Intravascular component	n/a	n/a	Yes	Yes	n/a
Extravascular component	n/a	Yes	Yes	Yes	Yes
Risk of infections	+	++++	++	++	+
Risk of embolism	+	++	+++	++	+
Primary healing	No	No	No	Yes	Yes
Secondary healing	Yes	Yes	Yes	No	No
Technical failure	+	++	++	+++	++
Operator failure	+	++	++	+++	++

+ least, ++++ most (1-4, 7-12)

collagen sponge, which are connected by an absorbable synthetic suture. Angio-seal™ is approved for both diagnostic and interventional procedures and comes as separate devices for 6 and 8 French sheath sizes. Finally, the Duett™ (Vascular Solutions, Minneapolis, MN) uses the inflation of a balloon catheter to anchor the sheath to the arterial wall allowing delivery of a procoagulant at the arteriotomy site. It is approved only for diagnostic procedures.

### Suture-mediated

Perclose™ (Abbott Vascular, Redwood City, CA) is the original suture-mediated closure device (1997, revised 2002) and is available in multiple configurations allowing closure of artery punctures up to 10 French in size. It is approved for both diagnostic and interventional procedures. One reported study utilized Perclose™ for arteriotomy closure in sheath sizes up to 27F after percutaneous abdominal aorta endograft stenting with promising results and an 85% success rate (13). While traditionally considered difficult to master, the latest versions of Perclose™ have improved ease of use.

### Staple and Clip-based Systems

The newest closure devices to be approved by the FDA are EVS™ (Angiolink, Taunton, MA, 2004) and Starclose™ (Abbott Vascular, Redwood City, CA, 2004), which utilize a 3 mm titanium staple and a 4 mm nitinol clip, respectively. The externally deployed staple or clip achieves a “purse-string” effect of tissue at the arteriotomy site. Both utilize intravascular wings to de-

ploy a purely extravascular adventitial staple or clip and have a limited foreign body effect. They are approved for diagnostic and interventional cases. Both devices have similar rates of success, vascular complications, reduction in time to hemostasis/ambulation, and low risk of infections reported (14, 15).

## Limitations and Complications of VCDs

### Device failure

Device failure may be operator or system dependent. The operator must have the necessary skill with the VCD, as studies have clearly demonstrated a learning curve with these devices (16). One of the limitations of the Perclose™ device is the complex steps necessary to deliver the suture, which includes positioning, needle deployment, suture capture, and needle removal for effective closure. The Starclose™ and Angiolink™ devices require an adequate sized skin tract for positioning and deployment of the nitinol clip or staple on the extravascular arterial surface.

### Infection

Development of an infection at the femoral artery access site is a potentially lethal complication, and the presence of a VCD may increase the risk beyond manual compression alone. A review of the FDA Center for Devices and Radiologic Health reported a disproportionate incidence of vascular complications and infections (up to 6.5%) with the VasoSeal™ device (17).

The Starclose™ and Angiolink™ devices use a “through the sheath” delivery system that may minimize infections introduced from the skin tract. Infection risk is increased in patients with diabetes, obesity, poor hygiene, a recent catheterization procedure, and in those who are immunocompromised, including transplant patients. In such high risk patients, one should consider antibiotic prophylaxis or simply deferring the use of a VCD for manual compression alone.

### **Thrombotic and Thromboembolic Events**

Residual intravascular device components, such as the collagen anchor of the Angio-seal™, have been reported to be the nidus for thrombus even though the polymer is labeled non-thrombogenic. Devices generally are not deployed in the branch vessels of the CFA because the smaller caliber is felt to increase the risk of a thrombo-occlusive complication. Thromboembolic events can occur from disruption of calcium and atherosclerotic plaque inside the femoral artery. The presence of heavy calcium at the arterial puncture site is also a common contraindication for a VCD because the device may not deploy properly. Similarly, peripheral arterial disease (PAD) creates the combination of a small caliber vessel with irregular and thickened walls that may be unsuitable for vascular closure.

