Access site management with vascular closure devices for percutaneous transarterial procedures

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The rising numbers in the aging population will undoubtedly lead to a corresponding increase in percutaneous endovascular procedures to address their cardiovascular health issues. With a constant drive to develop innovative treatment methods to achieve improved treatment outcomes while reducing procedural-related complications, endovascular interventionalists have focused on technologies to provide efficient hemostatic control of femoral artery access following percutaneous diagnostic or therapeutic angiographic procedures. Compared with the traditional hemostatic method using manual compression, several arterial closure devices (ACD) have been shown to reduce time of hemostasis, enable early patient ambulation, reduce hospitalization staff use, and improve patient outcome. However, these ACDs have their shortcomings as the interventionalists need to be familiar with these technologies as well as their potential complications. This article provides a comprehensive review of current closure device technologies as well as clinical experiences with these devices. The adjunctive role of these technologies in endovascular aortic aneurysm repair is also discussed. (J Vasc Surg 2010;52:1682-96.)

As the aging population continues to rise, there is a corresponding increase in the number of percutaneous radiologic and endovascular procedures to address their cardiovascular health issues. According to the United States Census Bureau, there will be 71 million people above the age of 65 years, and 19.5 million above the age of 80, ie, a >7% and 50% rise in 2030 compared with year 2000, respectively. Cardiovascular disease is the number one cause of death in the United States. Consequently, there is a constant drive to develop innovative methods and devices that enable interventionalists to achieve diagnostic or therapeutic goals while reducing procedural related risks and enhancing patient satisfaction, and performing outpatient procedures. One area of percutaneous vascular interventions, which has received intense focus in the past decade relates to technologies to achieve rapid and effective control of femoral arterial access, which is traditionally accomplished by manual compression. These arterial closure devices (ACD) have been shown to reduce time of hemostasis, enable early patient ambulation, reduce hospitalization staff utilization, and improve patient outcome. However, these ACD have their shortcomings and the interventionalists need to know about these devices, how they work, and their potential complications. Minor and major complications have been reported from 1.5% to 9% with up to 40% requiring surgical repair. Table I lists some of the complications reported with ACD use.

First introduced in conjunction with the Seldinger percutaneous puncture technique, manual compression (MC) has been regarded as the standard method to achieve hemostasis following percutaneous procedures for nearly five decades. Manual compression is performed with sustained pressure over the puncture site for 15 to 20 minutes followed by bed rest for an additional 6 hours. While this technique is sufficient in achieving groin hemostasis in the majority of patients undergoing percutaneous procedures, manual compression may not be effective in providing sustainable hemostatic pressure in obese patients. Additionally, patients with certain medical comorbidities related to lumbar or pelvic ailments may encounter difficulty with prolonged immobilization. With increased utilization of various anticoagulation regimens during percutaneous interventions, including antiplatelet glycoprotein IIb/IIIa inhibitors, groin-bleeding complications with MC have similarly risen sharply.

The shortcomings related to manual compression coupled with efforts to improve post-catheterization hemostasis have led researchers to develop a variety of vascular closure devices in the past decade. The primary advantage attributed to VCD is shortened duration to achieve hemostasis and avoidance of prolonged immobilization so that earlier ambulation and outpatient discharge can be achieved following percutaneous procedures.

There are no large randomized clinical trials comparing ACD vs manual compression (MC), but two meta-analyses showed marginal or no benefit of ACD over MC. However, there was significant heterogeneity of the studies reviewed in these meta-analyses in the setting with which the ACD were used, as well as the patients and the operator. In addition, most MC was done after reversal of activated clotting time (ACT), while ACD were deployed regardless of anticoagulation status. Strategies to reduce vascular complications with ACD have been effective and showed...
Table I. Complications of arterial closure devices

<table>
<thead>
<tr>
<th>Complication</th>
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<tbody>
<tr>
<td>Infection</td>
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<tr>
<td>Bleeding (minor, major)</td>
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<tr>
<td>Groin hematoma (minor, major)</td>
</tr>
<tr>
<td>Retroperitoneal bleed</td>
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<tr>
<td>Pseudoaneurysm</td>
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<tr>
<td>Arterial laceration</td>
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<tr>
<td>Arteriovenous fistula</td>
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<tr>
<td>Embolization</td>
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<tr>
<td>Limb ischemia</td>
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<tr>
<td>Femoral artery thrombosis</td>
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<tr>
<td>Dissection</td>
</tr>
<tr>
<td>Pain</td>
</tr>
<tr>
<td>Nerve injury</td>
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<tr>
<td>Death</td>
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</tbody>
</table>

promising reduction in complication rates.\textsuperscript{6,7} Also, new generation devices have been revised and improved with fewer complications reported.\textsuperscript{3,6}

This article provides an overview of the technologies available as an alternative to MC to achieve hemostasis after percutaneous catheterization procedures. Clinical data to support their utility and compare them with MC, as well as complications related to these closure devices are also discussed.

