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Why Extravascular Closure?

The Baptist Memorial Hospital Experience with the Mynx® Vascular Closure Device.

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As an alternative to manual compression for achieving hemostasis after coronary catheterization procedures, vascular closure devices (VCDs) have emerged with several advantages—and a few disadvantages—worthy of discussion.

From the physician perspective, closure puts the control of the access site in the hands of the operator. For many physicians, time spent up front to close the arteriotomy and achieve immediate hemostasis provides peace of mind that they will not be called back to inspect a groin or treat access-site complications after they leave the catheterization lab or move on to the next case, especially because research suggests that major bleeding after coronary catheterization (including access-site bleeding requiring reintervention and hematoma ≥ 5 cm) has been linked to increases in mortality, myocardial infarction (MI), revascularization, and stent thrombosis at 30 days postprocedure.[1] From the patient perspective, closure devices enhance comfort because they do not require the sustained pressure on the groin and prolonged bed rest that manual compression does. Lastly, from an economic standpoint, the costs associated with VCDs can be offset by earlier ambulation, which not only translates into improved patient comfort, but also earlier discharge, decreased nursing time, and increased throughput in the catheterization lab.

Study results are mixed as to whether complication rates associated with VCDs are higher, lower, or similar to manual compression,[2-9] even with the use of glycoprotein IIb/IIIa inhibitor therapy.[10] Many current-generation of VCDs incorporate an intravascular component. Complication rates associated with these devices, albeit relatively infrequent, tend to be more serious (eg, ischemic or embolic events or infection) than those associated with manual compression (eg, hematoma, pseudoaneurysm, rebleed).[2,4,11-15] Although manual compression can be uncomfortable, placement of the intravascular components of most VCDs, such as clips, sutures, or plugs, is often painful for the patient.

Recent refinements in closure device design and procedural technique may prove to reduce complications associated with arteriotomy closure devices.[16,17] One closure technology in particular stands out from the current array of VCDs for its absence of intravascular components. The Mynx Vascular Closure Device (Access Closure, Inc., Mountain View, CA) (Figure 1) achieves femoral artery hemostasis via delivery of an extravascular, water-soluble, bio-inert sealant to the arterial surface through the existing 5-, 6-, or 7-F sheath used for the catheterization procedure.[18] The sealant material, a fully resorbable polyethylene glycol hydrogel, expands upon contact with subcutaneous fluids to seal the arteriotomy and is resorbed by the body within 30 days. Thus, no intravascular components are left behind in the vessel that could potentially be a nidus for infection, injure the vessel, or present challenges for repuncture through the same access site. In fact, in a recent ovine study, arterial repuncture through recently placed Mynx closure devices and subsequent reclosure with a second Mynx device was successfully accomplished with no evidence of sealant prolapse into the artery, distal embolization of the sealant following repuncture, groin-site bleeding, or hematoma.[19]

Figure 1. The Mynx Vascular Closure Device (Access Closure, Inc., Mountain View, CA).

This article describes a single-center, single-operator evaluation involving more than 600 patients who underwent Mynx closure after diagnostic or interventional catheterization via the common femoral artery.

THE MYNX CLINICAL EXPERIENCE AT BAPTIST MEMORIAL HOSPITAL

Baptist Memorial Hospital in Memphis, Tennessee, is one of Tennessee's highest-volume hospitals. The Baptist Heart Institute, located within Baptist Memphis, includes

six catheterization labs and two electrophysiology labs performing approximately 7,200 catheterization cases and 1,850 electrophysiology cases per year. After the introduction of the Mynx in our institution (November 2007), we became interested in tracking its performance in a real-world setting.

Consequently, a single-center, retrospective analysis was conducted to evaluate outcomes after diagnostic and interventional catheterization procedures in which the Mynx device was deployed for femoral arteriotomy closure. All Mynx closure procedures performed by a single operator between January and December 2008 were included in the analysis. Among these 666 procedures, 31.4% were interventional catheterizations, 68.4% were diagnostic catheterizations, and procedural sheath sizes were primarily 6 F with an occasional 7- or 8-F case. The primary endpoint of the study was device success defined as successful deployment of the Mynx device and hemostasis achieved without conversion to manual compression (> 10 minutes) or another closure device. Major and minor complications were recorded and analyzed as secondary endpoints.

Baseline patient characteristics (Table 1) show that 46% of patients had previously undergone an ipsilateral femoral access procedure. Other higher-risk populations included documented bleeding disorder (19%) and history of peripheral vascular disease (PVD) (28%).

The Mynx device was successfully deployed in 98.9% (659/666) of patients with a 0.75% rate of major and minor complications. As shown in Table 2, five patients developed a complication before discharge, two of which were classified as major complications and three of which were minor complications. Due to the extravascular design of the Mynx, these complications did not involve more serious concerns such as infection, femoral artery compromise, arterial laceration, uncontrolled bleeding, or occlusion secondary to intravascular device components.

