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The Mynx® Vascular Closure Device

Adopting extravascular closure technology in the catheterization lab.

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In his annual review of vascular closure for *Endovascular Today*,[1] Zoltan G. Turi, MD, refers to a burgeoning evolution of closure devices toward minimizing both device footprint and long-term residence of foreign material in the vasculature. This comes as little surprise given the concern of many physicians regarding the consequences of leaving intraluminal components behind at arteriotomy sites. Despite the current market dominance of intravascular closure technologies, a new breed of extravascular closure devices appears to be on the rise.[1] The Mynx Vascular Closure Device (AccessClosure, Inc., Mountain View, CA) delivers a fully resorbable, polyethylene glycol (PEG) sealant to the arterial surface through the existing 6- or 7-F sheath used for the catheterization procedure (Figure 1).

Physicians who try the Mynx device typically do so because of its extravascular design and the theoretical benefits associated with sealing the vascular access site with a resorbable sealing agent rather than a thrombosing agent and/or sutures, plugs, or clips. Although intravascular closure devices clearly reduce time to hemostasis and ambulation (thus eliminating extended bedrest) compared with manual compression,[2,3] their association with infrequent but very serious complications (eg, infection, femoral artery thrombosis, uncontrolled bleeding, device embolism, and acute limb ischemia) is considered a major detractor by some physicians.[2,4,5] For those who stopped using closure devices after experiencing ischemic complications or infection arising from the presence of intraluminal device components, an extra-arterial, bioabsorbable sealant technology represents a valuable alternative. The early clinical experience with the Mynx has been promising,[6] and the device has quickly captured an impressive 15% market share. Given the significant clinical experience attained to date, it is important to evaluate the real-world performance of the device to discern how well it withstands the challenges of everyday clinical practice. Enthusiasm about the Mynx device has been primarily focused on its extravascular design, which, in theory, should reduce complications stemming from intravascular components and provide a better approach for achieving hemostasis in challenging patient subsets, such as those with peripheral vascular disease and bifurcation punctures.

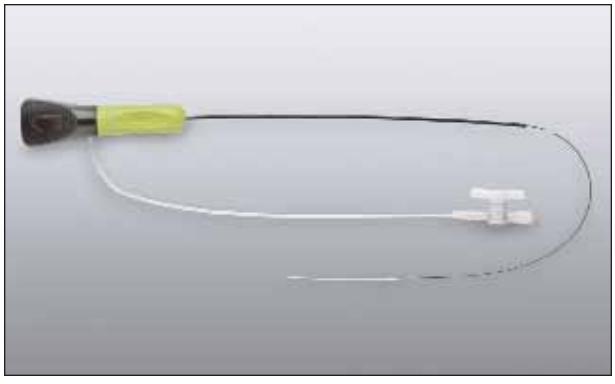

Figure 1. The Mynx Vascular Closure Device.

This article presents the experience from a single-center evaluation of patients who underwent a Mynx closure, as well as data from more than 50 institutions compiled to assess adoption of the technology, use of optimal technique, and effectiveness of the Mynx training program.

THE ST. VINCENT MERCY MEDICAL CENTER EXPERIENCE

At St. Vincent Mercy Medical Center in Toledo, Ohio, a retrospective review of 454 patients receiving the Mynx device for femoral access site closure revealed a device success rate > 95% with no major complications in 306 diagnostic catheterizations and 148 interventional catheterizations. As might be expected in the early phase of adopting a new closure technology, the majority of cases in this series were diagnostic (67%), owing to the tendency of physicians to try new closure technologies in procedures with lower levels of systemic anticoagulation. Currently, the Mynx device is the front-line closure device for patients undergoing catheterization procedures at St. Vincent and at Fairview Hospital, Cleveland, Ohio, where the Mynx is used in the majority of interventional cases (90%). Rates of device success and minor complications

