

Femoral arteriotomy closure using the Mynx vascular closure device: a profile of device efficacy and complications

Percutaneous coronary interventions, transarterial peripheral vascular interventions and neuroendovascular procedures are commonly performed procedures, with transfemoral access representing the preferred approach. Manual compression has traditionally been the mainstay of achieving femoral arteriotomy closure; however, numerous vascular closure devices have been developed as an alternative to manual compression and extended bed rest. Initially introduced in 2007, the Mynx product family of vascular closure devices (Access Closure, CA, USA) are one of the most popular devices on the market in the USA. The Mynx device consists of a catheter with a polyethylene glycol sealant designed to achieve suture-free arterial hemostasis by delivering a conformable, water-soluble sealant into the extravascular space over the arteriotomy. Given the increasing number of transarterial interventional procedures, a thorough understanding of device efficacy, as well as patient and procedural characteristics that predict failure of arteriotomy closure and complication development, is important to minimize patient morbidity.

Keywords: extravascular closure • femoral arteriotomy • Mynx • polyethylene glycol • vascular closure device

Vascular access for percutaneous coronary interventions (PCIs), peripheral vascular interventions and neuroendovascular procedures is established predominantly through percutaneous puncture of the femoral artery and, less commonly, via the radial artery. Arteriotomy closure is accomplished with either manual compression (MC) or with the use of a vascular closure device (VCD). While MC is considered the gold standard for mediating arteriotomy closure, numerous VCDs have been developed in recent years as alternatives to MC and extended bed rest. Initial studies posited VCD use as a means to increase closure efficacy and speed up time to ambulation and discharge [1–5]. Consequently, the putative benefits include maximized utilization of resources, increased patient throughput and reduced overall cost [6–8]. VCD-mediated arteriotomy closure has also been shown to increase patient comfort [6,9,10]. Given these considerations, over the

past few years, there has been an increase in the utilization of VCDs; however, widespread adoption of VCDs for femoral arteriotomy closure, in lieu of standard manual closure, has been tempered by operator learning curve, procedure-related costs, impaired or delayed ability to reaccess the femoral artery after deployment, and the potential for complication development [11–14], more specifically, an increased frequency of groin hematomas [15–20], iatrogenic pseudoaneurysms [2,19,21–25], retroperitoneal hemorrhage [21,26–29] and limb ischemia [21,30–35].

Device overview & design

The first iteration of the Mynx was approved by the US FDA in 2007. The next model, Mynx Cadence, approved in 2009, simplified the deployment system. Approved by the FDA in 2010, the MynxGrip VCD (Access Closure, CA, USA) is an active VCD that achieves arterial hemostasis by delivering a

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suture-free, conformable, water-soluble lyophilized polyethylene glycol (PEG) sealant into the extravascular space over the arteriotomy. The device consists of a catheter with PEG sealant and a 6-mm semi-compliant balloon at the tip (Figure 1). PEG is a bio-inert polymer that has been used extensively in medical devices, with an established record of biocompatibility and safety. There are two elements to the MynxGrip PEG sealant: a 14.5-mm porous matrix and a 1.5-mm distal tip with grip technology. The dual-action PEG sealant adheres to the artery by interlocking with the vessel wall and instantly absorbs bodily fluids, expanding up to three- to four-times its original size, providing a mechanical seal over the arteriotomy and within the tissue tract (Figure 2). Its matrix structure allows for infiltration of blood and serves as a scaffold for hemostasis. After deployment, the sealant undergoes steady hydrolysis into PEG monomers and is completely dissolved within 30 days.

The Mynx VCD is designed so that it can be inserted into 5–7 Fr procedural sheaths, thus avoiding the need for sheath exchange or tract dilation. Intra-arterial deployment of the sealant is prevented by the inclusion of the balloon and by the self-expanding nature of the sealant material. In addition, PEG is not known to interact with platelets or immune cells, theoretically making intravascular and inflammatory complications less likely.

