What is your preferred closure method for standard percutaneous revascularization procedures performed via femoral access?

FIRAS F. MUSSA, MD, MS, FACS
Assistant Professor of Surgery
Vascular and Endovascular Surgery
Division of Comparative Effectiveness and Decision Science
Department of Population Health
NYU School of Medicine
New York, New York

Dr. Mussa has disclosed that he is a consultant to Abbott Vascular.

I think the key to successful percutaneous closure starts at the time of puncture. It is worth spending the extra 5 to 10 minutes at the beginning of the case to choose the puncture site using ultrasound (in transverse and longitudinal planes) and fluoroscopy. My routine is to gain access at a noncalcified spot just above the bifurcation of the common femoral artery. This is immediately confirmed with an oblique angiogram while pulling the sheath to the ipsilateral side. This small last maneuver allows me to see exactly where the puncture was and confirm that I will be able to use a closure device. If using a sheath larger than 12 F, I would dilate the track at this time and cut any skin bridges within the puncture site.

Over the years, I have used most closure devices, and I can say that I have had a fair number of failures until I started using the routine I described previously. My preferred device now is Perclose ProGlide (Abbott Vascular, Santa Clara, CA), and I use it for most peripheral interventions involving a 6-F (or larger) sheath. I also use the same device to preclose the arteriotomy during endovascular abdominal and thoracic aneurysm repairs. Although the data on most closure devices are similar in terms of safety and effectiveness, I am more comfortable using a device involving a prolene suture. It is the closest to what I would do if I had to treat the vessel via open surgery. I like the feature of never losing wire access until hemostasis is confirmed. Lastly, if I ever need to go back to explore that femoral artery, the inflammatory reaction to the closure device is the least with ProGlide, in my experience.

STEPHEN KEE, MD
Chief of Interventional Radiology
UCLA Medical Center
Los Angeles, California

Dr. Kee has disclosed that he has no financial interests related to this article.

In our practice, we perform a wide variety of procedures, the majority of which do not require arterial access. However, we do perform a significant quantity of arterial interventions in patients with peripheral arterial disease, as well as in order to direct chemotherapy in patients with underlying cancers. In general, we perform between 60 and 80 arterial interventions requiring femoral access per month. The group has access to all the available arterial closure devices, with the big three—Perclose, StarClose (Abbott Vascular), and Angio-Seal (St. Jude Medical, Inc., St. Paul, MN)—being the most commonly utilized. We have also worked with the Boomerang device (Cardiva Medical, Inc., Sunnyvale, CA), are using the Mynx (AccessClosure, Inc., Mountain View, CA) in selected cases, and are about to start a trial of the FISH system (Femoral Introducer Sheath and Hemostasis; Morris Innovative, Inc., Bloomington, IN).

My own personal practice focuses mainly on patients with peripheral vascular disease. Great care needs to

be taken when considering a closure method in this group of patients, either because of poor-quality access vessels, which put patients at high risk of the closure device further compromising the vessel at the puncture location, or due to the use of anticoagulants or antiplatelet agents, which put them at high risk of bleeding. The latter issue is routinely encountered, as essentially, all of these patients are on some agent to promote the patency of the repaired vessel. When possible, we aim to discharge these patients on the same day, usually 3 to 4 hours after their procedures.

At the termination of these cases, I evaluate the access vessel carefully using an oblique, magnified angiogram, and if the vessel is of adequate diameter (> 6 mm), I place an Angio-Seal device. Before device insertion, I resterilize the groin and administer extra lidocaine, both superficially and deep, adjacent to the vessel.

My preference for this particular device is based on simplicity of use and the low incidence of device failure I have encountered. It is imperative that these patients do not develop hematomas, as they must have their antithrombotic agent in the initial postprocedure period, and their overall benefit is greatly enhanced by their ability to ambulate early.

In patients without an adequate vessel for closure, we still routinely perform manual compression. I feel it is important to have the initial sheath pull and stasis performed by the senior operator involved, as this is the most significant aspect. We then rotate staff, applying pressure for 10 minutes each, usually for a total of 30 to 40 minutes. After this, I will apply a FemoStop (St. Jude Medical) for a further 2 to 3 hours. This encourages the patient to remain still and adds extra confidence that we will achieve an adequate seal. These patients are not allowed to ambulate for 5 hours after sheath removal. If the procedure is finished late in the day, this may require an overnight stay, so when possible, we try to complete these procedures early.

The last group of patients includes those who require a large introducer sheath (10 F or larger). These are rare and usually involve a complex disease process such as an aneurysm or dissection before or after previous repair. Also, trauma patients occasionally require the use of larger stent grafts, and the sheath size can be an issue. In these patients, we will perform a preclose technique using two ProGlide devices before placing the sheath and closing after removal. This has worked well in such patients.

