Manual, Mechanical, and Device Hemostasis

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28.1 Introduction

The scope of minimally invasive techniques has expanded broadly over the last few decades in part because of the increasing focus on patient comfort and satisfaction, as well as the need to effectively treat patients with higher risks of morbidity and mortality. In particular, the areas of cardiovascular, neurologic, and radiologic endovascular interventions have seen increasing adoption and considerable advancements of both techniques and equipment. Even as the possibilities of endovascular treatment continue to push beyond the current boundaries, safe vascular access and closure remain fundamental to a successful procedure.

The introduction of vascular closure devices (VCDs) in the mid-1990s brought a new option for vascular access site management, providing a rapid and effective alternative to what had historically been manual compression (MC) and immobilization. A variety of studies have demonstrated that VCDs reduce the time required for hemostasis and improve patient comfort and satisfaction in comparison with MC [1–3]. Yet, adoption of VCDs has remained heterogeneous, ranging from 24% to 60% in percutaneous coronary interventions (PCI) in the USA and the UK [4, 5], owing in part to high device costs, the unresolved impact of VCD on vascular complication rates, and increasing use of nonfemoral access sites.

This chapter reviews the principal percutaneous vascular closure strategies, provides an overview of current devices, and briefly discusses the clinical experience with each device.

28.2 Manual and Mechanical Compression

28.2.1 Manual Compression

Manual compression was initially the only option available for femoral vascular access site management. Even with the array of VCDs available, many patients' femoral anatomy or other clinical considerations preclude the use of these devices. Although transradial cardiac catheterization has been shown to be safe and to decrease the rate of access site complications [6–9], the majority of PCI procedures at many centers throughout the world are still performed via the femoral route [5, 10]. Therefore, effective manual or mechanical compression of the femoral arterial access site remains the foundation of vascular access management for cardiac catheterization procedures.

The advantages of MC for access site hemostasis include the ability to perform continuous patient monitoring, a high rate of success, low rates of vascular complications, and low material costs. However, MC requires significant personnel time, causes discomfort for both the patient and practitioner, and mandates a prolonged period of immobilization. Additionally, the hazards of achieving hemostasis and bedrest time increase with the arteriotomy size, thereby limiting MC as a practical technique for managing sheaths larger than 12–14 French (12–14F). The requirement for prolonged bedrest does not apply to transradial procedures, and the required duration is greatly reduced with successful vascular closure device use. Therefore, MC makes the catheterization procedure more uncomfortable for the patient than procedures performed via transradial approaches or use of VCDs.

A variety of clinical protocols have been used to identify a safe delay from the completion of the PCI procedure to the time of sheath withdrawal after transfemoral catheterization. Among those most commonly used is monitoring of the activated clotting time (ACT) and waiting until it is less than 180 seconds before sheath removal is performed. The technique of femoral artery MC is a skill that must be learned and should not be delegated to untrained personnel. It is generally recommended that the tips of the fingers be positioned longitudinally along the course of the common femoral artery, such that the index and middle fingers are placed just cranial to the point of sheath entry into the artery, and the fourth and fifth digits are used to compress over the arteriotomy site itself. Care must be taken to ensure that compression is applied to the arteriotomy rather than the skin entry site, which is located more distally in the standard retrograde catheterization access. The patient's leg is kept straight and not rotated inward, to avoid pulling the common femoral artery away from the femoral head.

A typical MC protocol for removing a 6F arterial sheath should start with sufficient pressure being applied to abolish the pulses in the foot for a period of up to 5 min, followed by firm but

lighter pressure, permitting palpation of distal pulses, for a period of 15 min before checking on hemostasis. Premature assessment of hemostasis—the most common error—may lead to brisk arterial bleeding and formation of a hematoma, which subsequently makes adequate compression of the arteriotomy against the femoral head more difficult. After a total compression time of 20 min and confirmation of no further bleeding or hematoma formation, a period of strict bedrest with immobilization of the ipsilateral leg for 6 hours is advised. The total compression and bedrest time vary slightly, depending on the standard institutional practice. Some centers utilize a compression time of 3 min per French size for arterial sites and 1–1.5 min per French size for venous sites, followed by 2–8 h of total bedrest time, depending on the size of the sheath.

28.2.2 Hemostasis Pads

Hemostasis pads employ a procoagulant coating to enhance coagulation. Several products are available including Clo-Sur P.A.D. (Merit Medical Systems, Inc., South Jordan, UT, USA), SyvekNT and SyvekExcel patches (Marine Polymer Technologies, Inc., Dankers, MA, USA), D-Stat Dry (Vascular Solutions, Minneapolis, MN, USA), and Neptune Pad (TZ Medical, Inc., Portland, OR, USA). Clinical studies examining use of hemostasis pads as an adjunct to MC versus MC alone have generally demonstrated a relatively small impact on hemostasis because of high failure rates, no difference in vascular complications, and similar times to ambulation [11–16]. The largest study included data from the National Cardiovascular Data Registry (NCDR) CathPCI Registry on over 1.8 million patients undergoing catheterization, and did demonstrate small, but statistically significant, reduced incidence of bleeding or vascular complications associated with the use of hemostasis pads as compared with manual compression [17].

28.2.3 Compression Devices

While MC has remained the standard femoral arterial access management method for over two decades, mechanical compression devices were developed both to reduce the necessity of having a clinician apply manual pressure and to permit standardization of compression on the arterial access site itself. A variety of devices exist, with most simple devices consisting of a sterile compression surface (e.g., a disk) attached to a handle for better ergonomics for the practitioner. Examples include the Compass, PressureMate, and ComfortPress (Advanced Vascular Dynamics, Portland, OR, USA) (Fig. 28.1a); and the D-Stat clamp accessory and handle (Vascular Solutions). The SafeGuard pressure-assisted device (Merit Medical Systems, Inc.) uses an inflatable air bladder to compress the vascular puncture site as an adhesive band holds the device in place (Fig. 28.1d). More sophisticated compression devices hold compression in place of the operator. These devices resemble a C-clamp with various adjustments to allow proper positioning and apply constant pressure while maintaining limb perfusion monitored by only one nurse. Examples include the CompressAR System (Advanced Vascular Dynamics) (Fig. 28.1b) and the ClampEase mechanical compression devices (ClampEase, Portland, OR, USA).

The FemoStop compression device (Abbott Vascular, Santa Clara, CA, USA) (Fig. 28.1c) consists of an inflatable dome and manometer attached to a plastic arch. A belt wrapped around the patient's hips secures the device while it applies external pressure to the arteriotomy site. Use of the FemoStop involves inflating the dome to a pressure 20 mmHg above systolic blood pressure for 3–5 min, followed by incremental decreases in the dome pressure as hemostasis is maintained. The ExpressAR (Advanced Vascular Dynamics) is a similar system but uses a compression disk adjusted with a screw mechanism instead of an inflatable dome.

Clinical Experience

Studies of compression devices demonstrate successful use in nearly all patients with generally equal efficacy but mixed results in terms of femoral vascular complication rates [18–28]. For example, the incidence of hematomas was higher with use of compression devices than with MC [19, 23, 25]. Rates of access site ecchymosis and oozing were similar with compression devices and MC [19]. Compression devices did cause more patient discomfort than MC [19, 21, 27, 28] or VCDs [3, 20].

Fig. 28.1 The ComfortPress **a**, CompressAR **b**, FemoStop **c**, and SafeGuard **d**, compression devices

28.3 Precautions for Vascular Closure Device Use

Approved indications for VCD use include closure of common femoral artery (CFA) access in patients who have undergone diagnostic and interventional endovascular procedures. Appropriate selection of patients in whom to use VCDs may influence the rate of successful deployment and minimize the risk of complications. Proper vascular access technique minimizes vessel damage and permits safe use of VCDs at the conclusion of the procedure. Access sites with a hematoma from multiple punctures during a difficult vascular access or an oblique rather than anterior vascular wall puncture are not ideal for VCD deployment, for example. Routine femoral angiography is recommended to identify situations that contraindicate VCD deployment. Several situations require special consideration including use of vascular sheaths larger than the sizes the device are designed to close (▶ Sect. 28.7.1), early reaccess after closure, arterial access above the inferior border of the inferior epigastric artery (▶ Sect. 28.7.3), arterial access at or below the CFA bifurcation (▶ Sect. 28.7.3), the presence of peripheral arterial disease (▶ Sect. 28.7.2), arteries <4–5 mm in diameter, nonfemoral artery and venous closure (▶ Sects. 28.7.3–28.7.6), and utility of VCD in vascular bypass grafts.

28.4 Closure Mechanisms

Three general mechanisms have been used for VCDs. The first is the procoagulant plug, which may be purely extravascular or secured with an intravascular anchor. The first VCD approved for use in the USA in 1995 was the VasoSeal device (Datascope Corporation, Mahwah, NJ, USA), which utilized an extravascular collagen plug to seal arterial access sites up to 8F in size. The VasoSeal device saw high failure rates in clinical use, and while some clinical studies did not independently demonstrate increased complication rates in comparison with MC [29–36], larger pooled analyses [1, 37, 38] have repeatedly shown higher rates of complications with use of this device. Datascope discontinued VasoSeal in 2006. Today, the Angio-Seal device (Terumo Medical Corporation, Somerset, NJ, USA) is the prototypical «plug» device, which includes an intravascular anchor component.

A second common closure mechanism relies on percutaneous sutures for mechanical arteriotomy closure in a fashion similar to surgical vessel repair. A popular device using this closure mechanism is the Abbott Vascular Perclose device. The last common mechanism uses an extravascular clip or staple to mechanically close the arteriotomy. The Abbott Vascular StarClose device is an example of this class of device using a nitinol clip to secure vessel closure.