TABLE 1. ST. VINCENT MERCY MEDICAL CENTER: MYNX DEPLOYMENT IN 454 PATIENTS

	Diagnostic (n = 306)	Interventional (n = 148)	*P* Value[a]
Patient Characteristics – n (%)			
Male gender	192 (62.7%)	105 (70.9%)	.093
BMI, mean (kg/m^2)	32.2 ± 7.9	31.3 ± 6.5	.225
BMI ≥ 35 kg/m^2 (n = 301, 145)	92 (30.6%)	35 (24.1%)	.179
History of renal insufficiency	34 (11.1%)	22 (14.9%)	.287
History of diabetes mellitus	68 (22.2%)	37 (25%)	.553
Procedural Medications – n (%)			
Bivalirudin	0 (0%)	103 (69.6%)	<.001
Heparin	11 (3.6%)	23 (15.5%)	<.001
Bivalirudin + heparin	0 (0%)	7 (4.7%)	<.001
Glycoprotein (GP) IIb/IIIa	0 (0%)	6 (4.1%)	.001
Heparin + GP IIb/IIIa	1 (0.3%)	6 (4.1%)	.006
Closure Outcomes – n (%)			
Device success	95.1%	95.9%	.814
Major complications	0 (0%)	0 (0%)	–
Minor complications[b]	2 (0.7%)	2 (1.4%)	.599

[a]P values displayed for descriptive purposes.
[b]Pseudoaneurysms treated with thrombin injection.

were numerically comparable between diagnostic and interventional procedures (70% of which included anticoagulation with bivalirudin) (Table 1). Of the total population, a substantial 29% of patients had an elevated body mass index (BMI). Patients with a history of diabetes comprised 23% of the population, and 12% of patients had a history of renal insufficiency. Patient factors associated with an increased risk of complications are provided in Table 2. There were no differences detected in device success, major complications, and minor complications for patient subsets comparing higher BMI ranges (BMI, ≥ 35 and < 35) and lower BMI ranges (BMI, ≤ 25 and >25), male and female gender, and diabetic and nondiabetic populations. The absence of major complications, as well as the comparable outcomes between diagnostic and interventional patients and subset populations known to be challenging and higher risk, was both surprising and encouraging, particularly given the fact that many Mynx procedures assessed in this retrospective analysis occurred during the early experience of Mynx operators.

EXTRAVASCULAR CLOSURE: PHYSICIAN DEPLOYMENT AND PATIENT COMFORT

In the St. Vincent experience with the Mynx device to date, there have been no instances of major complications. In our view, the most important aspect of the Mynx design is that we are not leaving behind any intravascular components. Debate over the best closure device design continues. However, devices that are affixed intra-arterially can in the long run be more complicated from the standpoint of compromised blood flow, embolization, and infection. An extravascular approach to closure seals the vessel without the potential burden that intravascular components impose, albeit in rare circumstances.

Although use of intravascular closure devices is generally avoided in patients with plaque at the access site, our collective experience has been that the Mynx is easily and safely deployed even in these more challenging cases, perhaps because the sealant is deployed outside the vessel lumen without the need for sheath exchange, leaving no foreign material to reside in the artery long-term. When delivered to the tissue tract, a 6-mm, semicompliant balloon is used to ensure extra-arterial placement and apposition to the anterior arterial wall. During deployment, the compliant balloon protects the artery from embolization without exerting dilating force. The porous sealant immediately absorbs blood and subcutaneous fluids, swelling to 3 to 4 times its original size and establishing immediate hemostasis by sealing the arteriotomy site and tissue tract.

TABLE 2. ST. VINCENT MERCY MEDICAL CENTER: OUTCOMES IN HIGHER-RISK PATIENTS			
Outcomes (Higher BMI Patients)	**BMI ≥ 35 (n = 127)**	**BMI < 35 (n = 319)**	***P* Value[a]**
Device success	122 (96.1%)	304 (95.3%)	1.000
Major complications	0%	0%	1.000
Minor complications	1 (0.8%)	3 (0.9%)	1.000
Outcomes (Lower BMI Patients)	**BMI ≤ 25 (n = 66)**	**BMI > 25 (n = 380)**	***P* Value[a]**
Device success	63 (95.5%)	363 (95.5%)	1.000
Major complications	0%	0%	1.000
Minor complications	0%	4 (1.1%)	1.000
Outcomes (Male vs Female)	**Male (n = 297)**	**Female (n = 157)**	***P* Value[a]**
Device success	283 (95.3%)	150 (95.5%)	1.000
Major complications	0%	0%	1.000
Minor complications	4 (1.3%)	0%	0.303
Outcomes (Diabetic Population)	**Diabetic (n = 105)**	**Nondiabetic (n = 349)**	***P* Value[a]**
Device success	100 (95.2%)	333 (95.4%)	1.000
Major complications	0%	0%	1.000
Minor complications	0%	4 (1.1%)	0.578

[a]P values displayed for descriptive purposes.