OVERVIEW OF VASCULAR CLOSURE DEVICES

Significant advances have occurred in the past decades in vascular closure technologies leading to several important design features that merit consideration when choosing a vascular closure device. There is no ideal device; each one has its own inherent problems. Despite the advances made to improve these ACD, their use did not increase rapidly, some reporting only one-third utilizing it after a diagnostic catheterization.\textsuperscript{8} This is due to lack of superiority of ACD over MC, concern for cost, and lack of reimbursement.

Ideally, a closure device should be simple to use without cumbersome deployment mechanism and should be safe. The activation of the device closure mechanism should be reliable and consistent with low complication rates comparable to traditional manual compression methods. The utilization of a closure device should not incite significant inflammatory reaction in the surrounding tissue. The latter feature allows procedural safety if postinterventional repeat puncture or surgical access is necessary. Lastly, an ideal device must be cost effective. Cost-effectiveness is a tough issue to decipher; it depends not only on cost but also on reimbursement, on the reduction of cost related to complications as well as comparison to what mechanism of external compression is used as MC. Using a C-clamp or other similar device is cheaper than a staffing personal putting external pressure. There are no CPT codes for reimbursement; the codes available for ACD are codes used by physicians and institutions to report or track their use. Cost reduction driven by reduction in vascular complications is small especially in patients undergoing diagnostic procedures where the complication rate is lower.\textsuperscript{5,8} All these different factors make the cost-effectiveness calculation very complex and difficult. A small randomized trial comparing ACD with MC showed a modest reduction in hospital stay of \( \sim \) 70 euro per patient.\textsuperscript{9} This cost saving could be potentially lost if a fem-stop or similar device was used, which is cheaper than a nurse or health personnel applying MC.

Based on the mechanism and technology utilized by these devices to achieve hemostasis, they can be divided into three broad categories. They include (1) collagen-based technology, (2) suture-mediated technology, and (3) staple or clip-based technology. Commonly used vascular closure devices based on these three mechanisms are listed in Table II.

COLLAGEN-BASED VASCULAR DEVICES

Devices that utilize collagen to achieve hemostasis are primarily based on bovine biodegradable products to augment thrombus formation. The hemostatic formation of collagen-based closure devices is based on two biochemical reactions. The collagen plug is deployed outside the vessel wall on the arteriotomy site. This exogenous collagen material forms an extracellular lattice, which triggers a hemostatic cascade by promoting platelet aggregation, adherence, and activation.\textsuperscript{10} Second, upon contact with blood, the collagen expands its physical mass resulting in mechanical occlusion of the vessel puncture site and tissue tract.\textsuperscript{11} Because of the degradable nature of these proteinaceous bioproducts, the resorption of these collagens may lead to varying degrees of inflammatory processes in the surrounding soft tissue.\textsuperscript{12} Repeat puncture or surgical exploration of the same artery may lead to increased difficulty due to subcutaneous inflammatory tissue reaction. In vivo studies have shown that collagen plugs are resorbed within 4 weeks, which subsequently leads to the recommendation that repeat access or surgical exploration of the same vessel should not be performed for 4 weeks following the deployment of the collagen-based devices.\textsuperscript{4,10,13} Common examples of these collagen-based closure devices include Angio-Seal (St Jude Medical, St Paul, Minn), VasoSeal (St Jude Medical), and Duett (Vascular Solutions, Minneapolis, Minn).

Angio-Seal. The Angio-Seal (St Jude Medical) received its initial approval from the Food and Drug Administration (FDA) in 1996. With more than 7 million devices distributed worldwide since its introduction, Angio-Seal is one of the most widely used arterial closure devices. This device went through multiple revisions, and the current one is very user friendly. This is a bioabsorbable collagen closure device, which consists of an absorbable, intra-arterial anchor, a small bovine collagen plug, and an absorbable traction suture (Fig 1).\textsuperscript{14,15} At the completion of the percutaneous angiography, the anchor and collagen plug are inserted into the artery through a specially designed sheath and then pulled up snugly against the arterial wall to seal the puncture site. The intra-arterial anchor is a T-shaped material composed of copolymers of polylactic and polyglycolic acids. When deployed, the combination of
anchor, collagen plug, and absorbable suture effectively sandwiches the puncture site between the anchor and the extravascular collagen plug to seal the arterial puncture site. The Angio-Seal is available in a 6F or 8F system. Femoral arteriography is recommended prior to device deployment as calcified vessel walls may preclude safe device anchor deployment and device activation. Additionally, angiographic confirmation of the puncture site is necessary, as the device should not be deployed in the external iliac artery, superficial femoral artery, or profunda femoris artery. Another consideration to avoid the use of this device is in peripheral vascular disease patients and vessels less than 5 mm in diameter. The intraluminal anchor and collagen plug are absorbed within 30 days. Therefore, vessels should

