Medical Device Innovation Workshop

Vascular Closure Devices
Vascular Closure Device

A medical device designed to control blood flow after a procedure requiring catheterization.

Image from Wikimedia Commons

Images retrieved 11/2/10, from:
Competitive Analysis

Mynx Vascular Closure Device (AccessClosure, Inc.)

- Biodegradable style closure
- CE Mark, FDA PMA 2007
- Immediate restick possible
- Polyethylene glycol (PEG) polymer closure
  - Biocompatible: currently under investigation as tissue engineering substrate, used in some lubricants, drug coatings, etc.
  - Resorbed in ~ 30 days
- Clinical study highlights
  - 1.3 minute average hemostasis
  - Ambulation consistently within 2 hours
  - Reduced scarring
  - Reduced inflammation

Vascular Closure Systems, Inc.

- Multiple closure techniques
  - Bioabsorbable plug, similar to competitors
  - Swellable and bioabsorbable plug
  - Self closing Nitinol clip
  - RF thermal closure
- All styles do not need some type of internal support (balloon, stent, etc.)
- Temporary or permanent implant deployment system

Procedure: Just Mynx It

The Mynx is an intuitive, single-operator device designed for gentle deployment and patient comfort.

**STEP A - POSITION THE BALLOON**
Insert the Mynx into the existing procedural sheath and inflate a small semi-compliant balloon to create temporary hemostasis.

**STEP B - DEPLOY THE SEALANT**
Deliver and unsleeve the sealant, exposing it to blood and subcutaneous fluids, producing a durable hemostasis.

**STEP C - REMOVE THE DEVICE**
Deflate balloon and remove device. The sealant is now on the surface of the arterial lumen, providing a platform for natural vessel healing.

**LEAVES NOTHING BEHIND**
Within 30 days, the sealant dissolves, leaving nothing behind but a healed artery.

- All pre-clinical
- Claimed price of ~$150 per set
- Compatible with any standard introducer sheaths
- Based on technology from CardioVascular Technologies, Inv.
- Not FDA approved
- Images retrieved 11/2/10, from: http://www.vclosure.com/

**Abbott**
- Suture mediated and clip based (~6 products)
- Pioneer in closure technology
- FDA approved

**CardivaCatalyst II**
- Nitinol based
- Coated with protamine sulfate to locally neutralize heparin
D-Stat Flowable (Vascular Solutions, Inc.)
- Listed similar to their Duett and Duett Pro products
- Viscous liquid procoagulant
- Works via Factors V, VII, and XII in coagulation cascade
- Seals arteriotomy and tissue tract
- FDA approved
- Image retrieved 11/2/10, from:
  http://vascularsolutions.com/products/dstat-flowable

Angio-Seal (St. Jude)
- Bioresorbable, resorbed in 60-90 days
- Allows immediate restick like other bioresorbable products
- FDA approved
- Image retrieved 11/2/10, from:
  http://www.sjmprofessional.com/Products/US/Hemostasis-Management/Angio-Seal-VIP.aspx

The Angio-Seal Vascular Closure Device uses three bioabsorbable components to actively seal the arteriotomy:

- Anchor
  Bioabsorbable co-polymer anchor placed against the inside of the vessel wall
- Collagen
  Placed on top of the arteriotomy in the tissue tract
- Suture
  Cinches the anchor and collagen together to form a secure seal

All components are fully absorbed within 60-90 days.

Hot Patents
1. The first patent to mention “vascular closure”, by Perclose, who was purchased by Abbott. It is suture based. (‘974 patent)
2. The first patent to mention a clip style closure. (‘155 patent)
3. The first patent to mention resorbable closure. (‘570 patent)
4. The first patent to mention radio frequency closure. (‘744 patent)

Note: All of these patents are quite “young” and the first patent in each was listed because the first patent usually locks up a lot of intellectual property.
Vascular closure device

Vascular closure devices are medical devices used to achieve hemostasis of the small hole in the artery after a cardiovascular procedure of endovascular surgery requiring a catheterization.

Cardiovascular procedures requiring catheterization include diagnostic procedures that help diagnose diseased blood vessels and interventional procedures such as angioplasty, the placement of a stent and coronary thrombectomy.

During such procedures, a small incision is made in the groin area and a hole is created in the femoral artery to gain access to the artery. This hole is referred to as the access site or puncture site. At the completion of the procedure, the hole needs to be closed.

Goals

The main goal of a Vascular Closure Device is to provide rapid hemostasis of the artery as well as reduce access site complications.[1] VCD's also help reduce time to ambulation and time to hospital discharge.[2] In addition, VCD's are more comfortable for the patient compared to manual compression.

History

Prior to the development of VCD's, the main method for closing the femoral artery was manual compression. Manual compression involves up to 30 minutes of manual pressure or mechanical clamps applied directly to the patient's groin, which is very painful, followed by up to 8 hours of bed rest in the hospital recovery room.

Vascular Closure Devices were introduced in the early 1990s in an effort to reduce the time to hemostasis, enable early ambulation and improve patient comfort. Initially, devices focused on technologies involving a suture or a collagen plug.[3] These technologies are effective at closing the hole; however, they often leave an intravascular component in the artery, which can cause complications. In addition, these technologies failed to accurately address patient pain.

More recent methods to close the hole involve the use of novel materials that dissolve over a short period of time, such as polyethylene glycol found in the Mynx vascular closure device. These technologies incorporate a more gentle deployment of the material to the outside of the artery and avoid the use of intravascular components, leaving nothing behind in the artery and consequently improving patient comfort.[4]

References


Angio-Seal™ Evolution

Controlled Deployment for Confident Closure

Angio-Seal Evolution features a standard deployment system that is designed to assist in overcoming many procedural variables and deliver a virtually instantaneous seal of the arteriotomy. It may also support increased confidence in the number of cases where the use of a mechanical seal is possible.

Overview | Tech Specs | How It Works | Indications, Safety & Warnings

Active Closure System

Angio-Seal Evolution features the fully bioabsorbable Active Closure System with an innovative intra-arterial anchor, suture and collagen seal. Designed to hold the system in place, the Active Closure System provides rapid, safe and reliable hemostasis.

Delivery Components

Bioabsorbable Anchor

Suture

Collagen

At Deployment  After 30 Days  After 60 Days  After 90 Days

For more information related to Angio-Seal please visit the following sites:
The Knowledge Center is an online resource for interventional cardiologists. The website provides a complete collection of education materials related to PCI optimization - Fractional Flow Reserve and Optical Coherence Tomography - as well as Access and Closure.

Clinical Discoveries provides background information on clinical challenges and research. It also provides access to clinical resources, such as downloadable PowerPoint presentations and publications.

References

MATERIALS & LINKS

Angio-Seal Evolution Registry Subset Whitepaper [PDF 175KB]

Angio-Seal Evolution Brochure [PDF 2MB]

Everyday Use of Angio-Seal for Interventional Radiology Procedures [PDF 750KB]

AngioSeal Evolution Registry Whitepaper [PDF 102KB]

Improving Productivity with use of Angio-Seal [PDF 454KB]

Staged Procedures With Use of Angio-Seal [PDF 129KB]

Resnick Brochure [PDF 229KB]

Angio-Seal Same-Day Discharge [PDF 445KB]

The Knowledge Center

Leaf Updated: September 20, 2013
The StarClose SE Vascular Closure System is indicated for the percutaneous closure of common femoral artery access sites while reducing risks to hemostasis, embolism, and in-hospital and 30-day mortality. It is designed to reduce radiation exposure to patients as well as healthcare workers. The system is indicated for use in patients who have undergone diagnostic, interventional, or therapeutic procedures utilizing a 5F or 6F procedural sheath.

The StarClose SE Vascular Closure System is intended for use in allowing patients who have undergone diagnostic-endoventricular catheterization procedures to ambulate and be eligible for discharge as soon as possible after device placement.

Contraindications:

The StarClose SE Vascular Closure System is contraindicated for use in patients with known hypersensitivity to nickel-titanium.

Warnings:

Do not use the StarClose SE Vascular Closure System if the packaging or sterile barrier has been previously opened or damaged or if the components appear to be damaged or defective.

Do not sterileize or re-use the StarClose SE Vascular Closure System and accessories are intended for single use only.

Do not use the StarClose SE Vascular Closure System if the sterile field has been broken before bacteriological contamination of the skin or surrounding tissues may have occurred, since such a broken sterile field may result in infection.

Do not use the StarClose SE Vascular Closure System if the puncture site is located above the most inferior border of the inferior epigastric artery (IEA) and/or above the inguinal ligament based upon bony landmarks, since such a puncture site may result in a retroperitoneal hematoma. Perform a femoral angiogram to verify the location of the puncture site.

Do not use the StarClose SE Vascular Closure System if the puncture site is through the posterior wall or there are multiple punctures, since such punctures may result in a retroperitoneal hematoma.

Do not use the StarClose SE Vascular Closure System if the puncture site is located in the superficial femoral artery or the profunda femoris artery, since such puncture sites may result in a pseudoaneurysm, intra-arterial dissection, or an acute vessel dissection (fracture of small artery wall). Perform a femoral angiogram to verify the location of the puncture site.

Precautions:

The StarClose SE Vascular Closure System should be used only by operators trained in diagnostic and interventional catheterization procedures who have been certified by an authorized representative of Abbott Vascular Inc.

The StarClose SE Vascular Closure System is provided sterile and non-sterile; is unopened undamaged packaging. Products are sterilized with ethylene oxide and intended for single use only. Do not re-sterilize. Store in a cool dry place.

Prior to use, inspect the StarClose SE Vascular Closure System to ensure that the sterile packaging has not been damaged during shipment. Examine all components prior to use to verify proper function. Exercise care during device handling to reduce the possibility of inadvertent device breakage.

As with catheter-based procedures, infection is a possibility. Observe sterile technique at all times when using the StarClose SE Vascular Closure System. Employ appropriate personal protective equipment and post-procedure handwashing to prevent infection.

Use a single wall puncture technique. Do not puncture the posterior wall of the artery.

Do not use the StarClose SE Vascular Closure System in cases where the puncture site is adjacent to the femoral artery bifurcation or where there are less than 3 cm.

Do not deploy the Clip in areas of calcified plaque.

The StarClose SE Vascular Closure System can be used with pediatric patients. It is contraindicated in cases where the puncture site is adjacent to the femoral artery bifurcation or where there are less than 3 cm.

Do not advance or withdraw the StarClose SE Vascular Closure Device against resistance until the cause of the resistance has been determined. Excessive force used to advance or torque the StarClose SE Device should be avoided, as this may lead to significant vessel damage and/or breaks / collapse of the device, as well as subsequent interventional and surgical removal of the device and vessel repair.

Adverse Events:

Potential adverse events that could be associated with use of this device include:

- Major Vascular Complications
- Vascular Injury Requiring Repair
- Surgery: Angioplasty: Ultrasound Guided Compression: Thrombotic Itherization or Other Percutaneous Procedure
- New or Earlier therapy: Arteriovenous fistula
- Access Site-related bleeding requiring transfusion
- Access Site-related infection: Arteriovenous fistula: Herniation +/- only Late access site-related bleeding: Transient: Infection: retroperitoneal hematoma: Inception: deep vein thrombosis: Transient access site-related bleeding: Inception: deep vein thrombosis

Prior to use, please reference the instructions for use at AbbottVascular.com for more information on indications, contraindications, warnings, precautions, and adverse events.
NOW AVAILABLE
The Cordis EXOSEAL®
Vascular Closure
Device

Experience the Difference of Closure Uncomplicated

The EXOSEAL® Vascular Closure Device is designed for a safe, simple, and secure close, offering an ideal combination of benefits that result in faster time to hemostasis (TTH) and ambulation (TTA) than manual compression, with a low risk of major vascular access complications.

- No anchor left inside the artery
- Two unique visual indicators enable precise positioning
- Easy-to-learn deployment helps efficiently achieve procedural success
- Simple 3-step procedure
- Available in 3 French sizes

Making Closure Uncomplicated for You and Your Patients

SAFE
- Precise extravascular positioning with unique lockout mechanism designed to help reduce the risk of intravascular deployment

SIMPLE
- Easy-to-use functionality with unique visual indicators to help achieve procedural success

SECURE
- Provides peace of mind with a secure closure

EX500  EX600  EX700

Available in 3 sizes, compatible with standard French size sheath introducers

Please refer to the complete “Instructions For Use” including the table of compatible sheaths, before using the EXOSEAL® Vascular Closure Device.

For more information, contact your Cordis representative or Customer Service, at 1-800-327-7714 or www.cordis.com
QuikClot® Interventional Hemostatic Bandage™ consists of a soft, white, double sterile, hydrophilic pad impregnated with kaolin, an inert mineral that does not contain animal or human proteins or botanicals. It is double-wrapped in a blister package and foil pouch for aseptic technique. Also included is a 3M® Tegaderm® bandage. QuikClot® Interventional Hemostatic Bandage is applied topically as an adjunct to manual compression and is indicated for the local management and control of external bleeding from vascular access sites and percutaneous catheters or tubes utilizing sheaths up to 12 Fr.

- Effective, Simple, and Safe
- Easy to use and remove
- Non-invasive
- Inert
- Multi-layer pad (1.5”x1.5”x.5”)

The QuikClot family of products for hemostasis has been chosen by EMS, Law Enforcement, Military, and Healthcare Professionals to save lives every day.

Available in two easy-to-use formats:

- QuikClot® Interventional Hemostatic Bandage - Product Number: 183
- QuikClot® Interventional Hemostatic Bandage (with Silt) - Product Number: 188

QuikClot® Interventional (QCI) Hemostatic Bandage has found many uses in the healthcare setting including:

- Interventional Radiology
- Cardiology
- Cath Labs
- Diagnostic and Interventional Nephrology
- Dialysis

Precautions:

- For prescription use only
- For external use only
- Sterility not guaranteed if package is damaged or opened
- Do not wet the pad prior to use
- Avoid contact with eyes
- Single use only
- Do not reuse or re-sterilize
- Store in a cool, dry place

Questions?
Ask Dr. Basadonna M.D. PhD >>

Dr. Basadonna M.D. PhD
is Z-Medica's Chief Medical Officer and Professor of Surgery at UMass, Worcester

How To Order
To place an order please call our sales staff at (203) 294-0000
Vascular closure devices (VCDs) introduce a novel means for improving patient comfort and accelerating ambulation after invasive cardiovascular procedures performed via femoral arterial access. Vascular closure devices have provided simple, rapid, and reliable hemostasis in a variety of clinical settings. Despite more than a decade of development, however, VCD utilization has neither been routine in the U.S. nor around the world. Their limited adoption reflects concerns of higher costs for cardiac procedures and a lack of data confirming a significant reduction in vascular complications compared with manual compression. Recent data, however, suggest that VCD are improving, complication rates associated with their use may be decreasing, and their utilization may improve the process of care after femoral artery access. Challenges in the second decade of VCD experience will include performing definitive randomized trials, evaluating outcomes in higher-risk patients, and developing more ideal closure devices. (J Am Coll Cardiol 2007;50:1617–26) © 2007 by the American College of Cardiology Foundation

VCDs: The First Decade

A brief history. Vascular closure devices are in their second decade of development for diagnostic and interventional cardiovascular procedures. The technologies approved from 1995 to 1998 focused on active closure methods including suture alone (2), extravascular collagen alone (6), and suture-collagen combinations (1) (Fig. 1). Since their introduction, the original devices (Perclose, Abbott Vascular, Redwood City, California; Angio-Seal, St. Jude Medical, St. Paul, Minnesota) have undergone multiple iterations while maintaining their core concept (7). Recently, a conceptually different type of active-closure VCD involving surgical staple/clip technology has also become available (StarClose, Abbott Vascular, Redwood City, California; EVS-Angiolink, Medtronic Co., Minneapolis, Minnesota) (8–10) (Fig. 2, Table 1). “Passive closure” technologies have been developed in parallel with the active closure devices. Passive closure approaches have focused on enhanced manual compression utilizing external patches with prothrombotic coatings (Syvek Patch, Marine Polymer Technologies, Danvers, Massachusetts) (11,12), wire-stimulated track thrombosis (Boomerang Wire, Cardiva Medical, Mountainview, California) (13), or assisted compression with me-
The adoption of VCD has occurred because of a clear technological feat: VCD reliably shortens the time to hemostasis (elapsed time between sheath removal and first observed hemostasis) compared with manual compression and thus allows earlier patient ambulation (1,8,10,16,17) (Table 2). Alternative strategies for achieving early ambulation are the use of smaller sheaths for diagnostic catheterization as well as the use of the radial artery approach. The advantage of femoral vascular closure is that it can be performed immediately at the end of the procedure regardless of anticoagulation status; procedural success is expected in >95% of patients, and time to hemostasis is generally less than 5 min with Angio-Seal, Perclose, and staple/clip-mediated VCD (1,2,10,18). This compares favorably with hemostasis times of 15 to 30 min with standard 6-F manual compression. In addition, sheath removal via manual compression generally requires the operator to wait for the activated clotting time to reach a level of 180 s (19), while VCD allows immediate removal of the femoral sheath regardless of anticoagulation status. While length of stay for PCI patients will not necessarily be reduced by early ambulation (unless same-day PCI is adopted), it can be reduced for diagnostic patients (2,16,20). And, for many patients, VCD can allow improved patient satisfaction and comfort related to the avoidance of prolonged sheath insertion and manual compression (19). Given this technological feat, it may be somewhat surprising that VCD have not become the standard of care for invasive cardiac procedures (21).