Clinical profile

Device efficacy

Published in 2007, the first prospective clinical investigation of the Mynx VCD involved 190 patients undergoing percutaneous coronary procedures in five European centers [12]. The study population was split equally between patients who underwent interventional procedures and those who underwent diagnostic procedures. Aspirin and clopidogrel were used in 80.4 and 28% of patients, respectively, and median sheath size used in the study was 6 Fr, with a 6 or 7 Fr sheath in 99.5%

of procedures. The average BMI among patients in the study was 27.54 kg/m². The device had a success rate of 93.2% in the study population with a mean time-to-hemostasis of 1.3 min and mean time-to-ambulation of 2.6 h. In addition, the authors found a negligible difference in the efficacy of the Mynx VCD between diagnostic and interventional groups.

A more recent study from the cardiac literature of 238 patients who had undergone PCI and subsequent Mynx closure demonstrated successful closure in 90.8% of cases, a particularly impressive rate given that all patients received preprocedural aspirin and clopidogrel loads, as well as intraprocedural intravenous heparin boluses to achieve activated clotting times between 200 and 300 s [16].

Within the neuroendovascular realm, the Mynx VCD has demonstrated similar efficacy. A publication from our group involving a cohort of 766 patients undergoing diagnostic cerebral arteriograms or neuro-interventions detailed a device success rate of 92%, in-line with the previously published results. Of note, compared with the previous studies in cardiac patients, our patients overall had less risk factors for bleeding [37].

Complications

Prior studies of complications associated with the Mynx VCD have cited rates ranging from 0 to 4.2% [16,37–43], with rates varying based on length of follow-up, consistency of follow-up, and definition of major and minor complications. Scheinert and colleagues reported eight complications (4.2%) in 190 patients, with one major complication involving access-site bleeding, which required a blood transfusion [38]. The seven minor complications included six groin hematomas and one femoral artery pseudoaneurysm, none of which required subsequent treatment. Despite the large number of patients on antithrombotic medications, the authors were unable to find a correlation between activated clotting time and complication development [38]. Azmoon *et al.* encountered five major complications (2.1%) and no minor complications: two cases of retroperitoneal bleeding requiring surgical intervention, two pseudoaneurysms requiring surgical intervention, and one patient who experienced access-site bleeding and required a blood transfusion [16]. Interestingly, their study also showed a statistically significant difference in device failure between Mynx and AngioSeal (St Jude Medical, MN, USA; 9.2 vs 3.7%; $p = 0.033$) [16]. Among our 766 patients, we had 23 complications (2.45%); there were 13 major complications (1.39%), including seven patients who needed an operation for treatment of a femoral artery dissection or pseudoaneurysm and six patients who required a blood transfusion following the development of a groin

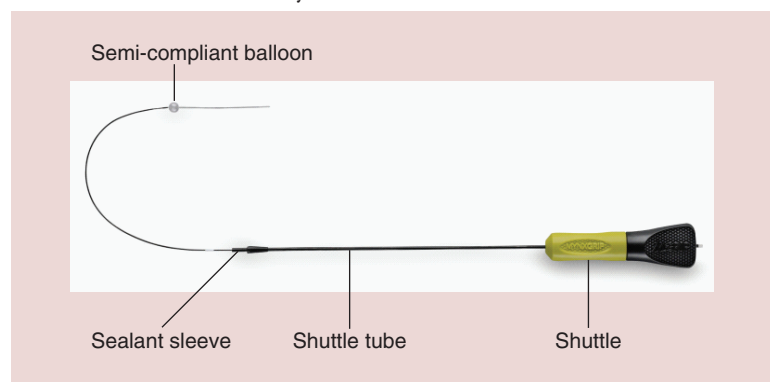


Figure 1. Design of the Mynx vascular closure device. Image courtesy of Access Closure (CA, USA) [36].

