Quick Compendium in Extravascular Closure: The Mynx Vascular Closure Device
A Concise Compilation of Contemporary, Relevant Studies

Published Studies
MedStar Washington Hospital Center Reviews Safety and Efficacy of Active vs Passive VCDs in Large, Single-Center Study

Same-Day Discharge of Elective Coronary Angiography Patients With Mynx Use in Retrospective, Single-Center Study

Patients Experience Less Pain With Mynx Use in Prospective, Randomized, Single-Blind Trial of Patient Comfort Following Vessel Closure

Decrease in Emergent Access Site Surgeries After Mynx Introduction at a Single Center

Safety and Efficacy of MynxGrip in Antegrade Peripheral Interventions in a Single-Center, Prospective Study

Ongoing Clinical Trials
The Safety and Efficacy of an Extravascular, Water-Soluble Sealant for Venous Access Site Closure

Randomized Comparison of MynxGrip vs Manual Compression for Closure Following Femoral Access Angiography: The CLOSE-UP III Trial

Use, Safety, and History
Mynx Vascular Closure Devices
Ron Waksman and colleagues (MedStar Washington Hospital Center, Washington, D.C.) report in the *Journal of Interventional Cardiology* the results of a study of patients, who underwent closure of the femoral artery with either the Angio-Seal (St. Jude Medical) or Mynx (Cardinal Health) vascular closure device (VCD).* They found similar rates of safety and efficacy between the two devices, and posit that the passive anchoring system of the Mynx may prove preferable, since it leaves no intra-arterial component after device removal.

The analysis included 4704 PCI patients at MedStar Washington Hospital Center (2008-2014), who received a Mynx or Angio-Seal VCD, in an effort to directly compare the safety and efficacy of each device. The Mynx is considered a “passive” hemostasis device, since it delivers an extravascular sealant with no intra-arterial anchor. On the other hand, the Angio-Seal is considered an “active” device, delivering an extravascular sealant with a resorbable intra-arterial anchor. Analysis included patients with stable or unstable acute coronary syndromes (ACS), with both non-ST-elevation myocardial infarction (non-STEMI), and STEMI. Patients with cardiogenic shock were excluded from the analysis. Device choice and pharmacologic therapy strategy were left up to the individual operator. Safety was defined as rate of complications (access-site bleeding and vascular injury) within 30 days. Composite safety at 30 days was 2.3% (Angio-Seal) vs 1.5% (Mynx), *P*=0.6. Efficacy (defined as successful deployment of the device, with achievement of hemostasis and the absence of pulsatile arterial bleeding or hematoma) was similar between the two devices, with device failure at 7.5% (Angio-Seal) and 8.1% (Mynx), *P*=0.4.

Limitations of the study included those of observational analysis, particularly the aspect of operator comfort with one device vs another, low event rates prohibiting use of a more detailed statistical analysis, and higher rates of device failure than shown in randomized clinical trials. However, the authors point out that the study contains a representative population, with reassuring results for operators who may have been hesitant about the efficacy of using a passive VCD. They believe the Mynx passive device, with no intra-arterial anchor left behind, may prove more desirable in light of the equivalent safety and efficacy of the two devices.

*Author disclosures for this study are not available.

**Figure.** Composite safety (vascular injury, access site bleed) at 30 days in the overall population.
Nadim Malik and colleagues (Institute of Cardiovascular Sciences, University of Manchester, Oxford Road, Manchester; and Stepping Hill Hospital, Stockport, Greater Manchester, United Kingdom) report in the *Journal of Invasive Cardiology* the results of a retrospective analysis of success, complication rates, and associated factors in patients undergoing elective outpatient coronary angiography in a single U.K. center. Same-day discharge was possible in 99.5% of patients.

