Vascular Closure Update

The current trends and future directions of vascular closure technology.

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Vascular closure continues to be an ever-expanding field since its introduction in the early 1990s, with new devices being introduced every year. As endovascular procedures increase both in number and specialties involved, the need for safe and efficient access site hemostasis is important. Although manual compression remains the gold standard, its use is limited in patients who are undergoing anticoagulation therapy or endovascular interventions and for those with large-French access sites. In addition, as more procedures move to the outpatient office, vascular closure devices not only allow for early ambulation and improved patient comfort, but they also free up medical personnel for other duties.

There is a wide variety of products designed to decrease compression time, time to ambulation, and patient discomfort after arteriotomy with the goal of also increasing institutional efficiency. The available devices are based on a few central concepts, with the exact technology and implementation varying from device to device. The most commercially popular products, as well as a few new devices, will be discussed in detail. A more thorough list, with brief descriptions, is outlined in Table 1.

We have undertaken to categorize vascular closure devices (VCD) based on their mechanism of action. Active approximators physically close the arteriotomy with the use of a suture or a nitinol clip. Passive approximators deploy a sealant or gel at the arteriotomy to achieve hemostasis. These devices often require adjuvant manual compression for 1 to 3 minutes. Novel devices simulate manual compression or create a short intramural tract to achieve hemostasis. Finally, topical hemostasis patches are also available to accelerate hemostasis.

ACTIVE APPROXIMATORS

Collagen Footplate

Angio-Seal (St. Jude Medical, Inc., St. Paul, MN) continues to be the most widely used VCD. The Angio-Seal device uses an intravascular anchor pulled up against the vessel lumen and suture to closely approximate an extravascular collagen plug on top of the arteriotomy site.

To deploy the Angio-Seal Evolution device at the completion of a procedure, the Angio-Seal guidewire is placed into the procedural sheath, and the procedural sheath is removed. The Angio-Seal locator/sheath assembly is then placed over the Angio-Seal guidewire. It is advanced until blood flows out through the exit hole in the locator, then withdrawn until blood flow ceases, and subsequently advanced until flow restarts. The locator and guidewire are removed leaving the sheath in place. The Angio-Seal is inserted into the sheath, and the intravascular anchor is deployed. The device is then retracted with the anchor held in place by gentle pullback until the colored compaction marker is revealed. The compaction tube is automatically advanced forward to compact the suture knot, collagen, and anchor sandwich with the arteriotomy site to achieve hemostasis. The suture is then released and cut below the skin level (Figure 1). The Angio-Seal Evolution VCD utilizes an innovative deployment mechanism that allows for one-handed use and decreased deployment variability.

All components, including the intravascular anchor, are fully absorbed within 60 to 90 days. The device is unique in that active closure achieved via approximation of the anchor to the collagen plug is combined with the hemostatic properties of the collagen plug. These factors produce effective hemostasis without the need for compression. A consideration for Angio-Seal is that if reentry is necessary within 90 days, reentry is recommended to be at least 1 cm from the previous access site.

Suture-Based Devices

Several products are available that work by efficiently deploying sutures on either side of the arteriotomy site. The sutures are then pulled together, closing the arteriotomy site, resulting in mechanical hemostasis.

The most popular VCD in this category is the Perclose series (Abbott Vascular, Santa Clara, CA) of which there are

several variations. The Perclose device is advanced over the guidewire, and when in adequate position, blood return is observed. The footplate is deployed by raising the lever and then retracted to the vessel wall. Two needles are deployed through the sheath through the vessel wall to the footplate by depressing the plunger. The needles and suture are engaged, and the suture is withdrawn through the proximal portion of the device by withdrawing the plunger (Figure 2). The device is then removed. These steps may be performed before the procedure for preclosure, with the slipknot advanced to the arteriotomy site using a knot pusher after completion of the procedure to seal the arteriotomy site. The Perclose device is suitable after procedures that utilize 5- to 8-F access, with 7 F being the most commonly used.

The principal advantage of the Perclose device is that it provides complete tissue apposition, resulting in mechanical closure of the wound, theoretically making coagulation irrelevant. Furthermore, there are no reaccess restrictions, and these devices can effectively close arteriotomies from a variety of sheath sizes. The Prostar XL (Abbott Vascular) is available in 10 F, whereas the SuperStitch (Nobles Medical Technology) is available in 12 F. The main limitation of these devices is the learning curve and luminal distortion secondary to suture.