**Issues Challenging VCD Adoption: Complications and Cost**

What is the current rate of vascular complications associated with VCD? Vascular closure device pivotal studies have generally included 250 to 600 randomized patients. Given their limited sample sizes, such studies can reliably identify those complications that occur in 3% to 5% of the highly selected subjects enrolled in the trials (1,2,8,10,22). Vascular closure device trials have not been expanded to higher-risk patient cohorts; thus, there is a lengthy list of precautions and warnings on the instructions for use for each device (Table 1). For example, in the randomized trial leading to Food and Drug Administration (FDA) approval of the StarClose nitinol clip system for diagnostic cardiac catheterization, the list of angiographic and clinical exclusions included obesity, small femoral artery diameters, bleeding diatheses, femoral arterial disease, and nonfemoral sheath insertion (20).

There are concerns that the VCD may cause increased rates of rare complications, primarily based upon anecdotal case reports. Infections, femoral artery compromise, arterial laceration, uncontrolled bleeding, pseudoaneurysm, atrioventricular fistula, as well as device embolism and limb ischemia have all been reported after VCD utilization (4,23). These reports span all VCD types including Perclose (24,25), Angio-Seal (26), and StarClose (27). One study suggests that the severity of individual complications may be worse after VCD use compared with manual compression for PCI patients as VCDs are deployed at the point of maximal anticoagulation while manual compression is de-
some studies define “vascular complications” differently (37). Nevertheless, there are several conclusions that may be drawn from these larger studies of vascular complications:

- Among patients undergoing diagnostic cardiac catheterization, there is a 0.5% to 1.7% rate of vascular complications (4,7,16,31,34,38); this risk is not consistently increased or decreased by VCD usage across all studies; the largest study, from the ACC-NCDR, suggested a significant decrease in complications with VCD usage compared with manual compression (4); it is possible this reduction in complications is directly related to the VCD or alternatively reflects a reluctance by the operator to use a VCD in patients who are already having a complication at the completion of the diagnostic procedure or in circumstances where both VCD use and manual compression have been associated with increased complications (e.g., high or low femoral insertion sites).

- Among patients undergoing PCI, there is a 0.8% to 5.5% rate of heterogeneously defined vascular complications; with the exception of Vasoseal, there are no data to clearly suggest an increased risk of vascular complications with VCD use (4,29,33); some studies suggest that VCDs decrease complications compared with manual compression (17,33,34,36), some studies suggest potentially increased risk with VCD (22,28,30), and some suggest complication rates are similar (7,29,31,35); the ACC-NCDR study suggests a nonsignificant reduction in complications with VCD as compared with manual compression for patients undergoing PCI (4).

Given the equipoise with respect to vascular complications suggested by overview of these many VCD studies, it is not surprising that manual compression has remained the most common method for achieving hemostasis after invasive cardiac procedures both in the U.S. and worldwide (4,8) (Fig. 2). An example of this practice pattern can be seen in the TARGET (Comparison of 2 Platelet Glycoprotein IIb/IIIa Inhibitors, Tirofibran and Abciximab, for the Prevention of Ischemic Events With Percutaneous Coronary Revascralization) trial comparing abciximab to tirofiban (4); of 4,809 patients undergoing PCI, 4,736 had femoral access. Use of VCD was left to the discretion of investigators—only 20% (n = 985) were treated with a VCD (35). While the interventional cardiology community has been noted for its aggressive adoption of new technologies beyond FDA labeling and randomized clinical trial conclusions (3), VCD utilization demonstrates the critical perspective that hospitals and interventional cardiologists do bring to adoption of new technology.

### Factors Affecting Vascular Complication Rates: Patient Selection, Newer Anticoagulation, and Antiplatelet Strategies and Device Improvements

Accurate estimation of the relative benefits of VCD versus manual compression should also reflect what appears to be a change in the incidence of vascular complications in the

---

**Table 1**

<table>
<thead>
<tr>
<th>Indications, Contraindications, and Cautions for 3 VCDs</th>
<th>Anglo-Seal *</th>
<th>Perclose †</th>
<th>StarClose ‡</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Closure indication</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostic cath</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>PCI</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>5-F sheath</td>
<td>NM</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>6-F sheath</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>7-F sheath</td>
<td>+</td>
<td>+</td>
<td>No</td>
</tr>
<tr>
<td>8-F sheath</td>
<td>+</td>
<td>+</td>
<td>No</td>
</tr>
<tr>
<td>Ipsilateral access &lt;90 days</td>
<td>1 cm higher</td>
<td>No restriction‡</td>
<td>Not indicated</td>
</tr>
<tr>
<td>MRI safe</td>
<td>NM</td>
<td>NM</td>
<td>+</td>
</tr>
<tr>
<td><strong>Contraindication</strong></td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**Warnings:** “Do not use if…”

- SFA or Profunda insertion
- Bifurcation insertion
- Above inguinal ligament
- Posterior wall puncture
- Multiple punctures

**Precautions:** “Safety and effectiveness of the VCD has not been established…”

- Patient on warfarin
- Inflammatory disease
- Morbid obesity
- Thrombolysis
- Access via vascular graft
- Significant PVD
- Uncontrolled HTN
- Bleeding diathesis
- Ipsilateral venous sheath
- Femoral artery calcium
- Small femoral artery size
- Iliofemoral stenosis >50%
- Use of GP IIb/IIIa inhibitor

---

*Instructions for Use Angio-Seal VIP; St. Jude Medical February 2006 (www.sjm.com); †Instructions for Use Perclose A*T (August 2006) and StarClose (February 2007). Abbott Vascular (www.abbottvascular.com/ifu); ‡No restriction is only for reaccess after prior arteriotomy repaired with Perclose.

---

layed (27). Thus, the severity of bleeding complications (when they occur) would be expected to be greater with VCD than manual compression.

Reports of adverse events after VCD use prompted the FDA to initiate the largest study of 166,680 patients via the ACC-NCDR database “to assess the relative risk of complications after the use of the 2 main types of hemostasis device” (4). However, concerns that VCD outcomes are worse in comparison with manual compression are not supported by review of published meta-analyses, multicenter registries, and longitudinal registries (Table 3). These studies evaluated a larger number of patients than were studied in the pivotal trials, but are limited by variable study end points. Some studies use a composite end point (4,7,17,22,28–34), some studies use a single end point, (16,35,36), and
current era. In studies from the 1990s, vascular and bleeding complications after PCI were frequently in the 3% to 6% range (17,28,30,39,40). Recently, rates of major vascular complications after PCI are estimated at closer to 2% (4,40,41) (Fig. 3). This observation is supported by data from the PCI Registry of the Northern New England Cardiovascular Study Group. Using a standard definition of major vascular complications (arterial injury and/or arterial-injury-related bleeding), there has been a 42% relative decrease in complications from 2002 to 2006 (p < 0.001) (D.J. Malenka and W.D. Piper, personal communication, January 2007) (40). Changes in the characteristics of patients undergoing PCI do not appear to account for this reduction in complications, since the major known risk factors for vascular complications have remained constant during this period—advanced age (39,40), vascular disease

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>n</th>
<th>Device Comparison</th>
<th>End Point</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cura et al. (28)</td>
<td>Registry</td>
<td>2,918</td>
<td>VCD vs. MC</td>
<td>Vascular complication*</td>
<td>Angio-Seal 2.9%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Perclose 3.2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MC 3.1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>p = NS</td>
</tr>
<tr>
<td>Dangas et al. (30)</td>
<td>Registry</td>
<td>5,093</td>
<td>VCD vs. MC</td>
<td>Surgical repair</td>
<td>VCD 2.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MC 1.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>p = 0.03</td>
</tr>
<tr>
<td>Resnic et al. (17)</td>
<td>Registry</td>
<td>3,027</td>
<td>VCD vs. MC</td>
<td>Vascular complication</td>
<td>MC 5.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>VCD 3.0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>p = 0.002</td>
</tr>
<tr>
<td>Dangas et al. (22)†</td>
<td>Pooled randomized trials</td>
<td>2,095</td>
<td>VCD vs. MC</td>
<td>Device complications</td>
<td>VCD 8.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MC 5.9%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>p = 0.02</td>
</tr>
<tr>
<td>Tavris et al. (4)†</td>
<td>ACC-NCDR</td>
<td>166,680</td>
<td>VCD vs. MC</td>
<td>Vascular complication</td>
<td>1.05% to 1.48% VCD</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.70% for MC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Exaire et al. (35)†</td>
<td>TARGET trial substudy</td>
<td>4,736</td>
<td>VCD vs. MC</td>
<td>Transfusions</td>
<td>VCD 1.0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MC 0.8%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>p = NS</td>
</tr>
<tr>
<td>Koreny et al. (16)†</td>
<td>Meta-analysis</td>
<td>4,000</td>
<td>VCD vs. MC</td>
<td>Hematoma</td>
<td>RR 1.14 for VCD (0.86–1.51)</td>
</tr>
<tr>
<td>Vaitkus et al. (33)†</td>
<td>Meta-analysis</td>
<td>5,045</td>
<td>VCD vs. MC</td>
<td>Vascular complication</td>
<td>RR 0.89 for VCD (0.86–0.91)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Increased risk for VasoSeal</td>
</tr>
<tr>
<td>Nikolsky et al. (29)</td>
<td>Meta-analysis</td>
<td>37,066</td>
<td>VCD vs. MC</td>
<td>Vascular complication</td>
<td>p = 0.06 for Angio-Seal benefit compared with MC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Increased risk for VasoSeal</td>
</tr>
<tr>
<td>Applegate et al. (7)</td>
<td>Registry</td>
<td>4,699</td>
<td>Angio-Seal vs. MC</td>
<td>Vascular complication</td>
<td>Angio-Seal 1.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MC 1.7%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>p = NS</td>
</tr>
<tr>
<td>Arora et al. (34)†</td>
<td>Registry</td>
<td>12,937</td>
<td>VCD vs. MC</td>
<td>Vascular complication</td>
<td>42% to 58% reduction in vascular complications with VCD vs. MC</td>
</tr>
</tbody>
</table>

*Vascular complication may be defined differently for each study; †data include both diagnostic and interventional cardiac procedures.

ACC-NCDR = American College of Cardiology-National Cardiovascular Data Registry; MC = manual compression; RR = relative risk; other abbreviations as in Table 1.
(47,40), female gender (44,40), emergent procedures (4,40), and low body surface area (7,40). The reasons for the decrease in vascular complications possibly reflect the influence of several factors: better patient selection for VCD, improved femoral access techniques, changing PCI pharmacology, improved VCD, and improved operator experience with VCD use (32).

**Patient selection.** Routine femoral angiography at the end of the catheterization procedure is a significant advance (42–44). Such angiography allows identification of the major risk factor for retroperitoneal hemorrhage—sheath insertion above the inferior epigastric artery (44–46). In addition, femoral angiography identifies the estimated 13% of patients with nonfemoral artery sheath insertion for which VCD utilization is of unclear efficacy (Fig. 4) (20,43).

Identification of significant femoral arterial disease may allow selective use of manual compression in situations where implantation of an intravascular device may be associated with an increased risk of complications (Table 1) (7,47). Furthermore, femoral angiography may be especially important in the setting of multiple procedures at the same femoral access site; there is limited data regarding the safety of repeat access, and further study regarding the pathological and potential anatomical effects of repeat access with different devices is warranted (48–50).

**Newer anticoagulation and antiplatelet strategies.** Lower doses of unfractionated heparin have almost certainly contributed to the reduction in vascular complications (51). Bivalirudin also reduces the risk of bleeding complications after PCI compared with heparin + glycoprotein IIb/IIIa inhibitors (41). Thus, changes in PCI-related pharmacology could be expected to decrease bleeding and vascular complication rates up to 40%. Whether or not PCI pharmacologic changes may have preferentially benefited VCD or manual compression requires further clarification via prospective trials or subgroup analysis of recent trials (52).

**Device improvements.** The first VCD (Vasoseal) was a collagen device and the only VCD significantly associated with increased risk of vascular complications compared with manual compression in 2 meta-analyses (29,33). The dominant types of VCD in current practice are the suture-mediated device (Perclose), the collagen-anchor-suture-mediated device (Angio-Seal), and clip-mediated VCD (StarClose). The learning curve for each device may be steep, and thus complication rates may have been higher in the mid-to-late 1990s related to slow improvement in operator proficiency (29,30,32). In addition, each of these devices has undergone modification and simplification over time. For example, 1 longitudinal registry observed that the use of the third generation of Angio-Seal VCD was...
associated with a 37% lower risk of vascular complications compared with the first Angio-Seal VCD (7).  

**Cost concerns.** One important consideration in determining the optimal role of VCDs is their cost. Although most VCDs currently cost on the order of $150 to $200, given the large volume of both diagnostic angiograms and PCI procedures at many U.S. hospitals (5), even such a modest incremental cost has the potential to substantially impact catheterization laboratory and hospital budgets. Whether their utilization is cost effective depends on a variety of factors including the frequency of vascular complications, the impact of VCD use on the complication rate, and the potential for VCD to substantially alter post-procedure management patterns.

To date, several studies have examined the cost-effectiveness of vascular closure devices. The first such analysis was performed by Bos et al. (53). They used a decision analytic model to examine the potential cost-effectiveness of a collagen plug versus manual compression for achieving hemostasis at arterial puncture sites. Although they concluded (based on fairly limited evidence at the time) that a collagen plug (either Vasoseal or Angio-Seal) could reduce complications by ~50%, they estimated that use of a VCD would increase post-procedure costs by ~$135/patient with an overall cost-effectiveness ratio of $9,000 per vascular complication avoided. They concluded that this represented a relatively inefficient use of medical resources compared with other treatments. Whether this analysis is applicable to a contemporary U.S. catheterization laboratory population is debatable, however. In particular, it is unclear whether the vascular complication rates in their study (which were derived from a very small number of early studies) are comparable to those observed in current practice.

More recently, Resnic et al. (54) used a decision analytic approach to evaluate the potential cost savings associated with routine use of a collagen-suture plug (Angio-Seal) compared with manual compression. Data on specific complication rates for the 2 strategies were derived from pooled analysis of published randomized clinical trials while costs associated with various complications were derived from a matched case-control study conducted at a single U.S. academic medical center. They concluded that compared with manual compression (using the Femostop device, Radi Medical, Uppsala, Sweden), routine use of the Angio-Seal reduced both complications and cost. Most of the cost savings they projected were driven by reductions in vascular complications such as rebleeding, which they estimated to have an attributable cost of ~$5,000 per event. It is important to note that the conclusions of this study were somewhat sensitive to the cost of the compression strategy. In particular, VCD use was no longer cost saving if the manual compression strategy cost <$66/patient (as might be anticipated with manual compression alone). Thus, it is unclear whether their conclusions can be generalized to all U.S. hospitals.

Moreover, these findings probably do not apply to patients undergoing diagnostic catheterization alone where the expected risk of vascular complications is substantially lower than with PCI (4).

The strongest economic argument in favor of VCDs may be their potential to convert an inpatient PCI procedure into an outpatient procedure (55,56). This possibility was explored in a small randomized clinical trial by Rickli et al. (57). They randomized 191 patients undergoing elective PCI at a single Swiss hospital to either a routine manual compression strategy or use of a suture-based closure device (Perclose). Patients assigned to manual compression underwent sheath removal 4 h after PCI and were kept at bed rest overnight. In contrast, patients assigned to suture-mediated closure underwent immediate sheath removal and were ambulated after 4 h of bed rest. Although there were no significant differences between the 2 strategies in terms of major or minor vascular complications, use of suture-mediated closure was associated with a 12-h reduction in the post-PCI bed rest requirement (6.8 vs. 18.4 h) with associated benefits in terms of groin pain, back pain, and urinary problems. Their cost minimization analysis suggested that despite the cost of the closure device ($225€), this was more than offset by reductions in hospital length of stay and physician time with net savings of ~70€/patient. Although similar savings might be achievable in a U.S. setting as well, given the current U.S. reimbursement system (which may reimburse substantially more for an inpatient PCI procedure than a similar procedure performed on an outpatient basis), many hospitals may actually lose substantial revenue by adopting such a strategy.

