CLOSURE

The MYNX® VCD Platform: A New Approach to Vascular Closure

Preclinical and clinical data supporting the safety and utility of the MYNX® and MYNXGRIP® vascular closure devices.

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Portions of this article have been previously published by Hoang Minh Thai, MD, FACC, FSCAI, and Barry S. Weinstock, MD, in Endovascular Today *(Thai HM, Weinstock BS. The MynxGrip™ vascular closure device. Endovasc Today. 2012;11(4):28–33).*

Percutaneous femoral vascular closure devices (VCDs) have been in existence since 1995, with the aim of reducing bleeding and access-site complications and improving hemostasis and ambulation times. Since their first introduction, VCDs have been rapidly integrated into clinical practice to improve not only patient satisfaction but also patient turnover.

The MYNXGRIP® VCD (Cordis, a Cardinal Health company) consists of a catheter with a 6-mm balloon at its tip. The device delivers a sealant on top of the femoral vessel through the existing procedural sheath.The dry polyethylene glycol (PEG) sealant is delivered at an extravascular position above the arteriotomy or venotomy site and over the shaft of the catheter using the prescribed delivery procedure (Figure 1). Blood and subcutaneous fluid immediately fill the porous structure of the sealant, causing it to expand two to three times its dry diameter. This provides a conforming, tissue-like seal over the femoral vessel and within the distal portion of the tissue tract.

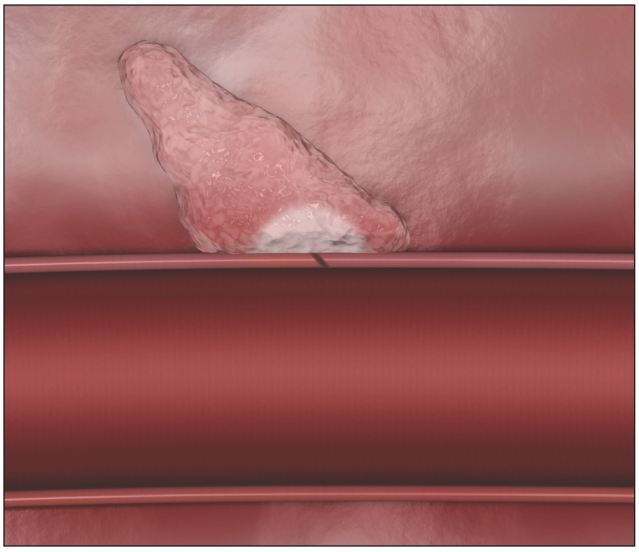

Figure 1. The MYNX® sealant expands and fills the tissue tract, while at the tissue tract simultaneously contracts inward.

Several design features serve to minimize closure-related complications. Placement of the balloon inside the femoral vessel creates temporary hemostasis during deployment and provides the operator with tactile feedback that the sealant is properly placed. Further, as the sealant swells upon contact with blood, it immediately loses column strength and spreads horizontally, thereby mitigating the risk of intravascular deployment. The soft, sponge-like form of the sealant conforms to the shape of the femoral vessel tract and is subsequently compressed by the surrounding tissue.

THE MYNXGRIP® SEALANT

The original MYNX® VCD sealant was a passive closure solution that was designed to produce femoral artery hemostasis via extravascular delivery of a conformable water-soluble sealant over the arteriotomy site. When deployed, the in situ expanded sealant was 5% PEG and 95% blood and tissue tract fluids. PEG is a commonly used bioinert polymer material used for a range of medicinal applications with an established safety profile.[1,2] Compared to traditional collagen sealants, PEG differs in several ways. It is a synthetic sealant rather than a bioactive thrombogenic agent, has a less fibrous consistency than collagen, and resorbs by hydrolysis. Also, the biocompatible nature of PEG allows the sealant to reside in the body without initiating excessive platelet activation or abnormal inflammatory response or generating fibrous scar tissue.[3]

The MYNXGRIP® sealant provides the added advantage of active closure while maintaining all of the advantages of the original MYNX® sealant. The MYNXGRIP® sealant was developed by fusing the new proprietary Grip Tip

technology to the distal end of the original MYNX® sealant (Figure 2A). With the original MYNX® sealant, the PEG components were cross-linked during the manufacturing process. The cross-linked mixture was then freeze dried, creating a porous structure that absorbed blood and subcutaneous fluids. This absorption expands the sealant two to three times the original size filling the tissue tract.