Researchers explored safety in a real-world cohort with the Mynx device.* They looked at the rate of complications in 432 consecutive patients undergoing elective and diagnostic coronary angiography, and receiving the Mynx device between September 2011-March 2013 at a single center. Researchers also sought to define any patient characteristics that may contribute to device failure and complications. Study findings demonstrated the Mynx device was safe and efficacious, with low rates of conversion to manual pressure/FemoStop (14 patients, 3.2%), and a small number of patients expressing any discomfort with the procedure (2 patients, 0.5%). Importantly, device deployment was considered safe, with low complication rates (Figure) even in patients with a high body mass index and those on dual antiplatelet therapy. Same-day discharge was possible in 99.5% of patients, with 2 patients requiring overnight hospitalization. Hematoma of any size occurred in 16 patients (3.7%), with 3 patients (0.7%) having confirmed hematoma >5 cm in diameter. A clinical diagnosis of groin site infection occurred in 1 patient (0.2%) and required oral antibiotics. No pseudoaneurysms were identified in any patients. The majority of bleeding complications correlated with adjustable risk factors, including sheath size and periprocedural blood pressure. Limitations include no formal follow-up of patients or routine imaging of the arteriotomy site, as well as the fact that patients were asked to self-report complications after hospital discharge, with the accompanying potential for patients being lost to study follow-up. The study concluded that the Mynx device is safe, efficacious, and comfortable in patients undergoing elective coronary angiography with femoral access. They recommend attempting to reduce possible complications by using lower sheath sizes (5 rather than 6 French) and optimizing blood pressure control prior to coronary angiography.

Authors’ disclosure: Dr Malik reports lecture honoraria from Biosensors, UK. The remaining authors report no conflicts of interest.


*This study utilized an earlier generation Mynx. The newest generation is the MynxGrip (released in 2013, and currently commercialized).
Published Studies

Patients Experience Less Pain With Mynx Use in Prospective, Randomized, Single-Blind Trial of Patient Comfort Following Vessel Closure

The Journal of NeuroInterventional Surgery 2011

Kyle Fargen, MD, and colleagues (Department of Neurosurgery, University of Florida College of Medicine, Gainesville, Florida) report in the Journal of NeuroInterventional Surgery the results of a blinded, randomized, controlled trial comparing Mynx* and Angio-Seal (St. Jude Medical) for patient comfort from pre to post closure. Pain at deployment was evaluated by patients through use of a visual analog scale (VAS) and was found to be significantly lower with Mynx than with Angio-Seal.

Most vascular closure devices (VCD) utilize a compression element that internally exerts pressure upon the femoral artery at deployment, exposing patients to a significant amount of pain and discomfort. Based on initial experience, the Mynx appeared to cause less pain to patients, and researchers decided to compare the Mynx* to another VCD with a self-tightening suture, the Angio-Seal device. Sixty-four patients undergoing diagnostic cerebral angiography were enrolled, with 32 in each treatment arm. All patients received 10 ml of 1% lidocaine with epinephrine for local anesthesia. All patients received 50 mg of intravenous fentanyl during the procedure in two 25-mg fentanyl doses, the second of which was administered at least 10 minutes prior to deployment of the VCD. To evaluate pain, patients were trained to use a visual analog scale (VAS), where 0=no pain and 10=worst possible pain, during a pre-procedure visit. Patients were asked to describe their pain levels prior to closure, immediately following device deployment, and post procedure. When compared with Angio-Seal, the Mynx arm experienced significantly lower pain at closure (2.94 ± 0.42 vs. 5.03 ± 0.56; P=0.009). The primary endpoint, increase in pain from baseline to closure, was also significantly lower in the Mynx arm (2.31 ± 0.35 vs 4.44 ± 0.49, P=0.002). When patients were asked to report the most painful part of the procedure, 88% of patients receiving an Angio-Seal reported the deployment of the VCD as the most painful, compared with 34% of patients receiving the Mynx (P<0.001). Limitations of this study include a single-center trial, the proceduralist was not blinded as to the VCD deployed, it is not necessarily representative of all VCDs with a compression element, and manual compression was not directly evaluated as an alternative. Researchers concluded that the large pain gradient between the study arms, demonstrating significantly lower pain with use of the Mynx device, is likely due to the absence of a compression element in the Mynx device. They note that this reduction in pain is likely to improve overall patient satisfaction, but also reduce the amount of periprocedural pain medication necessary to facilitate both early ambulation and post-procedure discharge.

Authors’ disclosure: This study was funded in part by a scientific research grant from AccessClosure, Inc.; however, this was an independently run physician-initiated study, and AccessClosure, Inc. had no input into data collection, analysis or presentation.