What can we conclude from the available studies? First and foremost, there is no single answer to the question whether VCDs are cost effective. The answer depends on a large number of factors, most of which are particular to the local healthcare environment. For example, if a hospital routinely utilizes adjuncts to manual compression (such as the Femostop device or additional staff), it appears that by reducing vascular complications a VCD device might be cost neutral or cost saving for the vast majority of patients. However, if the relevant comparator is true manual compression without additional staff, the cost offset is probably not sufficient to fully offset device costs at the present time. In this case, a more restrictive patient selection might be justified by which VCD use was reserved for those patients at greatest risk for bleeding (38,40) or for patients where a prolonged period of bed rest would lead to unacceptable discomfort or risk of complications. Finally, the major economic value of VCDs appears to be their potential to convert PCI from an inpatient to an outpatient procedure, at least for select individuals judged to be at low risk for coronary ischemic complications (55). Whether this strategy becomes accepted and viable within the U.S. health care system will depend more on changes to the reimbursement system and the associated financial incentives than on the potential cost-effectiveness of the overall strategy, however.
VCDs: The Next 10 Years

Definitive clinical trials. To date, there have been no large-scale randomized clinical trials comparing outcomes with VCD use with those with manual compression. Nor have there been large-scale trials pitting devices head-to-head to determine the possible superiority of 1 device over another. There are several factors that account for these deficiencies in our current evidence base. First, from the standpoint of revenue, the VCD market represents a relatively small component of the total interventional cardiology market (5). As such, the incentive for device companies to sponsor expensive large-scale clinical trials is reduced. Second, sheaths are pulled only after the effects of anticoagulants have worn off for manual compression but are removed immediately after PCI when a VCD is used. Thus, any clinical trial comparing manual compression to VCD would represent a comparison of 2 alternative closure strategies as well as a direct comparison of closure efficacy. Additionally, there have been no consistent standards for defining vascular complications, particularly hematoma formation (37). More recently, a consistent definition has been adopted as part of the FDA approval process and that definition would need to be the basis of any future randomized trials (10). These prior limitations have led to the circumstances of a less-than-optimal evidence base to guide VCD use. If the results of a large randomized clinical trial establishing vascular outcomes with VCD compared with manual compression indicated that rates of vascular complications were lower with VCD, however, such a study would provide a strong impetus for VCD use in routine clinical practice.

Challenges for expanded VCD utilization. Vascular closure devices decrease the time to ambulation, the time to discharge, and decrease complications for patients undergoing diagnostic angiographic procedures (4): How can similar benefits be shown for a broader group of patients? Two groups believed to be at high risk for VCD use have been routinely excluded from the pivotal studies leading to VCD approval: patients undergoing PCI for acute myocardial infarction (58) and patients who have documented femoral arterial disease or other peripheral vascular disease (8,20,40,47). Prior studies of PCI patients with clinically important peripheral vascular disease have suggested an enhanced relative risk of vascular complications of 40% to 89% with absolute rates of complications from 2.6% to 8.9% (7,40,59–62) (Fig. 4). There are only limited data regarding use of VCDs in patients with vascular disease involving the femoral artery (59,60). Whether use of an extravascular VCD could result in an overall reduction in PCI-related vascular complications for high-risk populations such as those with femoral arterial disease is an intriguing concept that requires further study (49,60,62,63) (Fig. 5).

We believe that several studies should be performed before expanding VCD use for both diagnostic and PCI patients. Several of these potential studies are enumerated in the following text:

- A randomized trial of VCD versus manual compression among patients at high risk of vascular complications; if major vascular complication rates with manual compression were expected in >5% of an enriched control population (i.e., those with femoral disease [62] and/or PCI for acute myocardial infarction [58,64]), a device that incurred a <2% rate of major vascular complication could be studied and shown to be superior to manual compression (p < 0.05) in a 1,000-patient randomized trial.
- Surveillance registries to identify high-risk patient subsets and low-frequency adverse events; utilization of post-marketing surveillance registries of >10,000 patients may be advantageous given the relatively low rate of current vascular complications; this concept is directly

![Image](http://content.onlinejacc.org/1623.jpg)
analogous to the challenges with analyzing other low-frequency events in high-frequency procedures (i.e., drug-eluting stent thrombosis) (65); one advantage of VCD studies is that major vascular complications occur early and thus the design of these studies (as opposed to drug-eluting stent thrombosis) might require only 30-day patient follow-up; utilizing data from only 2001, the ACC-NCDR provided the largest registry data so far on VCD (4); expanding this study to the period 2003 to 2006 could provide even more convincing data on VCD impact on complications for diagnostic and PCI patients especially among subgroups for which there are current cautions (Table 1).

Studies to enhance detection of complication risk; use of a surrogate marker for clinically important vascular complications could provide a marker for device and manual compression complications (15); for example, a smaller randomized trial might utilize routine 30-day femoral arterial duplex ultrasound (15,66) to determine whether issues of nonclinical vascular compromise warrant caution with staple, collagen, suture, or manual closure methods.

It is clear from the first decade of experience with VCD use that outcomes in an individual patient reflect characteristics of the patient, the operator, and the device. While a considerable number of studies have identified “high”-risk patient characteristics (40,44), there are fewer studies that have evaluated the role of the operator in contributing to vascular complications. One criticism of the trials used to obtain FDA approval for a VCD is that the results reflect initial operator experience with the device, and in some cases the initial experience with closure devices in general (32). Thus, the rates of device failure and device-associated vascular complications in early studies may represent outcomes from the steep portion of the “learning curve” of VCD experience. Studies have documented a “learning curve” phenomenon associated with VCD use (26,62). Importantly, in the study by Warren et al. (26), there was a >3-fold increase in device failure for the first 50 patients treated with Angio-Seal compared with subsequent deployments (14% early learning curve failure rate vs. 3.5% later experience of nondeployments, p = 0.009) (26). In the study by Balzer et al. (62), the learning curve for technical success with suture-based closure was even steeper and longer (>350 patients).

While not definitive, these data strongly suggest that operator and programmatic expertise occurs only after substantial VCD experience has accrued. If VCD utilization is to achieve its maximum potential to improve clinical outcomes, it will thus be imperative to provide the educational and practical opportunities to achieve a high level of expertise. This education must address more than a particular VCD device: excellent access technique as a part of a successful VCD procedure cannot be overemphasized. It is difficult to determine what percentage of VCD failures are a result of suboptimal access technique, but expanding the use of VCDs will most likely occur in the setting of enhanced access skills.

**Toward a more ideal VCD.** Although the Angio-Seal and Perclose devices, the 2 VCDs with the longest period of commercial availability, have both undergone significant evolution and improvement (7), closure failures with these devices still occur. Moreover, the newest commercially available closure device, StarClose, has not eliminated this problem. In the CLIP (CLosure In Percutaneous Procedures) study, there was an 11% failure rate in the PCI arm of the study (10). Closure failure may occur for a number of reasons independent of the VCD used. Clinical and treatment factors, such as use of glycoprotein IIb/IIIa inhibitors and advanced age (40), will likely always challenge arterial access management. Procedural factors such as multiple attempts to gain access, back wall sticks, and access sites outside of the common femoral artery likely contribute to closure failure (10). The challenge for successful VCD use in these situations is substantial.

The patient factors influencing closure success notwithstanding, the “ideal” closure device remains to be developed. What would this device look like? 1) A single device capable of providing successful closure for all patient and access site anatomical variations; 2) an atraumatic device without a foreign body or vascular alteration of the femoral artery; and 3) a simple-to–use device with >95% procedural success and low cost. Access site closure with heat, delivered via ultrasound guidance, may be the closest approximation to the ideal VCD to date—an active closure with no potential compromise of the femoral artery (67). Unfortunately, the Therus device (Therus Corporation, Seattle, Washington) has had limitations that have delayed its introduction into clinical practice. Further innovation will be required to achieve the “ideal VCD” in the next decade.

**Conclusions**

Over the past decade, our information base has improved; so have the devices, pharmacology, and techniques associated with VCD. Based upon these more recent data, should all patients get a VCD? No—those with severe femoral arterial disease and sheath insertion above the inferior epigastric artery may have a higher risk with VCD than manual compression (45). Should most patients undergoing femoral arterial access get a VCD? For diagnostic cases, the answer may be “yes” based upon both decreased complication rates and improved time to ambulation (1,4,8,16,54). As outlined in the preceding text, however, there are numerous subgroups of diagnostic patients for whom insufficient data are available to make a clear recommendation. For PCI patients, contemporary data support a neutral effect on complications in the setting of ongoing concerns regarding device costs. The ability to convert an inpatient PCI procedure to an outpatient procedure (without adversely
The second decade of VCD launches with a history that is characterized by cautious adoption of this particular technology and frightening case reports of adverse experiences (4,32). Fortunately, the studies of the past 5 years seem to suggest that selected VCD technology not only improves time to hemostasis, but also reduces complications at least in patients undergoing diagnostic cardiac catheterization (4,33,54). Expanded use of VCD technology seems likely over the next decade as cost-effectiveness is demonstrated with respect to reduction in complications; the driver for this expanded use will be definitive trials in enriched populations, adoption of same-day PCI, mega-registries with information on high-risk subgroups, and improving technology/pharmacology/closure technique.

Reprint requests and correspondence: Dr. Harold L. Dauerman, University of Vermont College of Medicine, Fletcher Allen Health Care, 111 Colchester Avenue, McClure 1 Cardiology, Burlington, Vermont 05401. E-mail: harold.dauerman@vtmednet.org.

REFERENCES


Arterial Closure Devices Versus Manual Compression for Femoral Haemostasis in Interventional Radiological Procedures: A Systematic Review and Meta-Analysis

Rajib Das · Kamran Ahmed · Thanos Athanasiou · Robert A. Morgan · Anna-Maria Belli

Received: 17 April 2010 / Accepted: 27 July 2010 / Published online: 29 October 2010
© Springer Science+Business Media, LLC and the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) 2010

Abstract

Purpose The use of arterial closure devices (ACDs) in interventional radiology (IR) procedures has not yet been validated by large-scale randomised controlled trials or meta-analysis. Improved haemostasis and early mobilisation are publicised advantages; however, anecdotal evidence of haemorrhagic and ischaemic complications with ACDs is also apparent. Meta-analysis from interventional cardiology cannot be directly extrapolated for IR patients.

Materials and Methods Systematic review, performed according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines was performed to assess four ACDs: Angioseal; StarClose; Perclose; and Duett in peripheral vascular interventions: uterine artery embolisation, transhepatic chemoembolisation, and cerebral diagnostic and interventional procedures. Procedures requiring cardiac, aortic, or nonfemoral access, as well as those requiring >8F sheath size, were excluded. The outcomes assessed were device deployment failure, haematoma, bleeding, groin pain, retroperitoneal haematoma, arteriovenous fistula, infection, distal ischaemia, need for vascular surgery, need for manual compression, and death.

Results Search of MEDLINE and other major databases identified 34 studies from 15,805 records. Twenty-one noncomparative studies (3,662 participants) demonstrated total complication rates of 3.1–11.4%. Thirteen comparative studies were analysed separately, and random-effects meta-analysis yielded 10 studies (2,373 participants).

Conclusion Meta-analyses demonstrated no statistically significant difference, but there were marginally fewer complications with pooled ACDs compared with manual compression (odds ratio [OR] 0.87, 95% confidence interval [CI] 0.52–1.48, \( p = 0.13 \)). The Angioseal group compared with the manual-compression group (total complication rate: OR 0.84, 95% CI 0.53–1.34, \( p = 0.49 \)) and the Perclose group compared with the manual-compression group (total complication rate: OR 1.29, 95% CI 0.19–8.96, \( p = 0.01 \)) each demonstrated trends for and against the specified ACD, respectively. Adequately powered randomised controlled trials are required to further elucidate the efficacy of ACDs.

Keywords Arterial closure devices · Angioseal · StarClose · Perclose · Duett · Manual compression · Femoral · Systematic review · Meta-analysis

Introduction

It has been established that interventional radiology (IR) is a key component of modern patient diagnosis and treatment [1]. Vascular procedures, such as angiography, angioplasty, or stenting, are performed by way of femoral access, often as day-case procedures, and incur fewer risks than traditional vascular surgery [2]. The techniques in use are safe and have acceptable rates of procedural complications.

Recent evidence from the publication of the British Society of Interventional Radiology Iliac Artery Angioplasty-Stent III Registry (BIAS III) has demonstrated an increase in the use of arterial closure devices (ACDs) and a low rate of complications in both day-case and inpatient cases admitted for elective vascular interventions [3].
Haemostasis of the femoral puncture site has a major impact on patient recovery, patient turnaround time, and efficiency in the IR suite. Arterial puncture site complications can carry significant morbidity ranging from haematoma to pseudoaneurysm formation and significant arterial haemorrhage. Complications lead to extended immobility, extended inpatient hospital stay, and in some circumstances the need for vascular surgery. Difficulties in achieving haemostasis with manual compression can occur in obese patients, in patients on anticoagulant or antiplatelet therapy. Further difficulties can arise in confused patients, or when using large-bore sheaths [4].

Manual compression to the femoral artery is a successful method of haemostasis and is widely used. The need for a quicker, more effective method of haemostasis led to the development of ACDs in the 1990s. ACDs, which are based on collagen plug, clip, or suture-based mechanisms, have been publicised to allow quicker and more convenient haemostasis compared with manual compression [5].

The use of ACDs may further facilitate patient mobilisation and confer benefits of early discharge from the hospital. The increased costs of ACDs may be offset by fewer complications and thus decreased duration of patient stay. However, there are concerns (1) that ACDs may not in fact decrease the rate of haemorrhage or (2) that in the case of deployment failure, major haemorrhage may go undetected until there has been significant blood loss. A serious concern emanating from multiple published case series and anecdotal evidence involves localized arterial stenosis or distal embolisation of the device components, which can cause major morbidity and the need for emergency vascular surgery [6].

It has not yet been clarified by way of robust analytical means whether ACDs have an acceptable device complication rate and whether their ability to achieve haemostasis outweighs these complications. No current United Kingdom guidelines have been formulated for the use of ACDs. No systematic review or meta-analysis has been published in the context of interventional radiological procedures to date.

There are many different proprietary ACDs in circulation at present, and the numbers are constantly increasing. This study is mainly concerned with the four most widely used devices: Angioseal (St. Jude Medical, St Paul, MN, USA), StarClose (Abbott Vascular, IL, USA), Perclose (Abbott Vascular, IL, USA), and Duett (Vascular Solutions, Minneapolis, MN, USA). These devices are the most widely used ACDs worldwide and are subjects of the largest body of published literature.

Differences in the Use of ACDs in Cardiology Versus IR

Interventional cardiologists have been quicker to adopt the widespread use of ACDs than interventional radiologists. The reason behind this is likely multifactorial but may be due to time pressures stimulating a greater need for ACDs, the use of larger-bore sheaths, the number of outpatient procedures in cardiology, or the increased use of antiplatelets/anticoagulants in their patient populations.

There are differences in the types of procedures performed by cardiologists, which generally include coronary angiography, angioplasty, and stent deployment, whereas vascular interventional procedures may be frequently performed in patients with atherosclerotic aortoiliac and infranigual arterial disease. Vascular interventional and interventional oncology procedures also treat a variety of other disease processes, including haemorrhage, involving a wide range of organs other than the heart.

Because these significant differences exist, we hypothesise that it is appropriate to analyse the use of ACDs in IR separately from those used in cardiology. The information derived from a specialty-specific systematic review will be of greater use to the practising specialist because the data can be applied to their own patient group.

Published Systematic Reviews and Meta-Analyses in Interventional Cardiology

Three systematic reviews and meta-analyses, published in 2004, have been performed in interventional cardiology patients. Koreny et al. [7] found no significant evidence that ACDs were superior to manual compression, and some analyses suggested that the risk of haematoma and pseudoaneurysm is increased in association with ACD use. However, heterogeneity amongst several studies was noted. Nikolsky et al. [8] found no difference between Angioseal and manual compression in the diagnostic coronary angiography setting, with there being a trend toward fewer complications with Angioseal in the percutaneous coronary intervention (PCI) setting, yet more complications with VasoSeal (Datascope). Vaitkus [9] also performed a meta-analysis in this subject and found a risk reduction associated with the use of Angioseal yet a neutral result with Perclose. VasoSeal is not widely used in interventional radiological practice and has therefore not been included in this systematic review. The overall picture is not clear in the cardiology literature and less so for IR patients.

Objective

We sought to examine, by way of systematic review and meta-analysis, whether ACDs decrease or increase the rate of haemorrhagic, infective, and ischaemic complications as well as determine the need for vascular surgical intervention compared with manual compression in femoral haemostasis in interventional radiological procedures.
Methods

The method of assessing data from trials has been identified as a key aspect in the quality of a systematic review [10]. In this systematic review, the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement was followed using the PRISMA 27-point checklist to ensure thorough reporting of all aspects of the study [11, 12].

Eligibility Criteria

A full literature search was performed with the focus on the detection of studies including all comparative and non-comparative studies that used one of the four main proprietary ACDs (Angioseal, StarClose, Perclose, or Duett) compared with standard manual compression in interventional radiological procedures. This included randomized controlled trials (RCTs), nonrandomised controlled trials, case-control studies, and cohort studies. Case reports, case series (<5), and small noncomparative studies were not included. Other less widely used devices (e.g., VasoSeal, QuickSeal) or adjuncts to manual compression (FemoStop) were not specifically included unless they were featured in a secondary minor capacity in a study that was already included.

The search criteria were designed to include all studies involving the four main ACDs and manual compression in interventional procedures by way of femoral arterial access. Studies using brachial, radial, and venous punctures were not included. Studies using both antegrade and retrograde femoral punctures were included because these are part of the routine variation in interventional radiological practice. All coronary or cardiac catheterization studies were excluded. The procedures included were lower-limb (iliac and infrainguinal) arterial intervention (angiography, angioplasty, or stenting), renal artery intervention, uterine artery embolisation (UAE), and transhepatic chemoembolization or radioembolisation. In addition, neuroradiological diagnostic and interventional studies were included because they are also performed by radiologists and include a similar spectrum of techniques.

In addition to excluding cardiac procedures, endovascular aneurysm repair and aortic interventions were also excluded because these procedures require large-bore arterial access (>8F). To enable consistency in these criteria, studies using sheath or device sizes >8F were excluded from the systematic review because most routine IR procedures are performed with <8F sheaths, and thus ACDs are primarily aimed at these sheath sizes.