The sealant expands in the limited space directly on top of the artery creating enough pressure to seal the access site without excessive pressure that results in pain. The fully expanded sealant, which is 95% blood and fluids and 5% PEG, hydrolyzes within 30 days, leaving PEG monomers small enough for renal clearance and ultimately no trace of the sealant in the body.

The Mynx is deployed through the existing 6-F procedural sheath; this is particularly helpful in cases in which access can be challenging due to extreme obesity[7] (29% of patients in the St. Vincent study) or existing peripheral vascular disease (21% of patients in the Mynx New User Program; Table 3). Deployment requires little pressure on the vessel relative to the tamping, suturing, or clipping required with intravascular closure devices. While the benefits of leaving no foreign material behind in the vessel may be theoretical, the Mynx device has resulted in noticeably less pain and discomfort for patients undergoing catheterization at St. Vincent as well as at Fairview Hospital in Cleveland. Physicians note that patients are not aware when the Mynx is placed and rarely complain of pain or discomfort at the access site; patients also rarely report feeling a nontender lump at the access site. In contrast, a lump, either painful or merely bothersome, is more commonly reported over the ensuing hours, days, or weeks with the intravascular closure devices. Furthermore, when nurses graded patients' outward signs of discomfort or pain (0 indicating no discomfort, 5 indicating very uncomfortable) in a multicenter data collection of new users of the Mynx device, the vast majority of patients were rated as experiencing little or no discomfort.

TRANSITIONING TO EXTRAVASCULAR CLOSURE: TRAINING AND TECHNIQUE

Adopting new technologies, although a way of life in the endovascular community, still involves a learning curve. Rarely is the effectiveness of new user training for the ever-expanding array of endovascular technologies evaluated systematically. The Mynx New User Program data, however, assessed how closely new users of this novel extravascular sealant technology implemented proper deployment techniques learned in their device training. Data from 50 sites in the United States involving 2,235 procedures were collected after the formal training period at each site to assess how the device was being used relative to the training provided (Table 3).

This multicenter population had a mean age of 64

TABLE 3. THE MYNX NEW USER PROGRAM: PATIENT AND PROCEDURAL CHARACTERISTICS

Patient Characteristics	**All Interventions (N = 2,235) % (n/N)**
Male	58.6 (1,293/2,206)
Age (years), mean (range)	64.4 (23, 96)
BMI (kg/m^2), mean (range)	30.2 (16.3, 69.7)
BMI > 35 kg/m^2	15.6 (321/2,063)
History of peripheral artery disease	20.8 (414/1,995)
Procedural Characteristics	
Diagnostic	67 (1,484/2,215)
Retrograde	90 (1,519/1,688)
Coronary catheterization	86.6 (1,935/2,235)
Procedural sheath size	
6 F	92.2 (2,034/2,206)
7 or 8 F	7.8 (172/2,206)
Compliance With Key Procedural Steps	
Femoral angiography performed before close	94.8 (2,089/2,204)
Mynx aligned with procedural sheath	100 (2,216/2,216)
Open stopcock before shuttling	99.2 (2,191/2,208)
Minimal tension while retracting sheath	99.7 (2,203/2,210)

years (consistent with the St. Vincent population in terms of a modest male majority [59%]), mean BMI in the obese category (30 kg/m^2), and a notable proportion of patients classified as at or near extreme obesity (16% with BMI > 35 kg/m^2). Also, similar to the St. Vincent study, this early use of the Mynx device primarily included coronary catheterizations (87%) most often using 6-F sheaths (92%) in diagnostic procedures (67%), which are known to pose a lower risk of bleeding complications. The preponderance of diagnostic patients was consistent with appropriate case selection during the operator training period. Broader application of the device in an interventional population is now routine as evidenced by use in 90% of the author's interventional patients at Fairview Hospital.