In the Grip Tip segment, the PEG components are combined and manufactured without cross-linking. Once deployed inside the body, the components react and cross-link in response to the physiological pH level and temperature. This causes the Grip Tip to soften and interlock with the contours of the vessel wall (Figure 2B), which anchors the sealant to the vascular wall. The result is a sealant that actively grips to the vessel while expanding and filling the tissue tract to provide durable hemostasis (Figure 3). MYNXGRIP® received FDA and CE Mark approvals in 2011.

PRECLINICAL TESTING

MYNXGRIP® was evaluated by Thai et al, who conducted a femoral artery closure study in porcine models, with angiographic follow-up, ultrasound, and assessment of tissue responses and bioabsorption profiles at the arteriotomy site.[4] In this study, 11 pigs (12 arteriotomies) underwent femoral catheterization (6-F sheath) followed by vascular closure using the MYNXGRIP® VCD. Successful hemostasis in all 12 arteriotomies was verified by clinical assessment, postclosure transcarotid angiography, and transcutaneous ultrasound. Serial angiographic images during and after the index procedure and at 28-day follow-up showed smooth vessel wall contours. In addition, a smooth flow profile was demonstrated on ultrasound, and clinical assessment confirmed the absence of bleeding, bruits, or thrills. The histopathological response at the puncture site and absorption patterns of the MYNXGRIP® sealant were also assessed. At 3 days postclosure, the puncture site showed a fibrinocellular cap filling the arterial wall breach with masses of sealant in the extravascular space, as well as perivascular blood. At higher magnification, neutrophilic infiltration at the arteriotomy site is evident, with beginning fibroplasia indicating initiation of the wound-healing process. At 28 days, the previous arterial wall breach was closed, with evidence of focal fibrous healing, patchy areas of fibrous scarring, and minimal scars in the adventitia. The cell types are lymphoplasmacytic, indicating normal wound healing. The authors concluded that the absence of sealant material and the presence of granulomatous inflammatory infiltrate indicate complete absorption of the sealant after 28 days and demonstrate that the tissue reactions are consistent with the normal wound-healing process.[4]

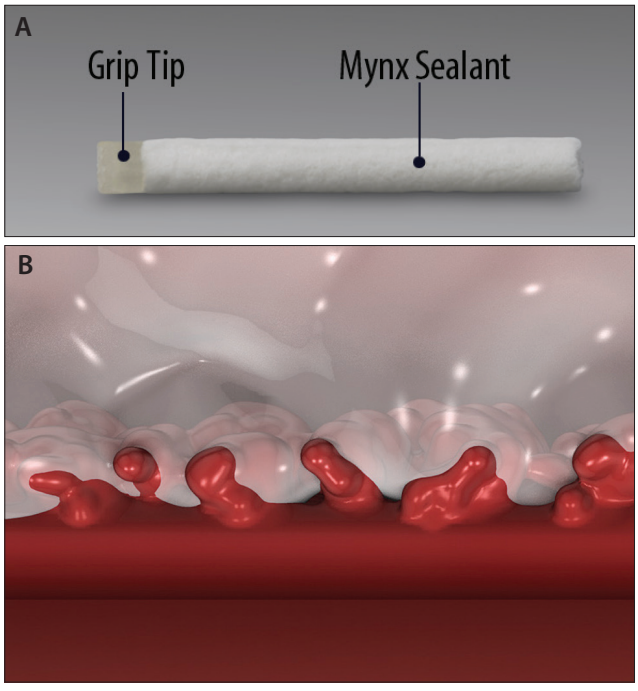

Figure 2. The MYNXGRIP® sealant technology (A). Grip Tip technology (white) interlocking with vessel wall tissues (red) (B). Reprinted from Thai HM, Weinstock BS. The MynxGrip vascular closure device. Endovasc Today. 2012;11(4):28–33.

Srivatsa et al conducted a similar study assessing the safety, effectiveness, and bioresorption profile of the MYNXGRIP® sealant after femoral vein closure. In this porcine study, 10 femoral veins underwent catheterization with 7-F sheaths and were subsequently closed with the MYNXGRIP® VCD. Acute (postclosure), 3-day, and 30-day venography and vascular ultrasound were used to assess outcomes. The authors concluded that the extracellular bioresorbable MYNXGRIP® sealant achieved effective venous closure and preserved long-term vessel patency without venous thromboembolism.[3]

CONTEMPORARY CLINICAL EVIDENCE FOR MYNX®/MYNXGRIP®

The safety and effectiveness of the MYNX® and MYNXGRIP® VCDs have been demonstrated in femoral artery closure after coronary procedures, antegrade approaches to peripheral artery disease (PAD), and femoral vein closures. Baker et al evaluated the prevalence of complications and failure rates of the MYNX® VCD and the Angio-Seal™ VCD (Terumo Interventional Systems) in a retrospective analysis of patients (all-comers) undergoing coronary procedures at a tertiary care center in the United States.[5] A total of 4,074 patients who underwent femoral artery closure between 2008 and 2014 were studied. There