<table>
<thead>
<tr>
<th>Device category</th>
<th>Device name</th>
<th>Manufacturer</th>
<th>Recommended sheath size (F)</th>
<th>Maximum wire compatibility (inch)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collagen-based device</td>
<td>Angio-Seal VIP, Angio-Seal STS Plus</td>
<td>St Jude Medical</td>
<td>6, 8</td>
<td>0.038&quot;</td>
<td>These are earlier versions of Angio-Seal family, which deliver collagen plugs to close the arteriotomy. Collagens are reabsorbed within 90 days. Device application allows for immediate repeat access. This is most recent generation of Angio-Seal, which creates an automated collagen compaction. All components are reabsorbed within 90 days. Device application allows for immediate repeat access.</td>
</tr>
<tr>
<td></td>
<td>Angio-Seal Evolution</td>
<td>St Jude Medical</td>
<td>4-8</td>
<td>0.038&quot;</td>
<td>These devices do not leave any intravascular collagen component. The collagen is deposited in extravascular space, which is bioabsorbable.</td>
</tr>
<tr>
<td></td>
<td>VasoSeal VHD, ES, Elite</td>
<td>St Jude Medical</td>
<td>5-8</td>
<td>0.038&quot;</td>
<td>This is designed to accommodate smaller sheaths including 4F or 5F puncture sites.</td>
</tr>
<tr>
<td></td>
<td>VasoSeal Low Profile</td>
<td>St Jude Medical</td>
<td>4, 5</td>
<td>0.038&quot;</td>
<td>These devices do not leave any intravascular collagen component. The collagen is deposited in extravascular space, which is bioabsorbable.</td>
</tr>
<tr>
<td></td>
<td>Duet Pro, Duet</td>
<td>Vascular Solutions</td>
<td>5-9</td>
<td>0.038&quot;</td>
<td>Device is delivered through existing sheath. This device uses thrombin and collagen procoagulant solution, which is delivered through existing sheath. A balloon catheter is also utilized to aid hemostasis. Duet Pro is approved for use in patients with GP IIb/IIIa inhibitors.</td>
</tr>
<tr>
<td>Suture-based device</td>
<td>Perclose A-T</td>
<td>Abbott Vascular</td>
<td>5-8</td>
<td>0.038&quot;</td>
<td>This is an early version of Perclose family, which deploys braided polyester sutures.</td>
</tr>
<tr>
<td></td>
<td>Perclose ProGlide</td>
<td>Abbott Vascular</td>
<td>5-8</td>
<td>0.038&quot;</td>
<td>This device delivers a monofilament polypropylene suture with automated knot creation.</td>
</tr>
<tr>
<td></td>
<td>Prostar XL</td>
<td>Abbott Vascular</td>
<td>8.5-10</td>
<td>0.038&quot;</td>
<td>Commonly used for procedures requiring large introducer sheaths, such as endovascular aortic aneurysm procedure. The device uses braided polyester suture for arteriotomy closure.</td>
</tr>
<tr>
<td></td>
<td>X-Site</td>
<td>St Jude Medical</td>
<td>5, 6</td>
<td>0.038&quot;</td>
<td>The device delivers a braided polyester suture with automated suture knot creation. Its clinical applicability is compared less with Perclose family since it is only approved for 5F and 6F puncture sites.</td>
</tr>
<tr>
<td></td>
<td>SuperStitch</td>
<td>Sutura</td>
<td>6-12</td>
<td>0.038&quot;</td>
<td>This device uses polypropylene suture and delivers through existing sheath. It is available in 12F introducer sheath size.</td>
</tr>
<tr>
<td>Metal clip or disc-based device</td>
<td>StarClose</td>
<td>Abbott Vascular</td>
<td>5, 6</td>
<td>0.038&quot;</td>
<td>This is the first generation of StarClose family, which delivers an extravascular nitinol clip that mechanically approximates the arteriotomy.</td>
</tr>
<tr>
<td></td>
<td>StarClose SE</td>
<td>Abbott Vascular</td>
<td>5, 6</td>
<td>0.038&quot;</td>
<td>This is the second generation of StarClose family with improved ease-of-use design.</td>
</tr>
<tr>
<td></td>
<td>Angidlink EVS</td>
<td>Medtronic</td>
<td>6-8</td>
<td>0.038&quot;</td>
<td>This device delivers an extravascular nitinol staple at the adventitial layer for arteriotomy closure.</td>
</tr>
<tr>
<td></td>
<td>Boomerang</td>
<td>Cordiva</td>
<td>4-10</td>
<td>0.038&quot;</td>
<td>This device uses a nitinol-based wire with a temporary nitinol braided mesh disc to achieve hemostasis. No foreign materials are left in intraluminal or extravascular space.</td>
</tr>
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</table>
not be accessed for 1 month following placement of an Angio-Seal device. If reaccess is needed, then it can be done 1 cm above the previous access site. Similarly, if surgical exploration or femoral revascularization is a possibility following arteriography, this type of bioabsorbable collagen device should not be utilized. If device deployment fails, hemostasis can still be achieved with manual compression. Infrequent complications such as acute femoral artery thrombosis can occur due to inadvertent plug deployment within the intraluminal space, which will necessitate urgent surgical exploration and plug removal (Fig 2).