Information Sources

The search was performed in March 2010 using MEDLINE, Cochrane Collaboration, and Google Scholar databases. Additional studies that met the criteria for inclusion were identified by checking the references of located, relevant papers and searching for studies that cited these papers. The term, “related articles,” was also used in PubMed to identify potential studies. Details of the electronic search are included in the Appendix (MEDLINE medical-subject headings used in the primary search).

Eligibility Assessment

Eligibility assessment was performed in an unblinded standardised manner by a primary reviewer, and articles requiring clarification were discussed with co-reviewers and agreed upon by consensus for inclusion.

Study Selection and Data-Collection Process

Data were extracted from the full-text published version of each included study. Studies were categorised as comparative or noncomparative. The data and information were rechecked for errors or ambiguity, and any items of ambiguity were discussed with the co-reviewers. To ascertain the validity of eligible studies, the following was determined for each study from the full-text of the published article: adequacy of randomisation and concealment of allocation; blinding of patients, health care providers, and data collectors; and extent of loss to follow-up.

Risk of Bias in Individual Studies

To quantify the variability and quality of included studies, scoring devices were used to assist. Few RCTs were available in this study, but those RCTs available were assessed according to the Jadad score [13], and nonrandomised studies were assessed by the methodological index for nonrandomised studies (MINORS) scoring system. The MINORS scoring system was developed and published in 2003 to evaluate nonrandomised studies [14] and consists of 12 items, with the global ideal score being 16 for noncomparative studies and 24 for comparative studies. Most studies included were nonrandomised trials, generally of weak methodology, and best evaluated by the MINORS score and not by more stringent tests.

Particularly in the noncomparative studies, the risk of bias is high because the tendency will have been to use the ACD on patients without adverse cofactors or to report only those that were successful or without complication.
Scoring systems aim to dissect through these factors and identify the weaker studies.

Summary Measures and Synthesis of Results

The meta-analysable studies were assessed using Review Manager (RevMan computer program), version 4.2 for Windows (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark 2003). Relative risks (RRs) and odds ratios (ORs) were calculated using a random-effects model. A dichotomous statistical analysis was used, and standardised means and 95% confidence intervals (CIs) were calculated using Review Manager.

RR and OR ratios of rates of haematoma, bleeding, pseudoaneurysm, retroperitoneal haematoma, and arteriovenous fistula were calculated for haemorrhagic complications. Infection, groin pain, distal or worsening ischaemia, need for vascular surgery, and need for adjunctive manual compression were also calculated as RRs and ORs to 95% CIs. Tests of heterogeneity were performed by RevMan according to the DerSimonian [15] technique using the Q statistic with a \( \chi^2 \) distribution and is displayed on all Forest plots generated.

Additional Analyses

Data were collected to allow subgroup analyses to assess contributory factors to complications. Patient sex, sheath size, and other procedural details were recorded to correlate with rates of complications. Unfortunately the majority of studies did not clearly correlate complications with specific factors, and so further subgroup analyses were noncontributory in the majority.

Results

Study Selection

The search generated 15,805 studies in total. A large number of searched studies were duplicates and were therefore automatically excluded. Of these, 105 further studies were discarded after initial review. The full text of the remaining 71 citations was examined in detail. After examination, 37 studies did not meet the inclusion criteria as described, and 34 studies met the inclusion criteria and were included in the systematic review.

Study Characteristics

Thirty-four studies were identified for inclusion in the systematic review. Thirteen studies were comparative in nature, either of an ACD compared with manual compression or one ACD versus another ACD. Of the thirteen comparative studies, 4 were randomised trials. The remaining 21 studies were noncomparative and predominantly assessed the complications from a single ACD. Comparative and noncomparative studies are assessed separately in this review.

Results of Individual Studies and Synthesis of Results

Noncomparative Studies

In total, there were 21 noncomparative studies comprising 4,115 common femoral arterial punctures in 3,662 patients. Patient sex was reported in only 3,087 patients and consisted of 1,754 men and 1,333 women. Direction of puncture was specifically stated in 3,476 cases and consisting of 890 antegrade and 2,586 retrograde punctures. The noncomparative cases (a small number of studies were ambiguous in defining the nature of the intervention) comprised 307 diagnostic peripheral angiograms, 1,766 peripheral interventions (mainly angioplasty or stenting), 10 renal artery interventions, 773 diagnostic cerebral angiograms, 886 neurointerventional procedures, 328 UAEs, and 35 other miscellaneous peripheral arterial interventions.

In several studies, not every outcome was assessed, and unless this fact was explicitly stated in the full-text article, the study was judged not to have assessed for a particular parameter. Therefore, no assumptions were made, and all outcomes assessed in this review were specifically stated within the included article (Tables 1, 2).

The findings from the noncomparative studies should be interpreted with care. All of the studies are of relatively low methodological quality, and not every parameter listed here was measured in each study. Therefore, a negative finding does not necessarily confer a low rate of complication but may rather reflect that a parameter may not have been evaluated. Parameters that were reliably analysed throughout most studies include haematoma, pseudoaneurysm, and distal ischaemia.

These results reflect that the percentage risk of haematoma is slightly lower in Angioseal and Perclose recipients than in those undergoing manual compression (although the manual-compression group is small [consisting of 2 studies]), and rates of distal ischaemia are low (0.2–0.4%) in all groups. However, sample sizes are unequal, and the marked heterogeneity of these studies make formal conclusion difficult.

Comparative Studies

Thirteen studies compared an ACD with manual compression or another ACD. The studies were categorised as
Table 1 Noncomparative studies (n = 21)

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Journal</th>
<th>Year of publication</th>
<th>Country</th>
<th>Procedure</th>
<th>Antegrade puncture</th>
<th>Retrograde puncture</th>
<th>Total no. of punctures</th>
<th>Total no. of patients</th>
<th>Prospective or retrospective</th>
<th>Follow-up (wk)</th>
<th>MINORS score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angioseal (n = 8)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Katzenschlager [16]</td>
<td>Angiology</td>
<td>2009</td>
<td>Austria</td>
<td>Lower-limb interventional</td>
<td>69</td>
<td>36</td>
<td>105</td>
<td>105</td>
<td>Prospective</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>Aksoy [17]</td>
<td>Eur J Vasc Endovasc Surg</td>
<td>2006</td>
<td>France</td>
<td>Miscellaneous lower-limb interventional, renal, cerebral</td>
<td>N</td>
<td>N</td>
<td>79</td>
<td>79</td>
<td>Prospective</td>
<td>36</td>
<td>8</td>
</tr>
<tr>
<td>Makohdpay [18]</td>
<td>Eur J Radiol</td>
<td>2005</td>
<td>UK</td>
<td>Lower-limb interventional</td>
<td>21</td>
<td>0</td>
<td>21</td>
<td>21</td>
<td>Retrospective</td>
<td>B</td>
<td>4</td>
</tr>
<tr>
<td>Biondi-Zoccai [19]</td>
<td>Int J Cardiol</td>
<td>2007</td>
<td>Italy</td>
<td>Lower-limb interventional</td>
<td>5</td>
<td>0</td>
<td>5</td>
<td>5</td>
<td>Prospective</td>
<td>A</td>
<td>2</td>
</tr>
<tr>
<td>Geyik [20]</td>
<td>Neuroradiology</td>
<td>2007</td>
<td>Turkey</td>
<td>Neurodiagnostic, neurointerventional</td>
<td>0</td>
<td>1,443</td>
<td>1,443</td>
<td>1,099</td>
<td>Retrospective</td>
<td>X</td>
<td>4</td>
</tr>
<tr>
<td>O’Sullivan [22]</td>
<td>Clin Radiol</td>
<td>1999</td>
<td>UK</td>
<td>Lower-limb interventional</td>
<td>N</td>
<td>N</td>
<td>50</td>
<td>45</td>
<td>Prospective</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Pierot [23]</td>
<td>Neuroradiology</td>
<td>2006</td>
<td>France</td>
<td>Neurointerventional</td>
<td>N</td>
<td>N</td>
<td>119</td>
<td>119</td>
<td>Prospective</td>
<td>X</td>
<td>6</td>
</tr>
<tr>
<td>Angioseal totals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>151</td>
<td>1,479</td>
<td>1,878</td>
<td>1,528</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Starclose (n = 5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fantoni [25]</td>
<td>Int J Cardiology</td>
<td>2008</td>
<td>Italy</td>
<td>Lower-limb interventional</td>
<td>30</td>
<td>0</td>
<td>30</td>
<td>30</td>
<td>Prospective</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Williams [26]</td>
<td>J Endovasc Ther</td>
<td>2007</td>
<td>UK/France</td>
<td>Lower-limb interventional</td>
<td>222</td>
<td>0</td>
<td>222</td>
<td>221</td>
<td>Retrospective</td>
<td>A</td>
<td>8</td>
</tr>
<tr>
<td>Branzan [27]</td>
<td>J Endovasc Ther</td>
<td>2009</td>
<td>Germany</td>
<td>Lower-limb interventional</td>
<td>37</td>
<td>194</td>
<td>231</td>
<td>226</td>
<td>Prospective</td>
<td>A</td>
<td>11</td>
</tr>
<tr>
<td>Chiu [28]</td>
<td>J Endovasc Ther</td>
<td>2010</td>
<td>Australia</td>
<td>Lower-limb interventional</td>
<td>40</td>
<td>103</td>
<td>143</td>
<td>132</td>
<td>Retrospective</td>
<td>B</td>
<td>6</td>
</tr>
<tr>
<td>Starclose totals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>457</td>
<td>391</td>
<td>848</td>
<td>809</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perclose (n = 6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duda [29]</td>
<td>Radiology</td>
<td>1999</td>
<td>Germany</td>
<td>Lower-limb interventional</td>
<td>80</td>
<td>0</td>
<td>80</td>
<td>80</td>
<td>Prospective</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>Morris [33]</td>
<td>AJNR</td>
<td>1999</td>
<td>United States</td>
<td>Neurointerventional</td>
<td>0</td>
<td>69</td>
<td>69</td>
<td>65</td>
<td>Prospective</td>
<td>X</td>
<td>1</td>
</tr>
<tr>
<td>Chrisman [34]</td>
<td>JVIR</td>
<td>2005</td>
<td>United States</td>
<td>UAE</td>
<td>0</td>
<td>328</td>
<td>328</td>
<td>328</td>
<td>Prospective</td>
<td>52</td>
<td>9</td>
</tr>
<tr>
<td>Perclose totals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100</td>
<td>446</td>
<td>1,070</td>
<td>1,042</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
listed in Table 3. Only the larger groups studying Angioseal compared with manual compression, Perclose compared with manual compression, Angioseal compared with Perclose, and all four ACDs compared with manual compression were meta-analysable, and the results of these are presented later in the text. The remaining comparison groups all consisted of one study each, which is too limited for comparative fixed or random-effects model analysis, but their results can be interpreted separately.

The term “total complication rate” in this study refers to the sum of haematoma, bleeding, pseudoaneurysm, groin pain, retroperitoneal haematoma, infection, arteriovenous (AV) fistula, and need for vascular surgery and excludes data values for device deployment failure and need for manual compression. The specific characteristics of the comparative studies are listed in Table 4.

**ANGIOSEAL Versus Manual Compression (n = 6)**

Due to inadequate numbers in each group or a large number of negative outcomes, bleeding, groin pain, retroperitoneal haematoma, AV fistula, and infection could not be subjected to meta-analysis. 6 studies included 940 participants. The analysed end points are presented below:

- Risk of haematoma—OR 0.86 (95% CI 0.51–1.45) ($p = 0.78$)
- Risk of pseudoaneurysm—OR 0.30 (95% CI 0.04–2.07) ($p = 0.93$)
- Risk of distal ischaemia—OR 0.80 (95% CI 0.22–2.94) ($p = 0.58$)
- Need for vascular surgery—OR 0.83 (95% CI 0.18–3.85) ($p = 0.53$).

Figure 1: Forest plot of total complication rate—Angioseal versus Manual compression—OR 0.84 (95% CI 0.53–1.34) ($p = 0.49$).

**STARCLOSE Versus Manual Compression (n = 1)**

For StarClose versus manual compression the data could not be subjected to meta-analysis.

**PERCLOSE Versus Manual Compression (n = 3)**

Due to inadequate numbers in each group or a large number of negative outcomes, haematoma, bleeding, groin pain, retroperitoneal haematoma, AV fistula, infection, distal ischaemia and need for vascular surgery could not be subjected to meta-analysis. 3 studies included 856 participants.

Figure 2: Forest plot of total complication rate—Perclose versus Manual compression—OR 1.29 (95% CI 0.19–8.96) ($p = 0.01$).
Table 2 Analysis of noncomparative study findings

<table>
<thead>
<tr>
<th>Type of complication</th>
<th>No. (%) of Angioseal studies (n = 8)</th>
<th>No. (%) of StarClose studies (n = 5)</th>
<th>No. (%) of Perclose studies (n = 6)</th>
<th>No. (%) of manual-compression studies (n = 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device failure</td>
<td>12 (0.6)</td>
<td>46 (5.4)</td>
<td>43 (4.0)</td>
<td>X</td>
</tr>
<tr>
<td>Haematoma</td>
<td>22 (1.2)</td>
<td>24 (2.8)</td>
<td>20 (1.9)</td>
<td>10 (3.1)</td>
</tr>
<tr>
<td>Bleeding</td>
<td>14 (0.8)</td>
<td>21 (2.5)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Groin pain</td>
<td>0</td>
<td>17 (2.0)</td>
<td>68 (6.4)</td>
<td>0</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>8 (0.4)</td>
<td>3 (0.4)</td>
<td>4 (0.4)</td>
<td>2 (0.6)</td>
</tr>
<tr>
<td>Retroperitoneal haematoma</td>
<td>7</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>AV fistula</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Infection</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Distal ischaemia</td>
<td>3 (0.2)</td>
<td>1 (0.01)</td>
<td>4 (0.4)</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Need for vascular surgery</td>
<td>17</td>
<td>33</td>
<td>40</td>
<td>1</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Total complicationsa</td>
<td>59</td>
<td>71</td>
<td>104</td>
<td>13</td>
</tr>
<tr>
<td>Total punctures</td>
<td>1,878</td>
<td>848</td>
<td>1,070</td>
<td>319</td>
</tr>
<tr>
<td>Percentage complication rate (%)</td>
<td>3.1</td>
<td>8.3</td>
<td>9.7</td>
<td>4.1</td>
</tr>
</tbody>
</table>

X not applicable

* Excluding device failure and need for manual compression

Table 3 Comparative studies: methods of comparison

<table>
<thead>
<tr>
<th>Haemostatic method 1</th>
<th>Haemostatic method 2</th>
<th>No. of studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angioseal</td>
<td>Manual compression</td>
<td>6a</td>
</tr>
<tr>
<td>StarClose</td>
<td>Manual compression</td>
<td>1a</td>
</tr>
<tr>
<td>Perclose</td>
<td>Manual compression</td>
<td>3</td>
</tr>
<tr>
<td>Duett</td>
<td>Manual compression</td>
<td>1</td>
</tr>
<tr>
<td>All 4 ACDs</td>
<td>Manual compression</td>
<td>10</td>
</tr>
<tr>
<td>Angioseal</td>
<td>StarClose</td>
<td>1a</td>
</tr>
<tr>
<td>Angioseal</td>
<td>Perclose</td>
<td>3</td>
</tr>
<tr>
<td>Angioseal</td>
<td>Duett</td>
<td>0</td>
</tr>
<tr>
<td>StarClose</td>
<td>Perclose</td>
<td>0</td>
</tr>
<tr>
<td>StarClose</td>
<td>Duett</td>
<td>0</td>
</tr>
<tr>
<td>Perclose</td>
<td>Duett</td>
<td>0</td>
</tr>
</tbody>
</table>

a Refers to one study by Ratnam et al. [41], who performed a prospective, nonrandomised trial of Angioseal, StarClose and manual compression by way of separate outcome analysis and thereby features in three comparison groups in this study.

DUETT Versus Manual Compression (n = 1)

For Duett versus manual compression the data could not be subjected to meta-analysis due to the presence of a single study and limited positive outcome findings in this study.

ANGIOSEAL Versus STARCLOSE (n = 1)

For Angioseal versus Starclose the data could not be subjected to meta-analysis due to the presence of a single study and limited positive outcome findings in this study.

ANGIOSEAL Versus PERCLOSE (n = 3)

Bleeding, groin pain, retroperitoneal haematoma, AV fistula, infection, and need for vascular surgery could not be subjected to meta-analysis due to inadequate numbers in each group or a large number of negative outcomes. 3 studies included 2,199 participants.

- Risk of haematoma—OR 1.39 (95% CI 0.65–3.01) (p = 0.18)
- Risk of distal ischaemia—OR 2.12 (95% CI 0.23–19.21) (p = 0.96)
- Need for manual compression—OR 0.44 (95% CI 0.31–0.63) (p = 0.66)
- Device deployment failure rate—OR 0.44 (95% CI 0.31–0.63) (p = 0.66).

Figure 3: Forest plot of total complication rate—Angioseal versus Perclose—OR 1.01 (95% CI 0.65–1.58) (p = 0.52).

