

The Mynx™ Vascular Closure Device

Initial clinical experience using a novel approach to vascular closure.

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As the momentum to develop less-invasive medical procedures continues to build, millions of percutaneous procedures are now performed each year throughout the world. In an effort to improve patient comfort and safety, mechanical vascular closure devices (VCDs) have begun to replace manual compression as the primary means of sealing the percutaneous arteriotomy site. The most widely used VCDs today utilize suture-, metallic-, or collagen-based technologies to stitch, clip, or compress the arteriotomy. Compared with manual compression alone, VCDs have demonstrated the ability to expedite hemostasis, reduce the time to ambulation, increase patient comfort, accelerate time to discharge, and improve patient satisfaction.¹

However, despite these advantages, many existing devices have clinical limitations that may provoke device-related complications and patient discomfort. Specific device-related complications include arterial trauma during device placement, issues with the intra-arterial components required for closure, and/or adverse effects from the residual metallic or animal-based implants.² Various significant complications may be related to the use of the currently available VCDs, including hemorrhage, hematoma, pseudoaneurysm, arteriovenous fistula, dissection, thrombosis, access-site infection, femoral endarteritis, femoral vein closure, and septic emboli. Overall, a vascular complication rate of 1.5% to 9% has been reported.^{2,3} Additionally, serious infectious complication rates with VCDs have been reported to be as high as 5.1%.⁴ Taken in total, these events may result in prolonged hospitalization, significant patient morbidity, and added healthcare costs.

Complications from the traditional devices may lead to the need for surgical or further endovascular intervention, thereby creating a clear need for an extravascu-

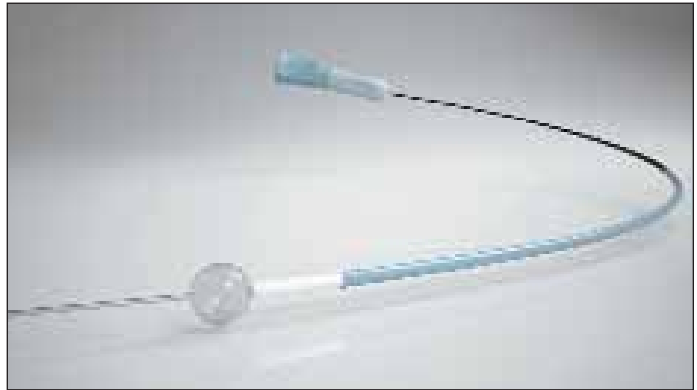


Figure 1. The Mynx Vascular Closure Device.

lar closure method that does not expand the initial arteriotomy, minimizes trauma to the artery, and presents a minimal risk of infection and inflammation. Other associated events that are less frequently studied, but are important clinically, are patient pain and incomplete hemostasis from tract oozing. Thus, the optimal device should also deliver immediate hemostasis with minimal oozing, allow early repeat arterial puncture, be rapidly resorbed, have a short deployment time with predictable outcomes, and be painless to the patient.

TECHNOLOGY OVERVIEW

AccessClosure, Inc. (Mountain View, CA) has recently introduced the FDA-approved Mynx Vascular Closure Device, which attempts to address many of the clinical challenges associated with vascular closure. When delivered to the arteriotomy site, the Mynx (Figure 1) utilizes a water-soluble, freeze-dried polyethylene glycol (PEG) material, which rapidly expands inside the tissue tract by absorbing blood and subcutaneous fluids. The PEG sealant (Figure 2) provides an immediate mechanical seal over the arteriotomy site and within the tissue tract. As the sealant's porous structure fills with blood,



Figure 2. Dry sealant.



Figure 3. Hydrated sealant.

it provides a platform for clot formation that facilitates natural hemostasis and subsequent healing of the tissue tract. The sealant swells three to four times its original size (Figure 3) and expands both horizontally and vertically within the tissue tract. Once deployed, the Mynx sealant loses all column strength, thus decreasing the likelihood that it could be advanced into the artery. The sealant's loss of column strength theoretically may also allow for early reaccess. Reaccess has been successfully observed as soon as 2 hours to 1 week after the procedure in early clinical experience.

When delivered inside the tissue tract, the sealant is composed of 5% PEG and 95% blood and subcutaneous fluids. PEG is a hydrophilic, bioinert polymer with a well-established safety profile. It is commonly used in a wide range of medical applications from gel caps to cranial sealing (DuraSeal, Covidien, Hazelwood, MO). Within 30 days, the sealant hydrolyzes and fully dissipates from the closure site.