**VasoSeal.** The VasoSeal (St Jude Medical, St Paul, Minn), is a closure device utilizing a purified bovine collagen-based plug to achieve hemostasis at the arterial punctured site (Fig 3). Since the first generation of the VasoSeal device was approved by the FDA in 1995, there have been a total of four different platforms of VasoSeal which include (1) VasoSeal Vascular Hemostasis Device (VHD), (2) VasoSeal ES (Extravascular Security), (3) VasoSeal Low Profile, and (4) VasoSeal Elite. These various platforms are intended to be used for varying diameters of the arterial punctured site. Both VasoSeal Elite and ES utilize a temporary J-shaped locator segment, which is deployed so the collagen plug is deposited on the outer surface of the vessel wall along the puncture tract. The main difference between the Angio-Seal and VasoSeal is that the latter device does not possess any intraluminal components, while an Angio-Seal deploys an intraluminal plug to achieve hemostasis. The VasoSeal device may be used with the maximum sheath size of 8F introducer sheath. Following the VasoSeal device deployment, patients only need to remain in bed rest for 1 hour before they can be ambulatory. Repeat arterial puncture can be performed after 6 weeks of deployment of the VasoSeal device. Because this device deploys an extravascular collagen plug, femoral artery calcification or peripheral artery disease is not considered a contraindication for VasoSeal deployment. Also, there is no need for a femoral angiogram prior to deployment. However, the VasoSeal
Device is contraindicated in obese patients, due to device length limitations. Because the collagen plug is deployed in the extraluminal space, patients frequently experience an irritated skin lump due in part to the inflammatory reaction caused by the collagen plug resorption. The manufacturer has addressed this issue by reducing the amount of bovine collagen inserted in later versions of the device. In the event of device deployment failure, hemostasis of the arterial puncture can be remedied with the conventional manual compression. Infrequent complications such as acute femoral artery thrombosis can occur due to inadvertent plug deployment within the intraluminal space, which will necessitate urgent surgical thrombectomy and plug removal.

**Duett device.** The Duett sealing device (Vascular Solutions) combines the procoagulant effect of thrombin with the platelet activation of collagen plus a 3F balloon catheter. This closure technology is based on an extraluminally placed collagen-based hemostatic component. The balloon catheter is first deployed through any existing 5F to 9F vascular sheath. The catheter is subsequently delivered into the artery, which is followed by the inflation of a 3 mm × 7 mm balloon (Fig 4). The inflated balloon is then withdrawn anteriorly against the intraluminal surface of the arteriotomy to create a temporary puncture site hemostasis. This is followed by the injection of procoagulant agents into the sidearm of the sheath as it is slowly withdrawn. Continual infusion of the procoagulant while the sheath is withdrawn triggers an accelerated clotting cascade and platelet activation to close the subcutaneous tract. This cascade is characterized by the conversion of fibrinogen into fibrin by the action of thrombin in the presence of collagen resulting in accelerated coagulation reaction. The balloon is lastly deflated and withdrawn completely from the puncture site. This is a low profile catheter and does not disrupt the plug upon removal. Additional manual compression for 3 minutes is necessary to achieve hemostasis.

Similar to the VasoSeal device, there is no intraluminal anchor. The Duett device has been shown to be effective in achieving satisfactory hemostasis and early ambulation compared with manual compression. Vessels, which have been treated with the Duett closure device, can undergo repeated puncture immediately for angiography and cause minimal local inflammation. Potential accidental injection of collagen into intraluminal space can occur due to suboptimal balloon inflation. This could happen in peripheral artery disease patients where the balloon gets stuck to the posterior plaque and does not seal the arteriotomy from the thrombin injection. Consequently, one potential complication of the Duett device is that of inadvertent infusion.
of the procoagulant solution into the artery resulting in acute arterial thrombosis. This complication has been treated with either thrombolysis or thrombectomy.

**SUTURE-BASED VASCULAR CLOSURE DEVICES**

These devices achieve arterial hemostasis by deploying sutures, which are tied to form a surgical knot to close the arteriotomy. The knot is tied by a built-in mechanism within the closure device, but can also be tied manually if necessary. Because there is no proteinaceous biomaterial left behind in the puncture tract, there is no bioresorption or inflammatory soft tissue reaction associated with this closure technology. Consequently, repeat arterial access or immediate surgical exploration of the same artery can be performed safely. Common examples of these suture-based closure devices include Perclose (Abbott Vascular Devices, Redwood City, Calif), X-Site (Datascope, Montvale, NJ), and SuperStitch (Sutura, Fountain Valley, Calif).

A list of these suture-based closure devices is provided in Table II.

