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Two Years of Extravascular Closure With the Mynx® Vascular Closure Device

The Baptist Memorial Hospital experience revisited.

BY DAVID WOLFORD, MD, FACC

The incidence of vascular complications after catheterization procedures remains of critical interest because bleeding is the most common noncardiac complication of percutaneous coronary intervention (PCI), and studies show that such complications may compromise longer-term morbidity and mortality.[1,2] Since adoption of the Seldinger technique, manual compression has been considered the gold standard of access site hemostasis. Although the efficacy of closure devices is generally not disputed, early studies show mixed safety results.[3-5] However, during the last decade, clinical studies comparing closure devices to manual compression have demonstrated a shift toward favorable results with closure devices.[6,7]

CLINICAL EVIDENCE SUPPORTING USE OF VASCULAR CLOSURE DEVICES

Recently, reports and trends have emerged showing the benefits of vascular closure devices (VCDs) in reducing the risk of access site bleeding complications favoring the use of closure devices over manual compression.[8,9] In results from the Acute Catheterization and Urgent Intervention Triage Strategy (ACUITY) Trial evaluating the affect of VCDs and antithrombotic therapy on access site bleeding in 11,621 acute coronary syndrome patients, VCD use, bivalirudin monotherapy, or both were shown to minimize rates of major access site bleeding.[8] Although rates of major access site bleeding were lowest in patients treated with bivalirudin monotherapy and VCD use combined, VCD use alone was an independent determinate of freedom from major access site bleeding as compared with no VCD use (2.5% vs 3.3%; relative risk, 0.76).

In a large, multicenter PCI registry (National Cardiovascular Data Registry [NCDR]) evaluating the use of VCDs and bivalirudin in 1.5 million patients,

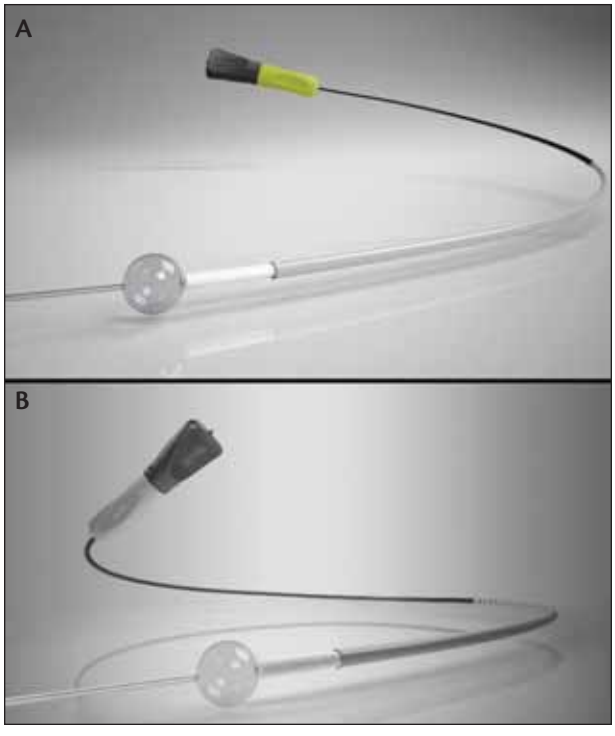

Figure 1. The Mynx® Vascular Closure Device. 6/7F Mynx Vascular Closure Device (A); Mynx M5 Vascular Closure Device (B).

Marso and colleagues showed significantly lower bleeding rates, particularly among patients at greatest risk for bleeding.[9] Among high-risk patients, VCD use plus bivalirudin was associated with an absolute 3.8% lower rate of bleeding.

There are a number of VCD options on the market today, but Mynx is the device of choice in our lab due to low complication and high device success rates. In a 2009 report, the initial clinical experience from proce-

"Cumulative results in 1,207 patients show favorable outcomes, including consistently achieved hemostasis (98.4%) and a low rate of complications (0.5%)."

dures performed at Baptist Memorial Hospital (Memphis, TN) with the Mynx Vascular Closure Device (AccessClosure, Inc., Mountain View, CA) was presented in *Endovascular Today*.[10] Outcomes after Mynx closure in 666 diagnostic or interventional coronary catheterization patients were favorable, and as a result, use of the Mynx device, with its extravascular approach to closure, predominates in my lab.

Other important clinical reports have been published supporting the use of Mynx.[11-13] Most recently, Noor and colleagues outlined a retrospective review of surgeries performed to repair vascular access site complications of 6- and 7-F femoral cardiac and peripheral catheterizations at a single hospital.[14] The surgery rates among three closure methods (Mynx, Angio-Seal [St. Jude Medical, Inc., St. Paul, MN], and manual/mechanical compression) over a 2-year period were compared. Of 11,006 catheterization procedures, 26 (0.24%) surgeries were performed secondary to access site complications: 14 (0.61%) in Angio-Seal patients, 10 (0.19%) in manual/mechanical compression patients, and 2 (0.06%) in Mynx patients ($P < .0001$ vs Angio-Seal; $P = .14$ vs compression). The Mynx device achieved a significant reduction in surgeries secondary to arterial access site complications compared to Angio-Seal and equivalent complications compared to manual compression.