The Mynx sealant appears to facilitate tissue healing with theoretically less potential for intravascular complications than with other commonly used devices. Intravascular-based implants can cause complications related to malpositioning, excessive fibrotic responses, or distortion of the vessel architecture that makes future reaccess more difficult.³ Importantly, because the Mynx sealant is delivered through the existing 6- or 7-F procedural sheath, it does not require tract dilation or sheath exchange, which may increase the potential for infection and/or enlarge the arteriotomy site. The fact that Mynx does not involve tract dilation may also help explain why, in our experience, postdeployment oozing has been minimal.

Chronic 30-day animal studies suggest there is mini-



Figure 4. The artery 27 days after Mynx closure.

mal to no inflammatory response in the weeks after placement. This lack of inflammation is likely due to the bioinert, nonthrombogenic composition of the sealant. The same findings noted in the preclinical setting have been observed now in the clinic. The first case study in this article summarizes one such patient example.

CASE STUDY 1

An 86-year-old man with a history of peripheral vascular disease (PVD) had an elective nonsurgical abdominal aortic aneurysm repair performed on August 22, 2007, by Drs. Nishit Choksi, Kirit Patel, and Thanh Phan at St. Joseph's Mercy Hospital in Pontiac, Michigan. The patient had undergone an interventional carotid procedure 27 days earlier by Dr. Choksi, who had used the

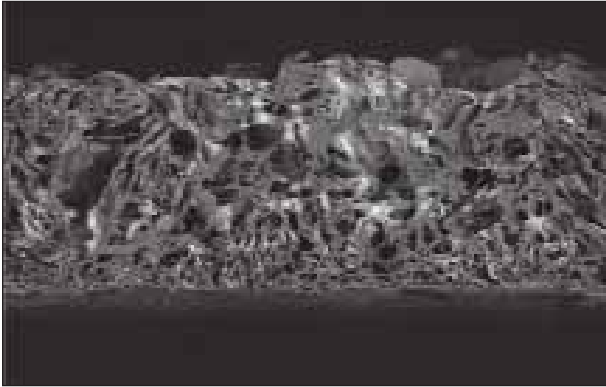


Figure 5. Microscopy image of sealant.

Mynx Vascular Closure Device to obtain hemostasis at the right common femoral artery (CFA) access site.

As per standard abdominal aortic aneurysm procedure, a cutdown was performed that exposed the right CFA. The artery and surrounding tissue were closely examined for any signs of scar tissue or evidence of the PEG sealant. As shown in Figure 4, the artery was well healed with no evidence of scar tissue or inflammation.

PROCEDURE OVERVIEW

After completion of diagnostic angiography or percutaneous intervention, the Mynx device is delivered through a standard 6- or 7-F procedural sheath, ≤ 15 cm in overall length. The device consists of a catheter with a 6-mm semicompliant balloon at its tip. A strip of dry, compressed sealant resides on the catheter shaft, and by catheter advancement, the dry-form sealant is placed over the arteriotomy site in an extra-arterial position. This position is ensured by positioning of the semicompliant balloon opposed to the anterior arterial wall. Blood and subcutaneous fluid immediately fill the porous structure of the sealant, providing a conformable seal over the arteriotomy and within the distal portion of the tissue tract (Figure 5).

STEPS

1. The Mynx device is inserted into the existing procedural sheath, and the semicompliant balloon is inflated to create temporary hemostasis (Figure 6).
2. The sealant is delivered and unsleeved, exposing it to blood and subcutaneous fluids (Figure 7).
3. The balloon is deflated, and the device is removed. The sealant is now located on the surface of the arteriotomy (Figure 8).

In our early clinical experience, the Mynx has produced little or no pain in the vast majority of patients. This is presumably because the delivery mechanism

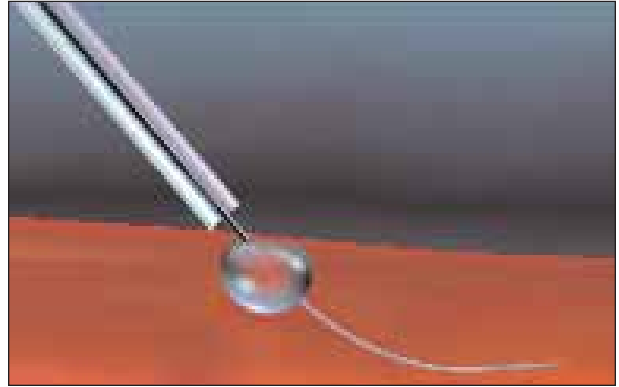


Figure 6. Insert the Mynx and inflate the balloon.