28.5 Contemporary Vascular Closure Devices

A selection of currently available devices employing various closure mechanisms is listed in ◘ Table 28.1.

28.5.1 Plugs and Sealants

Angio-Seal

The Angio-Seal device consists of an intravascular anchor connected to an extravascular collagen plug by an absorbable suture. The ease of use and quick deployment have made Angio-Seal the market leader among VCDs. Use of the Angio-Seal device involves exchanging the procedure sheath over a wire for a dedicated arteriotomy locator sheath (◘ Fig. 28.2c). When the device has been properly positioned within the vessel, the collagen plug is loaded, the intravascular anchor is released, and the device is pulled back to expose the collagen plug. Tamping the collagen plug against the vessel seals the arteriotomy site between the plug and the anchor, achieving hemostasis. The suture is cut below the skin level after removing the device. Complete absorption of all device components occurs within 90 days. Three Angio-Seal devices are currently available in both 6F and 8F sizes. The Angio-Seal VIP (V-Twist Integrated Platform) packages the collagen plug in a manner to allow more complete extravascular arteriotomy coverage when delivered (◘ Fig. 28.2a). The Angio-Seal STS Plus uses a self-tightening suture to connect the anchor and the collagen plug, as well as a redesigned arteriotomy locator to minimize trauma to the vessel wall. The Angio-Seal Evolution incorporates a mechanism that advances the tamping tube to compact the collagen plug onto the vessel as the device is withdrawn, allowing single-handed deployment after proper positioning (◘ Fig. 28.2b).

Clinical Experience

The first randomized trial of the Angio-Seal device compared its use with MC in 435 patients undergoing diagnostic catheterization or angioplasty [39]. The device was successfully deployed in 96% of patients. The mean time to hemostasis was significantly shorter in the Angio-Seal group (2.5 min) than in the MC group (15.3 min). While the rates of bleeding were found to be significantly lower in the Angio-Seal group, overall rates of complications including hematomas, pseudoaneurysms, and arteriovenous fistulas were not different. However, in the subgroup of patients undergoing PCI, the incidence of bleeding and hematomas was lower in the Angio-Seal group despite a longer ACT at the time of sheath removal.

Subsequent studies continued to highlight the strength of the Angio-Seal device in terms of its ease of use and effectiveness. Angio-Seal was successfully deployed more often than the StarClose [40], Perclose [41], and Mynx [42] devices. Times to hemostasis and ambulation were consistently

Table 28.1 Contemporary vascular closure devices

Mechanism	Device name	Manufacturer	French sizes	Guidewire sizes	Early reaccess	Absorption
Plug/sealant	Angio-Seal VIP	Terumo Medical	6F, 8F	0.035″ (6F), 0.038″ (8F)	1 cm proximal to previous access	90 days
	Angio-Seal STS Plus					
	Angio-Seal Evolution					
	ExoSeal	Cordis	5F, 6F, 7F	Deployed through existing sheath	Not studied	60–90 days
	FemoSeal	Terumo Medical	7F	0.038″	Not studied	90 days
	FISH	Morris Innovative	5F, 6F, 7F, 8F	Sheath and closure on same device	Contralateral or 2 cm above previous access	30 days
	MynxGRIP	Cardinal Health	5F, 6/7F	Deployed through existing sheath	Immediate	30 days
	Mynx ACE		5F/6F/7F			
Suture	Perclose Prostar XL	Abbott Vascular	8.5–10F	0.038″	Immediate	NA
	Perclose A-T		5–8F			
	Perclose ProGlide		5–8F			
Clip	StarClose SE	Abbott Vascular	5–6F	0.038″	Immediate	NA
Disc	Catalyst II	Cardiva Medical	5–7F	Deployed through existing sheath	Not studied	NA
	Catalyst III		5–7F			
Shallow arteriotomy	Axera 2	Arstasis	5F, 6F	0.018″	Not studied	NA

FISH Femoral Introducer Sheath and Hemostasis, *NA* not applicable

shorter with use of Angio-Seal than with use of MC or Perclose [37, 40, 41, 43–46]. Patient discomfort was also improved in comparison with MC, use of the FemoStop compression device, or use of Perclose [3, 46]. Vascular complication rates in these studies were similar with MC and VCDs except in one pooled analysis where Angio-Seal use was associated with lower complication rates [38].

Reaccess to vessels closed with Angio-Seal within 90 days was performed in 181 patients without occurrence of major complications [47]. When available, femoral angiograms were reviewed to guide the puncture 1 cm proximal to the previously placed device.

ExoSeal

The ExoSeal device (Cordis Corporation, Miami Lakes, FL, USA) seals an arteriotomy by using an extravascular polyglycolic acid (PGA) plug (Fig. 28.3a). The ExoSeal device is advanced

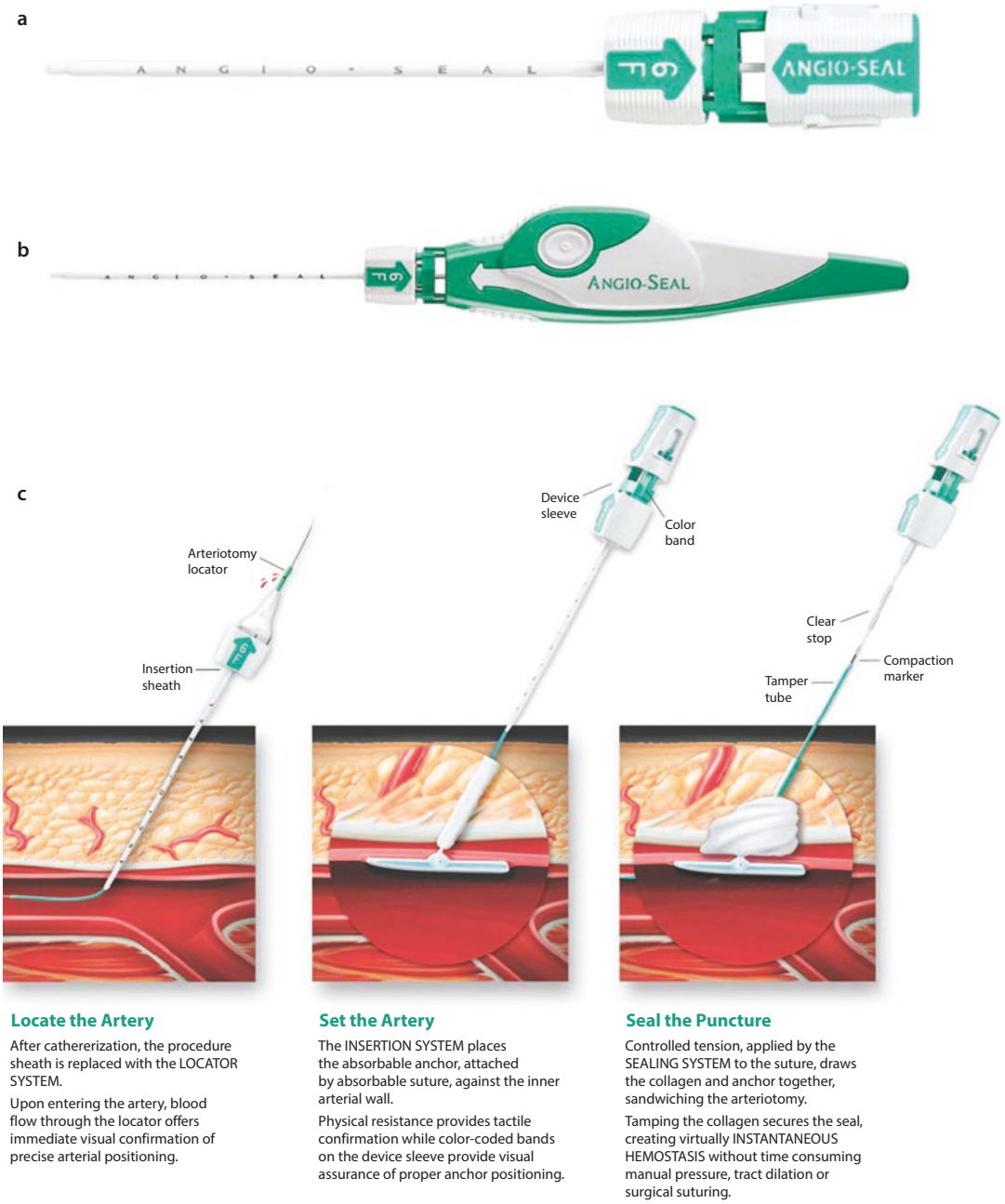

Fig. 28.2 The Angio-Seal VIP **a** and Angio-Seal Evolution **b** closure devices. Steps for deploying the Angio-Seal **c**

through the existing sheath and an «indicator wire» footplate is exposed. Pulsatile blood flow exiting the side port confirms the intravascular position (Fig. 28.3b). Withdrawal of the device and sheath until the indicator wire abuts the vessel wall positions the device for extravascular deployment of the plug, after which the device is removed under gentle MC. The PGA plug is completely absorbed over 60–90 days. The ExoSeal device is available in 5–7F sizes.

