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The MYNX ACE® Vascular Closure Device

Early experience demonstrates reliability and patient comfort.

BY RAJESH M. DAVE, MD, FACC, FSCAI

With 100% clinical success during a prospective evaluation of early user experiences involving 206 cases performed in five United States hospitals, the next-generation MYNX ACE® Vascular Closure Device (VCD) (AccessClosure, Inc., a Cardinal Health Company) (Figure 1) demonstrated strong potential as a safe and reliable closure device (Table 1). In addition, the new device displayed the benefits of versatility and patient satisfaction in a diverse and challenging patient population.

IMPROVING THE GOLD STANDARD

Manual compression has long been considered the gold standard in achieving hemostasis of an arteriotomy site. It is limited, however, by the need to interrupt anticoagulation, prolonged bed rest, patient discomfort, and time demands for health care providers. In addition, a complication rate of up to 6% has been reported.[1] Considering that approximately 7 million invasive endovascular procedures are performed annually worldwide (a number that is expected to increase with the aging population and epidemic of chronic disease[2]), VCDs have been developed to decrease vascular complications, reduce the time to hemostasis and ambulation, and, consequently, reduced health care–related costs.[3-5] The MYNX® family of VCDs (Cardinal Health, formerly AccessClosure) are secure extravascular devices that use a water-soluble sealant to create an immediate tissue-like seal at the arteriotomy site. In addition to a more rapid time to hemostasis and ambulation, the complication rate is low because the technology does not require the use of sutures, collagen plugs, or metallic clips, which may cause intravascular complications.[6-8] Due to the gentle delivery of the biodegradable sealant, the Mynx devices have shown improved patient comfort, an important benefit given the growing focus on patient satisfaction.[9]

This article describes the early experience with the Mynx Ace VCD for hemostatic closure in patients who underwent a diagnostic or an interventional procedure.

Figure 1. The Mynx Ace VCD.

TABLE 1. CLINICAL AND DEVICE RESULTS

	N = 206
Clinical success[a]	100 (206/206)
Device success[b]	98.1 (202/206)

Note. Results are % (n/N).
[a]Clinical success defined as lack of major/minor complications.
[b]Device success defined as hemostasis achieved.

MYNX ACE VASCULAR CLOSURE DEVICE

The Mynx Ace device uses a dual-action GRIP™ sealant composed of polyethylene glycol (PEG) to provide secure extravascular closure. Upon deployment, the human body temperature and pH level cause the Grip sealant to soften and interlock with the contours of the vessel wall, forming a secure seal (Figure 2). The sealant also contains a porous structure that absorbs blood and subcutaneous fluids. In doing so, the sealant fills the tissue tract by expanding three to four times its initial size. The Grip sealant is nonthrombogenic, biocompatible, and dissolves within 30 days, leaving no remnant.

The novelty of the Mynx Ace device is a simple deployment system that minimizes operator variability,

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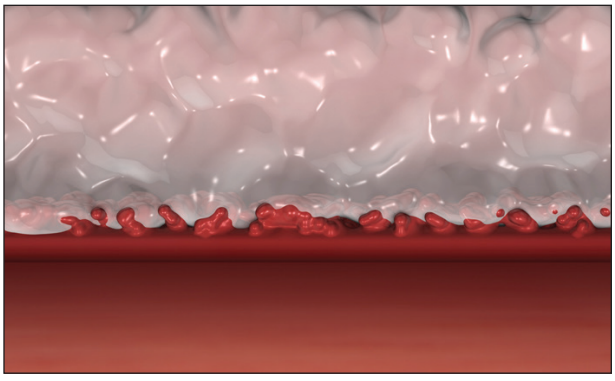

Figure 2. The Grip technology sealant.

including sealant positioning at the arteriotomy. The deployment of the sealant occurs after the balloon is positioned at the arteriotomy site, providing consistent extravascular placement of the sealant. After the completion of the diagnostic angiography or percutaneous procedure, vascular closure is achieved following a simple three-step process (Figure 3):

A. After insertion, the 6-mm semicompliant balloon is inflated and pulled back to the arteriotomy creating temporary hemostasis.

B. The sealant is delivered and compressed a fixed distance onto the extravascular arteriotomy site, where it interlocks with the surface of the vessel wall and expands to fill the tissue tract.