All complications after Mynx deployment were resolved with relative ease. An obese patient with a history of bleeding disorder developed a pseudoaneurysm 1 day after the procedure that did not require treatment. A patient with a history of PVD and an international normalized ratio of 1.5 was administered periprocedural heparin and developed a moderate hematoma at the access site that required 42 minutes of manual compression to achieve hemostasis. Another patient with a history of PVD who received periprocedural heparin and bivalirudin had a small amount of oozing from the access site. When oozing had not resolved after approximately 20 minutes of manual compression, a mechanical compression device was placed over the access site for 2 hours and no further oozing was noted.

TABLE 1. PATIENT AND PROCEDURAL CHARACTERISTICS

Characteristic, n (%)	N = 666
Male	365 (54.8%)
Age (y), mean (SD)	64 (13)
Body mass index	29 ± 6.4
Previous ipsilateral femoral access procedures	308 (46.2%)
Tobacco use < 6 months	144 (21.6%)
Hypertension	526 (79.0%)
Hypercholesterolemia	496 (74.5%)
Diabetes mellitus	207 (31.1%)
History of CVA/TIA	65 (9.8%)
History of congestive heart failure	139 (20.9%)
History of cardiovascular disease	546 (82.0%)
Chronic renal insufficiency	104 (15.6%)
Documented bleeding disorder	129 (19.4%)
History of peripheral vascular disease	186 (27.9%)
Anticoagulation regimen	
Aspirin	8 (1.2%)
Clopidogrel	88 (13.2%)
Heparin	642 (96.4%)
Bivalirudin	197 (29.6%)
Glycoprotein IIb/IIIa inhibitors	4 (0.6%)
International normalized ratio (n = 551), mean (SD)	1.1 (0.13)

Abbreviations: SD, standard deviation; CVA, cerebrovascular accident; TIA, transient ischemic attack.

The two major complications were also promptly resolved with either surgical or percutaneous vessel repair. One patient developed a right femoral artery pseudoaneurysm 3 days after the procedure, which was successfully treated with surgical repair. One other patient with a history of PVD had an occlusion in the proximal superficial femoral artery with a surrounding hematoma (diagnosed by computerized tomography 3 days postprocedure), which was successfully treated with angioplasty and stenting. As evidenced above, our early experience with the Mynx has demonstrated noteworthy success with > 99% of cases free from any complication.

The Mynx device performed equally well in patients undergoing diagnostic (n = 457) and interventional (n = 209) procedures despite 42% of interventional patients receiving clopidogrel (compared with 0% diagnostic patients) and 93% receiving bivalirudin (compared with 0.7% of diagnostic patients); complication rates were comparable between patients with diabetes (n = 207) and patients without diabetes (n = 459) (Table 2).

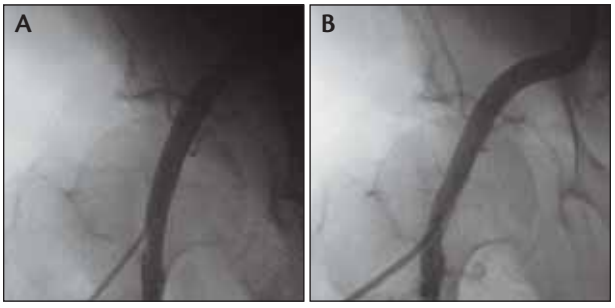

Figure 2. Still-frame common femoral angiogram of a patient with repuncture of an arterial site previously closed with the Mynx device (A). The initial diagnostic catheterization (B). An interventional catheterization performed 4 days later was also closed with the Mynx.

CASE REPORT: REPEAT ARTERIAL PUNCTURE

With Mynx closure, we have experienced success after restick in the vicinity of a previous catheter insertion. An 86-year-old man with a history of coronary artery disease and previous MIs presented to the emergency department and was diagnosed with an acute MI with elevated troponin level (6.8 ng/mL). His numerous comorbid conditions included cardiomyopathy with congestive heart failure, arrhythmias, permanent pacemaker, chronic obstructive pulmonary disease, degenerative joint disease, depression, anxiety, alcohol abuse, and tobacco use.

One day after admission, the patient underwent a diagnostic cardiac catheterization procedure performed via the right common femoral artery through a 6-F procedural sheath. The results demonstrated severe left ventricular systolic dysfunction with an estimated ejection fraction of 15%, near-total stenosis (99%) of the left anterior descending artery (LAD), 70% stenosis of a small ramus, total occlusion of the diagonal branch with collateral filling, and total occlusion of a small distal branch of the right coronary artery. A femoral angiogram was performed to visualize the insertion site, after which the Mynx device was successfully deployed for femoral artery hemostasis.