The recent introduction of a number of competing devices may well result in my changing some of my practices. However, for now, this is my current strategy.

RICHARD C. KOVACH, MD, FACC, FACP
Chair, Interventional Cardiology
Director, Adult Cardiac Cath Lab
Director, Interventional Cardiology Fellowship Program
Deborah Heart and Lung Center
Browns Mills, New Jersey

Dr. Kovach has disclosed that he has no financial interests related to this article.

Clearly, there are numerous closure devices currently available. Choice of device is largely based on operator experience and familiarity with a device and vascular anatomy, but it is also often related to which vendors an institution may have contracts with.

At our institution, we have access to the Mynx with Grip Technology, Angio-Seal, and Perclose. My own particular preference is the Mynx with Grip Technology. Of the three devices, this is the only one that is completely extravascular, and with care, it can still be used in patients with significant peripheral arterial disease. In patients who are still fully anticoagulated after an interventional procedure, the new Grip Technology allows the polymer to bind fairly securely to the vessel surface, creating a good seal (much more so than the older-generation device, which did not have this feature). I have used this device with heparin, IIb/IIIa inhibitors, and lytics on board. Deployment is relatively painless, and the vessel can be immediately reaccessed afterward.

Angio-Seal is also an excellent closure device, but because of the internal foot process, it should be used with extreme caution in patients with peripheral arterial disease. I have managed several patients who have had acute closure or thrombosis of their common femoral artery because of this foot process. Patients typically experience a great deal of discomfort upon deployment. The device is often associated with a fairly robust local inflammatory response, and reaccess in the same vessel may need to be delayed as long as 6 weeks.

I have found Perclose to often fail in calcified vessels, due to the inability of the relatively flimsy needle to penetrate the tissue, often requiring a second device and thereby increasing the cost of the closure. At times, the knot gets stuck in the subcutaneous tissue and cannot be pushed all the way to the vessel, resulting in an inadequate seal. As with Angio-Seal, the device is also often quite painful upon deployment. Finally, with the suture left behind, there is the potential for increased risk of infection, although this was probably more of a concern with the older braided suture rather than the monofilament that is currently being used in the device.

JAAFER GOLZAR, MD, FACC, FSCAI
MidAmerica Cardiovascular Consultants
Chicago, Illinois

Dr. Golzar has disclosed that he has been a paid consultant and speaker for Arstasis, Boston Scientific, and Covidien, and a paid speaker for Cardiovascular Systems Inc.

In recent years, my approach to femoral arterial access and closure has evolved significantly. I have plugged, stapled, and sutured arteries throughout my career. Closure device–related complications can cause significant anxiety, especially after a seemingly successful complex intervention or even a routine diagnostic procedure. As I see it, there are major limitations to the traditional modes of femoral arterial closure. Inherent to arterial implants for closure are failure modes that can result in acute closure of the arterial access site. Furthermore, these devices are not recommended in significantly calcified arteries or at the bifurcation of the superficial and profunda femoral arteries. The advantage of manual compression is obvious in that there is nothing left behind to result in acute arterial closure. However, the archaic practice of 6 hours of bed rest after intervention is inconvenient to our patients and inefficient for the catheterization laboratory.

In February 2011, I began using the Axera device (Arstasis, Redwood City, CA). Since then, I have used this method of access in the majority of my patients for both diagnostic and interventional cases. The Axera device is unlike traditional closure devices, in that it is used to access the artery. Axera creates an ultrashallow-angle arteriotomy, which allows the internal hemodynamic pressure to aid in closing the access channel after sheath removal. There are multiple advantages of this device over traditional closure devices. Bed rest times are minimized (1 hour for diagnostic, 2 hours for interventions) while preserving the safety profile of manual compression. The patient is allowed to sit up at 45˚ after 30 minutes, further improving patient convenience and satisfaction. Because no foreign object is implanted in or around the artery, there is no risk of device migration requiring surgical removal, nor is there a risk of infection due to a contaminated suture. In my experience, Axera has resulted in fewer device-related complications and problems with reaccessing the artery.

The major limitation of the device is its limited use in patients with iliac stenosis or occlusion. Severe iliac tortuosity can also be challenging, which should be improved after the shorter, angled-tip wire is introduced. With more than 400 uses, our success with this method has been exceptional. Arterial access and closure is one of the cornerstones of coronary and peripheral vascular intervention. I use Axera because it has the advantages of manual compression without the drawbacks of arterial implants. ■