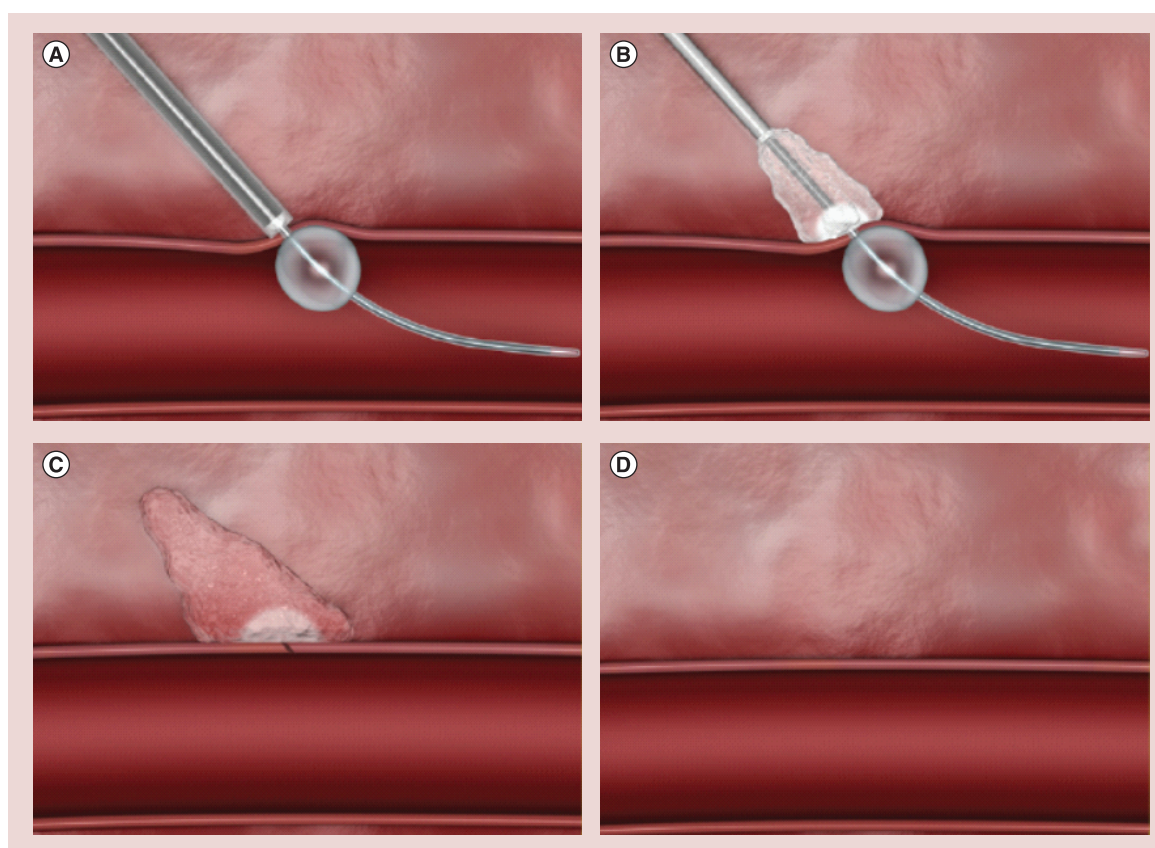


Figure 2. Mynx device deployment. Hemostasis is achieved utilizing a soft, bioabsorbable polyethylene glycol (PEG) plug, which involves **(A)** first inserting the device into the femoral sheath and inflating the small, semi-compliant balloon to create temporary hemostasis. **(B)** The PEG sealant is then delivered to produce permanent hemostasis and **(C)** the device is removed. **(D)** Within 30 days, the PEG sealant dissolves. Image courtesy of Access Closure (CA, USA) [36].

hematoma. Of the ten patients with minor complications (1.07%), four had groin hematomas that did not require transfusions, three developed infections at the femoral access site, one experienced puncture site pain, and one had a nonflow limiting femoral artery dissection. We found that older age, lower BMI, higher number of antithrombotic medications used and device failure conferred a statistically significant increased risk of complication development. Our data corroborated findings from previous studies involving VCDs, which demonstrated a correlation between low BMI and increased rate of complications [20,44,45].