Clinical studies about closure devices advance the understanding of their safety and effectiveness and identify the need for continued surveillance of these technologies in specific patient populations. This article expands on the previous single-center, single-operator evaluation and details new results from 2009 while highlighting the cumulative experience in more than 1,200 patients in whom the Mynx device has been used since introduction at Baptist Memorial Hospital.

CUMULATIVE RESULTS IN 1,207 PATIENTS AT BAPTIST MEMORIAL HOSPITAL

The Mynx device (Figure 1) is distinct in its extravascular approach to closure achieved through delivery of a water-soluble sealant in an easy-to-perform procedure that is quite comfortable for patients. Once positioned at the arteriotomy surface, the bioinert polyethylene glycol hydrogel sealant expands on contact with subcutaneous fluids to seal the arteriotomy and is fully resorbed by the body within 30 days.[11] Achieving hemostasis without leaving something behind has long been included in descriptions of the ideal closure device. This characteristic coupled with its placement on the exterior surface of the artery make the Mynx an attractive option.

In the current, retrospective study evaluating outcomes with the Mynx device, a total of 541 Mynx closures were performed from January 1, 2009 through December 31, 2009. The majority of procedures performed were after diagnostic cases; however, more than 30% of PCI patients underwent Mynx closure performed primarily through a 6-F procedural sheath. A large number of patients (56%) had previously undergone an ipsilateral femoral access procedure. Other higher-risk populations included hypertension (85.0%), hypercholesterolemia (83.2%), diabetes mellitus (35.5%), documented bleeding disorder (25.5%), renal insufficiency (15.9%), and peripheral vascular disease (PVD) (28.1%). The majority of patients had more than two comorbid conditions. The baseline patient characteristics for the combined 2-year experience are included in Table 1. In regard to periprocedural anticoagulation regimens, 30.3% of patients received bivalirudin, and 13.2% of patients received clopidogrel. A small percentage of patients (0.6%) also received glycoprotein IIb/IIIa platelet inhibitors.

Endpoints of the study included device success and access site-related complications. Device success was defined as successful deployment of the Mynx device and hemostasis achieved without conversion to manual compression (requiring > 10 minutes) or another closure device. All in-hospital complications (major and minor) were recorded. (Table 2).

The Mynx device was successfully deployed and achieved hemostasis in 98.2% of procedures. One major (0.2%) vascular access site complication occurred in a patient with a history of significant PVD and multiple additional comorbidities who experienced leg pain after deployment. Severe iliac, superficial femoral, and common femoral artery disease was revealed during surgical intervention. Thrombectomy was performed successfully without further complications. No minor complications occurred in the study.

Outcomes with the Mynx during 2008 and 2009 were comparable (98.9% device success, 0.75% rate of combined major and minor complications for 2008; 98.2% device success, 0.2% rate of combined major

and minor complications for 2009). Table 2 presents the cumulative rates of major and minor vascular access site complications occurring in all study patients and classified by diagnostic or PCI procedure. The Mynx device performed equally well in diagnostic and interventional procedures (0.6% vs 0.3% rate of any complication, respectively).

OPTIMIZING CLOSURE FOR DIAGNOSTIC CATHETERIZATION PATIENTS

Cumulative results from 2 years of experience with the Mynx device in more than 1,200 patients provide evidence supporting observational impressions that the Mynx device performs exceptionally well in routine, real-world use. In this experience, the Mynx device was used primarily in diagnostic cases, which comprise approximately 70% of my total patient volume. Although the Mynx device is a valuable resource for interventional patients, it is particularly well-suited for use in patients undergoing diagnostic procedures.

Debate remains about the importance of anchoring closure devices to the arterial wall, which has been suggested to improve the durability of hemostasis.[15] Presumably, the necessity for anchoring fixtures to the arterial wall is decreased in diagnostic procedures. These patients are less likely to receive aggressive anticoagulation protocols and therefore are at a lower risk for bleeding complications. My experience with the Mynx has not exposed decreased safety and efficacy due to the absence of an anchoring fixture. Access site complications in patients with normal coronary catheterization findings are particularly onerous, and it makes sense to avoid placement of intra-arterial components when another option is available.