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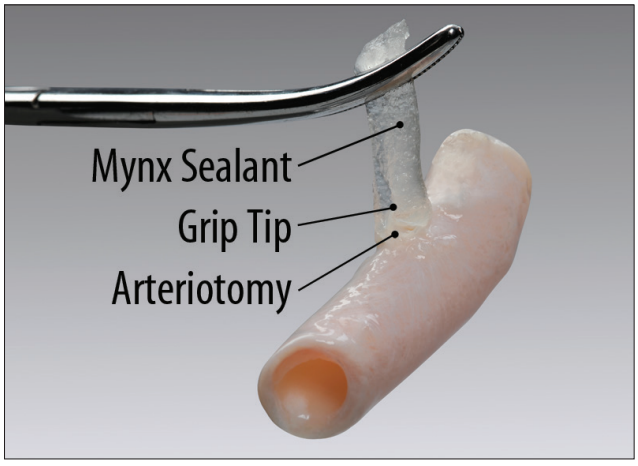

Figure 3. Bovine vessel suspended by the MYNXGRIP® sealant. Reprinted from Thai HM, Weinstock BS. The MynxGrip vascular closure device. Endovasc Today. 2012;11(4):28–33.

were 1,164 MYNX® VCD patients and 2,910 Angio-Seal™ VCD patients. Although patient demographics and treatment patterns substantially overlapped, including the use of anticoagulation agents, the MYNX® VCD group was associated with older age and increased prevalence of PAD; the Angio-Seal™ VCD group was associated with higher use of 7-F sheaths prior to closure. The safety and effectiveness outcomes were similar between groups. Composite safety (vascular injury and access site bleed) was 2.3% in the Angio-Seal™ VCD group compared to 1.5% in the MYNX® VCD group ($P = .6$). The efficacy (defined as device failure rates) was also similar between groups (7.5% for Angio-Seal™ vs 8.7% for MYNX®; $P = .4$). The authors concluded equal safety and device failure rates for the MYNX® VCD and Angio-Seal™ VCD and pointed out that there may be a possible benefit to MYNX®'s passive anchoring system, as it leaves no intra-arterial anchors after device removal.[5]

In transcatheter treatment of PAD, the antegrade approach is emerging as a preferred method. With this approach, the needle is aimed distally at the puncture and the guidewire is passed down in an antegrade fashion into the affected limb. This method, however, is impacted by high complication rates of manual compression and instructions for use limitations of most closure devices. Unlike many other closure devices, the MYNXGRIP® VCD may be used in the femoral artery after the antegrade approach. Pruski et al recently assessed the safety and efficacy of the MYNXGRIP® VCD in 66 patients undergoing peripheral interventions at a single center in the United States. All patients were discharged home on the day of the procedure. They were observed for adverse events at 1 and 30 days of follow-up, and no major complications occurred. There were 3% minor complications and a 5.9% device failure rate. The authors concluded that the MYNXGRIP® VCD was safe and effective for sealing access sites after antegrade femoral artery puncture and allowed same-day discharge.[6]

Finally, Ben-Dor et al conducted a multicenter randomized prospective study of 208 patients who underwent diagnostic/interventional procedures via access of the femoral vein. The study was designed to assess the safety and effectiveness of the MYNXGRIP® VCD in femoral vein closure. There was no difference between the MYNXGRIP® VCD and manual compression regarding closure complications or venous thrombosis. In terms of effectiveness, however, the MYNXGRIP® VCD was associated with a shorter time to hemostasis compared with manual compression (0.12 min vs 7.6 min; $P < .001$). The authors concluded that the MYNXGRIP® VCD is safe and effective for femoral venous access site closure.[7]

CONCLUSION

The presented clinical support for the MYNXGRIP® VCD provides important information about a new approach to vascular closure. The preclinical results confirmed complete absorption of the MYNXGRIP® sealant after 30 days, and tissue reactions were consistent with the normal wound-healing process. The clinical success rates in coronary, peripheral, retrograde, and venous procedures suggest a potential broader utility and a versatility of the MYNXGRIP® VCD in today's patients. The MYNXGRIP® VCD offers an exciting option that encompasses an extravascular, patient-friendly, versatile closure device with the enhanced safety properties of the MYNXGRIP® technology. ■

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