Inadvertent intravascular deployment of sealant can lead to embolization of the sealant and arterial occlusion. Although the Mynx VCD has features that are designed to minimize the likelihood of intravascular sealant deployment, there have been cases of arterial occlusion caused by embolized sealant. Of further note is the fact that intravascular sealant deployment does not always result in clinically symptomatic complications, which could lead to a potential under-reporting of this phenomenon. In a retrospective study in which

patients who received repeat femoral arteriograms approximately 1 week after an initial diagnostic procedure in which a Mynx VCD was used, Fields and colleagues observed five instances (18%) of intravascular sealant on follow-up vascular imaging [39]. Of the five patients, one had a near occlusion of the superficial femoral artery, which required a surgical intervention, while the remaining four were asymptomatic [39]. By contrast, a separate study by Fargen and colleagues demonstrated no cases of intraluminal filling defects on follow-up angiography in 31 patients who underwent repeat arteriography after prior closure with Mynx. The average time to repeat angiography among the patients was 6.2 days, with a median of 5.5 days [42].

Alternative devices

Given the increasing number of patients undergoing diagnostic and interventional coronary, peripheral vascular and neuroendovascular procedures, improved patient comfort associated with VCD use, and systems-based concerns relating to patient throughput

and resource utilization, an increasing number of VCDs are being used in the clinical setting. VCDs currently on the market can be classified according to their mechanism of action into three categories: suture devices (Perclose and Prostar; both Abbott Laboratories, IL, USA), vessel plugs (Mynx, AngioSeal, EXOSEAL [Cordis Corporation, NJ, USA] and FemoSeal [St Jude Medical]), and vascular clips (StarClose [Abbott Laboratories]). Suture devices and vascular clips achieve hemostasis through direct closure of the defect in the external arterial wall. Vessel plugs achieve closure through extravascular filling of the defect with biomaterial. Plugs are made with a number of different materials and vary by brand. Commonly used materials include PEG (Mynx), collagen (AngioSeal), and polyglycolic acid (EXOSEAL). FemSeal utilizes an intravascular and an extravascular plug that are held together with a suture.

As previously mentioned, MC remains the gold standard for achieving arteriotomy closure. Koreny *et al.* merged 30 randomized controlled trials of VCDs versus MC and found similar risks for hematoma, local bleeding and pseudoaneurysm between VCD and MC cohorts [19]. Patients who underwent VCD-mediated arteriotomy closure experienced shorter times to

hemostasis, duration of bed rest and earlier hospital discharge [19]. Noor and colleagues performed a retrospective study of rates of surgical repair following arteriotomy closure with Mynx, AngioSeal and MC in 11,006 diagnostic and interventional transfemoral cardiac and peripheral 6/7 Fr catheterization arteriotomies. In that study, Mynx had a lower surgical repair rate than both AngioSeal (0.06 vs 0.61; $p < 0.0001$) and MC (0.19; $p < 0.14$) suggesting that Mynx is superior to AngioSeal and comparable to MC with regard to complications requiring surgical intervention [40]. Although Mynx has lower rates of surgical repair than AngioSeal, its device success rate of 91–93% is lower than 97–99.7% with AngioSeal and comparable to 94% with EXOSEAL [16,38,46,47].

Conclusion

MC remains the gold standard for arteriotomy closure because of its extensive record of safety and efficacy. The dramatic growth seen in the utilization of Mynx and other VCDs in recent years is in part due to the belief that VCDs are more cost effective than MC, due to the reduction in postprocedural time to ambulation, and, as a consequence, decreasing the duration of hospital stay and resources needed for patient monitoring.