Clinical Experience

The ECLIPSE Trial randomized 401 patients in a 2:1 fashion favoring treatment with an ExoSeal 6F device or MC [48]. Half of each treatment arm underwent interventional procedures. ExoSeal

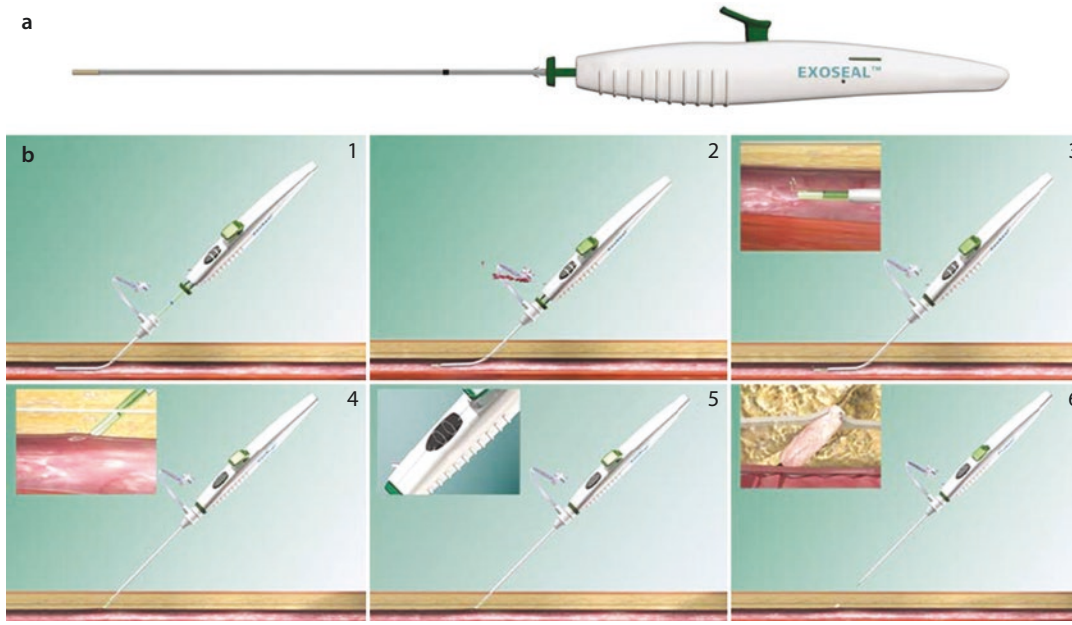

Fig. 28.3 The ExoSeal vascular closure device **a** delivers an extravascular polyglycolic acid plug **b** for closure of arterial punctures

was successfully deployed in 89% of attempts. The mean times to hemostasis (4.4 min versus 20.1 min) and ambulation (2.4 h versus 6.2 h) were shorter with ExoSeal use. While there were no major adverse events in either study group at 30 days, vascular complications occurred in 8.5% of patients treated with ExoSeal. Rebleeding after initial hemostasis (5.4%) and access site hematoma measuring >6 cm (2.4%) were the most common complications with ExoSeal. Overall, the rates of complications did not differ between ExoSeal and MC.

Other studies have demonstrated successful deployment and immediate hemostasis rates of 91–95% and complication rates up to 7.5%, which were higher than those seen with Angio-Seal or Perclose ProGlide [49–51]. Angiographic irregularities of the femoral artery were found in nearly 7% of patients undergoing repeat angiograms after a median of 28 days [51]. ExoSeal has proven quite effective in antegrade femoral closure, with success and complication rates similar to those seen with retrograde access closure [49, 52].

FemoSeal

The FemoSeal device (Terumo Medical Corporation) closes vessels by compressing the puncture site between an inner seal disc and an outer locking disc (Fig. 28.4). Both disks are composed of a fully bioabsorbable polymer without collagen or other thrombosing agents and are held together by a bioabsorbable suture. The device is introduced over a standard guidewire after removal of the arterial sheath. Intravascular position is confirmed by blood return into the proximal window of the device as the device dilator and guidewire are removed from the vessel. Pressing the button on the device releases the inner disk. Withdrawing the device pulls the inner disk against the vessel wall and releases the outer disk. Pushing the button again pulls the plates toward each other to sandwich the puncture site. The device is removed and the remaining suture is cut below the skin. The device has been approved for closure of 6F access sites.

Clinical Experience

The CLOSE-UP randomized trial of 1001 patients having diagnostic coronary angiography using a 6F sheath compared FemoSeal with MC and found a significantly shorter time to hemostasis (median 1 min versus 8 min, $p < 0.0001$) and a lower incidence of hematomas >5 cm (2.2% versus 6.7%, $p = 0.002$) in the FemoSeal group [53]. The shorter time to hemostasis was also observed in the ISAR-CLOSURE randomized trial of 4524

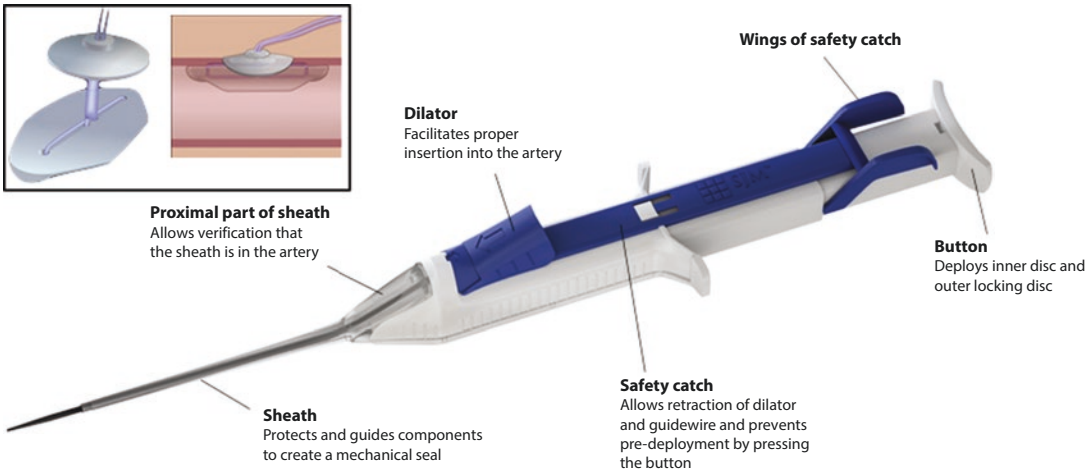

Fig. 28.4 The FemoSeal vascular closure device utilizes two bioabsorbable disks connected by a bioabsorbable suture to sandwich the arteriotomy

patients comparing FemoSeal, ExoSeal, and MC, although use of either VCD was noninferior ($p < 0.001$) but not superior ($p = 0.23$) to MC in the incidence of access site–related vascular complications [54]. FemoSeal was also associated with a shorter median time to hemostasis (0.5 min versus 2 min, $p < 0.001$) and fewer access site–related complications (6.0% versus 7.8%, $p = 0.043$) than ExoSeal in this study. Use of the FemoSeal device in closure of 7F arterial punctures (currently approved for 6F sites) was successful in all patients in a small series, and only one of the 50 patients developed a local hematoma [55].

FISH Device

The Femoral Introducer Sheath and Hemostasis (FISH) device (Morris Innovative, Bloomington, IN, USA) combines a procedure sheath with a vascular closure patch to allow use of a single device for the entire procedure (Fig. 28.5a). The vascular closure patch (in the shape of a long ribbon) is made of porcine small intestinal submucosa (SIS) and acts as an extracellular matrix scaffold for remodeling. Full absorption of the SIS patch occurs by 30 days. The SIS ribbon is initially attached longitudinally on the FISH device sheath. After sheath insertion, the distal end of the SIS ribbon is freed in the arterial lumen. At the conclusion of the procedure, a compression suture draws the SIS ribbon into the arteriotomy (Fig. 28.5b). Brief application of MC completes hemostasis. The FISH device is available in 5–8F sizes.

Clinical Experience

A randomized trial of 297 patients undergoing both diagnostic and interventional catheterization procedures examined use of the FISH device compared with MC [56]. Among the results reported for the 206 patients having diagnostic coronary angiography, patients treated with FISH had shorter mean times to hemostasis (8.9 min versus 17.2 min) and ambulation (2.4 h versus 4.3 h) than patients receiving MC. Overall, the FISH group had device failure in four cases, as well as three access site hematomas and two pseudoaneurysms. To date, the complete results of the interventional cohort have not been reported.

Mynx Vascular Closure Device

The Mynx vascular closure device (Cardinal Health, Dublin, OH, USA) uses an extravascular polyethylene glycol (PEG) sealant for arterial and venous closure (Fig. 28.6a). The Mynx device is inserted through the existing sheath (Fig. 28.6c). Withdrawing the device after inflation of a small intravascular anchor balloon until it abuts the arterial wall confirms the correct position for deployment of the sealant immediately outside the vessel. The sealant expands as it absorbs blood, resulting in coagulation over the arteriotomy site. With hemostasis, the balloon is deflated and removed without leaving behind any intravascular component. The PEG sealant completely dissolves by 30 days. A second-generation Mynx Cadence device had minor design changes to simplify sealant delivery. The current third-generation