Final Analysis—All 4 ACDs Pooled Versus Manual Compression

Final analysis was performed pooling all outcomes for all 4 ACDs (Angioseal, Starclose, Perclose and Duett) versus manual compression.

End points of groin pain, bleeding, retroperitoneal haematoma, AV fistula and infection could not be subject to meta-analysis due to inadequate positive cases. Meta-analyses are presented below:
<table>
<thead>
<tr>
<th>Investigator</th>
<th>Journal</th>
<th>Year</th>
<th>Country</th>
<th>Procedure</th>
<th>Antegrade</th>
<th>Retrograde</th>
<th>Total no. of punctures in study</th>
<th>Total no. of patients in study</th>
<th>M</th>
<th>F</th>
<th>No. of ACDs (1)</th>
<th>No. of man comp/ACDs (2)</th>
<th>Prospective or retrospective</th>
<th>Follow-up period (wk)</th>
<th>Randomised MINORS score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angioseal versus manual compression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>100</td>
<td>100</td>
<td>57</td>
<td>43</td>
<td>50</td>
<td>50</td>
<td>Prospective</td>
<td>12</td>
<td>Y</td>
</tr>
<tr>
<td>Beyer-Enke [37]</td>
<td>CVIR</td>
<td>1996</td>
<td>Germany</td>
<td>Lower-limb interventional</td>
<td>X</td>
<td>X</td>
<td>100</td>
<td>100</td>
<td>58</td>
<td>0</td>
<td>58</td>
<td>34 26</td>
<td>Retrospective</td>
<td>X</td>
<td>N</td>
</tr>
<tr>
<td>Looby [38]</td>
<td>CVIR</td>
<td>2008</td>
<td>Ireland</td>
<td>Lower-limb interventional</td>
<td>X</td>
<td>X</td>
<td>239</td>
<td>188</td>
<td>104</td>
<td>88</td>
<td>220</td>
<td>19</td>
<td>Retrospective</td>
<td>12</td>
<td>N</td>
</tr>
<tr>
<td>MacDonald [40]</td>
<td>CVIR</td>
<td>2002</td>
<td>UK</td>
<td>Lower-limb interventional</td>
<td>X</td>
<td>X</td>
<td>426</td>
<td>426</td>
<td>234</td>
<td>192</td>
<td>167</td>
<td>108</td>
<td>Prospective</td>
<td>B</td>
<td>N</td>
</tr>
<tr>
<td>Ratnam [41]</td>
<td>CVIR</td>
<td>2007</td>
<td>UK</td>
<td>Lower-limb diagnostic and interventional</td>
<td>X</td>
<td>X</td>
<td>100</td>
<td>100</td>
<td>68</td>
<td>32</td>
<td>50</td>
<td>50</td>
<td>Prospective</td>
<td>6</td>
<td>Y</td>
</tr>
<tr>
<td>Upponi [42]</td>
<td>Eur J Radiol</td>
<td>2007</td>
<td>UK</td>
<td>Lower-limb diagnostic and interventional</td>
<td>0</td>
<td>0</td>
<td>100</td>
<td>100</td>
<td>X</td>
<td>X</td>
<td>60</td>
<td>108</td>
<td>Prospective</td>
<td>6</td>
<td>Y</td>
</tr>
<tr>
<td>Totals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>593</td>
<td>347</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Starclose versus manual compression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>426</td>
<td>426</td>
<td>234</td>
<td>192</td>
<td>151</td>
<td>108</td>
<td>Prospective</td>
<td>B</td>
<td>N</td>
</tr>
<tr>
<td>Ratnam [41]</td>
<td>CVIR</td>
<td>2007</td>
<td>UK</td>
<td>Lower-limb diagnostic and interventional</td>
<td>X</td>
<td>X</td>
<td>100</td>
<td>100</td>
<td>58</td>
<td>28</td>
<td>52</td>
<td>50</td>
<td>Prospective</td>
<td>58</td>
<td>Y</td>
</tr>
<tr>
<td>Perclose versus manual compression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>102</td>
<td>102</td>
<td>74</td>
<td>28</td>
<td>52</td>
<td>50</td>
<td>Prospective</td>
<td>58</td>
<td>Y</td>
</tr>
<tr>
<td>Wagner [44]</td>
<td>JVIR</td>
<td>2003</td>
<td>United States</td>
<td>UAE, TACE, diagnostic/interventional lower limb</td>
<td>0</td>
<td>0</td>
<td>200</td>
<td>200</td>
<td>30</td>
<td>170</td>
<td>100</td>
<td>100</td>
<td>Retrospective</td>
<td>X</td>
<td>N</td>
</tr>
<tr>
<td>Khagany [45]</td>
<td>AJNR</td>
<td>2005</td>
<td>United States</td>
<td>Neurointervention</td>
<td>0</td>
<td>0</td>
<td>554</td>
<td>554</td>
<td>416</td>
<td>327</td>
<td>475</td>
<td>79</td>
<td>Prospective</td>
<td>A</td>
<td>N</td>
</tr>
<tr>
<td>Totals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>627</td>
<td>229</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duett versus manual compression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>426</td>
<td>426</td>
<td>211</td>
<td>215</td>
<td>211</td>
<td>215</td>
<td>Retrospective</td>
<td>4</td>
<td>N</td>
</tr>
<tr>
<td>Hong [46]</td>
<td>JVIR</td>
<td>2005</td>
<td>United States</td>
<td>TACE</td>
<td>0</td>
<td>0</td>
<td>426</td>
<td>426</td>
<td>214</td>
<td>211</td>
<td>215</td>
<td>215</td>
<td>Retrospective</td>
<td>4</td>
<td>N</td>
</tr>
<tr>
<td>Angioseal versus Starclose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>426</td>
<td>426</td>
<td>234</td>
<td>192</td>
<td>167</td>
<td>151</td>
<td>Prospective</td>
<td>B</td>
<td>N</td>
</tr>
<tr>
<td>Ratnam [41]</td>
<td>CVIR</td>
<td>2007</td>
<td>UK</td>
<td>Lower-limb diagnostic and interventional</td>
<td>X</td>
<td>X</td>
<td>100</td>
<td>100</td>
<td>68</td>
<td>32</td>
<td>50</td>
<td>50</td>
<td>Prospective</td>
<td>6</td>
<td>Y</td>
</tr>
</tbody>
</table>
Figure 4: Forest plot of Haematoma (All ACDs vs. Manual compression)
OR 0.90 (95% CI 0.56–1.44) (p = 0.45).

Figure 5: Forest plot of Pseudoaneurysm (All ACDs vs. Manual compression)
OR 0.37 (95% CI 0.07–1.89) (p = 0.20).

Figure 6: Forest plot of Distal ischaemia (All ACDs vs. Manual compression)
OR 1.00 (95% CI 0.33–3.03) (p = 0.59).

Figure 7: Forest plot of Need for vascular surgery (All ACDs vs. Manual compression)
OR 0.75 (95% CI 0.28–2.04) (p = 0.52).

Figure 8: Forest plot of Total complication rate (All ACDs vs. Manual compression)
OR 0.87 (95% CI 0.52–1.48) (p = 0.13).

Risk of Bias Across and Within Studies

Biases within each study are presented as the MINORS score. Selection bias was evaluated by assessing whether consecutive or prospectively recruited patients were used, and loss to follow-up was also accounted for. Unbiased assessment of end points was also evaluated. In the case of comparative studies, MINORS assesses for the use of contemporary and equivalent groups and appropriate statistical methods employed.

Random-effects models were used in the meta-analyses. Each meta-analysis included a Cochran Q test. Q combined with degrees of freedom calculated the I² (proportion of variation due to heterogeneity.) Although planned in the initial study protocol, further subgroup analysis was not deemed suitable due to the nature and variability of the studies included. Therefore, subgroup analyses of the type of intervention, size of vascular access, or other demographic characteristics were not included. It was believed that they would not significantly contribute to this study or hold statistical validity. Subgroup analysis using only higher-quality studies (high MINORS scores) led to limited numbers in each comparison group and precluded meta-analysis due to inadequate numbers.

Discussion

Summary of Evidence

No previous systematic review has been published on the comparison of ACDs and manual compression in IR patients. Interventional cardiologists have performed some
RCTs on the use of ACDs in cardiac catheterisation and have published a small number of meta-analyses. There are several differences between the techniques used by interventional cardiologists and radiologists, and it is not necessarily justified to extrapolate information from one specialty for use in the other. Radiologists have been less
forthcoming in the publication of data from their use of ACDs, and therefore studies are more limited in quality and number than those in the cardiology literature.

Two of three meta-analyses of ACDs in the cardiology literature failed to demonstrate their superiority compared with manual or mechanical compression. Koreny et al. [7] analysed 30 trials, including 4,000 patients, comparing ACDs (Angioseal, VasoSeal, Duett, and Perclose) with standard manual compression in 2004. This meta-analysis found a marginal increase in RR of groin haematoma (RR = 1.14 95% CI 0.86–1.51, p = 0.35) and pseudoaneurysm (RR = 1.19 95% CI 0.75–1.88, p = 0.46) when using ACDs. However, there was a high degree of heterogeneity amongst studies, and many studies in their group were of suboptimal methodological quality. Koreny et al. conducted RCTs; however, they did not exclude articles that were published as only abstracts or short reports and therefore have been criticised for not being fully systematic in their analysis [8].

Also published in 2004, a second meta-analysis [8] examined 30 studies and found a similar risk of access-site complications with ACDs compared with mechanical compression. Angioseal and Perclose showed a trend toward slightly fewer complications when examining only PCIs in RCTs. A third meta-analysis [9] published in 2004 found a decrease in the risk of complications when using...
Angioseal, but a neutral risk associated with Perclose and an increased risk associated with VasoSeal, when examining 16 studies and recommended further research with large, appropriately powered RCTs to further examine this issue.

This systematic review and meta-analysis was designed to detect differences between ACDs and manual compression in the setting of IR. Many operators have adopted ACDs by necessity due to the need for faster turnaround times, increased patient throughput, and reluctance to physically apply manual compression, which is time-consuming. The disadvantages are described but are deemed “safe” due to their relatively infrequent occurrence. In general, data regarding the occurrence of complications in percutaneous IR procedures are scarce, and this adds to the difficulty in detecting significant differences.

From review of the literature, the initial study hypothesis before commencing this systematic review and meta-analysis was that there would be a decrease in haemorrhagic complications when using ACDs (Angioseal > StarClose and Perclose) and potentially an increase in local or distal ischaemic complications compared with manual compression. This study demonstrated a trend, but the differences are not marked enough to reach statistical significance.

Six studies were analysed that compared Angioseal with manual compression. Three studies were of higher quality...
(e.g., Beyer-Enke [37], Ratnam [41], and Upponi [42] [MINORS scores 13–14/24]) than the others. Random-effects analysis demonstrated ORs of 0.86 (95% CI 0.51–1.45, \( p = 0.78 \)) for haematoma events and ORs of 0.30 (95% CI 0.04–2.07, \( p = 0.93 \)) for pseudoaneurysm.

Both marginally favour a trend toward Angioseal as having fewer complications than manual compression. However, neither is statistically significant and must be interpreted with caution because there are few studies in the analysis. Ischaemic complications (OR 0.8, 95% CI 0.22–2.94, \( p = 0.58 \)) and need for vascular surgery (OR 0.83, 95% CI 0.18–3.85, \( p = 0.53 \)) both showed no significant difference, with just a minimal trend toward fewer events using Angioseal. Analysis of total complications using Angioseal compared with manual compression also showed no significant difference between the two groups (OR 0.84, 95% CI 0.53–1.34, \( p = 0.49 \)). This was the largest comparison of ACD with manual compression (940 participants).

Analysis of Perclose compared with manual compression comprised three studies in the analysis (856 participants.) There was a trend favouring manual compression in the analyses of total complication rate (OR 1.29, 95% CI 0.9–8.9, \( p = 0.01 \) [statistically significant]). The only meta-analysis between two ACDs was between Angioseal and Perclose (2,199 participants). Total complication rate showed no difference between the two devices (OR 1.01, 95% CI 0.65–1.58, \( p = 0.52 \)). A subanalysis of Angioseal and Perclose was performed because these two devices were the only two device groups that met criteria for subanalysis. The other devices (i.e., StarClose, Duett) and other comparisons (e.g., Angioseal vs. StarClose) could not be performed due to incomplete numbers for meta-analysis.

The final analysis pooled all four ACDs compared with manual compression. This includes 10 studies and a total of 2,373 participants. Most analyses (haematoma, pseudoaneurysm, need for vascular surgery) and total complication rate marginally favour the pooled ACDs (OR 0.87, 95% CI 0.52–1.48, \( p = 0.13 \)), but this did not achieve statistical significance.

This systematic review reflects the findings of the three main meta-analyses [7–9] in interventional cardiology patients with a marginal trend toward fewer complications with ACDs, particularly with Angioseal, but statistical significance has not been demonstrated. This review allows consolidation of a varied range of studies by interventional radiologists and aims to determine whether ACDs are of benefit. At present, only anecdotal and case-based evidence exists for and against the use of ACDs, and unfortunately this systematic review is limited by the quality and heterogeneity of the included studies. Studies were separated according to comparative and noncomparative study types, and this ensures that the levels of evidence from these studies were differentiated. The noncomparative studies were of lower MINORS scores (>11 of 16) and were not meta-analyzable. In the noncomparative study group, many procedures were diagnostic or were performed using small-bore sheaths (usually 4F to 5F). In these cases, it is questionable if the use of an ACD, which is usually of 6F diameter, is indicated.

Each study was assessed and particular care exerted to ensure that only explicitly stated end points were counted in the review. Many studies presented their findings in prose or descriptive format, and specific care was taken to ensure that no assumptions were made. All studies were
analysed in their full-text format, and no abstract-only or non-full text articles were included.

Limitations

There are some limitations of this systematic review and meta-analysis. Many of the included studies were of poor methodological quality, and almost no randomised controlled trials were available. The randomised trials that were included were not of high methodological quality. It may be argued that it is not appropriate to draw conclusions from all four ACDs pooled together because they are of different haemostatic technique, and care should be employed when interpreting these results because they are not readily applicable in practice.

Each study exhibited variability in its definitions and measurement of end points, which leads to increased heterogeneity of studies. Whilst some studies provided a clear definition of haematoma, e.g., size in centimetres, others did not, which in part reflects normal clinical practice. Differences between studies using ultrasound or clinical assessment also pose variability problems. It may also be considered that the status of blood coagulation and administration of anticoagulant medication may differ between studies.

This systematic review did not exclusively include RCTs and may therefore be open to criticism. However, the inclusion of comparative nonrandomised studies is an established method and has been advocated when large randomised trials are not available [50]. They are, however, prone to more bias and can lead to misleading outcomes. Using small studies in meta-analysis may limit the ability to detect differences because of the infrequent incidence of the outcome measure under analysis. This factor affected the outcome of this review because the incidence of complications in general is low (<2 to 3%), and therefore large numbers of patients are required to detect a difference. At present, the body of reliable evidence and RCTs is not available in the field of IR.

Conclusion

In conclusion, this systematic review has shown no significant difference between the use of ACDs compared with manual compression in interventional radiological procedures. A marginal trend favouring Angioseal compared with manual compression and favouring manual compression compared with Perclose was seen, but heterogeneity factors make it difficult to use this evidence definitively. ACDs appear to be safe, and no statistical evidence to support adverse outcomes can be concluded. The fact that there seems to be no advantage to ACDs compared with manual compression is a valid point and should be taken into consideration along with the cost implications of using these devices. The finding that ACDs have no demonstrable disadvantage compared with manual compression may further encourage their use in difficult patient groups more prone to complications with manual compression (e.g., immobile, obese, or noncompliant patients). This study was not able to assess the duration of inpatient stay or time to ambulation with ACDs or manual compression due to the variability in reporting of this data, and the potential advantages of increased patient throughput and early discharge could not be assessed. A large-scale randomised controlled trial in the IR community is warranted to examine whether there is benefit with the use of ACDs compared with manual compression.

Conflict of interest None.

Appendix: Search Strategies

Electronic Search Strategy

The full electronic search strategy for MEDLINE is presented below.