Secondary to safety but of great importance is the issue of patient comfort. Generally, VCDs have been shown to enhance patient comfort,[16-19] and based on my experience, the Mynx device by design provides the best patient comfort profile of all available options. By virtue of the extravascular positioning of the Mynx sealant, there is no undue exertion on the innervated arterial wall. In fact, proper technique requires extremely gentle maneuvers that comparatively decrease push and pull forces exerted on the arterial wall. Additionally, sheath exchange is not required with the Mynx procedure, eliminating the associated discomfort with this step. In combination, the lack of anchoring and gentle procedural technique account for the highly positive patient comfort profile of this device.

For diagnostic procedures performed at Baptist Memorial Hospital, the Mynx device has proven to be the best option as shown by the clinical experience

TABLE 1. PATIENT AND PROCEDURAL CHARACTERISTICS

Patient Characteristics, n (%)	**2-Year Experience N = 1,207**
Male	659 (54.6%)
Age (y), mean ± SD	65 ± 13
Body mass index	30 ± 6.5
Previous ipsilateral femoral access procedures	611 (50.1%)
Recent tobacco use (< 6 months)	263 (21.8%)
Hypertension	986 (81.7%)
Hypercholesterolemia	946 (78.4%)
Diabetes mellitus	399 (33.1%)
History of CVA/TIA	148 (12.3%)
History of congestive heart failure	281 (23.3%)
History of cardiovascular disease	1047 (86.7%)
Chronic renal insufficiency	190 (15.7%)
Documented bleeding disorder	267 (22.1%)
History of peripheral vascular disease	338 (28%)
Procedural Characteristic, n (%)	**N = 1,207**
Interventional procedure	375 (31.1%)
Sheath Size	
6 F	1,188 (98.4%)
7 F	4 (0.3%)
8 F	7 (1%)
Anticoagulation Regimen	
Aspirin	20 (1.7%)
Clopidogrel	159 (13.2%)
Bivalirudin	366 (30.3%)
Glycoprotein IIb/IIIa inhibitors	7 (1.0%)
International normalized ratio (n = 1,030), mean ± SD	1.1 ± 0.16
Systolic BP (mm Hg), mean ± SD	131 ± 22

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

TABLE 2. COMPLICATIONS BEFORE DISCHARGE BY TYPE OF PROCEDURE (2-YEAR EXPERIENCE)

	All Patients (N = 1,207)	Diagnostic Procedures (N = 832)	Interventional Procedures (N = 375)
Device success, n (%)	1188 (98.4%)	817 (98.2%)	371 (98.9%)
Major complications	3 (0.3%)	3 (0.4%)	0 (0%)
Surgical/vascular repair	3 (0.3%)	3 (0.4%)	0 (0%)
Transfusion	0 (0%)	0 (0%)	0 (0%)
Access site-related nerve injury	0 (0%)	0 (0%)	0 (0%)
Ipsilateral ischemia	0 (0%)	0 (0%)	0 (0%)
Infection requiring hospitalization/IV antibiotics	0 (0%)	0 (0%)	0 (0%)
Minor complications	3 (0.3%)	2 (0.2%)	1 (0.3%)
Hematoma ≥ 6 cm	0 (0%)	0 (0%)	0 (0%)
PSA not requiring treatment	1 (< 0.1%)	1 (0.1%)	0 (0%)
PSA treated with thrombin	0 (0%)	0 (0%)	0 (0%)
AV fistula	0 (0%)	0 (0%)	0 (0%)
Bleed requiring >30 minutes of MC	2 (0.1%)	1 (0.1%)	1 (0.3%)
Ipsilateral DVT	0 (0%)	0 (0%)	0 (0%)
Transient access site nerve injury	0 (0%)	0 (0%)	0 (0%)
Local infection requiring oral antibiotics	0 (0%)	0 (0%)	0 (0%)
Any complication	6 (0.5%)	5 (0.6%)	1 (0.3%)

Abbreviations: IV, intravenous; PSA, pseudoaneurysm; AV, arteriovenous; MC, manual compression; DVT, deep vein thrombosis.

and outcomes with this extravascular closure approach in 817 diagnostic procedure patients studied during the last 2 years, and the consistently positive reception by patients regarding comfort.

CLINICAL VERSATILITY WITH THE MYNX DEVICE

The Mynx device is used in approximately 95% of all my cases with exceptions including procedures requiring larger sheath sizes (> 7 F) or significant peripheral vascular disease in the vicinity of the sheath insertion site, where use of any VCD is not preferred. Interventionists are accustomed to the challenges posed by anatomical variations and patient and procedural complexities. Several features of the Mynx device lend to increased versatility in managing some of these clinical complexities, which are worthy of notation.

The technique for positioning the Mynx device at the arteriotomy is easily performed based on tactile feedback during withdrawal of the localization balloon at the distal end of the device. However, in situations where the puncture site is located at or near the common femoral artery bifurcation, or where proximal disease may inhibit correct positioning of the arteriotomy localization balloon, visualizing the contrast-filled balloon (50:50 solution normal saline and contrast medium) using fluoroscopy guides the operator and ensures precise positioning of the sealant at the arteriotomy.[20] This technique is not employed in most procedures, but in the patients previously identified (common femoral artery bifurcation and proximal disease), it is clearly advantageous and unique to the Mynx device.