**Perclose device.** The Perclose device (Abbott Vascular Devices) was the first suture mediated closure system approved by the FDA in 1997. There are various Perclose platforms including (1) the ProGlide, (2) Perclose A-T, (3) Closer S, and (4) Prostar XL, which can deploy single or double nonabsorbable sutures and are intended for various introducer sheath sizes ranging from 6F to 10F. These devices differ in the sheath size, suture type, and suture deployment. To deploy the Perclose device, it is first advanced into the artery over a guidewire. After proper positioning, a braided 3-0 polyester suture is deployed, and the device is removed after the knot has been tightened down around the puncture site (Fig 5). The Prostar XL device was the earliest version, which utilizes a series of complex mechanisms that involve the delivery of either 2 or 4 needles from inside of the artery. These suture-attached needles are punctured across the artery, which are engaged by the barrel of the delivery system. Once engaged in the arterial wall, the sutures are manually tied in a conventional surgical slipknot, which is pushed down toward the surface of the arteriotomy to achieve suture-mediated closure.

These devices were not popular because the operator needs to form and push down the knot. The newer devices have a pretied knot. The recent platforms of Perclose devices, including the ProGlide, Perclose A-T, and Closer, are based on a different design in which needles are deployed from outside the vessel and the device captures the suture immediately. The Closer device requires the operator to tie the suture manually, while the Perclose A-T device already has a pretied knot. The Closer and A-T device may be utilized to achieve hemostasis following the use of 5F to 8F sheaths. Similar to the Angio-Seal system, the Perclose device provides arterial anchoring to achieve hemostasis, which is a beneficial feature in patients who receive anticoagulants. Similar to the Duett device, the Perclose system can be applied in the same artery immediately following its deployment. Unlike all other collagen-based closure systems, the closure mechanism in the Perclose device, which is based on a monofilament polypropylene suture, represents a permanent foreign material in the extravascular space.

**X-press device.** The X-press device (X-Site) was a recently introduced suture-mediated closure device. This device consists of three mechanical components to achieve hemostasis, which includes an over-the-wire device, a suture attached to two needles, and a knot pusher, which also functions as a suture cutter. Unlike the Perclose device, the X-Site system contains no intra-arterial component for suture-mediated closure. Deployment of this device involves sequential engagement of the first needle with a subsequent 180° twist, which is followed by the deployment of the second needle. The sutured knot is then tied down manually or by using a knot tier. Unlike the Perclose device, which has a wide range of applicability of various...
deploy either metal staple or clip that penetrates the vessel

**CLOSURE DEVICE**

**METAL CLIP OR DISC-BASED VASCULAR CLOSURE DEVICES**

Devices, which utilize metal clip-based technology, deploy either metal staple or clip that penetrates the vessel wall to achieve hemostasis. Upon deployment, the metal clip or staple remains in situ over the vessel wall and forms a geometric configuration that approximates adventitial vessel layers to close the arterial hole. Unlike the collagen-based devices, these metallic clips or staples do not undergo a bioresorption reaction, which therefore does not trigger significant soft tissue inflammatory response. Repeat puncture or surgical exploration of the artery can be done safely. Common examples of these closure devices include AngioLink EVS Vascular Closure System (Medtronic) and StarClose (Abbott Vascular). A list of these clip-based closure devices is provided in Table II.

**StarClose closure system.** The StarClose device (Abbott Vascular, Redwood City, Calif) features a 4-mm-diameter, flexible nitinol clip, which is designed to close femoral arteriotomies created by sheaths up to 6F in size. The system consists of an introducer sheath, dilator, guide wire, and a clip applier. Activation of the locator button deploys small flexible wings that form the locator. An implantable nitinol clip is positioned in the clip applier. When the device is activated, the nitinol staple is engaged in the adventitial layer of the vessel whereby its tines grasp the edges of arteriotomy and draw them together to close the puncture hole (Fig 7). In contrast to collagen-based devices, the nitinol used in the StarClose device is a widely utilized metallic material commonly used in intra-arterial stent or stent graft devices, which has a low profile in bioreactivity in inducing inflammatory soft tissue reaction.4,12

**AngioLink EVS vascular closure system.** The AngioLink EVS Vascular Closure System (Medtronic, Santa Rosa, Calif) deploys an extraluminal titanium staple to achieve vascular hemostasis without penetrating all three layers of an artery. Prior to the staple deployment, a series of vessel stabilizers align the arteriotomy hole into a linear configuration. A titanium staple is deployed at the adventitial layer, which approximates the puncture site to achieve hemostasis. Similar to the nitinol material of the StarClose device, the inert properties of titanium in the AngioLink device induces minimal biologic response or inflammatory tissue reaction in comparison to collagen-based devices.4,12