The following search combinations were used:

- “closure device” AND “puncture” AND “peripheral vascular” OR “pseudoaneurysm”
- “closure device” AND “arterial” AND “lower limb”
- “closure device” AND “intervention”
- “closure device” AND “angiography” AND “hemorrhage” OR “haematoma”
- “closure device” AND “angioplasty” AND “embolisation” OR “embolization”
- “closure device” AND “stent”
- “closure device” AND “randomised” OR “randomized”

After this, the first word “closure device” was substituted with “manual compression,” “Angioseal,”
Angioplasty* Hemostasis, Surgical/instrumentation* Radiography, Interventional
Angioplasty, Balloon/adverse effects iliac Artery/pathology Radiology, Interventional/instrumentation
Arterial Occlusive Diseases/radiography iliac Artery/radiography Radiology, Interventional/methods
Arterial Occlusive Diseases/surgery iliac Artery/surgery Renal Artery
Arterial Occlusive Diseases/therapy* Liver Neoplasms/pathology Stents
Atherectomy/adverse effects Liver Neoplasms/therapy* Surgical Instruments*/adverse effects
Catheterization, Peripheral/instrumentation* Lower Extremity/blood supply* Suture Techniques/adverse effects*
Catheterization, Peripheral/methods Lower Extremity/radiography Suture Techniques/instrumentation*
Chemoembolization, Therapeutic/instrumentation* Lower Extremity/surgery* Treatment Failure
Device Removal Peripheral Vascular Diseases/epidemiology Treatment Outcome
Embolization, Therapeutic/instrumentation Peripheral Vascular Diseases/radiography Uterine Artery Embolization
Equipment Design Peripheral Vascular Diseases/surgery Vascular Diseases/epidemiology
Equipment Failure Peripheral Vascular Diseases/therapy Vascular Diseases/etiology
Femoral Artery* Postoperative Complications/diagnosis Vascular Surgical Procedures/adverse effects*
Femoral Artery/pathology Postoperative Complications/epidemiology
Femoral Artery/radiography Postoperative Complications/etiology*
Femoral Artery/surgery Postoperative Hemorrhage/prevention & control*
Hematoma/therapy Pressure
Hemorrhage/etiopathology Punctures
Hemorrhage/prevention & control* Punctures/adverse effects
Hemostatic Techniques/instrumentation* Punctures/instrumentation*

* denote major subheadings in MEDLINE

“StarClose,” “Perclose,” “Closer,” and “Duett.” Limits of human studies and publications after 1990 were used.

MEDLINE Medical Subject Headings Used in Search Strategy

References

Review of Vascular Closure Devices

By hmpeditor
Created 12/22/2010 - 00:11

Review of Vascular Closure Devices

- Volume 22 - Issue 12 - December, 2010 [2]
- Posted on: 12/22/10
- 0 Comments

Section:
Review

Issue Number: Volume 22 - Issue 12 - December, 2010 [3]

Pages: 599 - 607

Author(s):

Bryan G. Schwartz, MD\textsuperscript{a}, Steven Burstein, MD\textsuperscript{b}, Christina Economides, MD\textsuperscript{b}, Robert A. Kloner, MD, PhD\textsuperscript{a,c},
David M. Shavelle, MD\textsuperscript{c}, Guy S. Mayeda, MD\textsuperscript{b}

Image(s):

Figure 1. Femostop device. The belt wraps around the patient for support. The pneumatic bubble is inflated over the arteriotomy to compress the artery during and after sheath removal. Image courtesy of St. Jude Medical.
Figure 2. Angio-Seal. The Angio-Seal device is inserted until the arteriotomy locator indicates intraluminal position. The anchor is deployed and the device is withdrawn slightly, pulling the anchor against the arterial wall and positioning the collagen plug just outside the artery. The sheath and device are then withdrawn while the tampon tube is used to push the collagen plug gently against the artery wall. Image courtesy of St. Jude Medical.

Figure 3. Myrnx device. Once the balloon is inflated within the arterial lumen and pulled against the arterial wall ensuring proper positioning (A) the sealant is placed in the extravascular tissue track (B, C). The sealant expands to maintain hemostasis after the device is withdrawn (D). Image courtesy of AccessClosure.

Figure 4. Starclose device. Click 1, the Starclose device is in the common femoral artery. Click 2, the locator "wings" are deployed. Click 3, the device is withdrawn until the "wings" abut the arterial wall. Click 4, the nitinol clip is deployed which grasps the arteriotomy edges and pulls the vessel wall together to achieve hemostasis. Image courtesy of Abbott Vascular. © 2010 Abbott Laboratories. All Rights Reserved.
Figure 5. ProGlide device. Blood return in the marker lumen indicates that the ProGlide device is in the artery. Then, the “feet” are deployed and the device is withdrawn until the “foot” abuts the arterial wall and blood return will stop. The needle plunger is depressed which deploys the needles (a) through the arterial wall and into cuffs on the “feet” (b) which completes the suture loop. The device is then withdrawn and a knot is tied in the suture and pushed down to the arteriotomy site for hemostasis. Image courtesy of Abbott Vascular. © 2010 Abbott Laboratories. All Rights Reserved.

Figure 6. Prostar XL device. Once proper placement is confirmed visually, the right hand rotates and pulls the handle to deploy the needles which are pulled through the arterial wall and collected through the device hub. A knot is tied in each suture and pushed to the arteriotomy site forming two suture loops for hemostasis. Image courtesy of Abbott Vascular. © 2010 Abbott Laboratories. All Rights Reserved.
Review of Vascular Closure Devices

Figure 7. Clinical characteristics that increase the risk of vascular complications. Relative contributions of clinical characteristics to the risk of vascular complications in percutaneous coronary intervention. GP IIb/IIIa = glycoprotein IIb/IIIa inhibitors; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; PVD = peripheral vascular disease; Hx = history of; BSA = body surface area. Reproduced with permission from Elsevier, Limited.

Table 1. Influence of vascular closure devices on major vascular complication rates compared with manual compression

<table>
<thead>
<tr>
<th></th>
<th>Diagnostic</th>
<th>Intervventional</th>
<th>Interventional and Diagnostic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference</td>
<td>28</td>
<td>29</td>
<td>5</td>
</tr>
<tr>
<td>Angio-Seal</td>
<td>~ (1.08)</td>
<td>~</td>
<td>~</td>
</tr>
<tr>
<td>VasoSeal</td>
<td>~ (1.85)</td>
<td>~</td>
<td>~</td>
</tr>
<tr>
<td>Collagen plug</td>
<td>~</td>
<td>~ (0.68)</td>
<td>~</td>
</tr>
<tr>
<td>Perclose</td>
<td>~ (1.51)</td>
<td>~</td>
<td>~</td>
</tr>
<tr>
<td>Suture</td>
<td>~ (1.11)</td>
<td>~ (1.02)</td>
<td>~</td>
</tr>
<tr>
<td>Combined VCDs</td>
<td>~ (1.44)</td>
<td>~ (0.97)</td>
<td>~</td>
</tr>
</tbody>
</table>

Numbers in parentheses are odds ratios compared with manual compression; VCDs = vascular closure devices; ~ = not reported; ~ = no significant effect; ↑ = increases; ↓ = decreases; * = in randomized trials only; p=0.062

Table 2. Incidences and odds ratios of vascular complications with manual compression, suturing devices, and collagen plug devices

<table>
<thead>
<tr>
<th></th>
<th>Incidence (%)</th>
<th>Odds Ratio (p-Value)</th>
<th>VCDs vs. Manual Compression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematoma</td>
<td>1.13</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleeding</td>
<td>1.20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AV fistula</td>
<td>0.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>0.37</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dissection</td>
<td>0.02</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0.09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical repair</td>
<td>0.07</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leg ischemia</td>
<td>0.07</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>0.56</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* *= not reported; * = incidence data from Tavris et al.; ↑ = odds ratio for collagen plug devices only; VCD = vascular closure device; MC = manual compression; AV = arteriovenous.
Table 3. Predictors of vascular complications.

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Anticoagulation</th>
<th>Procedural Characteristics</th>
<th>Medical Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>greater age</td>
<td>larger heparin doses</td>
<td>duration/complexity of procedure</td>
<td>acute myocardial infarction</td>
</tr>
<tr>
<td>female gender</td>
<td>thienopyridines</td>
<td>longer time to sheath removal</td>
<td>shock</td>
</tr>
<tr>
<td>low body mass index</td>
<td>glycoprotein IIb/IIIa</td>
<td>major coronary dissection</td>
<td>renal failure</td>
</tr>
<tr>
<td>high body mass</td>
<td>receptor inhibitors</td>
<td>emergent priority</td>
<td>peripheral vascular disease</td>
</tr>
</tbody>
</table>

Table 4. Recommendations for closing arteriotomies.

<table>
<thead>
<tr>
<th>Clinical situation</th>
<th>VCDs to avoid</th>
<th>Recommended VCDs*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic procedure</td>
<td>VasoSeal, Duett</td>
<td>Angio-Seal, ProGlide, Starclose, MC</td>
</tr>
<tr>
<td>Interventional procedure</td>
<td>VasoSeal, Duett</td>
<td>Angio-Seal, ProGlide, MC</td>
</tr>
<tr>
<td>Arteriotomy &gt; 8 Fr</td>
<td>All other VCDs</td>
<td>Prostar, ProGlide (&quot;pre-close&quot;)</td>
</tr>
<tr>
<td>May need repeat access</td>
<td>All other VCDs</td>
<td>ProGlide, MC</td>
</tr>
<tr>
<td>Puncture site-related risk factors</td>
<td>All VCDs</td>
<td>MC</td>
</tr>
</tbody>
</table>

*Other VCDs are not recommended until more data become available.
VCDs = vascular closure devices; VCRF = vascular complication risk factors.

Note: This article is corrected from the print version to note that the Exoseal device's plug is not collagen, but polyglycolic acid, which is synthetic and not biologic like collagen. CLD regrets the error.

ABSTRACT: Background. Vascular access-site complications are an important cause of morbidity following catheterization procedures. Manual compression is the “gold standard” in achieving hemostasis of an arteriotomy site; however, manual compression is limited by the need to interrupt anticoagulation, prolonged bed rest, patient discomfort and time demands for healthcare providers. Vascular closure devices (VCDs) improve patient comfort, free medical staff resources and shorten the time needed for hemostasis, ambulation and discharge. However, the safety of VCDs remains in question and they may increase the risks of infection and leg ischemia. Compared with manual compression, the rate of major complications appears to be increased with VasoSeal, decreased with Angio-Seal and decreased in diagnostic cases with Perclose. The safety of VCDs cannot be assumed due to “class effect,” and nearly all individual trials are underpowered to detect differences in complication rates, so the safety of other individual VCDs is unclear. In the absence of puncture site-related risk factors, VCDs as a whole appear to have little influence on complication rates, and patients at high baseline risk for bleeding due to clinical factors may benefit from these devices. Screening with femoral angiography prior to VCD placement and avoidance of VCDs in the presence of puncture site-related risk factors might reduce the risk of vascular complications. This review describes the mechanism, efficacy and safety of VCDs including hemostasis pads, the Femostop, Clamp Ease, Mynx, Duett, FISH, Boomerang, ExoSeal, Starclose, VasoSeal, Angio-Seal and Perclose devices.


Key words: access site management, complications, new devices, puncture sealants

In the early 1990s, ~6% of patients undergoing percutaneous coronary intervention (PCI) developed peripheral vascular complications, of which 22–25% received a blood transfusion and 21–38% required vascular surgical repair.1,2 Recently, the rate of vascular complications has declined to approximately 2%.3–6 However, the 1-year mortality rate for patients with peripheral vascular complications was 7.5% compared with 1.1% for patients without such complications.2 Peripheral vascular complications prolong hospitalization and nearly double mean hospital costs (from $9,583 to $18,350).2 Arterial access sites were managed exclusively with manual compression (MC) and bed rest for 30 years after Seldinger introduced his technique of percutaneous arterial access in 1959. However, MC necessitates interruption of anticoagulation and requires considerable time and resources (i.e., wait for activated clotting time to decrease and maintain
MC for 15–30 minutes with a 6 French [Fr] sheath). Also, MC requires prolonged bed rest, which is associated with patient discomfort, back pain and urinary retention. Vascular closure devices (VCDs) were introduced in the early 1990s with the goal of limiting the time, labor, bed rest and patient discomfort associated with MC. There are two types of VCDs: active and passive. Passive VCDs enhance hemostasis with prothrombotic material or mechanical compression but do not achieve prompt hemostasis or shorten the time to ambulation. Active VCDs can be categorized as suture devices, collagen plug devices or clips. Active VCDs were used in 42% of over 1.5 million PCIs between 2004 and 2008 in a registry including 955 institutions. After 20 years of experience, the safety of VCDs remains controversial and some may increase the risk of limb ischemia and groin infection. Do the benefits of VCDs outweigh the risks? Do VCDs benefit certain patients more than others? Are all VCDs created equal? This review describes each VCD’s mechanism, efficacy and safety profile. It is important to note that few reports can be directly compared due to differences in patient population, procedural characteristics, operator experience, anticoagulation profile and definition of vascular complications, all of which influence the rate of peripheral vascular complications. Variations in study protocol greatly impact the time to hemostasis, ambulation and discharge. Several devices have evolved since their conception to improve their safety and ease of use. In addition, VCD complication rates decrease over time as operators gain experience with a particular device (the so-called “learning curve”). Despite these limitations, the risk-benefit profile of various VCDs will be described.

Manual Compression

MC remains the “gold standard” in achieving hemostasis of an arteriotomy site. With MC, the sheath can be removed immediately after a diagnostic procedure but is delayed (often 2–4 hours) after an interventional procedure to allow the activated clotting time to decrease to < 170 seconds. As the sheath is removed, firm manual pressure is placed over the femoral artery, typically 2 cm proximal to the skin entry site. Firm pressure is held for 10 minutes, then slightly less firm pressure for 2–5 minutes, then light pressure while applying a pressure dressing. Pressure should be maintained longer for larger sheath sizes and in the setting of anticoagulation. If bleeding persists, MC is maintained for an additional 15 minutes. Once hemostasis is achieved bed rest is recommended for 6–8 hours. When VCDs fail, MC is used to achieve hemostasis.

Passive Vascular Closure Devices

Hemostasis pads. Several hemostasis pads, including Chito-Seal (Abbott Vascular, Redwood City, California), Clo-Sur PAD (Scion Cardiovascular, Miami, Florida), SyvekPatch (Marine Polymer Technologies, Inc., Danksers, Massachusetts), Neptune Pad (Biotronik, Berlin, Germany) and D-Stat Dry (Vascular Solutions, Minneapolis, Minnesota) can be used in conjunction with MC. The pads are coated with procoagulant material to enhance coagulation and hemostasis. Hemostasis pads have been analyzed in small randomized trials with patients undergoing diagnostic or interventional coronary procedures or peripheral percutaneous interventions. Technical failure was reported in 5–19% of Clo-Sur PAD cases, and in 8% of D-Stat Dry cases. Compared with MC, no difference in complication rates was observed with the Chito-Seal, Clo-Sur PAD or SyvekPatch, whereas the D-Stat Dry reduced vascular complication rates and the Neptune Pad increased the risk of minor bleeding (15% vs. 3%). Compared with MC, the Neptune Pad and Clo-Sur PAD improved patient and physician comfort. Hemostasis pads did not shorten the time to ambulation compared with MC. The clinical utility of hemostasis pads is questionable since their influence on hemostasis is small and they do not reduce the time to ambulation. Compression devices: FemoStop and Clamp Ease. The FemoStop plus Compression System (Radi Medical Systems, Inc., Reading, Massachusetts) consists of a belt that wraps around the patient and a transparent, inflatable pneumatic bubble (Figure 1). A hemostatic dressing is placed on the arteriotomy site, then the bubble is positioned 1 cm above the arteriotomy. The bubble is inflated to ~70 mmHg while the sheath is removed, then to suprasystolic pressure for ~2 minutes, and it is deflated to the mean arterial pressure for 15 minutes (pedal pulse is palpable), then slowly deflated to 30 mmHg for 1–2 hours, and is finally carefully removed. The Clamp Ease device (Pressure Products Inc., Rancho Palos Verdes, California) consists of a flat metal pad that is placed under the patient for stability, and a C-arm clamp with a translucent pressure pad. As the sheath is removed, the C-arm clamp is lowered so that the pressure pad compresses the access site. These compression devices have high technical success rates approaching 100%, but do not shorten the time to hemostasis, ambulation or discharge compared with MC; they simply replace human compression with mechanical compression. Major complication rates associated with the compression devices are low. While
compression devices relieve healthcare workers from performing MC, allowing them to care for more patients and relieving hand fatigue, they are less comfortable for patients.

**Active Vascular Closure Devices**

**Cardiva Catalyst (Boomerang).** The Cardiva Catalyst (Cardiva Medical, Inc., Sunnyvale, California) uniquely facilitates hemostasis through the existing arterial sheath, although MC is still required. The Cardiva Catalyst is indicated for diagnostic or interventional procedures with sheath sizes up to 7 Fr. The device is inserted through the existing sheath. Once the tip is within the arterial lumen, a conformable 6.5 mm disk is deployed similar to an umbrella. The sheath is removed and the disk is gently pulled against the arterial wall where it is held in place by a tension clip. The disk, which is coated with protamine sulfate, provides temporary intravascular tamponade, facilitating physiologic vessel contraction and thrombosis. After 15 minutes of “dwell time” (120 minutes for interventional cases) the device is withdrawn and light MC is held for 5 minutes. The Cardiva Catalyst successfully facilitated hemostasis in 99% of 96 patients undergoing diagnostic catheterization with a 5 Fr sheath without any major vascular complications and with minor complications in 5% (rebleeding during bed rest). Most patients can ambulate 90 minutes after a diagnostic procedure with this device. The Cardiva Catalyst device does not leave any material behind in the body which minimizes the risk of ischemic and infectious complications and allows for repeat vascular access. The Cardiva Catalyst is compatible with most patients and has been used successfully in limited numbers of patients with peripheral vascular disease (6 patients), profunda artery or femoral bifurcation arteriotomies (19 patients), internal jugular arteriotomies (18 patients), and in pediatric patients.