Executive summary

Clinical rationale

- Numerous vascular closure devices (VCDs) have been developed in recent years as alternatives to manual compression and extended bed rest.
- VCDs have been shown to increase closure efficacy, speed up time to ambulation and discharge, and improve patient comfort. Consequently, the putative benefits of their use include maximized utilization of resources, increased patient throughput and reduced overall healthcare costs.

Device description

- The Mynx (Access Closure, CA, USA) VCD is an active VCD that achieves arterial hemostasis by delivering a suture-free, conformable, water-soluble lyophilized polyethylene glycol (PEG) sealant into the extravascular space over the arteriotomy.
- Studies of device efficacy within the cardiovascular and neuroendovascular realm have demonstrated $\geq 90\%$ clinical efficacy of achieving hemostasis, including patients on multiple antithrombotic medications.
- Complications associated with Mynx use include femoral artery dissection, pseudoaneurysm formation, arterial occlusion and limb ischemia, infection and groin hematoma formation.

Alternative devices

- Many other VCDs are currently available on the market. These devices can be classified according to their mechanism of action: suture-mediated devices (Perclose and Prostar); vessel plugs (Mynx, AngioSeal, EXOSEAL and FemoSeal); and vascular clips (StarClose).

Future perspective

- Manual compression remains the gold standard for arteriotomy closure because of its extensive record of safety and efficacy. The dramatic growth seen in the utilization of Mynx and other VCDs in recent years is in part due to the belief that VCDs are more cost effective, due to the reduction in postprocedural time to ambulation and, as a consequence, decreasing the duration of hospital stay and resources needed for patient monitoring.
- Ultra-fast ambulation protocols following transfemoral angiographic procedures are being developed and implemented in hospital systems. If these protocols prove to be efficacious in achieving hemostasis, the potential cost utility of VCD use could be in jeopardy; however, this must be taken into consideration with site-specific policies and resources.

The concept of analyzing VCD cost utility is complex, with many variables, including device cost, post-procedural nursing care and length of time required to monitor the patient after the angiogram. Wagenbach and colleagues reported results from the Mayo Clinic subsequent to the institution of an ultra-fast, early ambulation protocol among patients who underwent neuroendovascular procedures and experienced MC for arteriotomy closure [48]. Remarkably, 142 out of 214 patients (66.4%) who underwent a diagnostic neuroendovascular procedure and 21 out of 81 patients (25.9%) who underwent a neurointervention were able to ambulate within 3 h. Only 14 out of 295 patients (4.7%) required delayed ambulation due to local oozing, hematoma or pseudoaneurysm [48]. The feasibility, efficacy and safety of a similar, ultra-fast ambulation protocol following MC is currently underway at our institution. In turn, if this protocol can be further validated, the potential cost utility of Mynx and other VCDs could be questioned; however, given the lack of uniformity in postprocedural protocols throughout various hospital systems, as well as site-specific policies and resources, a true determination of whether VCD use is associated with cost savings is rather difficult. Several studies have found that a radial approach, which does not require a VCD, reduces global bleeding risk in patients undergoing PCI as compared with the femoral approach [49]. Increasing popularity and validation of radial approach for PCI can decrease the need for femoral access and VCD use.

Over the last several years, the manufacturers of the Mynx VCD have made improvements to its design and

have recently released the latest two iterations of the device: the MynxGrip and the MynxAce. Included in both of the new devices is a separate PEG sealant called grip technology, which is attached to the typical Mynx PEG sealant; this grip sealant is specifically designed to adhere to the outside of the artery for improved closure. New studies are needed to determine whether these design improvements will translate to improved clinical performance.

The Mynx VCD is one of the most common closure devices used today. It is well suited for arteriotomy closure in most patients, and its design avoids the need for sheath exchange or tract dilation. In addition, in comparison with other leading VCDs, it is associated with less pain [43]. Given recent clinical data showing a high success rate of over 90%, low complication rates, as well as decreased time to hemostasis, ambulation and hospital discharge, the Mynx VCD offers an efficacious and safe alternative to the traditional approach of MC and extended bed rest, as well as other currently marketed VCDs.

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The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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