C. The balloon is deflated, and the device is removed.

The Mynx Ace device includes safety features such as locking mechanisms that prevent users from unintentional sealant deployment and completing steps out of order. These safeguards, coupled with the easy deployment, help lessen the learning curve for new users.

Because there is minimal operator dependence on placing the sealant or the amount of compression applied during the sealant deployment, the Mynx Ace device provides the same, if not better, safety and efficacy in achieving hemostasis as the previous generations of Mynx closure devices. Whether a diagnostic or interventional case, ambulation is possible about 2 hours after deployment of the sealant.

EARLY CLINICAL EXPERIENCE WITH MYNX ACE

This early user evaluation involved 206 cases performed in five United States hospitals (21 operators) in which the majority of patients underwent interventional catheterization procedures. Patients were male in 57% of cases, the body mass index was 30.5 ± 6.0, and 70% had a previous catheterization procedure. The majority of procedures used a 6-F (63%) or 7-F (21%) sheath, 34% had peripheral vascular disease (PVD) in

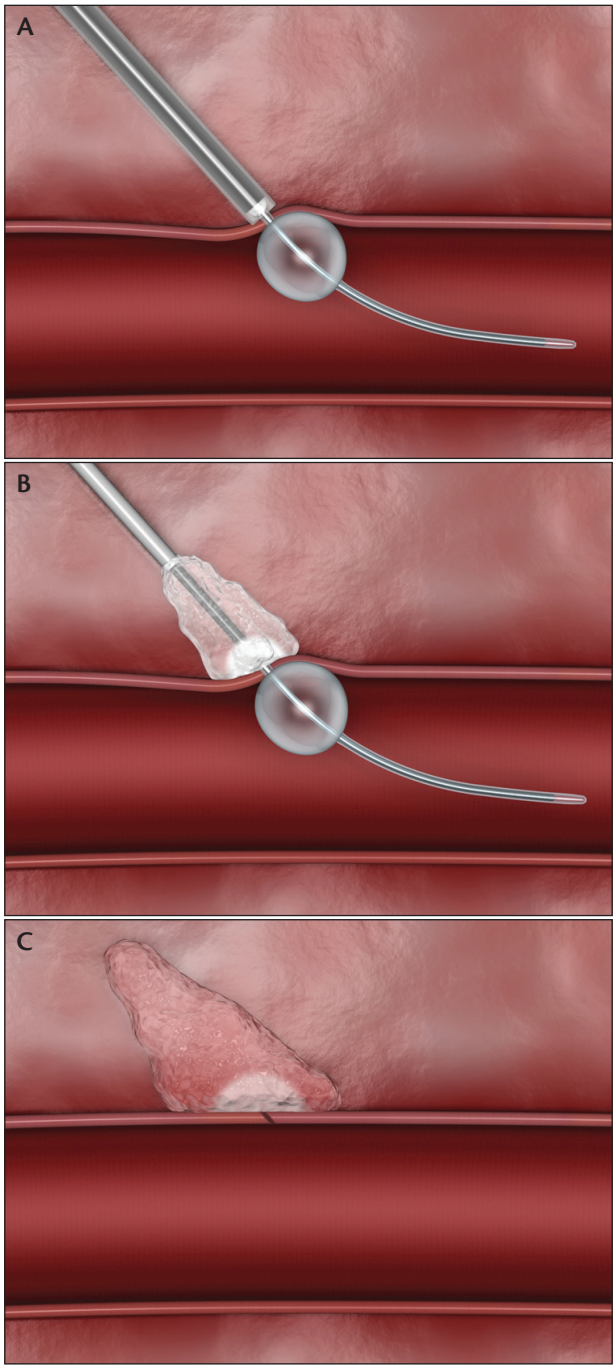

Figure 3. The three-step closure process: position (A), place sealant (B), remove the device (C).

the vicinity, and 21% had a puncture location outside of the common femoral artery (14%, superficial femoral artery; 6%, bifurcation; 1%, profunda). Patient baseline characteristics are presented in Table 2, and procedural data are presented in Table 3.