Clip/Staple-Based Devices

The most popular device in this category is the StarClose (Abbott Vascular), which deploys a nitinol clip over the arteriotomy with nothing left intravascularly. The StarClose device is inserted into the sheath, and the locator button is depressed, which then slides out until resistance is felt. The thumb advancer completes the splitting of the sheath. The device angle is raised, and the clip is deployed; the device is then removed (Figure 3). The StarClose device is designed not to affect lumen diameter or decrease distal blood flow; however, the metallic clip remains in place indefinitely. If magnetic resonance imaging is needed, susceptibility artifacts can limit evaluation of the immediately adjacent structures.

PASSIVE APPROXIMATORS

Sealant or Gel-Based

The most popular device in this category is the Mynx VCD (AccessClosure, Inc., Mountain View, CA), which functions by delivering a polyethylene glycol sealant to the extravascular space over the arteriotomy site. The sealant does not enhance coagulation but conforms to the arteriotomy site, sealing the vessel.

The Mynx device is inserted into the procedural sheath, and a small semicompliant balloon is inflated to create temporary hemostasis. The sealant is delivered and unsealed, exposing it to blood products and subcutaneous fluids, thus forming a water-tight seal and producing hemostasis. The balloon is deflated, and the device is removed (Figure 4).

Advantages of the Mynx device include no sheath exchange, easy delivery mechanism, no intravascular component, and complete sealant dissolution in 30 days, which explain the rapid increase in its use.

AccessClosure has recently added Grip Technology to the Mynx line to produce more reliable hemostasis. This advancement has received FDA approval but is not yet commercially available.

The Exoseal VCD (Cordis Corporation, Bridgewater, NJ) utilizes a similar mechanism by deploying a polyglycolic acid plug into the extravascular space over the arteriotomy site. The device consists of a delivery shaft, in which the plug is preloaded, and a handle assembly that is inserted into the existing procedural sheath.

The device and sheath are slowly retracted while looking for a change in returned blood flow from pulsatile to nonpulsatile, at which point, the rate of retraction is slowed, and the device indicator window will turn black when the device is in the appropriate position. The plug is then deployed, and the device and sheath are removed (Figure 5). Gentle pressure is applied for 2 minutes, and a bandage is placed. A multicenter, randomized controlled trial comparing the effectiveness of the Exoseal device

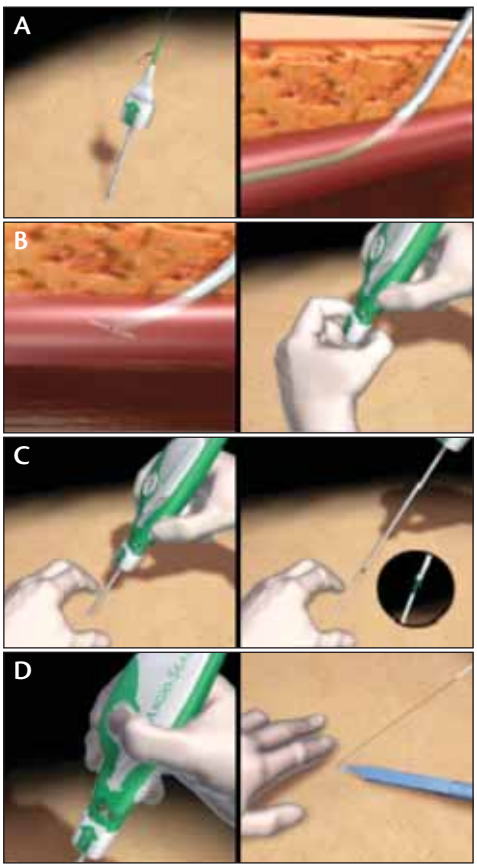

Figure 1. Angio-Seal deployment. The device sheath is advanced over the Angio-Seal guidewire (A). The anchor is deployed, and the device is retracted (B). Pullback to the colored compaction marker to compress the anchor-arteriotomy-collagen sandwich to achieve hemostasis (C). Release and cut the suture (D).