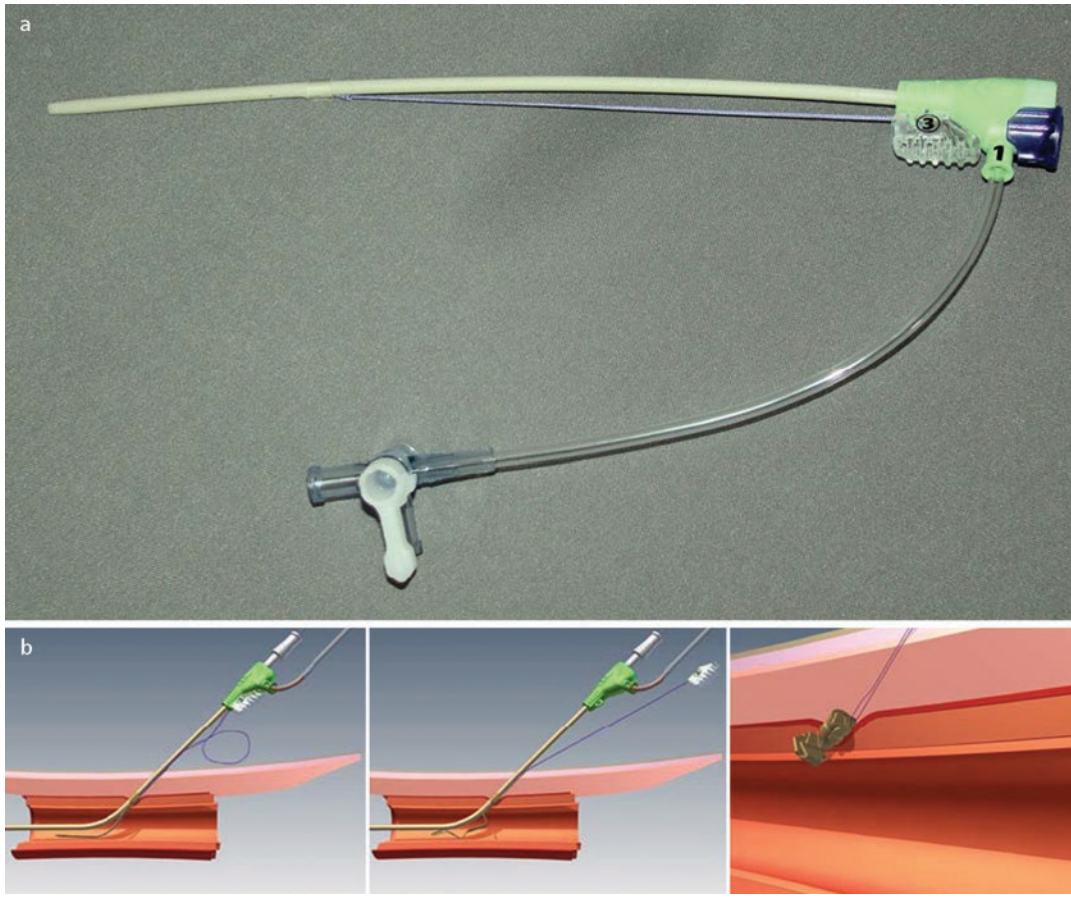

Fig. 28.5 The FISH device **a** incorporates an SIS "ribbon" with the procedure sheath so that one device can be used for the entire procedure. The SIS is drawn up using a suture to fill the arteriotomy at the conclusion of the procedure **b**

MynxGrip device incorporates a new sealant design by adding a different PEG formulation to the tip for improved adherence to the vessel wall. The Mynx Ace device (Fig. 28.6b) simplifies delivery of the sealant with a redesigned deployment system.

Clinical Experience

The first safety and efficacy study evaluated the Mynx device in a prospective multicenter European trial of 190 patients, with half of the patients undergoing diagnostic coronary angiography and the remaining half undergoing PCI [57]. 6F sheaths were used in 94% of procedures. The Mynx device achieved hemostasis in 93% of patients, with a mean time to hemostasis of 1.3 min and a mean time to ambulation of 2.6 h. In comparison with Angio-Seal, the rate of major vascular complications did not differ with Mynx [42, 58, 59] despite the higher rates of hemostasis with Angio-Seal than with Mynx (91% versus 96%) [42]. The rates of pseudoaneurysm formation have been reported to be as high as 11% [60]. The rates of major complications requiring surgical intervention were lower with Mynx than with Angio-Seal and no different from those seen with MC [61]. Despite employing an extravascular closure mechanism, deployment of at least a portion of the PEG sealant into the vascular lumen occurred in 18% of patients [60], with potential for distal embolization resulting in leg ischemia [62–64].

In contrast to earlier studies, more recent large-scale studies have demonstrated higher rates of bleeding and vascular complications with Mynx. An analysis of over 1.8 million patients in the NCDR CathPCI Registry first showed an increase in bleeding complications (odds ratio (OR) 1.32, $p < 0.001$) [17]. A regional study of data from five

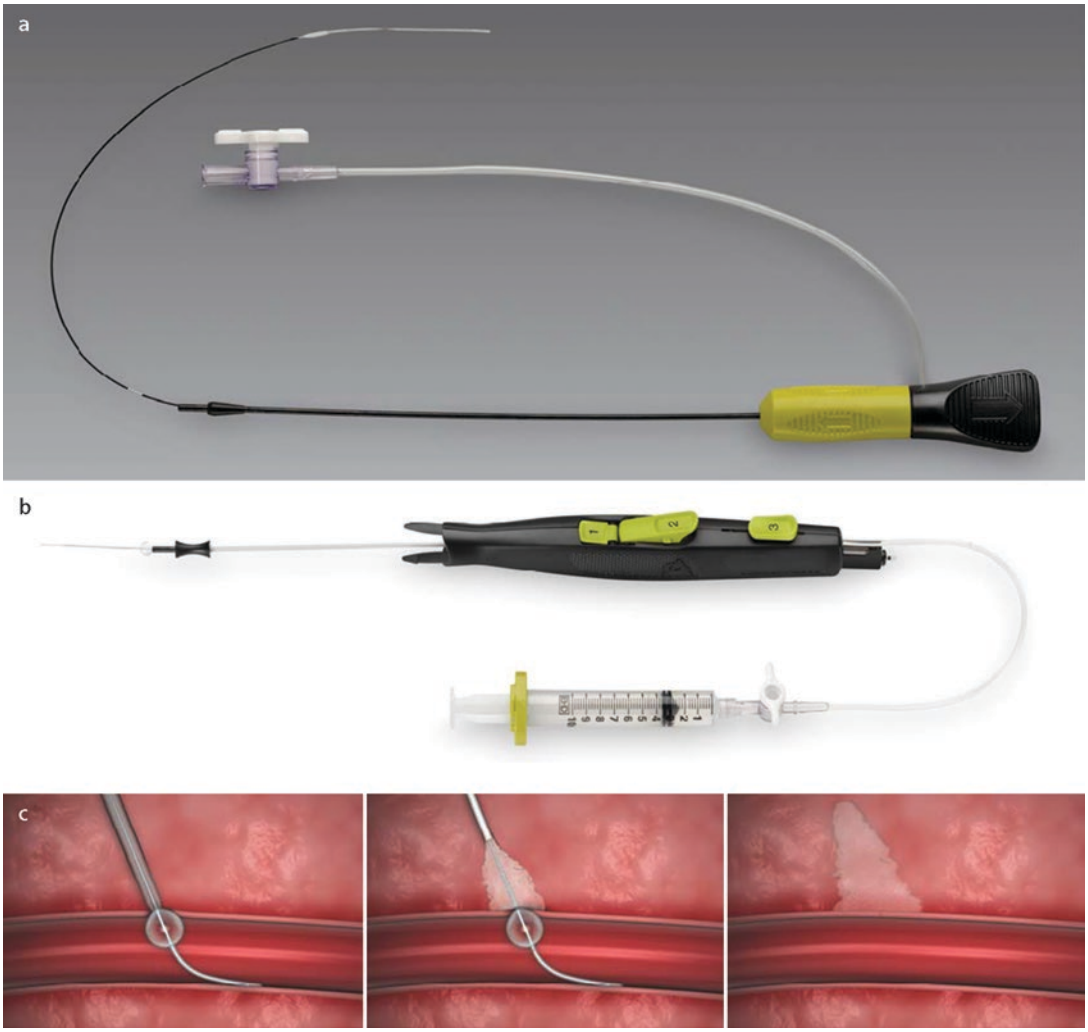

Fig. 28.6 The MynxGRIP **a** and Mynx ACE vascular closure devices **b** deliver an extravascular PEG sealant **c** for the closure of arterial punctures

PCI sites in Massachusetts also identified a trend, albeit nonsignificant, toward an increased rate of any vascular complication with the Mynx device [65]. Findings from the most recent analysis of the NCDR CathPCI Registry, using a tool developed for active postmarketing safety surveillance of medical devices, showed that the Mynx device is associated with a significantly increased risk of any vascular complication, access site rebleeding, or transfusion than alternative VCDs, including Angio-Seal, Perclose, and StarClose [66].

Acute reaccess to vessels closed with Mynx has been suggested to be safe in an animal model without evidence of sealant prolapse into the vessel lumen or distal embolization [67]. A second Mynx device could be placed safely and successfully closed the new arteriotomy sites in an animal model. Published clinical experiences of early reaccess after Mynx closure are lacking.