The clinical success, defined as lack of major or minor complications, was 100%. The device success, defined as

TABLE 2. BASELINE CHARACTERISTICS OF PATIENTS	
	N = 206
Male gender (%)	57 (116/204)
Body mass index (mean ± SD) (n = 107)	30.5 ± 6.0
Previous catheterization (%)	70 (128/184)
PVD or calcium at access site (%)	34 (69/203)

Abbreviations: PVD, peripheral vascular disease; SD, standard deviation.
Note: Results are % (n/N).
The denominators reflect the number of data points available for each endpoint.

TABLE 3. PROCEDURAL CHARACTERISTICS	
	N = 206
Interventional cases (%)	58 (115/198)
Diagnostic cases (%)	42 (83/198)
Vessel size, mm (mean ± SD) (n = 104)	7.0 ± 1.0
Ipsilateral venous sheaths (%)	8 (16/205)
Sheath size[a] (%)	
5 F	17 (34/200)
6 F	63 (125/200)
7 F	21 (41/200)
Puncture location	
Bifurcation (%)	6
Common femoral artery (%)	79
Profunda (%)	1
Superficial femoral artery (%)	14
Anticoagulation	
Aspirin	147
Bivalirudin	22
Clopidogrel	69
Heparin	73
Other[b]	30

[a]42% (85/200) sheath exchanges were reported.
[b]Includes ticagrelor (14), warfarin (8), prasugrel (7) and low-molecular-weight heparin (1).

the achievement of hemostasis, was 98.1% due to three cases of balloon loss of pressure and one case of inability to advance the introducer, which were resolved with manual compression. Results are presented in Table 1.

DISCUSSION

The main results of the 206-patient prospective evaluation, namely 100% clinical success and 98.1% device success, are highly encouraging, considering this challenging patient population (eg, obese patients, calcification in the vicinity of the puncture location, previous catheterization). The three cases of balloon loss of pressure occurred in patients with PVD in the vicinity, and all three had previous catheterizations. The case involving the inability to advance the introducer also occurred in a patient who had a previous catheterization. These positive clinical outcomes demonstrate the potential for improved outcomes with the simplified design of the Mynx Ace device compared to the original Mynx device, which showed a higher rate of

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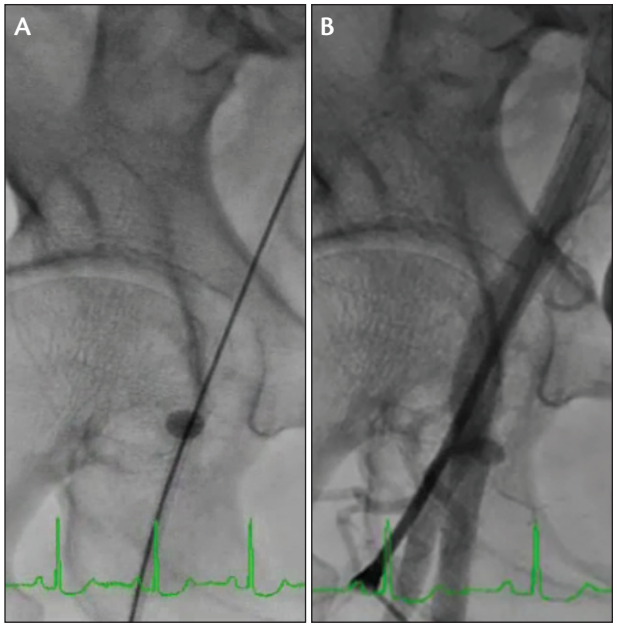

Figure 4. Use of 50/50 contrast to visualize the Mynx balloon at the bifurcation.

major (2.1%) and minor (9.2%) complications in a 2010 study.[10]

Of particular note is the high rate of punctures at or below the bifurcation (21%), which can be challenging cases for vascular closure. One explanation for this high rate might be that approximately 45% of femoral arteries have high bifurcations (above the inferior border of the femoral head).[11] The Mynx Ace balloon can be inflated with 50/50 contrast allowing for visualization of the balloon in order to confirm proper balloon positioning at the arteriotomy to close cases at or below the bifurcation (Figure 4). This feature greatly increases the versatility of the device relative to other closure devices.