*This study utilized a first-generation Mynx, released in 2009. The newest generation is the MynxGrip (released in 2013, and currently commercialized).
Sonya Noor and colleagues (Buffalo General Hospital, Buffalo, New York) report in *Vascular and Endovascular Surgery* the results of a retrospective review of access site complications requiring surgery. The rates of emergency surgery following 11,006 cardiac and peripheral vascular procedures (6,7 French) were reviewed across 3 closure methods: Mynx* (Cardinal Health), Angio-Seal (St. Jude Medical), and manual/mechanical compression. Mynx patients experienced emergency repair surgeries at a lower rate than Angio-Seal patients, while there was no statistically significant difference in rate of emergency surgery between Mynx and the manual compression subset (.06 vs .19%, *P*=.14) (Figure). Two patients who received the Mynx device underwent surgery for a hematoma evacuation and incision and drainage for an abscess. Angio-Seal patients experienced thrombectomy or embolectomy (3 patients), and 11 patients underwent vascular repair secondary to pseudoaneurysm (PSA), arteriovenous fistula (AVF), abscess and/or hematoma evacuation. Ten manual/mechanical compression patients underwent hematoma evacuations (2 patients) and vascular repairs secondary to PSA, AVF, and/or retroperitoneal hematoma (8 patients). The authors note their review is subject to the limitations of uncontrolled, retrospective studies, and that the low number of complications requiring surgery “preclude definitive conclusions regarding the nature and risk of surgical complications with the various closure methods.”

Authors’ disclosure: This study was funded in part by a scientific research grant from AccessClosure, Inc.; however, this was an independently run physician-initiated study, and AccessClosure, Inc. had no input into data collection, analysis or presentation.


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**FIGURE.** Rates of surgical repair following arteriotomy closure with Angio-Seal, Mynx, and manual/mechanical compression.


*This study utilized a first-generation Mynx, released in 2009. The newest generation is the MynxGrip (released in 2013, and currently commercialized).*
Radoslaw S. Kiesz and colleagues (San Antonio Endovascular and Heart Institute, San Antonio, Texas) report in *Vascular and Endovascular Surgery* the results of the first study to assess the safety and efficacy of the MynxGrip for closure of an antegrade puncture in peripheral vascular intervention patients.

Achieving hemostasis with manual compression can be difficult with antegrade femoral technique and may have a higher vascular complication rate than retrograde puncture. Vascular closure device safety and efficacy for antegrade puncture should be established prior to device use in such cases. In a prospective, single-center, single-arm study, researchers looked at 66 consecutive procedures in patients undergoing diagnostic and interventional peripheral vascular procedures with antegrade access using 6 French (F) and 7F procedural sheaths. Per standard protocol at the researchers’ institution, all patients received anticoagulation with bivalirudin. The primary safety endpoint was occurrence of major complications at 30-day (±7 days) follow-up. The primary efficacy endpoint was *procedural success* defined as MynxGrip deployment and hemostasis achieved without conversion to manual compression (<10 minutes). Overall, the procedural success rate was 95%. Post discharge, 2 (3%) of the 66 patients experienced a minor complication: 1 patient had a minor abscess requiring oral antibiotics and 1 patient had ipsilateral deep vein thrombosis (DVT) requiring oral anticoagulation. No major complications were observed. All patients were able to undergo same-day discharge and no patient required hospitalization. Mean time to discharge was 4 hours and 54 minutes. Limitations of this study include the sample size and lack of randomization. Researchers note the study results apply to a selected patient population undergoing elective procedures and who qualified for early discharge. Importantly, this study provides a first look at the safety and efficacy of the MynxGrip for use in sealing an antegrade femoral puncture in an outpatient setting. Researchers concluded that the MynxGrip appears to be efficacious and safe in sealing antegrade femoral puncture in elective peripheral endovascular intervention when patients are selected for same-day discharge.

Authors’ disclosure: This study was funded in part by a scientific research grant from AccessClosure, Inc.; however, this was an independently run physician-initiated study, and AccessClosure, Inc. had no input into data collection, analysis or presentation.

Ongoing Clinical Trials

### The Safety and Efficacy of an Extravascular, Water-Soluble Sealant for Venous Access Site Closure (NCT02438475)

**Ron Waksman, MD**  
Department of Interventional Cardiology, MedStar Washington Hospital Center  
Washington, D.C.

“We are eager to complete the venous closure study utilizing the Mynx device to learn about the safety and efficacy of this device against manual compression to close venous access.”

The need to control groin complications and minimize risks associated with postponed sheath removal under conditions of persistent anticoagulation has generated interest in the role of VCDs for venous access closure.