Four days after the diagnostic catheterization, the patient returned to the catheterization lab for an elective coronary intervention of the LAD. The right femoral artery was reaccessed without difficulty at the location of the previously deployed Mynx device using an 8-F procedural sheath. Ten thousand (10,000) units of heparin were administered, and an activated clotting time of greater than 300 seconds was achieved. The challenging intervention of the severely occluded LAD included rotational atherectomy, balloon angioplasty for predilatation, deployment of a 3- X 33-mm sirolimus-eluting stent, and postdilatation with an angioplasty balloon catheter. The procedure was complicated by an episode of atrial fibrillation that required electrocardioversion. A femoral angiogram was performed before vascular closure, which demonstrated a normal femoral artery with no defects or evidence of the previously closed access site. The Mynx device was deployed without complication for successful hemostasis in an area of repuncture where a Mynx device had been deployed 4 days earlier.

The patient received heparin intermittently during his hospitalization and was then converted to warfarin for short-term therapy and placed on clopidogrel. While on heparin, his platelet count dropped from 200,000 to 117,000 but rebounded to 255,000 before discharge. His creatinine level fluctuated during hospitalization with a low of 1.3 mg/dL to a high of 2.1 mg/dL, dropping to 1.8 mg/dL at the time of discharge.

The Mynx device achieved prompt and durable hemostasis in this complicated case in which a patient with numerous comorbidities presented with an acute MI. This case illustrates a typical arterial repuncture only a short time after the Mynx device deployment. The device was used successfully with the initial arterial access during the diagnostic procedure and with repuncture 4 days later on the ipsilateral side with deployment of a second Mynx after a complex percutaneous coronary intervention procedure. This patient had no groin complications despite being at a higher risk for bleeding with the administration of heparin, warfarin, and clopidogrel postintervention, along with a decreased platelet count and elevated creatinine level. Still-frame angiographic images from each of the two catheterization procedures are shown in Figure 2.

TABLE 2. COMPLICATIONS BEFORE DISCHARGE IN ALL PATIENTS BY TYPE OF PROCEDURE AND DIABETES STATUS

	All Patients (N = 666)	Diagnostic Procedures (n = 457)	Interventional Procedures (n = 209)	Diabetic Patients (n = 207)	Nondiabetic Patients (n = 459)
Device success	659 (98.9%)	452 (98.9%)	205 (98.1%)	205 (99.0%)	454 (98.9%)
Any complication	5 (0.75%)	4 (0.88%)	1 (0.48%)	2 (0.97%)	3 (0.65%)
Major complications	2 (0.3%)	2 (0.44%)	0 (0%)	1 (0.48%)	1 (0.22%)
Minor complications	3 (0.45%)	3 (0.66%)	1 (0.48%)	1 (0.48%)	2 (0.44%)

TECHNIQUES FOR EXTRAVASCULAR CLOSURE

As with any new technology, techniques must be learned, adopted, and refined. In our experience at Baptist Memorial, proficiency in deploying the Mynx device was rapidly attained; within three or four cases the mechanics and technique became clear, and by six to 12 cases, deployment of this novel extravascular technology became routine.

As the Mynx became our frontline closure device, we adapted techniques that helped us become more efficient at the end of the procedure. For example, when I hold mild pressure on the site, I use that time to talk with the patient about procedural findings and results as well as the plan of care. Whether it's interventional or diagnostic, light pressure is applied to allow the return of blood flow and ensure that there is no hematoma development after device removal. When withdrawing the disposable patient drape, which has an adhesive surface attached to the skin around the groin site, holding pressure on the access site while slowly pulling back the adhesive (rather than pulling it off rapidly) eliminates tugging near the access site that might potentially result in hematoma development. Other physicians have reported that their confidence in Mynx closure has allowed them to turn over the closure procedure to technicians. For physicians who prefer to maintain control of the closure procedure, the peace of mind gained from confirming that access-site hemostasis was successfully achieved is one of the primary reasons for using closure devices.

As with any closure device, obtaining a femoral angiogram under fluoroscopy is recommended before closure to visualize the insertion location relative to the patient's femoral anatomy. A unique and valuable aspect of the Mynx device is the ability to prepare the balloon with a diluted contrast solution (50% contrast/50% saline), which allows the physician to visualize the location of the balloon before sealant deployment. This technique is particularly helpful in patients with PVD because it can be difficult to visualize the arteriotomy site during balloon pull-back. The use of this technique can also be helpful in confirming appropriate vessel wall apposition in small vessels and bifurcation stick locations.

EXTRAVASCULAR APPEAL

The appeal of the Mynx device is its extravascular design, which should reduce the chances of serious vascular complications because no foreign material is left behind in the vessel. Furthermore, the absence of hardware in the vessel allows for repuncture at or near the original access site in the short term. Finally, extravascular placement of a resorbable sealant appears to be painless for the patient as compared to closure devices with intravascular components; the majority of patients are unaware that the Mynx sealant has even been deployed.

For physicians who want to see the arteriotomy closed with durable hemostasis and a stable groin site, closure will always be preferable to manual compression. At Baptist Memorial Hospital, the Mynx device has allowed us to achieve these objectives in a painless and efficient manner with low complication rates and high device success. ■

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