### **Choosing a VCD**

There are many factors to consider when choosing whether or not to use a VCD, and if so, which VCD to use. In particular, one should consider 1) the patient’s clinical history, including the risk of infection and the need for antibiotic prophylaxis and 2) the risk of closure based on the femoral angiogram, including the size of the vessel, vessel calcification, PAD, and location of the arteriotomy. The best way to handle a high femoral arteriotomy, particularly in the setting of PCI, is unknown. An initial assumption is that placing a VCD will decrease the risk of a RPH, but this does not appear to be the case. Prolonged manual compression in addition to a VCD has been considered, as has delayed closure, once all of the anticoagulation has cleared, combined with manual compression. The safest option may be deferring PCI (9). In the situation of a small caliber vessel (<4-5 mm) or access in a femoral artery branch vessel, manual compression should be considered, although use of an extravascular VCD may also be an option (18). If the patient is at risk for infection, one should not use Vasoseal™. However, Vasoseal™ is the only VCD that is FDA approved for patients with significant PAD at the arteriotomy site. Although not yet

approved for use in such patients, the newer extravascular closure devices may also be found to work well in patients with PAD while offering a lower infection risk (15, 18).

The Angiolink™ device has been studied in patients with PAD, small caliber vessels (<5mm), calcified vessels, and arteriotomy sites in the SFA or profunda artery with encouraging results (18). There is also an on-going registry evaluating the use of Starclose™ in non-ideal anatomy (20). Non-ideal anatomy is defined as a small caliber vessel < 5 mm, a calcified artery by fluoroscopy, PAD up to 70% stenosis, and arteriotomy site at or below the bifurcation in diagnostic catheterization procedures. VCD success is defined by manual compression of less than 5 minutes with reporting of time to initial hemostasis, time to ambulation of 20 feet, and freedom from major or minor vascular complications including vascular surgery. Results to date from the registry have been favorable with no major complications and only one patient requiring crossover to prolonged manual compression in this high-risk registry. This suggests that the Starclose™ device may be feasible and safe in patients with moderate PAD, calcified femoral arteries, or an arteriotomy site at or below the CFA bifurcation. Caution must still be used in patients with smaller caliber vessels and severe > 70% PAD at the arteriotomy site as there have been case studies of increased vascular complications requiring surgery. A randomized multi-center study is needed to further address the safety and efficacy of VCDs in high-risk subsets.

## Conclusion

Vascular complications remain a concern with percutaneous femoral access, but may be minimized with a strategic approach. VCDs have been utilized as an alternative to manual compression in certain patient subsets with a low, yet real risk of vascular events which appears comparable to manual compression. There is a definitive learning curve with vascular access and VCD success. VCDs have been studied in interventional patients and those receiving high-risk pharmacology and have been found to be safe in this patient cohort. A limited number of patients with high-risk common femoral artery anatomy (calcified or femoral artery stenosis, or a low stick in the bifurcation, SFA, or profunda) have been studied with promising results, but further evaluation is needed in randomized clinical trials.

## References

1. Nikolsky E, Mehran R, Halkin A, Aymong ED, Mintz GS, Lasic Z, Negoita M, Fahy M, Krieger S, Moussa I, Moses JW, Stone GW, Leon MB, Pocock SJ, Dangas G. Vascular complications associated with arteriotomy closure devices in patients undergoing percutaneous coronary procedures: a meta-analysis. *J Am Coll Cardiol* 2004 September 15;44(6):1200-1209.
2. Koreny M, Riedmuller E, Nikfardjam M, Siostrzonek P, Mullner M. Arterial puncture closing devices compared with standard manual compression after cardiac catheterization: systematic review and meta-analysis. *JAMA* 2004 January 21;291(3):350-357.
3. Lasic Z, Nikolsky E, Kesanakurthy S, Dangas G. Vascular closure devices: a review of their use after invasive procedures. *Am J Cardiovasc Drugs* 2005;5(3):185-200.
4. Vaitkus P. A meta-analysis of percutaneous vascular closure devices after diagnostic catheterization and percutaneous coronary intervention. *J Invasive Cardiol* 2004 May;16(5):243-6.
5. Berry C, Kelly J, Cobbe SM, Eteiba H. Comparison of femoral bleeding complications after coronary angiography versus percutaneous coronary intervention. *Am J Cardiol* 2004 Aug;94(3):361-3.
6. Chandrasekar B, Doucet S, Bilodeau L, Crepeau J, deGuise P, Gregoire J, Gallo R, Cote G, Bonan R, Joyal M, Gosselin G, Tanguay JF, Dyrda I, Bois M, Pasternac A. Complications of cardiac catheterization in the current era: a single-center experience. *Catheter Cardiovasc Interv* 2001 Mar;52(3):289-95.
7. Gutierrez MJ, Aggarwal A, Gilbert K, Sobel BE, Dauerman HL. Bleeding complications after contemporary pharmacoinvasive therapy for ST elevation myocardial infarction. *J Thromb Thrombolysis* 2004 December;18(3):187-192.
8. Schnyder G, Sawhney N, Whisenant B, Tsimikas S, Turi ZG. Common femoral artery anatomy is influenced by demographics and comorbidity: implications for cardiac and peripheral invasive studies. *Catheter Cardiovasc Interv* 2001 Jul;53(3):289-95.
9. Turi ZG. Optimizing vascular access: routine femoral angiography keeps the vascular complications away. *Catheter Cardiovasc Interv* 2005 June;65(2):203-4.
10. Farouque HM, Tremmel JA, Raissi SF, Aggarwal M, Fearon WF, Ng MK, Rezaee M, Yeung AC, Lee DP. Risk factors for the development of retroperitoneal hematoma after percutaneous coronary intervention in the era of glycoprotein IIb/III a and vascular closure devices. *J Am Coll Cardiol* 2005 Feb;45(3):363-8.