KEY PROCEDURAL OUTCOMES

The key finding of this data collection was that procedural techniques demonstrated in the new user training program were replicated in nearly all procedures (Table 3), indicating that the deployment techniques were easily adopted. Key procedural steps evaluated in the New User Program include routine femoral angiography, proper sheath and Mynx alignment, opening the stopcock before shuttling the Mynx sealant, and use of minimal tension as the sheath is removed.

Femoral angiography before closure was performed in 94.8% of procedures. When placing any closure device, obtaining a femoral angiogram is essential for identifying high femoral arterial punctures, which carry a risk for retroperitoneal hemorrhage.[8,9] Femoral angiography also allows the operator to ensure access site location, adequate arterial flow, lack of extravasation, vessel size > 5 mm, and presence of local arterial disease or other anomalies and variances.

The Mynx was properly aligned with the procedural sheath in 100% of cases. This practice ensures proper sealant placement, facilitates pullback during the first two stops for balloon positioning, and minimizes the possibility of excessive tension during unsheathing of the sealant.

The stopcock was open before shuttling the Mynx device in 99.2% of cases. Opening the stopcock with the balloon apposed to the arterial wall and prior to shuttling the sealant is a failsafe mechanism that allows blood and pressure to be released from the sheath to ensure the sealant does not expand prematurely while inside the sheath. This procedural step also helps to verify that the balloon is appropriately positioned at the arterial wall as demonstrated by temporary hemostasis.

Minimal tension was maintained while retracting the sheath in 99.7% of cases. Scaling back from the adequate tension needed to ensure balloon abutment against the

arteriotomy to minimal tension while retracting the procedural sheath helps ensure proper sealant placement and, thus, durable hemostasis. Excessive tension during sheath retraction could potentially tent the artery, creating a space between the artery and sealant once the artery returns to its native plane.

Based on the data collected in the Mynx New User Program, the deployment techniques for this novel extravascular sealant technology appear to be easily mastered in the early adoption period. Further to this point, the St. Vincent data showed that complication rates were no different when looking at the first 50 cases performed compared with the last 50 cases. In our collective experience, learning to use the Mynx technology has been quite simple, involving fewer steps than other closure technologies and leading to mastery in just a few cases. Deployment is so easily mastered that at Fairview Hospital, where approximately 90% of the author's cases are interventional, the Mynx closure procedure is routinely performed by a trained technician.

EXTRAVASCULAR CLOSURE AND CLINICAL VERSATILITY

Cases involving peripheral artery disease, bifurcation sticks, and extreme obesity continue to pose challenges with access-site closure despite the otherwise well-established and routine nature of catheterization procedures.

In the case of peripheral disease at the access site, intravascular closure devices have traditionally been avoided due to difficulty placing intraluminal components into a narrowed vessel and concerns about subsequent ischemia. One might ask whether the same concerns hold true for extravascular closure. A certain willingness to attempt placement of an extravascular sealant in diseased peripheral vessels is reflected in the 21% of patients with peripheral vascular disease documented in the Mynx New User Program. Indeed, in our collective experience, extra-arterial placement of the Mynx sealant in the presence of peripheral artery disease has not resulted in difficulty placing the device or ischemic complications. The conformable, extra-arterial nature of this device also allows for use in bifurcation anatomy in which complex angles pose challenges to the placement of intra-arterial components. Additionally, with the Mynx there is no concern about partial or total obstruction associated with placement of intraluminal components in the smaller vessels typically involved in bifurcation puncture.

Other patient and procedural characteristics known to be associated with increased risk of complications from arteriotomy closure were also represented in these two study populations. Women accounted for 35% of the St. Vincent population and 41% of the New User Program population. Renal insufficiency was documented in 12% of St. Vincent patients. Even in this early experience with a new closure technology, more challenging procedures were performed, such as those through an antegrade puncture (10% of cases in the Mynx New User Program).

CASE REPORT

The benefits of an extravascular closure device are well illustrated in this case involving a 64-year-old, asymptomatic man in whom duplex ultrasound identified a carotid stenosis. Carotid angiography was performed through a 6-F sheath to assess the severity of the carotid lesion and revealed a moderate stenosis of the right internal carotid artery. Medical treatment was planned for the patient. Per standard practice, femoral angiography was performed at the conclusion of the procedure. Two views of the femoral anatomy were taken to adequately appreciate the sheath insertion site, which was noted to be at the bifurcation of the deep femoral and superficial femoral arteries (Figures 2 and 3). The Mynx procedure was performed in the usual fashion, and hemostasis was achieved without any bleeding. The patient ambulated 2 hours later and was discharged home in 3 hours.