Figure 2. The Perclose ProGlide device (Abbott Vascular).

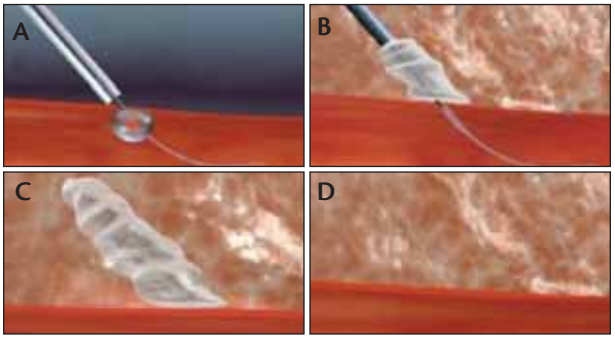

Figure 4. The Mynx device. The balloon is inflated and creates temporary hemostasis (A). Sealant is delivered (B). Sealant conforms to the arteriotomy surface, producing hemostasis (C). The device absorbed with healing (D).

demonstrated significantly decreased time to hemostasis and ambulation when compared to manual compression (4.4 minutes vs 20.1 minutes and 2.5 hours vs 6.2 hours, respectively).[1]

Bioabsorbable Plug

The FastSeal (Vascular Closure Systems, Palo Alto, CA) is a bioabsorbable plug (Figure 6) that is advanced through a 6- or 8-F procedural sheath, at which time, the plug expands intravascularly. The sheath is then withdrawn, and the plug locks into place at the arteriotomy site, producing hemostasis. If in adequate position, the safety tether is removed, and a dressing is placed. The intravascular component absorbs in 2 to 3 weeks, and the extraluminal component absorbs in approximately 2 months. The device is not US Food and Drug Administration approved at this time and is awaiting approval for human testing in Europe. Promising results have been demonstrated in preclinical studies, and ethical committee approval has been obtained.

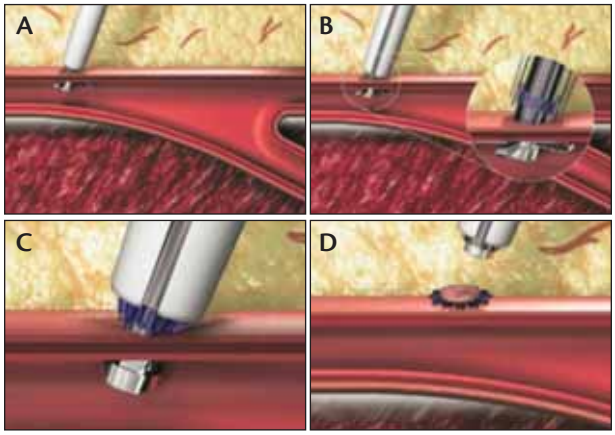

Figure 3. The StarClose device. The device is inserted into the sheath, and the locator button is depressed, which then slides out until resistance is felt (A). The thumb advancer completes the splitting of the sheath (B). The device angle is raised (C), and the clip is deployed (D).

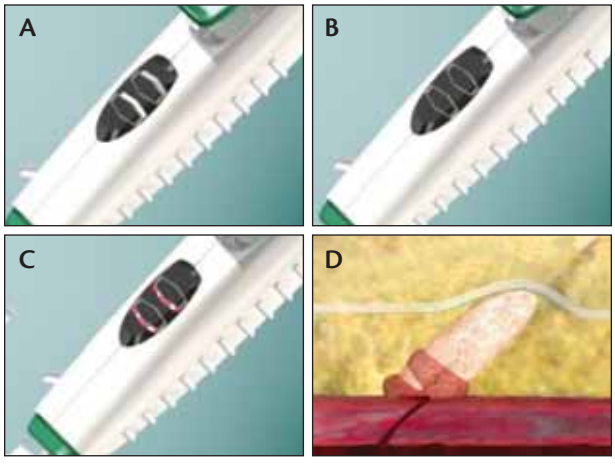

Figure 5. The Exoseal device. Black and white display, device is not positioned, and lockout feature is active (A). Black-black display, device is ready to deploy if reduced blood return is observed (B). Black and red display, plug can be deployed and retraction stopped (C). The bioabsorbable plug is held in place over the arteriotomy site due to tissue contraction and fascial layers (D).