11. Ellis SG, Bhatt D, Kapadia S, Lee D, Yen M, Whitlow PL. Correlates and outcomes of retroperitoneal hemorrhage complicating percutaneous coronary intervention. *Catheter Cardiovasc Interv* 2006 Apr;67(4):541-5.
12. Sherev DA, Shaw RE, Brent BN. Angiographic predictors of femoral access site complications: implication for planned percutaneous coronary intervention. *Catheter Cardiovasc Interv* 2005 June;65(2):196-202.
13. Torsello G, TeBarek J, Kasprzak B, Klenk, E. Treatment of aortic aneurysm with a complete percutaneous technique: An update after treatment of 80 patients. *Dtsch med Wochenschr* 2002;127:1453-57.
14. Ansel G, Yakubov S, Neilsen C, Allie D, Stoler R, Hall P, Fail P, Sanborn T, Caputo RP. Safety and efficacy of staple-mediated femoral arteriotomy closure: results from a randomized multicenter study. *Catheter Cardiovasc Interv* 2006 April;67(4):546-553.
15. Hermiller J, Simonton C, Hinohara T, Lee D, Cannon L, Mooney M, O'Shaughnessy C, Carlson H, Fortuna R, Yarbrough CA, Zapien M, Chou T. Clinical experience with a circumferential clip-based vascular closure device in diagnostic catheterization. *J Invasive Cardiol* 2005 Oct;17(10):504-10.
16. Winthrop D, Piper MS, Malenka DJ, Ryan T Jr., Shubrooks S, O'Conner GT, Robb JF, Farrell K, Corliss S, Hearne MA, Kellett MA, Watkins MW, Bradley WA, Hettleman BD, Silver TM, McGrath PD, O'Meara J, Wennberg DE, Northern New England Cardiovascular Disease Study Group. Predicting vascular complications in percutaneous coronary interventions. *Am Heart J* 2003; 145(6):1002-9.
17. Tarvis DR, Dey S, Albrecht-Gallauresi B, Brindis RG, Shaw R, Weintraub W, Mitchel K. Risk of local adverse events following cardiac catheterization by hemostasis device use - phase II. *J Invasive Cardiol* 2005 Dec;17(12):644-50.
18. Allie DE, Hebert CJ, Lirtzamn MD, Wyatt CH, Keller VA, Khan MH, McElderry M, Khan MA, Fail PS, Chaisson G, Allie SD, Kowalski JM, Mitran E, Allie AA, Caputo RP, Walker CM. A novel staple-mediated closure device: Successful closure in peripheral vascular disease, small vessel anatomy, and noncommon femoral artery sticks. *American Journal of Cardiology* 2003 September 15;92(6A):19L.
19. Hermiller JB, Simonton C, Hinohara T, Lee D, Cannon L, Mooney M, O'Shaughnessy C, Carlson H, Fortuna R, Zapien M, Fletcher DR, DiDonato K, Chou TM. The StarClose Vascular Closure System: interventional results from the CLIP study. *Catheter Cardiovasc Interv*. 2006 Nov;68(5):677-83.
20. Rashid M, Bradley J, Gilbert K, Straight F, Terrien C, Terrien E, Gogo P, Watkins M, Dauerman H. Extravascular Closure for Patients with High Risk Femoral Anatomy. Abstract submitted to TCT May 2007.