**Collagen plug device: Angio-Seal.** The Angio-Seal device (St. Jude Medical, Minnetonka, Minnesota) contains a small, flat, absorbable rectangular anchor (2 x 10 mm) an absorbable collagen plug and an absorbable suture (Figure 2). First, the existing arterial sheath is exchanged for a specially designed 6 Fr or 8 Fr sheath with an arteriotomy locator. Once blood return confirms proper positioning within the arterial lumen, the sheath is held firmly in place while the guidewire and arteriotomy locator are removed. The Angio-Seal device is inserted into the sheath until it snaps in place. Next, the anchor is deployed and pulled back against the arterial wall. As the device is withdrawn further the collagen plug is exposed just outside the arterial wall and the remainder of the device is removed from the tissue track. Finally, the suture which connects the anchor, the collagen plug, and the device is cut below skin level leaving behind only the anchor, collagen plug and suture, all of which are absorbable. Although Angio-Seal labeling indicates compatibility with 8 Fr or smaller procedural sheaths, the Angio-Seal has been used successfully to close 10 Fr arteriotomies utilizing a “double wire” technique. With this technique, at the conclusion of the procedure the Angio-Seal wire and a second, additional wire are placed through the sheath. The Angio-Seal is deployed in standard fashion using the Angio-Seal wire, leaving the second wire in place. If hemostasis is achieved, the second wire is carefully removed while maintaining pressure on the collagen plug. If hemostasis is not achieved, the second wire serves as a “back up/safety” to allow deployment of a second Angio-Seal device. Using this “double wire” technique, 21 of 21 arteriotomies > 8 Fr (17 were 10 Fr) were successfully closed (18 with a single device, 3 required a second device). In 4525 patients undergoing interventional procedures (89% with 8–9 Fr sheaths) the Angio-Seal had a device success of 97%. The Angio-Seal device significantly improved patient comfort at the time of discharge compared with MC. Compared with the FemoStop device, patients treated with the Angio-Seal device had significantly less discomfort at 4 and at 8 hours after the procedure. Angio-Seal safety data are described in detail below, but it reduced the risk of major vascular complications compared with MC in meta-analyses. Collagen plug device: Mynx. The Mynx Vascular Closure Device (AccessClosure, Mountain View, California) features a polyethylene glycol sealant (“hydrogel”) that deploys outside the artery while a balloon occludes the arteriotomy site within the artery (Figure 3). The Mynx device is inserted through the existing procedural sheath and a small semicompliant balloon is inflated within the artery and pulled back to the arterial wall, serving as an anchor to ensure proper placement. The sealant is then delivered just outside the arterial wall where it expands to achieve hemostasis. Finally, the balloon is deflated and removed through the tract leaving behind only the expanded, conformable sealant. The Mynx device was investigated prospectively in 190 patients (50% interventional, 94% 6 Fr) and retrospectively in 238 patients (100% diagnostic and 6 Fr). Device success was achieved in 91–93%. Mean time to hemostasis was 1.3 minutes and mean time to ambulation was 2.6 hours. Six of 190 patients (3.2%) developed a hematoma > 6 cm² and major complications occurred in 2.1%. The Mynx device leads to rapid hemostasis and ambulation, but additional studies are needed to confirm its safety. The Mynx is indicated for interventional and diagnostic procedures and, in addition to the 6/7 Fr model, a 5 Fr device was...
recently introduced. Polyglycolic Acid (PGA) plug device: ExoSeal. The ExoSeal device (Cordis Corporation, Miami Lakes, Florida) delivers a synthetic, bioabsorbable plug to the extravascular space adjacent to the arteriotomy using visual guidance for 6 Fr arteriotomy closure. In a randomized trial of 401 patients (41% interventional) device success was 94%, ambulation occurred in a mean of 2.5 hours and complication rates were not significantly different from MC.\textsuperscript{32} FISH. The FISH device (Morris Innovative, Bloomington, Indiana) is indicated for diagnostic procedures using 5–8 Fr procedural sheaths and uses a bioabsorbable extracellular matrix “patch” made from porcine small intestinal submucosa (SIS). The “patch”, which resembles a roll of wrapping paper, is inserted through the arteriotomy so that it straddles the arterial wall, then a wire is pulled to release the “patch” from the device. Next, a compression suture is pulled which incorporates the patch firmly in place. In a randomized trial of 297 patients (100% diagnostic, 90% 5–6 Fr) device success was 98%, which did not include the 27 early withdrawals and mean time to ambulation was 2.4 hours.\textsuperscript{33} More data are needed regarding the safety of the FISH device and of concern is that the patch resides on both sides of the vessel wall, meaning a portion of the patch remains extravascular. Clip device: Starclose. The Starclose device (Abbott Vascular, Redwood City, California) achieves hemostasis with a 4 mm nitinol clip implant (Figure 4).\textsuperscript{34} The device is inserted into the arterial lumen then “wings” are deployed such that when the device is withdrawn the wings are pulled against the arterial wall indicating proper positioning. The clip is then deployed just outside the arterial wall. The clip grasps the edges of the arteriotomy drawing them together for closure. The Starclose device is labeled for diagnostic and interventional procedures and for closure of 5–6 Fr arteriotomies, but has been used with 7–8 Fr arteriotomies. The device success of Starclose is reported as 87%–97% (majority interventional)\textsuperscript{34,35} and 91% with 7–8 Fr sheaths.\textsuperscript{36} For patients treated on an outpatient basis the median length of stay was 157 minutes.\textsuperscript{36} Minor complications were observed in 4%,\textsuperscript{34} 11%,\textsuperscript{39} and 15%.\textsuperscript{36} Major complications were reported in 1%,\textsuperscript{34,36} 2%,\textsuperscript{37,38} and 3.5% (7–8 Fr sheaths).\textsuperscript{39} Persistent oozing at the arteriotomy site was reported in 38% of patients treated with Starclose, which was significantly more than with Angio-Seal (21%; \(p = 0.001\)).\textsuperscript{35} Oozing of blood contributed to a significantly lower rate of successful hemostasis (Starclose 94%, Angio-Seal 99%, MC 100%; \(p = 0.002\)).\textsuperscript{35} In some patients oozing persisted for over 24 hours.\textsuperscript{35} At 1 month after the procedure, patients treated with Starclose had less pain at the puncture site than patients treated with MC.\textsuperscript{35} Complications requiring surgical repair have been reported in up to 1.3% of patients treated with the Starclose device.\textsuperscript{34,36,37,39} Case reports involving the Starclose device describe femoral artery laceration,\textsuperscript{40} arterial occlusion due to device capture of the anterior and posterior arterial walls,\textsuperscript{41} and high-grade stenosis causing debilitating symptoms 3 weeks after closure.\textsuperscript{42} In conclusion, the Starclose device improves patient comfort and bed rest time, but its utility may be limited in patients receiving anticoagulation because of persistent oozing. Suture devices: Perclose. Perclose (Abbott Vascular) offers suture-mediated VCDs that have evolved from the Prostar in 1994, to the Techstar, to the Closer, to the Perclose A-T, to the ProGlide. Originally, the Prostar and Techstar featured needles that were deployed within the arterial lumen and directed towards the skin, through the arterial wall. The Closer introduced a fundamental change whereby the needles were deployed outside of the artery and directed inward. To operate the ProGlide, the device is inserted over a guidewire until blood return indicates positioning within the lumen (Figure 5). Then, a lever is pulled which deploys “feet” within the arterial lumen. The device is gently pulled back positioning the feet against the anterior arterial wall. Needle deployment and formation of a suture loop is fully automated by depressing a plunger on the device. As the plunger is depressed, two needles are deployed within the tissue track and directed towards the feet. As the plunger is depressed further the needles are advanced through the arterial wall and into the feet. The needles create a suture loop. The device (containing the needles) is then removed, leaving behind the two suture tails. A knot is tied and pushed toward the arteriotomy to achieve hemostasis. The 6 Fr ProGlide is designed for procedures using 5–8 Fr sheaths, whereas the Prostar is used with 8.5–10 Fr sheaths. The Prostar uses 4 needles (two sutures) directed outward from within the arterial lumen. First, the Prostar is advanced over a guidewire until blood return indicates proper placement, which is confirmed visually (Figure 6). By pulling on the device handle, the needles are deployed and pulled through the arterial wall. The needles remain contained within the device shaft and are removed by pulling them up through the device shaft, leaving behind 4 suture ends (2 sutures). The sutures are tied and pushed toward the arteriotomy and the device is removed. Using the “pre-closure” technique, the ProGlide can be used to close larger arteriotomies. After placing a 6 Fr sheath and performing a femoral angiogram, the sheath is replaced with the ProGlide, the needles are deployed and the ProGlide is removed leaving behind only the suture. A larger sheath can then be placed for the procedure and at the conclusion of the procedure the suture is tied and pushed toward the arteriotomy for closure.\textsuperscript{43} Using two ProGlide devices simultaneously with the “pre-closure” technique,
successful hemostasis was achieved in 94% of 292 patients undergoing percutaneous endovascular aortic repairs, 64% of which had sheaths 18–24 Fr.44 Device success of the Perclose devices is 91–94%.26,45,46 Of 46 patients that experienced both Techstar and MC, 76% stated they would prefer Techstar and 17% would prefer MC (p < 0.001).47 A cost analysis suggested that Techstar, compared with MC, reduced post-PCI costs by 13% by facilitating earlier discharge.47 The meta-analyses discussed below indicate that Perclose devices improve major complication rates in diagnostic procedures compared with MC.28,29 However, these meta-analyses included older Perclose devices and complication rates have since improved as the device has evolved.48

**Benefits of VasoSeal, Angio-Seal and Perclose**

The VasoSeal, Angio-Seal and Perclose devices each decreased the time to hemostasis, ambulation and discharge compared with MC.49 The effects of these VCDs on time parameters in individual reports are influenced by protocol and publication bias making direct comparisons difficult.49 In a meta-analysis of reports comparing MC to the VasoSeal, Angio-Seal and Perclose devices, the VCDs decreased the time to hemostasis by a mean of 17 minutes, decreased bed rest time by a mean of 10.8 hours, and decreased hospital stay by a mean of 0.6 days.49

**Safety of VasoSeal, Angio-Seal and Perclose**

The VasoSeal, Angio-Seal and Perclose devices have been more extensively studied than the other VCDs. Still, most trials were small, underpowered and of poor quality.5,28,29 Meta-analyses were performed to improve the statistical power to assess the safety of VCDs (Tables I and 2).28,29,49,50 Each meta-analysis included diagnostic cases, but interventional cases predominated.28,29,49,50 A meta-analysis of 30 studies comparing VCDs to MC including 37,066 patients found that the incidence of major vascular complications was increased with all VCDs (odds ratio [OR] 1.34; 95% confidence interval [CI] 1.01–1.79) and with VasoSeal (OR 2.27; CI 1.35–3.80).28 No significant difference was observed with either the Angio-Seal or Perclose devices, although when only randomized studies were analyzed the Angio-Seal device tended to reduce the incidence of major complications in interventional patients (OR 0.46; CI 0.20–1.04; p = 0.062). A separate meta-analysis of 16 randomized studies with 5,048 patients reported that VCDs decreased the risk of major complications (OR 0.89; CI 0.86–0.91).29 When both diagnostic and interventional cases were considered, Perclose and Angio-Seal significantly decreased the incidence of major complications, whereas VasoSeal significantly increased the risk. In interventional cases, the risk of major complications was not affected by Perclose (OR 1.0; CI 0.13–7.48), was reduced with Angio-Seal (OR 0.51; CI 0.45–0.58), and was increased with VasoSeal (OR 1.18; CI 1.16–1.20).29 A registry including 214 institutions and 166,680 patients (113,025 MC; 25,495 suture device; 28,160 collagen plug device) (Tables 1 and 2) reported that the incidence of any vascular complication was decreased with VCDs compared with MC in diagnostic cases and in all cases (OR 0.83), but showed no significant effect in interventional cases.5 Even though the 3 articles listed in Table 1 reported inconsistent results, the evidence suggests that the rate of major complications is increased by VasoSeal, reduced by Angio-Seal, and reduced by Perclose in diagnostic cases, while Perclose has little influence on complication rates in interventional cases. The inconsistent results reported by the registry and meta-analyses may reflect the relative proportions within each report of each VCD, of interventional procedures, of various biases, and of the degree of anticoagulation. In particular, in many nonrandomized studies the MC group had a significantly higher incidence of risk factors for vascular complications. In the registry described above,5 the MC group had significantly greater risk factors, though the difference in vascular complication rates remained highly significant (p = 0.0004) after controlling for numerous variables. The authors pointed out, however, that unmeasured factors could have influenced the results.5 For instance, VCDs may have been avoided if vessel wall injury was apparent or if a femoral angiogram demonstrated high risk. Despite these limitations, the registry results reflect the incidences of vascular complications in the “real world” and indicate that, with appropriate patient selection, VCDs are associated with a low risk for vascular complications. The results of the meta-analyses differ from those of the individual underpowered studies, which almost uniformly concluded that the safety of the VCD studied was equivalent to or noninferior to MC.29 For example, both the Duett and VasoSeal devices, each of which is no longer in use, were reported to be “safe and effective” in small underpowered studies;18,51–54 however, the Duett device increased the risk of acute leg ischemia,55 and meta-analyses concluded that VasoSeal...
increased the risk of major vascular complications.\textsuperscript{28,29} This underscores the importance of adequate statistical power when evaluating safety and suggests that the safety of the newer VCDs remains unclear without more robust evidence. Furthermore, safety cannot be inferred by assuming a “class effect”. Angio-Seal and VasoSeal are both collagen plug devices, but Angio-Seal decreases the risk of major vascular complications where VasoSeal increases the risk.\textsuperscript{28,29}

**Risks of Individual Vascular Complications in Relation to VCDs**

Two meta-analyses of randomized trials compared the incidence of individual complications in patients treated with MC versus VCDs (Table 2).\textsuperscript{49,50} Bleeding is the most common vascular complication related to endovascular procedures comprising ~70% of all complications, followed by pseudoaneurysm (~20%).\textsuperscript{5} In meta-analyses VCDs tended to increase the incidence of local bleeding and did not appear to significantly influence hematoma, pseudoaneurysm or arteriovenous fistula formation.\textsuperscript{49,50} When analyzing only trials that reported an intention-to-treat approach, the risk of hematoma was higher (relative risk [RR] 1.89) and the risk of pseudoaneurysm was higher (RR 5.40) with VCDs.\textsuperscript{49} VCDs increased the risk of groin infection and tended to increase the risk of leg ischemia and a complication requiring surgical repair.\textsuperscript{49,50} A registry including 1,522,935 patients who underwent percutaneous coronary intervention at 955 hospitals between 2004 and 2008 analyzed bleeding complications, which occurred in 30,654 patients (2%).\textsuperscript{6} With similar baseline characteristics, patients who received a VCD (363,769) were less likely to suffer from bleeding complications compared with patients treated with MC (529,247) (2.1% vs. 2.8%, p < 0.001; OR 0.77, 95% CI 0.73-0.80). Not surprisingly, with increased baseline bleeding risk the use of MC increased and the use of VCDs decreased. Interestingly, however, the benefit of VCDs in decreasing the risk of bleeding was apparent in patients with intermediate (OR 0.76) and high bleeding risk (OR 0.79), but not with low bleeding risk (OR 1.07). This suggests that patients with high baseline bleeding risk are most likely to benefit from VCDs. But, these results should be interpreted with caution. Two meta-analyses of randomized trials\textsuperscript{49,50} concluded that VCDs increase the risk of bleeding, yet two large registries\textsuperscript{5,6} concluded that VCDs decrease the risk of bleeding. Bleeding risk was increased somewhat in the two meta-analyses because of the inclusion of VasoSeal and older device models. The influence of unmeasured factors in uncontrolled registries likely favored the use of MC in patients at high risk for bleeding due to puncture site-related factors observed during femoral angiography. All things considered, in the absence of puncture site risk factors, VCDs can be deployed safely. Patients with a high risk of bleeding related to clinical factors may benefit from a VCD in the absence of puncture site risk factors.

**Vascular Closure Device Related Complications**

VCDs can cause leg ischemia and groin infections which rarely occur with MC.\textsuperscript{7,8} In a retrospective analysis (VasoSeal 937, Angio-Seal 742, Techstar 1001, MC 1019 patients, respectively), infections occurred in 0.3–0.4% of all VCD patients and in none of the MC patients.\textsuperscript{8} Complications requiring surgical repair occur slightly more frequently with VCDs compared with MC.\textsuperscript{8,49,50,56,57} An analysis was done of all patients requiring surgical intervention following complications from percutaneous vascular access (hemostasis originally achieved with VCDs in 18 patients and with MC in 41 patients).\textsuperscript{56} The indications for surgery in the MC patients were primarily pseudoaneurysm (71%), hemorrhage (32%) and arteriovenous fistula (15%), all of which tended to occur more often with MC compared with VCDs. Infectious complications (5%) and limb ischemia (7%) were infrequent indications for surgery following MC but were significantly more common in the VCD patients that required surgery (infectious in 39%, ischemia in 28%). More complex surgical procedures were required for VCD patients, such as interposition of bypass grafts.\textsuperscript{56} VCDs can cause severe complications related to device misuse or malfunction. Although the risks of severe complications are low and probably decreasing as operators gain experience, patients should be examined diligently for complications after the use of a VCD, and VCDs should be avoided in patients with puncture site-related risk factors.