NOVEL TECHNOLOGIES

Access-Based

The Axera access system (Arstasis, Redwood City, CA) uses an innovative concept (the low-angle Arstaotomy procedure) to achieve quick, effective hemostasis. Access to the femoral artery is achieved using a 19-gauge needle and latchwire component. The needle is removed, and the Axera device is attached to the end of the latchwire component. The device is then advanced, with correct position con-

TABLE 1. VASCULAR CLOSURE DEVICES AND HEMOSTATIC PATCHES

Device Category	Device Name	Manufacturer	Sheath Size (F)	Intraluminal Component	Comments
Active Approximators					
Clip or staple	StarClose SE	Abbott Vascular	5, 6	No	Second generation. Extravascular nitinol clip approximates arteriotomy site.
Collagen based	Angio-Seal VIP, STS Plus, Evolution	St. Jude Medical	6, 8	Yes	Device deploys an absorbable collagen plug to close the arteriotomy site, secured in place by intraluminal anchor and absorbable suture. New delivery mechanism allows for one-handed and decreased variability.
Suture	Perclose A-T	Abbott Vascular	5–8	No	Percutaneous deployment of a braided polyester suture around the arterial puncture site.
	Perclose ProGlide	Abbott Vascular	5–8	No	Percutaneous deployment of a monofilament polypropylene suture with automatic knot formation. Patch remains in place after sheath removal.
	Prostar XL	Abbott Vascular	8.5–10	No	Percutaneous braided polyester suture delivered, designed for use after procedures requiring larger procedural sheaths.
	X-Site	St. Jude Medical	5, 6	No	Device utilizes a braided polyester suture and automatically creates a knot to seal arteriotomy site.
	Super Stitch	Nobles Medical Technology	6, 8, 12	No	Polypropylene suture delivered through existing sheath closes arteriotomy site.
Passive Approximators					
Sealant or gel based	Mynx, Mynx MS	AccessClosure, Inc.	5–7	No	Semicompliant balloon creates temporary hemostasis. Sealant is deployed into the extravascular space and creates immediate hemostasis.
	FISH	Morris Innovative (Bloomington, IN)	5–8	No	Device uses an extracellular matrix closure patch premounted onto the access sheath through which intervention is performed.
	Exoseal	Cordis Corporation	5–7	No	Device deploys polyglycolic acid plug through existing sheath into the extravascular space.
Bioabsorbable plug	FastSeal	Vascular Closure Systems	6, 8	Yes	Bioabsorbable plug is deployed through procedural sheath. Safety tether allows removal if position is inadequate.
Novel Technologies					
	Catalyst II	Cardiva Medical Inc. (Sunnyvale, CA)	5–7	No	Intravascular disc left in place under tension to create hemostasis. After hemostasis is achieved, the disc is removed.
	Catalyst III	Cardiva Medical Inc.	5–7	No	Intravascular disc left in place under tension to create hemostasis. Device has protamine coating to locally neutralize heparin. After hemostasis is achieved, the device is removed.
	Boomerang	Cardiva Medical Inc.	4–10	No	Nitinol wire and temporary nitinol mesh disc achieve hemostasis. All intravascular material then removed.
	Axera	Arstasis	5, 6	No	Access to femoral artery is obtained with a micropuncture kit. The Axera access device is then used to create an access tract with a longer and shallower trajectory. Brief compression is held for a few minutes.
Hemostatic Patch					
	SyvekExcel Vascular Access Hemostasis System	Marine Polymer Technologies (Danvers, MA)	N/A	No	Poly-N-acetylglucosamine–coated pad placed over the arteriotomy site activating platelets and accelerating the intrinsic coagulation system.
	MPatcH Vascular Closure Device	Medafor Inc. (Minneapolis, MN)	N/A	No	Patch uses porous mircospheres to dehydrate blood at the site, concentrating clotting factors accelerating hemostasis.
	Clo-Sur P.A.D.	Scion Cardio-Vascular, Inc. (Miami, FL)	6–8	No	Applied over arteriotomy site before holding compression. Pad is coated with positively charged polyprolate acetate biopolymer that attracts negatively charged red blood cells and platelets accelerating clotting.
	D-Stat Dry	Vascular Solutions, Inc. (Minneapolis, MN)	4–6	No	Applied over arteriotomy site before holding compression. Pad utilizes thrombin to activate clotting factors, platelets, and stimulate platelet aggregation.