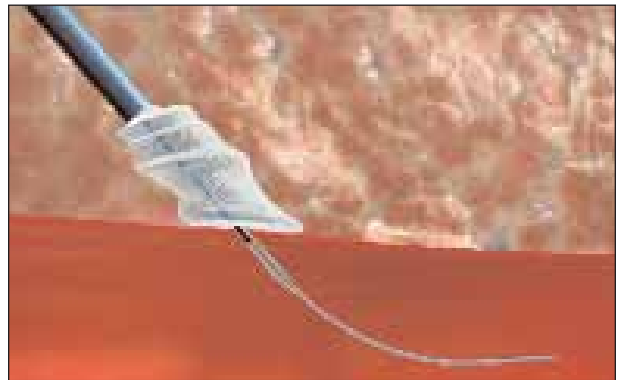


Figure 7. Deliver and unsleeve the sealant.

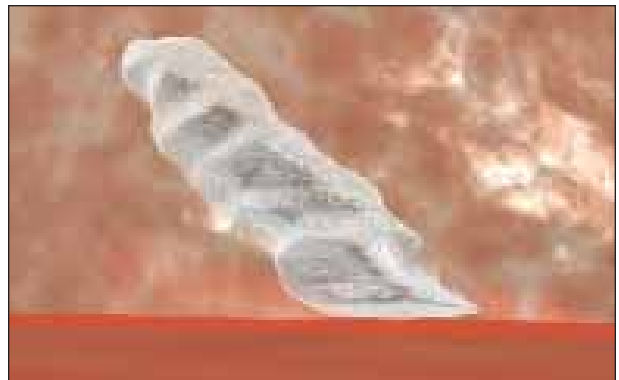


Figure 8. Deflate the balloon and remove the device.

does not involve the cinching or tugging on the innervated artery commonly required for other VCDs. Additionally, because further expansion of the tissue tract is rarely needed, and the tract is filled with the Mynx sealant and coagulum, tissue tract oozing may also be minimized. Although oozing is often of no clinical significance, nursing resources may still be required, the additional cost of hemostatic pads is often incurred, and ambulation may be delayed.

DATA

The sealant used in the Mynx device was first studied during a prospective, proof-of-concept trial involving 500 patients at 13 centers throughout the US. This study demonstrated the safety and efficacy of the sealant with improved times to hemostasis, ambulation, and time to discharge as compared to manual compression. The delivery system was subsequently redesigned to integrate the sealant within the catheter and thereby reduce the number of procedural steps and increase the speed of deployment. This next-generation Mynx was the subject of a prospective, multicenter, single-arm clinical investigation conducted at five European centers in patients undergoing percutaneous coronary diagnostic or interventional procedures using a 5-, 6-, or 7-F sheath.

“In our early clinical experience, the Mynx has produced little or no pain . . .”

The 190 patients enrolled in the study were divided evenly between diagnostic and interventional cases and included both low- and high-risk patients. High-risk patients enrolled in the study included those with (1) hypertension requiring medication (78%), (2) obesity (body mass index >30; 22%), and (3) elevated activated clotting time (defined as >220; 14%). The primary safety endpoint was the combined rate of major complications within 30 days. The primary efficacy endpoints were time to hemostasis and time to ambulation. Vascular closure using the Mynx technology was attempted in 190 patients. No sealant migration, embolization, or intra-arterial deployment was observed in patients treated with the Mynx device, and no patient experienced device-precipitated complications requiring surgical intervention for acute limb ischemia, vessel rupture, infection, or amputation. Of note is that the time to hemostasis and the number of major and minor complications were not significantly different in the high-risk versus the low-risk patients, suggesting that the Mynx may offer a faster, safer alternative to mechanical closure even in more challenging patients.

STUDY DATA HIGHLIGHTS

- 0.5% rate of major complications
- Absence of complications requiring surgical repair

- Rapid hemostasis (mean, 1.3 minutes) independent of anticoagulation status
- Comparable time to hemostasis achieved whether the patient underwent a diagnostic (median, 0.5 minutes) or interventional (median, 0.6 minutes) procedure
- Consistently rapid time to ambulation of 1.9 hours for diagnostic patients and 2 hours for interventional patients
- Low minor complication rates without need for additional intervention or hospitalization
- Ease of use as evidenced by high device success rates even in initial clinical experience with the device

POSSIBLE MYNX USE IN COMPLEX PATIENTS

Because of the increased risk of local ischemic complications, physicians are generally reluctant to use VCDs with intravascular components in patients with PVD. A significant number of patients undergoing coronary procedures also have PVD, which represents a substantial number of patients in whom manual compression is the default, and who thus do not receive the added comfort and other benefits of vascular closure. Obese patients present a special challenge in the angiography suite because access to the femoral vessels may be problematic, and hemostasis may be difficult to safely achieve. It is possible that the expansive, tissue-tract filling properties of the Mynx sealant will offer more efficient hemostasis to obese patients and minimize tract ooze.