Puncture sites at the femoral artery bifurcation occur periodically, and until the availability of the Mynx device at Fairview Hospital, hemostasis in this patient would have been achieved with manual compression. Positioning an intravascular component in bifurcation anatomy is naturally a concern for clinicians because patients may be at higher risk for ischemic events. In my experience at Fairview Hospital, the Mynx device is the ideal closure methodology for patients such as this. The device does not leave intravascular materials in place that may lead to thrombosis at the site, and patients have the added benefit of a very comfortable closure procedure. Additionally, the Mynx balloon can be filled with a diluted contrast solution (50% contrast/50% saline). This approach allows the operator to visualize the position of the balloon intra-arterially and to confirm it properly abuts the arteriotomy prior to delivery of the sealant. This technique offers a valuable safety benefit in closing challenging cases such as bifurcation sticks.

At present, there remain a few situations in which we do not use the Mynx device. These include existing hematoma or excessive scar tissue at the arteriotomy, high stick in which risk of retroperitoneal bleeding is a concern, severe calcification that could rupture the balloon, and staged procedures in which sheaths have been in place for an extended period.

Admittedly, the St. Vincent study is a single-center, retrospective analysis in which interventional volume accounted for only one-third of cases, and glycoprotein IIb/IIIa inhibitors were used infrequently. However, this early expe-

Figure 2. Left anterior oblique view of femoral artery.

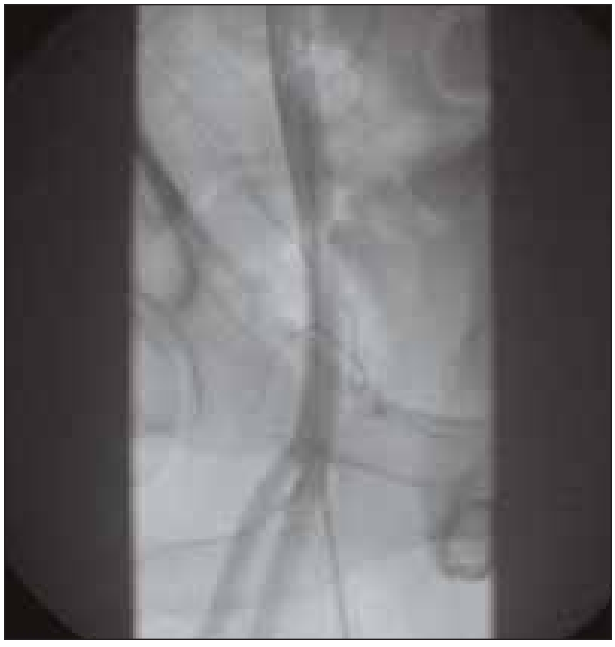

Figure 3. Right anterior oblique view of femoral artery.

rience in predominately diagnostic patients reflects case selection typical during the learning curve of any technology. In fact, the volume of interventional procedures closed with Mynx exceeds that of diagnostic patient closures in some practices. The Mynx experience from both St. Vincent Medical Center and Fairview Hospital reflect the challenges in real-world clinical practice, particularly as related to patients with peripheral vascular disease, diabetes, high BMI, and bifurcation and antegrade puncture. Additional evaluation of the Mynx in challenging patient subsets is warranted to support the growing endorsement from physicians who prefer an extravascular, painless approach to vascular access site management.

WILL EXTRAVASCULAR SEALING BE THE WAY OF THE FUTURE?

Can an extravascular sealant technology really do the job even in highly anticoagulated interventional procedures? The Mynx experience thus far suggests that it can. Early experience indicates that Mynx is effective in achieving immediate and durable hemostasis as evidenced by comparable outcomes in both diagnostic and interventional catheterization procedures. In our experience, Mynx has proven to be a clinically versatile closure technology that is suitable even in procedures in which peripheral disease, obesity, and bifurcation anatomy pose challenges with regard to arteriotomy access and closure. The most appealing features of the Mynx Vascular Closure Device are the complete lack of intraluminal components, the elegant and easily mastered deployment, and the virtual absence of patient discomfort. ■

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