28.5.2 Suture-Mediated Vascular Closure Devices

Perclose

The Perclose line of VCDs (Abbott Vascular) delivers a suture percutaneously to close an arteriotomy site. The earliest version of the Perclose system was the Prostar, designed for closure of 9–11F arterial punctures. Subsequent devices included a smaller Prostar Plus for 8–10F punctures, followed by Techstar for 6F punctures. The currently available

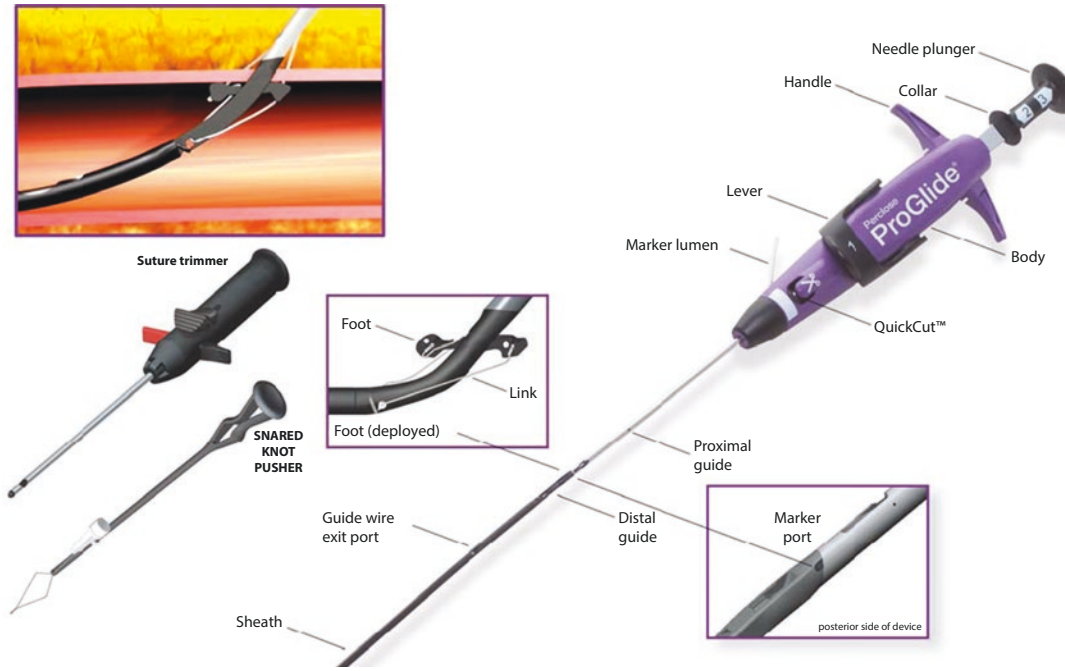

Fig. 28.7 The Perclose ProGlide suture-mediated closure system delivers a monofilament suture via needles from the outside of the vessel directed into cuffs on the intravascular foot (*inset*), which is then pulled into a complete loop and tightened with the use of the knot pusher and suture trimmer

Prostar XL is indicated for closure of 8.5–10F arterial punctures. Deployment of the Prostar involves replacing the procedure sheath with the device to deliver four intravascular needles attached to the ends of two braided sutures. The Techstar device delivered one suture attached to two needles. The needles are pulled through the vascular wall, retrieved from the extravascular device barrel, and cut from the sutures, leaving the suture ends free. A standard surgical knot is tied and advanced to the vessel wall, using a knot pusher to achieve hemostasis. The Closer 6F introduced a different delivery mechanism where two needles are deployed from outside the vessel and captured by intravascular needle cuffs. Retracting the needles pulls the suture into a loop where they are tied and advanced to the arteriotomy as with earlier devices. The current Perclose A-T and Perclose ProGlide (Fig. 28.7) devices use the same mechanism to deliver a pretied suture (a braided suture on the A-T and a monofilament polypropylene suture on the ProGlide) for closing femoral arteriotomies of 5–8F sheaths. The ProGlide has also received approval for closure of access sites up to 21F in size with at least two devices using the preclose technique.

Clinical Experience

Several studies have described use of the various Perclose systems compared with MC, as well as other closure devices. The initial experience with Perclose systems reported use of the Prostar device in closure of 29 arterial punctures and one venous puncture [68]. Device deployment succeeded in 88% of attempts. Among the 30 successful closures, oozing occurred frequently (20%), though only three closure sites had clinical evidence of a hematoma. Subsequent studies have reported better device success rates of 93–99% [44, 69–73], as well as shorter times to hemostasis [41, 70–77] and ambulation [41, 70–72, 74–78] than those seen with MC. In most studies, rates of vascular complications also did not differ between Perclose and MC [44, 69, 71, 72, 74–80]. In pooled analyses, Perclose tended to increase groin bleeding [1] but did not increase the overall rate of vas-

cular complications [1, 37, 38]. Although studies have shown that Angio-Seal has a lower failure rate, as well as shorter times to hemostasis and ambulation than those seen with Perclose [41, 44–46], they also showed no difference in vascular complications between the two devices [41, 44, 46]. A more recent analysis has suggested that Perclose was superior to other VCDs with regard to the risk of vascular complications and access site bleeding [66].

The versatility of the suture-mediated closure mechanism and delivery system has allowed Perclose ProGlide to be utilized in a variety of settings beyond femoral artery closure. Some of these applications are described in ▶ Sects. 28.7.1 through 28.7.6, including applications for closing large-bore arterial access sites, extra-femoral arterial access sites and venotomy site closure.

28.5.3 Clips, Disks, and Other Mechanisms

Axera

Arstasis (Fremont, CA, USA) has taken a different approach to vascular closure with the Axera device (◘ Fig. 28.8a), which creates a controlled shallow-angle arteriotomy allowing greater tissue overlap for a more durable closure with MC. A special wire is placed into the arterial lumen, using the standard modified Seldinger technique, and is used to guide the Axera device into the artery. A heel is deployed and allows the device to tent the artery in a position to allow a second needle to puncture the vessel at a shallow angle (◘ Fig. 28.8b). A wire is advanced through the second needle and the Axera is exchanged for a 5F or 6F procedure sheath, which is removed at the end of the procedure under MC.

Clinical Experience

The first described experience of the Axera device was a large single-center registry of 750 patients undergoing diagnostic and interventional procedures [81]. The mean time to hemostasis was markedly shorter in patients treated with the Arstasis access than in those treated with MC. Vascular complications occurred in only two patients, both of whom developed hematomas. The RECITAL study showed a short time to hemostasis (4.0 ± 2.5 min for diagnostic and 6.9 ± 5.1 min for interventional procedures) and a short time to ambulation (1.5 ± 1.2 h for diagnostic and 3.2 ± 3.3 h for interventional procedures) [82]. Access site–related adverse events occurred in 4.3% of patients, most often because of subclinical hematomas (1.2%).

Cardiva Catalyst

The Catalyst devices (Cardiva Medical, Sunnyvale, CA, USA) build upon the Cardiva Boomerang VCD to close 5–7F arterial punctures (◘ Fig.28.9a). These devices use an intravascular nitinol disk to provide temporary hemostasis via internal compression of the arteriotomy, allowing physiologic hemostatic mechanisms including vessel relaxation (the so-called Boomerang effect) and thrombosis to occur. The Catalyst device is inserted through the existing sheath where the intravascular disk is deployed and drawn back to the vessel wall (◘ Fig. 28.9b). The procedure sheath is then removed and a clip is attached to the Catalyst wire to provide gentle traction against the arteriotomy. After at least 15 min (or at least 120 min for interventional cases), the device is removed to leave a small 2F arteriotomy. Brief application of MC completes hemostasis. The Catalyst II and Catalyst III devices apply a hemostatic coating on the wire to promote coagulation within the tissue tract. The Catalyst III adds protamine sulfate to the wire hemostatic coating.

Clinical Experience

The initial published experience with the Cardiva devices looked at the safety and efficacy of the Boomerang in a series of 96 patients and found 99% device success and no major vascular complications in closing 5F arteriotomies [83]. A subsequent larger series of 397 patients undergoing both diagnostic and interventional procedures with bivalirudin for antithrombin therapy showed device success in 99.3% of patients and vascular complications in eight patients (2%), one of whom had a major vascular complication using the Catalyst II device [84]. A predominance of patients (77%) underwent procedures with 5F sheaths. The prospective randomized trial of 450 patients undergoing diagnostic and interventional procedures with 5–9F sheaths (the majority

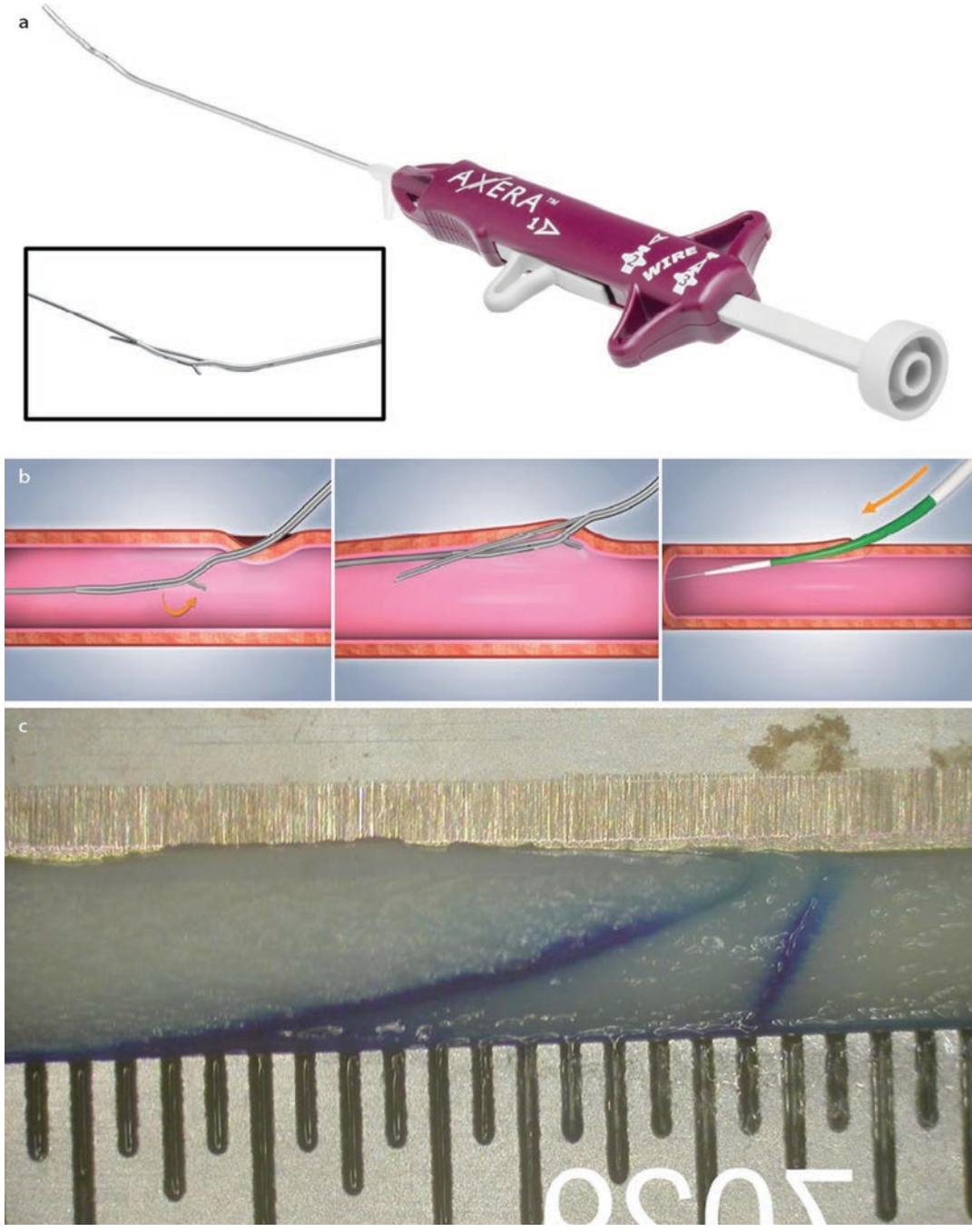

Fig. 28.8 The Axera device **a** creates a shallow arteriotomy **b** to allow for greater tissue overlap during manual compression. Cross-section of an arteriotomy created by the Axera device **c**