The need to repuncture the CFA is a common requirement after diagnostic catheterization or in emergent situations after interventional procedures. The extravascular deployment of the PEG sealant, its short absorption profile, and its lack of column strength are expected to result in an enhanced safety profile that will allow immediate reaccess to the site and minimize or eliminate the risk of intra-arterial device displacement. However, further study will be required before any formal recommendation can be made.

The case studies presented next illustrate how these features may translate into a clinical advantage during interventions accomplished via femoral artery access.

CASE STUDY 2

A 61-year-old man with a body mass index of 35.3 and history of end-stage renal disease (currently on hemodialysis), hypertension, hyperlipidemia, and non-healing foot wounds was admitted with symptoms of unstable angina. Hospital procedures included dialysis,

(Courtesy of Jeffrey W. Chambers, MD, Mercy Hospital, Metropolitan Cardiology Consultants, Minneapolis, MN.)



Figure 9. Femoral angiogram from Case Study 2.

right and left coronary angiography, and a CT angiogram of the abdominal aorta and lower-extremity runoff. Due to patient comorbidities, surgery was considered high risk, and the patient underwent rotational atherectomy, balloon angioplasty, and bare-metal stenting of the right coronary artery. Periprocedural Angiomax 16 mL (5 mg/mL) IV bolus (The Medicines Company, Parsippany, NJ), Angiomax IV drip (5 mg/mL), and 1,000 units of heparin were administered. The interventional procedure was successfully completed without complication. Femoral angiography (Figure 9) showed that although the arteriotomy was at the proper anatomical location (overlying the femoral head), the bifurcation was high and too close to the profunda femoris artery to safely use most of the currently available VCDs. Visible calcium and concomitant peripheral arterial disease seen at angiography made this access closure even more complex. However, the Mynx device was deployed in <1 minute, and hemostasis was achieved. The patient reported no pain and was discharged the next day.

CASE STUDY 3

A 52-year-old woman with history of coronary artery disease, unstable angina, type 2 diabetes, hypertension, chronic atrial fibrillation, and chronic leg edema was admitted for dyspnea and unstable angina, as well as increasing leg edema. The patient was morbidly obese with a blood pressure of 164/58, previous cardiac catheterization in 2004 and 2006, and previous renal



Figure 10. Femoral artery and vein access from Case Study 3.

stenting. At the time of admission, the patient was on both antiplatelet and antithrombotic agents, including aspirin, clopidogrel, and warfarin, as well as medication for hyperlipidemia, hypertension, and gastroesophageal reflux disease. Femoral vascular access was complicated due to central obesity and a large pannus, which was pulled back and taped to expose the access site. Right femoral artery (6 F) and right femoral vein (7 F) access (Figure 10) was obtained, and right and left heart catheterization, left ventriculography, and renal angiography were performed. The Mynx device was chosen for closure due to its ability to work through the existing procedural sheath, which eliminated the need for a potentially challenging sheath exchange in such an obese patient. The Mynx device was deployed without complication, and hemostasis was achieved.

CASE STUDY 4

A 60-year-old man with a history of peripheral arterial disease and recent ultrasound identification of proximal- and midvessel superficial femoral artery disease presented for angiographic evaluation of left lower-extremity claudication. Antegrade access was gained using a long 6-F Brite Tip sheath (Cordis Corporation, Warren, NJ), and angioplasty and stenting were performed. The left groin access site was seen at angiography to arise from the mid-CFA (Figure 11). The long 6-F sheath was then exchanged for a short 6-F Brite Tip sheath. The physician chose to use the contrast technique to demonstrate the Mynx mechanism of deploy-



Figure 11. Sheath insertion in the common femoral artery from Case Study 4.



Figure 12. Balloon visualization technique from Case Study 4.



Figure 13. Balloon at arteriotomy from Case Study 4.

ment. The balloon was prepped with a 3:1 mix of saline and contrast, and the device was inserted into the procedural sheath. Next, the balloon was inflated and visualized with the contrast technique, successfully pulled back through the existing stent (Figure 12) until the balloon was opposed to the anterior aspect of the femoral wall at the arteriotomy (Figure 13). The PEG sealant was then introduced, and the sheath was removed. The balloon was subsequently deflated and removed. Immediate hemostasis was achieved, and the patient was discharged the next day without complication.

CONCLUSION

The Mynx Vascular Closure Device offers several potential advantages to patients undergoing percutaneous procedures utilizing femoral arteriotomy. With the bioinert PEG sealant placed in the extravascular space and deployed through the existing sheath, the pool of patients eligible for the use of this vascular closure device may increase over currently available VCDs. Anecdotally, we have seen significantly less patient discomfort and tract ooze, making the Mynx device particularly attractive. Additional experience with the Mynx will provide data and insight beyond the initially positive experiences in challenging cases, such as atherosclerotic

disease near the arteriotomy site, antegrade puncture, use of anticoagulation, and obese patients. ■

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