> "With other closure devices, closing the leg was painful for every patient. With the Mynx, there is no sensation at all to the patient."

Venous closure with the Mynx device, although not routine, is important in specific situations (eg, electrophysiology [EP], right heart catheterization procedures) when access site hemostasis is more challenging due to anticoagulation or coagulopathies. For example, achieving hemostasis with the Mynx device has been highly effective in anticoagulated EP patients with 7- or 8-F venous sheaths in place. Use of the Mynx device in venous closure is not currently an approved indication; however, I have not observed any problems associated with use of the device in these patients, and they in turn benefit from ambulating sooner than with manual compression.

We have expanded on our initial success with the Mynx device in interventional cases for patients who require use of glycoprotein IIb/IIIa platelet inhibitors during coronary intervention. Generally, closure devices (including the Mynx) have not been studied in patients receiving IIb/IIIa platelet inhibitors. To help mitigate that potential risk, our protocol now includes a bolus instead of a drip, administered at the beginning of the procedure, and clopidogrel is given at the end of the procedure. There have been no instances of access site bleeding after interventions using this protocol.

INFLUENCE ON COST-EFFECTIVENESS AND PATIENT SATISFACTION

Published literature suggests that costs associated with VCD use can be offset by earlier ambulation, which translates into earlier discharge, decreased nursing time, and increased throughput in the catheterization lab, as well as improved patient comfort.[16,21] Hospital administration, however, often takes a narrower view of cost, in which the per-unit cost of closure devices is compared with the cost of manual compression. But manual compression is not, in fact, free. Costs for compression devices (FemoStop [St. Jude Medical], CompressAR [Advanced Vascular Dynamics, Portland, OR]), external patches with prothrombotic coatings, sedation, nursing time for sheath removal, and patient monitoring during the 4 to 8 hours of bed rest must all be tabulated to accurately reflect overall costs. Additionally, the attention required for diagnostic patients studied late in the day commonly results in significant overtime expenses. From an economic standpoint, in high-volume institutions with bed shortages, the need to expeditiously achieve hemostasis and ambulate and discharge patients is of great importance because a full recovery room compromises catheterization lab throughput.

In addition to the concrete costs associated with recovery after catheterization, patient satisfaction has an economic impact, especially when patients have a choice in selecting where they will have their procedures. Multiple factors influence patient decisions. For many patients, prolonged bed rest is prohibitive for a variety of reasons (eg, back pain, chronic obstructive pulmonary disease, inability to cooperate), and all patients prefer bathroom privileges over the alternative of Foley catheterization. Additionally, the prolonged hospital stay is often difficult for family members who take time away from work to be with the patient and provide postdischarge transportation. Like many physicians, I see patients at more than one hospital. When given the choice of having a closure device allowing expedited recovery versus manual compression with protracted bed rest, all patients preferred treatment at the hospital offering a closure device. Patient choice has a direct impact on the hospital's bottom line.

> "We see fewer complications with closure devices. With Mynx, extravascular is advantageous. You don't like to leave anything intravascular."

THE CASE FOR EXTRAVASCULAR CLOSURE

Studies citing significantly lower bleeding rates and favorable outcomes with respect to vascular access site complications in patients treated with a VCD compared to manual compression are the subject of numerous contemporary publications.[1,2] Many physicians who have come to rely on closure devices as the result of personal clinical experience showing improved outcomes and quality of care with enhanced patient throughput. Current studies provide the evidence-based foundation for these perspectives.

After broad experience with all the primary closure devices on the market, I have concluded that the Mynx device offers distinct advantages beyond the others. The Mynx device meets the requirements for arteriotomy closure in most of my patients, resulting in near-universal use of the device in my practice. A device with an extravascular approach is particularly well-suited to diagnostic catheterization patients in whom coagulation is relatively uncompromised, and intra-arterial components can add additional risk. The Mynx device is a valuable resource in interventional patients as well. In addition, clinical versatility derived from an extravascular approach presents the possibility of expanding use in patients previously considered to be relative contraindications (eg, PVD, sheath inser-

tion site at the bifurcation). Finally, as I have observed, patient pain during arteriotomy closure is not trivial, and the Mynx device is preferred because of its comfort profile.

Outcomes from the current analysis of patients studied at Baptist Memorial Hospital are consistent with the earlier analysis published in 2009. Cumulative results in 1,207 patients show favorable outcomes, including consistently achieved hemostasis (98.4%) and a low rate of complications (0.5%). The consistent high rates of safety and device and procedural success from 2 years of use, along with patient satisfaction, provide evidence supporting continued usage of the Mynx device. ■

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