Vascular closure device (VCD)-based venous closure has been anecdotally reported, but systematic evaluation of the safety and effectiveness of femoral vein closure is lacking. The objective of this study is to evaluate the safety of the MynxGrip for common femoral vein closure following both diagnostic and interventional procedures as assessed by clinical and imaging criteria for venous thrombosis at the site of closure device deployment.

This is a prospective, randomized, open-label evaluation of patients undergoing either diagnostic or interventional procedures with access and closure of the femoral vein. A total of 208 patients will be enrolled in this study and will be followed through hospital discharge for safety measures.

The primary safety endpoint will include both deep venous thrombotic and bleeding/vascular injury-related complications prior to discharge. Outcomes will be assessed via clinical evaluation and imaging when clinically indicated. Additionally, device/procedure failure rates will be tracked as a safety measure.

The study is actively enrolling patients at Medstar Washington Hospital Center, D.C.

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### Randomized Comparison of MynxGrip vs Manual Compression for Closure Following Femoral Access Angiography: The CLOSE-UP III Trial (NCT02237430)

**Niels R. Holm, MD**  
Aarhus University Hospital Skejby, Denmark

“The randomized CLOSE-UP III trial is aimed at providing robust clinical evidence on the safety and efficacy of the MynxGrip.”

Manual compression has long been considered the standard against which all vascular closure devices (VCDs) should be evaluated in terms of safety and adverse event rates in femoral access percutaneous diagnostic and interventional procedures.

The objective of this study is to determine if the MynxGrip is non-inferior to manual compression in the incidence of major adverse vascular events.

CLOSE-UP III is a prospective, randomized (1:1), controlled, non-blinded, single center study comparing the MynxGrip and manual compression. A total of 2000 coronary angiography patients will be enrolled in this study, and safety and efficacy endpoints will be reported at in-hospital, 30 days, and 6 months.

The primary safety endpoint is incidence at 30 days of serious access site-related major adverse vascular events (MAVE), which includes major bleeding and/or blood transfusion, pseudoaneurysm with indication for treatment, arteriovenous fistula, groin surgery of leg that definitely or possibly can be related to the closure procedure, and infection requiring antibiotics. Outcomes will be assessed via clinical evaluation and imaging when clinically indicated. Additionally, device failure rates will be tracked along with secondary measures including time to hemostasis and ambulation, requirement for new onset of manual compression, pain and discomfort related to the closure procedure, vasovagal reaction up through 5 minutes post closure procedure, and need for medical evaluation of possible closure device-related symptoms.

The study is actively enrolling patients at Aarhus University Hospital Skejby in Denmark.
These summaries are written and provided by HMP Communications and Cardinal Health. Both HMP Communications and Cardinal Health have attempted to summarize the published studies as accurately as possible. We refer the reader to the actual study for additional information. Cardinal Health will provide the full article upon request from healthcare professionals.

INDICATIONS FOR USE: The MYNXGRIP® Device is indicated for use to seal femoral arterial and femoral venous access sites while reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional endovascular procedures utilizing a 5F, 6F or 7F procedural sheath. Precautions: The MYNXGRIP® Device should only be used by a trained licensed physician or healthcare professional. The MYNXGRIP® Device should not be used in patients with a known allergy to PEG.

CONTRAINDICATIONS: There are no known contraindications for Mynx.

WARNINGS: Do not use if components or packaging appear to be damaged or defective or if any portion of the packaging has been previously opened. DO NOT REUSE OR RESTERILIZE. MynxGrip is for single use only. The balloon catheter is loaded with a single Hydrogel sealant. Reuse of the device would result in no delivery of Hydrogel sealant. Do not use MynxGrip if the puncture site is located above the most inferior border of the inferior epigastric artery [IEA] [for arterial application] and/or above the inguinal ligament based upon osseus landmarks, since such a puncture site may result in a retroperitoneal hematoma/bleed. Perform a femoral angiogram or venogram to verify the location of the puncture site. Do not use MynxGrip if the puncture is through the posterior wall or if there are multiple punctures, as such punctures may result in a retroperitoneal hematoma/bleed.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. For information on indications, contraindications, warnings, precautions, and adverse events, see Full Instructions for Use. AccessClosure, the AccessClosure LOGO, MYNX, MYNXGRIP, and MYNXACE are trademarks or registered trademarks of Cardinal Health and may be registered in the US and/or in other countries. All other marks are the property of their respective owners.

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