Figure 6. The FastSeal device. Deployment capsule and bioabsorbable plug is inserted into a standard sheath, with advancement plunger.

firmed with blood flash. Pulling back on the actuator then deploys the heel. Gentle traction is applied, and the integrated needle component is advanced at a very shallow 5º trajectory through the femoral artery wall by depressing the plunger. A guidewire is then advanced through the plunger, the heel is disengaged, the device is removed, and the procedural sheath is advanced over the guidewire. After completion, the procedural sheath is removed, and pressure is held for a few minutes. The shallower angle of the access trajectory (Figure 7) results in theoretically more rapid hemostasis due to increased arterial wall overlap, decreasing arterial pressure within this longer path, and tract compression by the radial pressure that the flowing blood applies to the vessel wall.

The principal benefit of the Axera device is that no implantable (absorbable or not) device is left in the patient. As such, the risk for component embolization and infection is eliminated in the absence of component fracture. Immediate reaccess, if needed, is also possible. The 351-patient, prospective, multicenter RECITAL study was presented at the 2011 Transcatheter Cardiovascular Therapeutics meeting in San Francisco, which demonstrated a 3-minute median time to hemostasis for diagnostic patients and a 5-minute time to hemostasis in interventional patients. The investigators also noted that patients sat up within 30 minutes and ambulated in just over 1 hour and 2 hours for diagnostic and interventional patients, respectively.

THE FUTURE

Development continues to advance in the field of VCDs. However, we still do not have the perfect device. We continue to strive for perfection with a device that allows early ambulation, improved patient comfort, effectiveness with anticoagulation, and no complications. As aortic endografts continue to be downsized, an ever-increasing number are being placed percutaneously, requiring a reliable VCD for larger access sites. On the opposite side of the spectrum, diagnostic catheterization also continues to be miniaturized, with many diagnostic cardiac catheterizations being performed from a radial approach. Safe and efficient closure is a necessity for all of our patients. ■

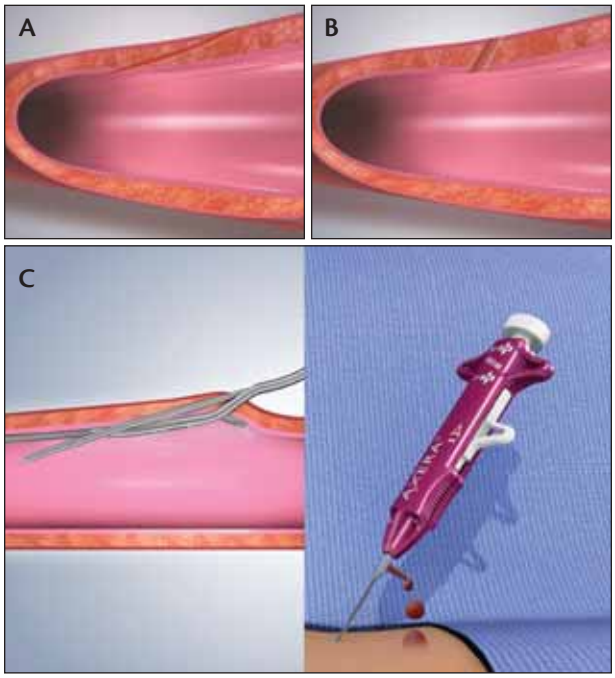

Figure 7. The Axera device. Ultra-low-angle Arstaotomy path with the Axera access device (A). Classic arteriotomy path (B). The Axera device is inserted in the artery, the heel has been engaged, gentle traction is applied, and the integrated needle advances at a shallower trajectory by depressing the plunger (C). Blood mark is seen at the port to confirm arterial access through the Arstaotomy channel.

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1. Wong SC, Bachinsky W, Cambier P, et al. A randomized comparison of a novel bioabsorbable vascular closure device versus manual compression in the achievement of hemostasis after percutaneous femoral procedures: the ECLIPSE (Ensure's Vascular Closure Device Speeds Hemostasis Trial). JACC Cardiovasc Interv. 2009;2;785-793.