using 6F sheaths) showed no device-related complications and no difference in vascular complications in comparison with MC [85]. The mean times to hemostasis and ambulation were significantly shorter in the device group.

Use of the Boomerang device in a pediatric population—patients who often require multiple catheterizations for complex heart disease—was reported in a small series and compared with MC [86]. Sheath sizes ranged from 4F to 8F and were

Fig. 28.9 The Catalyst devices **a** utilize a intravascular disk to provide temporary hemostasis to allow physiologic hemostatic mechanisms to work **b**

placed in femoral artery, femoral vein, and internal jugular vein sites. The overall device success rate was only 85%. While there were no major vascular complications, there was also no significant difference in times to hemostasis and extubation.

StarClose

The StarClose system (Abbott Vascular) uses a circular extravascular nitinol clip for closure of 5F and 6F arterial punctures (Fig. 28.10). Delivery of the clip involves exchanging the procedure sheath for a dedicated delivery sheath, through which the StarClose device is inserted and attached. Intravascular locator wings are deployed to confirm device position against the arteriotomy entry as the StarClose is withdrawn. Clip deployment results in hemostasis as the nitinol tines grab and approximate the arteriotomy edges. The nitinol clip further retracts as it is warmed to body temperature, providing additional tension on the arteriotomy closure.

Clinical Experience

The CLIP trial compared StarClose with MC in 594 patients undergoing diagnostic [87] and interventional [88] procedures. Device success was achieved in 94% of diagnostic patients and 87% of interventional patients. Compared with MC, StarClose decreased the mean time to hemostasis in both the diagnostic (1.46 min versus 15.5 min) and interventional (7.95 min versus 29.1 min) cohorts. The mean time to ambulation was also shorter in diagnostic patients treated with StarClose (163 min versus 269 min). At 30 days, the incidence of major vascular complications in the entire study population was 0.6% for both StarClose and MC [88]. Minor complications developed in 3.4% of patients receiving StarClose and 6.1% of patients receiving MC, with the majority of those patients having hematomas measuring ≥6 cm.

Use of StarClose for closure of 7F and 8F arteriotomies was examined in 226 consecutive patients [89]. The StarClose device closure was successful for 7F and 8F sheaths in 91.3% and 90.1% of attempts, respectively. Duplex ultrasound follow-up 24 h after closure showed major vascular complications in 3.5% of patients, including two massive retroperitoneal hemorrhages, three cases of new ipsilateral ischemia, and three pseudoaneurysms. This study suggests that StarClose may be safely deployed in larger sheath sizes with relatively few complications.

Fig. 28.10 The StarClose SE device delivers an extravascular nitinol clip (*inset*) to approximate the arteriotomy edges for closure of the arteriotomy puncture

28.6 Vascular Closure Devices in Clinical Practice

28.6.1 Safety and Efficacy

Most of the randomized trials examining the use of VCDs enrolled relatively few patients and thus a great deal of information about the safety and efficacy of VCDs is derived from larger observational studies and meta-analyses. The main benefits seen in trials evaluating the early generations of VCDs were shorter times to hemostasis, ambulation, and discharge, as well as greater patient comfort. Overall, use of VasoSeal, Perclose, and Angio-Seal resulted in a 17 min shorter average time to hemostasis [2]. The durations of bedrest and hospital stay were also shorter by 10.8 h and 0.6 days, respectively [2].

Despite the reductions in times to hemostasis and ambulation, use of VCDs has not been proven to reduce the incidence of vascular complications. One meta-analysis examined use of VasoSeal, Perclose, or Angio-Seal in patients undergoing diagnostic cardiac catheterization or PCI [37]. In patients treated with Angio-Seal or Perclose, there was no difference in the rate of vascular complications in comparison with MC. When only randomized studies of Angio-Seal use in PCI patients were examined, there was a near statistically lower rate of vascular complications. Use of VasoSeal led to an overall 2- to 3-fold increase in vascular complications in comparison with MC [37]. A more recent Cochrane systematic review and meta-analyses of randomized and quasi-randomized controlled trials on the matter demonstrated similar conclusions with no differences in efficacy or safety among the different VCDs and MC [90].

In contrast, other meta-analyses have shown a safety benefit with VCD use. A meta-analysis of 16 prospective randomized controlled studies comprising 5045 patients undergoing catheterization and PCI treated with VasoSeal, Perclose, Angio-Seal, or MC showed that use of any VCD decreased the risk of vascular complications by 11% in comparison with MC [38]. When the risk of complications for each device was analyzed separately, use of Angio-Seal or Perclose was associated with a reduced risk of vascular complications whereas use of VasoSeal was associated with a significantly increased risk. The subgroup of patients undergoing PCI showed the same findings with respect to individual devices. Another analysis of 40 randomized controlled trials also showed a reduction in vascular events with certain devices and trials published after 2005 [91].

A number of considerations may explain the discrepant results of VCD studies. Because certain puncture site features may contraindicate use of VCDs, studies have often excluded these patients, creating a selection bias against patients at high risk of bleeding. Meta-analyses have pooled highly heterogeneous studies, which may introduce significant confounding of the true effect. The analyses that have included studies using VasoSeal, which was shown to increase the

risk of bleeding complications, could have also skewed the results. It is unlikely that VCD safety and efficacy would be a class effect given the different mechanisms of hemostasis.

Multiple observational studies have provided evidence that use of VCDs may reduce bleeding or other vascular complications [4, 92–95]. Among patients undergoing PCI, the rates of access site complications have decreased over time. Studies looking at the Northern New England Percutaneous Coronary Intervention Registry [92], the Wake Forest University Baptist Medical Center [93], the Mayo Clinic [96], and the NCDR ACTION Registry—Get With The Guidelines and CathPCI Registry [97] have shown a statistically significant temporal decrease in rates of bleeding complications over the past decade. These results are remarkable considering the contemporary use of increasingly potent anticoagulants and antiplatelet agents in PCI procedures, which potentially increase the risk of bleeding complications.

The largest analyses of bleeding complications were conducted using data from the NCDR CathPCI Registry. Marso et al. reported finding from over 1.5 million patients undergoing PCI at nearly 1000 centers in the USA between 2004 and 2008 [4]. One major finding from this registry suggested that use of VCDs reduced the risk of bleeding, most notably in patients at intermediate and high risk of bleeding. Interestingly, the group at the lowest risk of bleeding, in whom no reduction in bleeding was demonstrated, had the highest rate of VCD use. The rate of VCD use decreased in the intermediate-risk group and was lowest in patients at the highest risk of bleeding. Another analysis of the same registry data including over 1.8 million patients between 2005 and 2009 examined specific hemostatic strategies including MC, mechanical compression devices, hemostatic patches, and VCDs [17]. Four commonly used VCDs—Angio-Seal, Perclose, StarClose, and Boomerang—were associated with significantly lower rates of bleeding or vascular complications than MC. The Mynx devices demonstrated significantly higher odds of bleeding complications. The most recent analysis of the CathPCI data, using tools developed for prospective postmarketing surveillance of medical device safety, again demonstrated a significantly lower rate of vascular complications, access site bleeding, or transfusions with VCDs than with MC [66].

These findings support the criticism that VCD studies have often demonstrated no benefit in reducing complications, because the studies may have been underpowered and additionally excluded high-risk patients, who may benefit most from VCDs. Recognizing this risk–treatment paradox, the term «bleeding avoidance strategies» has been used to describe the application of appropriate access techniques, pharmacologic agents, and VCDs to minimize bleeding complications according to a patient's risk profile [98].