**Boomerang closure device.** The Boomerang closure device system (Cardiva Medical, Mountain View, Calif) utilizes an 18-G conformable nitinol-based wire with a temporary nitinol braided mesh disc on a tether which is deployed inside the artery to achieve hemostasis. This device received an FDA approval in October 2004. It creates a site-specific compression between the arteriotomy and tissue tract, resulting in targeted internal compression. The hemostatic mechanism is based on the recoiling of the arteriotomy site, which is analogous to the “boomerang” effect (Fig 8). After a few minutes of device deployment, the nitinol mesh disc and wire are then removed, thus leaving no foreign body in either intraluminal or extraluminal space. This is then followed with 5 to 7 minutes of manual compression over the remaining puncture site to achieve complete hemostasis. The Boomerang device is designed to close femoral arteriotomy created by sheaths

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**Fig 5.** Deployment of the Perclose closure device. A, Insertion and positioning of the 6F Perclose device over the wire into the femoral access site until pulsatile flow through the marker lumen is seen indicating an adequate intraluminal device position. B, Deployment of foot and positioning against the arterial wall by pulling the device upward in preparation for needle deployment. Sutures are deployed around the arteriotomy and are pulled from the device outside the skin. C, The pre-tied knot is pushed down using the knot pusher that comes with the device. Once hemostasis is achieved, the suture is cut using a knot cutter. The final suture lies securely around the arteriotomy to achieve hemostasis.
from 4F to 10F in size. A recent study cited an impressive success rate of 99% in achieving complete hemostasis with an average time of 82 minutes from the end of device application to ambulation. However, the need for manual compression following the device application represents a potential drawback of this particular device.

APPLICATION OF PERCLOSE DEVICE IN ENDOVASCULAR STENT GRAFT PROCEDURE

While all available closure devices are effective in achieving hemostasis for the conventional interventional vascular procedure using either 5F or 6F introducer sheaths, the Perclose Prostar device utilizes a unique suture-mediated technology, which enables its application in percutaneous endovascular aortic stent graft procedures where large introducer sheaths up to 20F or 24F are routinely used. It is noteworthy that Prostar XL is approved for arteriotomy closure created by a 10F sheath size. Several studies have reported various off-label application of a “Preclose” technique or double deployment of either Prostar or Preclose devices to achieve hemostasis following percutaneous interventional procedures of sheath up to 24F in size. This “Preclose” technique requires placement of two Preclose devices 90° to each other at the beginning of the procedure leaving the knots untied. Alternatively, a single Prostar XL can be used for large introducer sheath applications. The puncture site is then dilated to the appropriate size, and the sutures are ultimately tied once the endovascular stent-graft procedure is completed. A brief description of this percutaneous technique using a single Prostar XL device for endovascular aortic stent graft procedures is provided below.

To perform a percutaneous endovascular aortic repair utilizing a Prostar XL device, it is important to first assess the femoral artery using an ultrasound to determine its diameter and associated vessel calcification. Only femoral
hemostasis and the device is retracted.

slightly less than 90°.

the splitting of the sheath. The device is raised to an angle of

tance is felt. The advancement of the thumb advancer completes

locator button is depressed. The device is pulled out until resis-

device that is inserted into the sheath after wire removal. The vessel

sheath is introduced first over a wire followed by the StarClose

10-F Prostar XL device is advanced into the common

femoral artery with the tip placed in the distal aorta (Fig 9).

stenosis, which a 6F sheath is inserted. A 1-cm incision is created

common femoral artery is obtained percutaneously in

femoral head and an Ultrasound-guidance access of the

arteries greater than 7 mm in diameter without circumfer-

ential calcification should be considered for this percutaneous

approach. Fluoroscopic imaging is used to identify the

femoral head and an Ultrasound-guidance access of the

common femoral artery is obtained percutaneously in

which a 6F sheath is inserted. A 1-cm incision is created

next around the sheath, with blunt dissection of the subcu-

tanous tissue. The sheath is removed over the wire and a

10-F Prostar XL device is advanced into the common

femoral artery with the tip placed in the distal aorta (Fig 9).