The early user evaluation also included a questionnaire aimed at evaluating the operators' and patients' satisfaction with the device. The questionnaire revealed that all operators rated the Mynx Ace device as reliable, easy to use, and providing of consistent results. It is also noteworthy that in 94% of cases, operators viewed the Mynx Ace device as less painful than other VCDs, including Angio-Seal (St. Jude Medical, Inc.), Perclose (Abbott Vascular), and StarClose (Abbott Vascular). Ninety-four percent of patients did not complain about pain during closure, therefore corroborating this view, as shown in Table 4. The lack of complaints regarding pain may be due to the Mynx Ace device's mechanism of deployment. The sealant is delivered with minimal tension on the vessel using a soft, semicompliant balloon as opposed to a suture, footplate, or metallic clip. These results are consistent with previous Mynx generations that showed improved patient comfort of the Mynx device compared to Angio-Seal.[9] With Medicare reimbursements being linked to patient satisfaction and surveys completed by patients, comfort is an important aspect of the patient experience.

VCDs have been used routinely for the past decade, but the advantages of the new Mynx Ace device are threefold: (1) the security and safety of the extravascular, 100% bioresorbable sealant; (2) the consistency of the new, easy to use delivery system; and (3) the added advantages of versatility and patient comfort. All these improvements in device technology lead to low procedural complications and overall periprocedural patient comfort.

CONCLUSIONS

In the current era of health care reform, decision makers and stakeholders have to carefully consider the costs and benefits of alternative therapies for managing a population that is increasingly older and has a growing prevalence of complex chronic conditions. The results presented herein demonstrate that the consistent use of the Mynx Ace VCD in contemporary clinical practice can lead to a reduced rate of periprocedural complications and overall patient satisfaction.

CASE STUDY

An 82-year-old man with a history of carotid artery disease, carotid artery stenting, hypertension, and hyperlipidemia was admitted for congestive heart failure symptoms and critical aortic stenosis. He underwent a cardiac catheterization procedure for evaluation of transcatheter aortic valve replacement. After the catheterization procedure, femoral angiography was

TABLE 4. USER FEEDBACK

	No	Yes	Unsure
Did the patient complain about pain during closure?	94%	6%	0%
Do you think Mynx Ace is less painful than other vascular closure devices?	3%	94%	3%

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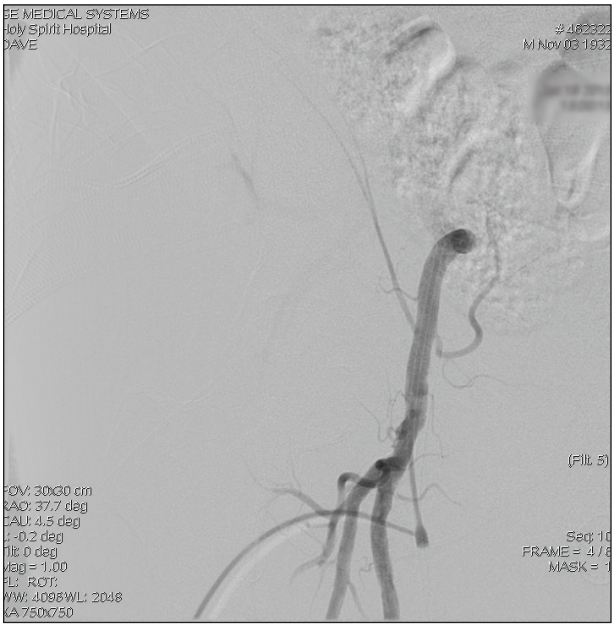

Figure 5. Femoral angiogram before closure with the Mynx Ace device.

performed (Figure 5). The patient had evidence of PAD in his common femoral artery. It was believed that the patient would benefit from an active closure device, which is extravascular. The Mynx Ace device was used for successful closure of the right femoral artery. The patient had excellent hemostasis after closure, ambulated in 1 hour, and was discharged for future aortic valve replacement. ■

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Early User Evaluation Participating Sites: Butler Memorial Hospital, Butler, Pennsylvania; Coastal Vascular Interventional Center, Pensacola, Florida; Gulfport Memorial Hospital, Gulfport, Mississippi; Holy Spirit Hospital, Camp Hill, Pennsylvania; Missouri Baptist Medical Center, St. Louis, Missouri.

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