28.6.2 Vascular Complications

Overall the incidence of major vascular complications with VCD use was reported as 2% in a large US registry [4]. ▶ Box 28.1 lists some of the common access site complications associated with VCDs. The most common vascular complications from endovascular procedures are bleeding and pseudoaneurysm [99]. Groin hematoma occurs in 5.3–8.1%, groin bleeding in 4.0–4.6%, pseudoaneurysm in 0.7–2.2%, and arteriovenous fistula in 0.3–0.6% [1, 2, 100]. Infections related to use of VCDs are rare, with an incidence of 0.2–0.4% [1, 100]. Studies have not consistently shown that use of VCDs reduces risks of groin hematoma, groin bleeding, arteriovenous fistula, or pseudoaneurysm in comparison with MC [1, 2]. However, there has tended to be an increased risk of leg ischemia and a significantly increased risk of infection with use of VCDs compared with MC [1]. Failure of VCDs can lead to bleeding both locally at the access site, resulting in small hematomas, or in large volumes, causing large hematomas in the lower-extremity compartments or even retroperitoneal hemorrhage. VCD failure, though infrequent, has also been found to be associated with a nearly 5-fold increase in any vascular complications and an over 3-fold increase in major vascular complications [101]. In a state registry of 23,813 consecutive patients undergoing PCI, VCD failure occurred in 3.3% of procedures and conferred a nearly 3-fold increased risk of any vascular complications [102]. Additionally, StarClose had a 5-fold increased risk of failure and Perclose had a 3-fold increased risk of failure in comparison with Angio-Seal after multivariate risk adjustment [102]. The incidence of retroperitoneal hemorrhage after diagnostic catheterization and PCI has been estimated at around

0.5–0.7% [103, 104]. In those studies, the strongest predictors of retroperitoneal hemorrhage were female gender, low body weight, and high femoral arteriotomy [103]; use of VCDs did not predict retroperitoneal hemorrhage [101, 103].

Box 28.1 Access Site Complications

Complication
- Bleeding
- Hematoma
- Retroperitoneal bleed
- Pseudoaneurysm
- Dissection
- Arteriovenous fistula
- Limb ischemia
- Vessel occlusion
- Embolization
- Local pain
- Nerve damage

28.6.3 Learning Curve

Adoption of new technologies requires careful training of practitioners. Operator experience plays an important role in the successful use of VCDs [100, 105]. Yet, few studies have described the learning curve for individual devices in depth. In an effort to better understand the reasons behind complications of Angio-Seal use, one study examined 252 attempts at vascular closure by a single operator and found that half of the device failures occurred within the first 50 cases [106]. Similarly, the failure rate for Perclose decreased from 8.8% after the first 50 patients to 3.1% after 930 patients [107]. A recent study using data from the NCDR CathPCI Registry found that on an institutional level, each doubling of StarClose deployments increased the success rate by 1.5% and appeared to peak after more than 3000 deployments [108]. This phenomenon held true regardless of the annual number of VCD implants at the institution. With regard to individual operators, outcomes continued to improve throughout the first 200 deployments per physician at an institution.

Device improvements also contribute to ease of use and ultimately clinical success. Several studies have demonstrated that use of newer generations of devices leads to higher clinical success rates [109, 110].

28.7 Special Situations

This section discusses many off-label uses of VCDs. While many small studies have demonstrated the potential feasibility of using VCDs in the situations described below, caution must be used to avoid potentially detrimental complications.

28.7.1 Large Arteriotomy Sites

Many endovascular procedures such as balloon valvuloplasty, percutaneous valve replacement or repair, and hemodynamic support devices that require large-bore vascular access are becoming increasingly common. While only the Perclose Prostar XL and ProGlide devices are approved for closure of arteriotomies larger than 8F, alternative techniques for deploying existing devices have shown success in closure of large access sites. The most common devices used in closing large arteriotomies are the suture-mediated Perclose devices, which allow guidewire reinsertion after suture delivery so that vascular access can be maintained. This so-called «preclose» or «preclosure» technique has been frequently described [74, 111–121]. After deploying the sutures, but without advancing the knot, a guidewire is reinserted the device removed. The free suture ends are collected and put aside. The arteriotomy is then dilated to the appropriate size for the procedure. When the sheath is removed at the conclusion of the procedure, the suture ends are tied in the normal fashion. Reports have described utilization of 8F and 10F Prostar devices for closing arteriotomies up to 14F in size after balloon aortic valvuloplasty [112, 116, 117, 119]. Experience of closing larger arteriotomies with the preclose technique has been studied extensively in endovascular aortic repairs where sheath sizes up to 24F are frequently used. The initial reports described the technique using the Prostar XL device for arteriotomy closure, with success rates of 62–100% [113, 114, 120–123].

The Perclose ProGlide devices have also demonstrated effectiveness in closing larger arteriotomies, and have now been approved for vascular closure after procedures using sheaths up to 21F in size when the preclosure technique is used. Initial studies utilized the preclose technique for closure of up to 8F sheaths [124], with success similar to that seen with the larger Prostar device [125]. A variation of the preclose technique using two ProGlide devices was

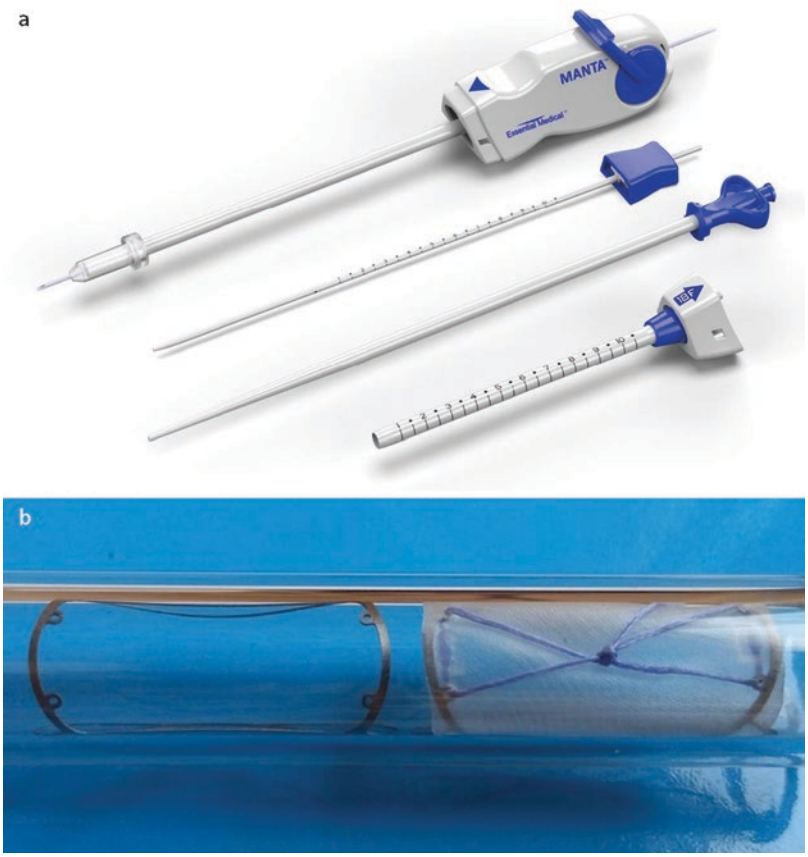

Fig. 28.11 The MANTA vascular closure device **a** uses a large intravascular resorbable anchor and extravascular bovine collagen to close 10–25F arterial access sites. The InClosure device **b** uses a bioabsorbable membrane mounted on a nitinol frame deployed within the vessel and tethered to the arterial wall by a resorbable suture to close 14–21F arterial access sites

described for closure of arteriotomies up to 24F in size where the first device was inserted and rotated 30 degrees medially and deployed, and a second device was rotated 30 degrees laterally and deployed to create an «X» pattern similar to that of the Prostar [126]. Other variations of preclose such as deploying two ProGlide devices in an interrupted longitudinal suture pattern [127] or three devices at 90 degrees to each other [128] have been described. In certain situations, balloon occlusion of the aorta [129] or contralateral balloon inflation [130] may help with hemostasis during large femoral arteriotomy closure.

Other devices have been utilized for closure of arteriotomies larger than 8F as well. One study described use of 8F Angio-Seals with a two-wire technique in closure of 9–12F arteriotomies in patients undergoing balloon aortic valvuloplasty (BAV) [131]. Using this method, an 8F Angio-Seal is deployed, leaving the second wire in place. If adequate hemostasis is achieved, the second wire is removed, otherwise a second device is deployed. A recent report demonstrated the potential for using an 8F Angio-Seal to close 10F arterial punctures in patients undergoing balloon aortic valvuloplasty [132]. A similar method has been described using two Mynx devices for closure of 14F arteriotomies after a balloon aortic valvuloplasty [133].

Experience with closure of large-bore femoral access has increased dramatically with rapid adoption of transcatheter structural heart procedures. Fully percutaneous procedures utilizing these closure techniques have been demonstrated to be safe and may offer advantages over traditional surgical cutdown, including minor vascular complications, patient comfort, and reduced length of stay [134–138]. Recent studies comparing the most commonly used closure devices for large-bore femoral arterial access suggest that ProGlide may be preferred to Prostar [139], even using only one ProGlide in the case of transfemoral transcatheter aortic valve replacement using sheaths up to 20F in size [140].

New devices are also being developed specifically for large-bore vascular closure. The MANTA vascular closure device (Essential Medical, Inc., Malvern, PA, USA) employs a design that is similar in concept to the Angio-Seal for closure of 10–25F punctures (Fig. 28.11a) The intra-arterial

anchor is made of a resorbable poly-lactic-co-glycolic acid polymer connected by a nonresorbable polyester suture to an extravascular bovine collagen pad. The initial experience in ten patients showed 100% successful hemostasis and no device-related vascular complications [141]. InClosure (InSeal Medical Ltd., Caesarea, Israel) utilizes a bioabsorbable membrane mounted on a nitinol frame, which is delivered into the vessel to form an intravascular seal of arteriotomies 14–21F in size (Fig. 28.11b). The membrane and tether suture dissolve, leaving behind only the nitinol frame. Both devices have received European Conformity (CE) Mark approval. The MANTA device has also received US Food and Drug Administration (FDA) approval to begin its US clinical trial.