When pulsatile blood flow is noted through the marker

lumen, which indicates the sutures and needles are within

the vessel lumen, all four needles and sutures are deployed

by aligning the barrel and withdrawing the ring (Fig 9). It

is important to maintain the proper amount of tension on

the shaft to avoid compression of the artery during deploy-

ment of the needles, which also ensures that the sutures are

placed adjacent to the arteriotomy and only in the anterior

wall of the artery. The two sutures which are colored white

and green are next separated from the Prostar XL and

placed under towels across the groin (Fig 9). The device is

removed over the wire, and progressive dilations are per-

formed to allow placement of the appropriate-sized sheath

for endograft deployment. The procedure can be repeated

on the opposite groin for the contralateral limb. The oper-

ator has to form the knot in each of the two Prostar XL

sutures using a sliding-knot technique. One end of the

suture is the rail end, which is used to pull the knot all

the way down to the arteriotomy site. The other end, the

non-rail end, is used to lock the knot. A wire is placed in the

monorail side port on the sheath of the device to maintain

arterial access in case of device failure. When the large

introducer sheath is withdrawn, both suture rails are pulled

with tension to slide the knots downward to the femoral

arterial wall (Fig 10). If there is no bleeding, the wire is

removed and a knot pusher (Abbott Vascular Devices,

Abbott Park, Ill) is used to advance the sliding knots to the

vessel wall (Fig 10). Lastly, the non-rail end of the suture is

pulled to lock the knot in place, and the sutures are cut

close to the arterial wall. Standard groin dressings are lastly

applied in bilateral groins. Clinical series using this Prostar

device or double Perclose devices have been reported with

remarkable success rates of 88% to 96% in achieving hemo-

stasis following percutaneous procedures with sheaths

greater than 16F in size.24,25,27,30 All authors from these

clinical series uniformly underscored a clear learning curve

in which early procedure failure is common. With proper

selection of the femoral artery and increased operator’s

experience, endovascular aortic procedures can be achieved

with the percutaneous approach using the Preclose device

with high success rates. In one study looking at early and

midterm outcomes of femoral arteries after PEVAR, at a

mean follow-up of 11.6 months, only 3 (1.92%) patients

required repair of their femoral artery.31 The overall early

technical success was 94.4%, but when looking at different

subsets of sheath sizes, the larger sheaths (>18F) had the

lowest technical success at 92.8%.31 In another study com-

paring percutaneous access with femoral cut down for

EVAR, the percutaneous group had lower overall compli-

cations as well as the subset of patients with calcified vessels

and obese patients.32

CLINICAL EXPERIENCE WITH VASCULAR

CLOSURE DEVICES

There is no large randomized study comparing the
different ACD to each other and/or to MC. In one single
institution randomized study involving 705 patients ran-
domized to three ACD (Angio-Seal, VasoSeal, and Duett)
in the setting of diagnostic and percutaneous coronary
intervention (PCI), which requires a larger sheath, all three
devices had a high rate of technical success with surgical
intervention rate of 1%.33 Angio-Seal provided earlier time
to ambulation compared with the other two devices. All
three devices were considered safe; however, the vasoaseal
device had a slightly higher rate of complication compared
with the other two in the PCI group.33 In another larger
series evaluating ACD use in the setting of PCI and anti-
coagulation in more than 4500 patients, ACD had a similar
or lower complication rate than MC.34 The two devices
used were Angio-Seal and Perclose.
In one meta-analysis reviewing 30 sources showed only a marginal benefit of ACD over MC at an increased risk of groin hematoma and pseudoaneurysm. As mentioned earlier, this meta-analysis did not look at the heterogeneity of the studies, and included reports on the early use of ACD with lack of operator comfort. Another meta-analysis looked at comparing ACD (Angio-Seal, Perclose, and VasoSeal) to MC in the setting of diagnostic angiogram and PCI in over 37,000 patients. It showed that in the setting of diagnostic angiogram, access-site related compli-
Citations were similar for all ACD compared with MC. However, in the PCI group, VasoSeal had a higher complication rate. The overall analysis favored MC over ACD.

As one of the most widely used closure devices, the Angio-Seal device has been reported in the literature with an abundance of clinical experience. All available studies cited a high clinical success rate in achieving hemostasis which ranged from 92% to 98%. Device failure is relatively uncommon in the clinical series with high procedural volumes, which ranged from 1% to 3%. Nonetheless, simple application of manual compression would almost uniformly achieve hemostasis even in the event of device failure. Common modes of device failure are related to the inability to advance the locator sheath in a scarred groin or improper anchor positioning which ultimately resulted in suboptimal application of the collagen plug. Several comparative studies analyzing Angio-Seal vs manual compression reported shorter time to hemostasis and ambulation in patients treated with the Angio-Seal device. A randomized trial comparing Angio-Seal with MC showed reduced time to hemostasis and earlier ambulation in the Angio-Seal group despite anticoagulation as well as reduced complication. In another randomized study comparing Angio-Seal to fem-stop device, the early benefit of Angio-Seal in the first 2 hours with reduced local groin complication was lost at 24 hours. However, the fem-stop group received external compression only when the ACT was <100; meanwhile the Angio-Seal was deployed regardless of anticoagulation status.

Inadvertent deployment of an intraluminal collagen plug can lead to femoral artery occlusion, which is a major complication with a reported incidence ranging from 0.8% to 3.6%. One can reduce this potential complication by avoiding placement of the Angio-Seal device in arteries less than 5 mm in diameter or in arteries with significant circumferential calcification or thrombus which may compromise the flow lumen. As with all percutaneous closure devices, the deployment of the Angio-Seal device in the common femoral artery can ensure the highest likelihood of clinical success.

The VasoSeal device has similarly endured a high degree of clinical scrutiny in the literature. Numerous clinical series have reported high technical success rates ranging from 90% to 100%. Several comparative studies between the VasoSeal device and manual compression demonstrated no differences in the rate of femoral artery pseudoaneurysm or hematoma formation. In the early 1990s, multiple randomized studies favored MC over VasoSeal use in patients undergoing PCI. However, other reports...

Fig 10. Using a Perclose Prostar device in endovascular aortic stent-grafting procedure (continued from Fig 9).

A, When an endovascular aortic procedure is completed, the pre-deployed sutures of a Perclose Prostar device are ready for knot tying. The white structure in these figures is the sheath. Both sutures are pulled upward to create an upward suture tension, making sure the same colored sutures are together. The operator has to form a knot, and one end, which locks the knot, called the non-rail end, is left alone till the knot is pushed all the way down to the arteriotomy site.

B, Endovascular sheath is removed and both suture rails (white and green) are pulled gently. This slides the knot down to the femoral arterial wall.

C, A knot pusher is used when the sheath is removed. If hemostasis is satisfactory, the non-rail suture is pulled to secure the knot on both sutures.

D, Once the hemostasis is achieved, extra sutures are cut.
published in the late 1990s showed the benefit of VasoSeal over MC. This difference was the result of the multiple revisions the VasoSeal received. Also, this device requires a large subcutaneous tract for device deployment. If the device fails, this could lead to an increase in local vascular complications.

Early versions of the VasoSeal device were associated with an increased incidence of groin infection. However, subsequent studies based on more recent device platforms showed no evidence of increased infectious complications. Similar to the Angio-Seal device, which deploys an extraluminal collagen plug, femoral artery occlusion due to inadvertent intraluminal collagen plug deployment with the VasoSeal device has been reported.

The clinical efficacy of the Duett device has been assessed in several studies, which uniformly noted high technical success rates which ranged from 93% to 100%. Clinical studies also demonstrated a faster time to hemostasis and ambulation in patients treated with the Duett device compared with those treated with manual compression. The efficacy of the Duett device was similarly remarkable regardless of whether angiographic procedures were performed for diagnostic or therapeutic intent. Similar treatment success was also reported in patients who received full anticoagulation. Other studies noted no differences in terms of complications, including femoral artery pseudoaneurysm, hematoma, or groin infection, between patients treated with the Duett device vs those treated with manual compression.

In the event of an unusual complication of a femoral artery thrombosis following the deployment of the Duett device, successful flow restoration has been reported using catheter-directed thrombolytic therapy. As the first approved device using a suture-mediated mechanism and replaced braided suture with monofilament polypropylene suture, has reduced the incidence of device failure and lowered the risk of infectious complication.

The StarClose device is the most commonly used device utilizing a metal-based staple technology. Several studies, which compared the efficacy of this device with manual compression, found that the StarClose device was associated with significantly reduced time to hemostasis and ambulation. A different study, which compared patients treated with StarClose vs Angio-Seal, found that both devices had similar efficacy and safety profile in achieving groin hemostasis. However, patients who received the StarClose device were more likely to require post-deployment manual compression than those treated with Angio-Seal device. We concur with this finding, and, from personal experience, noted that the nitinol ring was frequently deployed in the subcutaneous tissue rather than the adventitia upon femoral exploration during subsequent revascularizations. The nitinol ring misplacement narrowed or compressed the tract along with external compression hemostasis could still be achieved.

The use of ACD and their safety is still debatable. However, like any new technology introduced, it takes time for the operator to gain experience as well as make the ACD safer and easier to use. Recent data show that the newer ACD devices as well as operator experience are associated with less complications. Also ACD devices could be safely used in patients with peripheral vascular disease with no alteration of their ankle-brachial indices.

Calculating cost-effectiveness is multifactorial, and it is not known if ACD use is associated with reduced cost. But it is intuitive that ACD are cost-effective if they are associated with less vascular complications. Multiple studies have shown that ACD are associated with decreased hospital length of stay compared with MC. The biggest benefit would be if these devices could convert therapeutic interventions to an outpatient procedure. This might be eventually answered when the use of ACD is reimbursed. This will provide an incentive for a large randomized study evaluating their safety and cost-effectiveness compared with MC.

CONCLUSION

All available current devices have been shown to shorten time to hemostasis and ambulation compared with manual compression. These benefits could translate to a potential decrease in hospital stay and early discharge following percutaneous endovascular procedures. Despite the clinical efficacy of available closure devices, interventionists must be cognizant that all closure devices are associated with a definite learning curve. There is no one single device that is ideally suited for all patients. Familiarity with different devices will be helpful in using certain devices in differ-
ent clinical situations. For instance, the need for immediate percutaneous access or operative groin intervention may favor the use of a closure device, which does not utilize certain collagen-based plugs as the risk of soft tissue inflammation and operative scarring may be significant.

The current available arterial closure devices have made this technology an essential component of endovascular clinical practice. Interventionalists should consider all patients undergoing percutaneous arterial procedure as candidates for closure device application. Institutions should have their own algorithm for ACD use. They should examine the safety and cost as well as technical success and come up with an algorithm as to whether to use ACD or MC, while awaiting a large randomized study that will put these concerns to rest.

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