28.7.2 Peripheral Arterial Disease

Contraindications to the use of VCDs in management of arterial punctures include the presence of severe peripheral arterial disease (PAD) at the arteriotomy site. The lumina of diseased vessels are typically narrowed and placement of devices that utilize an intravascular component may compromise distal blood flow and cause ischemia. Additionally, heavy calcification of the vessels can prevent proper deployment of devices or may be subject to disruption as the intraluminal components are introduced during deployment. Several studies have examined the use of VCDs in patients with PAD. In a group of 105 consecutive patients with PAD, 33% of whom had heavily calcified vessels, the ASPIRE study demonstrated that use of Angio-Seal was safe, even with antegrade punctures [142]. In a prospective registry of 98 consecutive patients with high-risk femoral artery anatomy, including 24% with femoral artery calcification and 30% with moderate femoral artery stenosis, closure with StarClose resulted in only one minor vascular complication [143]. A registry of 500 arteriotomy closures using StarClose in patients with symptomatic PAD showed a 3% overall complication rate and a 2% major complication rate [144]. Use of suture-mediated Perclose devices in patients with peripheral vascular disease (PVD) was studied in a small randomized trial of 102 patients, showing no significant difference in rates of complications in comparison with MC [72]. The experience with the Cardiva Boomerang device in patients with PAD was also limited to six patients in the initial experience [83]. Although the use of VCDs in patients with PAD appears appealing because it avoids lengthy compression, the potential advantage should be weighed against the risk of deployment failure and resulting complications.

28.7.3 Noncommon Femoral Artery Access

Frequently, the femoral arteriotomy is not optimally located for closure with VCDs, such as at the CFA bifurcation or above the inferior border of the inferior epigastric artery. VCDs have not been approved for closure of these arteriotomy sites, and in fact, use of VCDs in these settings is not advised, because of the increased risk of complications. The few studies addressing this issue evaluated StarClose in small patient populations. One small prospective registry of 98 consecutive patients undergoing diagnostic catheterization, including 46% with sheath insertion outside the CFA, showed that use of StarClose for high-risk femoral artery anatomy did not result in any major complications [143]. Another study examined 106 consecutive patients undergoing PCI with an arteriotomy located distal to the CFA, with 72% located in the superficial femoral artery (SFA) [145]. The only complications that occurred were hematomas in 12% of patients and there was no Doppler ultrasound evidence of arterial stenosis. Use of StarClose for arterial punctures at or within 3 mm of the CFA bifurcation was studied in a prospective single-center propensity score–matched analysis of 217 patients undergoing diagnostic catheterization or PCI [146]. This study showed no statistical difference in major or minor vascular complications with puncture at or near the CFA bifurcation in comparison with cannulation of the CFA. Use of other types of VCDs in these settings has not specifically been studied, but caution should be exercised with use of a device with an intravascular component, because of the risk of vascular obstruction from the intravascular component or difficulty with proper placement of the intravascular piece. Use of other devices such as the Mynx in these settings is largely anecdotal.

Closure of «high-stick» arteriotomies located above the inferior border of the inferior epigastric artery or in the external iliac arteries has not been reported in the literature. Considerations with

arterial puncture in this region are that the devices were not designed to reach vessels at this depth; that as the external iliac artery dives posteriorly deep into the pelvic girdle, alignment of devices is not optimal; and that the many layers of subcutaneous tissue may prevent correct deployment of the closure mechanism. Considering the 4- to 18-fold increase in the risk of retroperitoneal hemorrhage from high arterial punctures, the use of VCDs is not recommended in these settings [104, 147]. Instead, the procedure sheath should be removed only after reversal of anticoagulation agents, preferably in the catheterization laboratory where balloon occlusion proximal to the arteriotomy site can be quickly applied in case of MC failure; availability of vascular surgery services at short notice is mandatory.

28.7.4 Brachial Artery Access

Endovascular procedures may require access from nonfemoral artery locations when access is not suitable for the procedure to be performed or its use is contraindicated. Similar considerations that are noted for placement of VCDs in vessels distal to the CFA bifurcation apply, as the brachial vessels are smaller than the CFA where many VCDs are designed to be deployed. Closure of brachial artery access was initially reported in four patients after PCI using 6F and 8F Perclose Prostar suture-mediated devices with good success and without complications or clinical evidence of significant arterial stenosis [148]. Gliech et al. reported use of Perclose systems to close brachial artery access in 18 patients with one unsuccessful device deployment, one hematoma, and no major complications [149]. A subsequent report studied ten brachial artery closures in both diagnostic cardiac catheterization and PCI, demonstrating successful closure in nine of ten attempts using a 6F Perclose Techstar system [150].

The Angio-Seal device has also been studied in closure of brachial artery punctures. The smaller size of a brachial vessel, which is prone to spasm and thrombus formation, makes use of this closure device less desirable, because of potential problems with its intravascular component. Additionally, because of the lack of subcutaneous tissue over the antecubital fossa along the course of the brachial artery, some have suggested infiltrating the access site with 5 mL of lidocaine solution to provide adequate room for placement and coverage of the collagen plug [151, 152]. Three single-center experiences have been published on the use of Angio-Seal in closure of brachial artery access [151–153]. In these studies, 261 brachial artery closures were performed using Angio-Seal, with hemostasis success rates of 97–100%. The overall complication rates were 3.1–16.7%. Two series [151, 152] reported no major complications, and the largest series [153] had major complications in 3.3% of deployments. Most of the complications were due to hematomas or pain. In these studies, the Angio-Seal device was not used if the vessel size was <4 mm or if the patient had evidence of arterial compromise during the procedures.

The only report using StarClose for closure of brachial artery puncture examined its use in 29 patients [154]. The device was successfully deployed in all patients, and complications were suffered by two patients including a large hematoma and brachial artery occlusion requiring surgical treatment. The remaining 27 patients had no evidence of arterial insufficiency, neurologic deficits, or evidence of infection after a mean follow-up of 7.5 months.

Experience of brachial artery closure with other devices is limited. There is one report of successful brachial artery closure without complications using a Cardiva Boomerang device after primary PCI for treatment of ST-segment elevation myocardial infarction [155].

28.7.5 Popliteal Artery Access

The popliteal artery is an alternative access point when routine femoral access is not feasible to use for endovascular procedures. The concerns about using VCDs in this vascular bed are similar to concerns regarding VCD use in the brachial arteries, namely the small vessel diameter. Closure of this arterial access has been described in several case series. The first report of VCD use in management of popliteal artery access employed Angio-Seal in three patients, who did not experience any complications [156]. However, anecdotal reports have suggested a high rate of arterial occlusion due to the intravascular anchor component. The suture-mediated Perclose Techstar 6F device was used successfully and without complications at 3-month follow-up in a report of one patient undergoing SFA angioplasty [157]. The largest series of VCD

use was reported by Noory et al. in 28 patients undergoing SFA revascularization using a retrograde popliteal approach [158]. In this group of patients, hemostasis was successfully achieved in 96.4% of attempts using the StarClose VCD, with development of three small hematomas and one case of arterial occlusion requiring angioplasty.

28.7.6 Venous Access

While VCDs were designed for arterial closure, they have also been employed in the management of venotomies. The majority of reports have utilized the suture-mediated Perclose systems for closure of venotomies up to 14F in size [112, 118, 159, 160]. The smaller 6F Perclose systems have been deployed by conventional techniques at the end of the procedure for venotomy sizes up to 11F [160] or using the preclose technique for larger venotomies [118, 159, 161] with success. The 8F and 10F Prostar devices for closure of 12–14F venous punctures with or without preclosure have also been successful [112, 160]. The technique for venous use of the Prostar device is similar to the arterial procedure, though it can be inadvertently deployed outside the vein or deep into the vein. To better position the Prostar device, a 21-gauge needle is used to inject contrast into the blood return port to verify the position under fluoroscopy.

The Angio-Seal device has also been used in venous closure in one report [162], although the presence of the large footplate inside the vein makes this device less attractive for many operators.

The Mynx device was shown to be effective in venous closure in a porcine model [163] and has received FDA approval for femoral venous closure.

28.7.7 Salvage Closure

Central venous access is commonly used in the management of patients who are critically ill. Incidental arterial puncture during placement of central venous catheters occur not infrequently. Management of inadvertent cannulation of brachiocephalic vessels by MC may not be optimal in these circumstances. For example, the subclavian artery cannot be compressed effectively, because it is positioned under the clavicle. Prolonged compression of the carotid artery may diminish cerebral blood flow. While no large-scale study has examined the safety and efficacy of VCD use in these situations, many reports in the literature suggest that it may provide an effective solution in exceptional circumstances where patients are considered poor surgical candidates. Successful closure of accidental subclavian artery cannulation during placement of various central venous catheters and even large-diameter dialysis catheters with Angio-Seal [164–172], Perclose [173–176], StarClose [177, 178], and Mynx [179] has been reported. One report has described the use of Angio-Seal for closure of the common carotid artery after direct carotid puncture for stent and coiling of an intracranial aneurysm [180]. As in other clinical settings, the intravascular anchor makes this device less than ideal for this application. The Cardiva Boomerang device was used in two cases of unintended carotid artery cannulation in the course of internal jugular central venous catheter placements [168]. Extreme salvage closure was reported using Angio-Seal to close an accidental 12F puncture of the aortic arch during placement of a percutaneous pleural drain [181].

28.8 Conclusion

A variety of contemporary closure technologies expand the strategies available to the endovascular interventionalist for vascular access management. The currently available devices have consistently demonstrated the ability to shorten times to hemostasis and ambulation in comparison with MC, and a decrease in access site–related complications has been more recently demonstrated. Careful observation of user instructions for individual devices and operators' expertise in their use are likely the most critical determinants of clinical success in on-label indications. Further studies are needed to define clinical benefits in specific patient subsets and to clarify the safety and efficacy of VCDs in real-life settings.

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