**Minimizing the Risk for Vascular Access-Site Complications**

The benefit of VCDs is reduced if early ambulation is not desired, so MC should be considered for such patients. For infection control during cardiac catheterization, the Society for Cardiovascular Angiography and Interventions and Centers for Disease Control recommend use of aseptic technique, including a cap, mask, sterile gown, sterile gloves, and a large sterile sheet.\textsuperscript{58} Also, antibiotic coverage is recommended for patients
with diabetes receiving a VCD.\textsuperscript{58} Although supporting evidence is not available, pre-procedure fluoroscopy and ultrasound imaging have been advocated to reduce the risk of inaccurate sheath insertion and vascular complications, with expected benefits in the small percentage of patients with unusual anatomy.\textsuperscript{59} 972 patients undergoing cardiac catheterization via a femoral approach were randomized to fluoroscopic guidance or anatomic landmark guidance for vascular access.\textsuperscript{60} There was no difference in deemed suitability for VCD placement (79.5% vs. 80.7%; $p = 0.7$), the study was not powered to detect a significant difference in vascular complication rate (2.1% vs. 2.8%; $p = 0.48$) and results suggested a benefit with routine fluoroscopy in obese patients and females.\textsuperscript{60} Femoral angiography should be performed before using an active VCD to confirm that the arteriotomy is in the common femoral artery, superior to the femoral artery bifurcation, inferior to the inferior epigastric artery and to confirm the absence of peripheral arterial disease and in particular vascular calcification at the access site.\textsuperscript{4} Device failure independently predicts vascular complications,\textsuperscript{26} so when VCD placement is challenging or high risk features are present, VCDs should be avoided. Numerous predictors of vascular complications have been identified (Table 3). The clinical\textsuperscript{12} factors associated with the greatest risk for vascular complications include female gender, advanced age ($\geq 70$ years), and low body surface area ($< 1.6$ m$^2$) (Figure 7).\textsuperscript{3} Patients undergoing more complex, interventional procedures are also more likely to be under full anticoagulation and are more likely to suffer bleeding complications. In most nonrandomized comparisons and registries, patients treated with VCDs had fewer risk factors than patients treated with MC reflecting operator preference to avoid VCDs in high risk patients. Furthermore, most randomized trials excluded high risk patients altogether. Active VCDs carry numerous cautions and warnings for restricted use, including non-common femoral sheath location, small femoral artery size ($< 4$ mm), bleeding diathesis, morbid obesity, inflammatory disease, uncontrolled hypertension, and significant peripheral vascular disease.\textsuperscript{4} The safety and efficacy of VCDs in high risk patients is unknown. Use of active VCDs is cautioned against in the presence of peripheral vascular disease because of higher complication rates.\textsuperscript{4} Also, VCDs can reduce the ankle brachial index. Mean ankle brachial index decreased by 0.05 in 214 patients treated with Angio-Seal and by 0.06 in 152 patients treated with Perclose.\textsuperscript{61} Moreover, 11% of patients experienced a decrease in ankle brachial index of $> 0.15$.\textsuperscript{61} Even the Starclose device, which achieves hemostasis with an extravascular clip, led to a decrease in ankle-brachial index of $> 0.10$ in 27 of 232 patients (11%) at 1 month after the procedure.\textsuperscript{38}

**Operator Experience/Learning Curve**

Operator experience with various VCDs provides insight that may not be apparent in clinical trials (Table 4). The Angio-Seal device is easy to use and has high technical success. The Starclose device is also simple to use, but since oozing occurs frequently, the Starclose\textsuperscript{14} device is better suited for diagnostic procedures than interventional procedures with full anticoagulation. The Boomerang device can be used in the presence of peripheral vascular disease and is preferred by many vascular surgeons because nothing is left behind in the artery. With Perclose, access to the artery is maintained (guide wire remains in place), even with device failure, and complications generally become evident immediately, as opposed to delayed complications that may occur with other VCDs. The Perclose devices allow for repeat vascular access immediately (this has not been studied), whereas the same site cannot be accessed for several weeks or months following deployment of collagen plug devices. However, in 181 patients previously treated with an Angio-Seal device, repeat access in the same artery in $< 90$ days was effective without major vascular complications (3 large hematomas, 1.7%).\textsuperscript{62} The Prostar and ProGlide, using the “pre-close” technique, are the only active VCD commonly used to close arteriotomies larger than 8 Fr; the ProGlide is preferred by many cardiologists whereas many surgeons favor the Prostar. Using a “double wire” technique, the Angio-Seal has been used successfully to close 10 Fr arteriotomies.\textsuperscript{25}

**Conclusion**

MC remains the gold standard for achieving hemostasis at a vascular access site. The FemoStop and Clamp Ease have high success rates in achieving hemostasis and can be used safely in most patients. Other than the FemoStop and Clamp Ease, VCDs improve patient comfort. All active VCDs shorten the time to hemostasis and ambulation to a relatively similar degree. The incidence of major complications is increased by VasoSeal, reduced by Angio-Seal, and reduced by Perclose in diagnostic cases. The safety of VCDs cannot be assumed due to “class effect” and nearly all individual trials are underpowered to detect differences in complication rates, so the safety of other individual VCDs is unclear. In the absence of
puncture site-related risk factors, VCDs as a whole appear to have little influence on complication rates and patients at high baseline risk for bleeding due to clinical factors may benefit from VCDs. VCDs increase the risk of leg ischemia, groin infection, and complications requiring surgical repair, which are rare with MC. Screening with femoral angiography prior to VCD placement and avoidance of VCDs in the presence of puncture site-related risk factors might reduce the risk of vascular complications.

References


From the aHeart Institute, Good Samaritan Hospital; the bDepartment of Cardiology, Good Samaritan Hospital, Los Angeles, California; and the cDepartment of Internal Medicine, Division of Cardiovascular Medicine, Keck School of Medicine at the University of Southern California, Los Angeles, California. Relevant disclosures: S. Burstein: honoraria – Abbott Vascular; D. Shavelle: Grants pending – Abbott Vascular; payment for development of educational presentations including service on speakers bureaus – Abbott Vascular; G. Mayeda: consultancy – Abbott Vascular, Access Closure; payment for development of educational presentations including service on speakers bureaus – Abbott Vascular. Manuscript submitted July 28, 2010, provisional acceptance given August 24, 2010, final version accepted September 21, 2010. Address for correspondence: Bryan G. Schwartz, MD, 1225 Wilshire Blvd. Los Angeles, CA 90017. E-mail: bschwartz15@hotmail.com

Source URL: http://www.invasivecardiology.com/content/review-vascular-closure-devices

Links:
[15] mailto:bschwartz15@hotmail.com

Review
Many formerly invasive diagnostic and interventional cardiology procedures have migrated to less invasive or percutaneous options. The subsequent rise in cath lab procedures has increased the need for alternatives to manual compression that promote hemostasis at the access site, allowing for quicker patient ambulation and throughput. Noninvasive methods, most commonly used with diagnostic procedures, provide topical hemostasis at the puncture site, whereas invasive devices penetrate the skin to close the wound — often with a plug or suture — within or on top of the tissue tract.

Despite the variety of devices available, the goal is universal: to promote rapid hemostasis and reduce access site complications.

With manual compression only, depending on the size of the sheath, pressure had to be applied for 10-20 minutes and patients would have to remain sedentary for approximately three to six hours, explains Michael C. Kim, M.D., director of the coronary care unit and director of medical education in the cardiac catheterization laboratory at Mount Sinai Heart, New York, NY.

“With closure devices, complete hemostasis is achieved before the patient even leaves the cath lab, and when properly performed, there is no need for manual compression or intense monitoring of the groin site,” noted Dr. Kim.

Compared to first-generation devices, today’s closure devices are much simpler to deploy, which has contributed largely to their overall acceptance and use. For example, closure devices, such as the Angio-Seal (St. Jude Medical) and PerClose (Abbott Vascular), are used in more than 90 percent of the cases in Mount Sinai’s cath lab.

The Angio-Seal is an intravascular device that sandwiches the arteriotomy between a bio-absorbable anchor and collagen sponge, which dissolve within 60 to 90 days. Because a mechanical seal is created, hemostasis does not depend on clot formation. The device’s VIP (V-Twist Integrated Platform) technology reportedly provides a larger collagen footprint for better arteriotomy coverage and is designed for enhanced conformability around the artery for a more uniform and secure seal.

“The Angio-Seal boasts a very difficult to beat combination of safety, efficacy and ease of use in both diagnostic and angioplasty procedures,” said Dr. Kim. “It is the first device that gave a great majority of operators the confidence to use a closure device and feel comfortable with the results.”

However, for patients who are likely to return within three months for repeat procedures, Dr. Kim opts...
for the suture-based PerClose, explaining that it is easier to navigate a needle through a suture than around a collagen plug.

Wired for Success

Arizona Heart Institute (AHI), a center purely dedicated to cardiovascular surgery and endovascular procedures, performs approximately 3,000 vascular and endovascular procedures per year. All endovascular procedures, including diagnostic, are performed surgically in one of the four dedicated endovascular suites within the OR.

As closure device technology evolved and the devices became easier to use, AHI gradually migrated away from exclusive use of manual compression. Initially, the facility used suture-based devices but found these devices could cause extensive scarring, which hindered reopening of the groin for repeat angiograms or endoluminal grafts. In addition, leaving a foreign substance behind in the body — a hook, plug, staple or suture — raises the the risk of infection, according to Venkatesh Ramaiah, M.D., director of peripheral vascular surgery and endovascular research at AHI.

In Dr. Ramaiah’s opinion, the purpose of closure devices is three-fold: (1) they should safe and effective, (2) they should be usable in any kind of vessel structure and (3) they should not be prone to causing infection or causing an occlusion of the artery.

Today, physicians at AHI rely on the Boomerang system from Cardiva for 70 to 80 percent of their cases in the OR. They were drawn to the device’s principle advantage: No foreign material is left behind in either the vessel or subcutaneous tissue. It is also quick and easy to deploy and can be used in small vessels, even ones that are calcified, according to Dr. Ramaiah. But the biggest benefit, he says, is the Boomerang allows blood flow to be maintained while the closure device is still in place.

The system is comprised of the Boomerang wire that is inserted into the femoral artery through the existing introducer sheath; a flat, low-profile disc that contours to seal the arteriotomy; and a clip placed on the skin to create site-specific compression of the arteriotomy and tract, establishing hemostasis. Once the fascial tract recoils back to its predilated state and the blood coagulates, the disc is collapsed, the wire is removed and finger pressure is applied.

Dr. Ramaiah finds the Boomerang suitable for almost all procedures, including in brachial arteries, for antegrade and retrograde punctures and in grafts. But because the system is a two-step procedure, with the second step — removing the device and applying manual compression for five minutes — being performed by recovery room nurses, there was initially some resistance to the device. "Why not use manual compression only?" they questioned.

"With the Boomerang, the amount and time of manual pressure is markedly decreased — by about 80 percent — versus manual compression alone,” explained Dr. Ramaiah, which could be reason enough to convince some doubters. But more importantly, he says, AHI’s studies report a zero infection rate associated with the Boomerang.

Fast ACTing Hemostasis

The University of Rochester Medical Center’s (Rochester, NY) full-service cath lab is staffed with six full-time faculty interventional cardiologists and performs more than 5,000 diagnostic and interventional procedures per year. Currently, the center is conducting a clinical trial involving the SafeSeal Hemostasis Patch from Possis Medical.

The noninvasive SafeSeal’s design is built on MPH (Microporous Polysaccharide Hemospheres) technology that reportedly facilitates dehydration of the blood cells, which concentrates and compresses cells, platelets and fibrin at the vessel access site.
“We are constantly re-evaluating and comparing devices. About a year ago, we began evaluating the SafeSeal versus manual compression alone to determine if the patch does indeed speed up hemostasis and by what degree,” said Craig Narins, M.D., associate professor of medicine and surgery, divisions of cardiology and vascular surgery.

While the trial data is still in the analysis stage, initial impressions of the SafeSeal are very favorable, says Dr. Narins. It allows for the removal of sheaths, even larger sizes, at higher ACT (active clotting time) levels, which means patients can ambulate sooner. Complete trial data should be in publication by the end of the year, Dr. Narins projects.

“Our staff was initially very skeptical that these patches that don’t even contact the artery would work. We found, however, that the artery seals off in under 15 minutes the majority of the time, even at higher ACT levels,” he said.

While not a replacement for vascular closure devices, Dr. Narins believes hemostasis patches definitely have a role in the cath lab and represent a good alternative when use of a closure device is not advisable.

Room for Improvement

Vascular closure technology is a fairly recent development and while there have been many advancements so far, the search for the ideal device continues.

“Today’s vascular closure devices are designed for 6-7 Fr sheaths, although they may be pushed to an 8 or 9 Fr. As a result, I believe there is big need for devices than can close larger holes required for procedures like endografting and aneurysms, etc.,” said Dr. Ramaiah.

Dr. Kim believes there is room for improvement in the areas of ease of deployment, reducing pain to the patient and further reduction of vascular complication risk, such as acute vessel closure.

According to Dr. Kim, “The ideal vascular closure device would be very effective and very safe, preferably leave no foreign material behind, eliminating the risk of infection and scarring, and would require minimal to no manual compression.”

More like this

- Boomerang Closure Device Leaves No Foreign Material Behind
- Wound Dressing Complements Invasive Vessel Closure
- AccessClosure’s Mynx Uses Hydrogel to Close Cath Site
- Vascular Closure Devices — Closing the Gap Through Innovation
Vascular Closure Devices: Is the Case Closed?

By hmpeditor
Created 12/21/2010 - 17:09

Vascular Closure Devices: Is the Case Closed?

- Volume 22 - Issue 12 - December, 2010
- Posted on: 12/21/10
- 0 Comments

Section:
Commentary

Issue Number: Volume 22 - Issue 12 - December, 2010
Pages: 568 - 570

Author(s):
Eugenia Nikolsky, MD, PhD and Rafael Beyar, MD

Image(s):

Figure 1. Information to be collected assessing vascular closure devices.
Vascular hemostasis is a key issue for the successful completion of either diagnostic or interventional percutaneous endovascular procedures. Traditionally, mechanical compression, either manual or using one of the commercially available femoral compression devices (FemoStop or C-Clamp), followed by prolonged bed rest (4 to 8 hours), was considered the gold-standard technique for achieving hemostasis after transfemoral percutaneous coronary interventions (PCI). Labor-intensive practice, prolonged immobilization, and considerable patient discomfort are the known limitations of mechanical compression techniques prompting a search for advantageous solutions.

Vascular closure devices (VCDs) represent an alternative approach to achieve hemostasis after PCI. The benefits of earlier ambulation and shorter hospital stays have led to increasing use of VCDs in the past decade.

Access-related vascular complications differ widely from a small hematoma to serious potentially fatal complications associated with prolonged hospitalization and increased costs. The incidence of vascular complications using mechanical compression depends on patient- and procedure-related characteristics, as well as operator experience and the learning curve.\(^1\)\(^-\)\(^3\) Female gender, older age, either too low or excessive weight and the presence of peripheral arterial disease are well-recognized patient-related factors associated with increased vascular complications, while larger introducer sheath size, longer procedural length and excessive anticoagulation, along with inaccurate location of the arterial puncture site, are the procedural factors known to increase local complication risk.\(^4\)\(^,\)\(^5\) The changing profile of the population treated with percutaneous techniques towards more elderly and high-risk patients, as well as increasing intervention complexity and introduction of composite adjunctive antiplatelet/antithrombotic therapy, may potentially affect the overall complication rate.

In this issue of the Journal, Hermanides et al, on behalf of the Zwolle Myocardial Infarction Study Group, present the results of the randomized ANGIO-Seal or manual Compression After coRonary intervention Evaluation (ANGIOCARE) study in patients undergoing PCI carried out using 6 French introducer sheaths.\(^6\) Patient ambulation was performed 4 hours after using the Angio-Seal and 8 hours after using manual compression. The trial was powered to demonstrate a superiority for the Angio-Seal versus manual compression, and a prespecified primary endpoint was a composite of large (> 5 cm) hematoma at the puncture.
site, groin bleeding resulting in prolonged hospital stay or blood transfusion or formation of arteriovenous fistula with or without surgical intervention at the puncture site. The study did not meet its primary endpoint, showing no significant differences in rates of vascular complications in PCI-treated patients managed with Angio-Seal or manual compression. In other words, Angio-Seal demonstrated the same safety profile as manual hemostasis. Only in a subgroup of patients with hypertension, the use of Angio-Seal was associated with a significantly lower rate of major vascular complications. Secondary endpoints including a post-procedural change in hemoglobin values and the overall duration of hospitalization were similar in the two groups.

Angio-Seal was one of the first devices to effectively close arterial punctures, and was approved for marketing by the U.S. Food and Drug Administration in 1996. It is an intraluminal VCD that creates a mechanical seal by “sandwiching” the puncture site between a bioabsorbable anchor and purified bovine collagen sponge which dissolves within 8 to 12 weeks. Among numerous reports on the Angio-Seal, very few are well-designed randomized, controlled studies.\(^7\)\(^{-11}\) The majority of publications are cohort and case-controlled studies and registries. While these studies in large, unselected populations define practice patterns and assess the overall incidence of complications, they have inherent limitations such as suboptimal data collection, lack of monitoring and/or the lack of an appropriate control arm.

The authors of the manuscript should therefore be acknowledged for conducting a large prospective, randomized trial comparing use of the Angio-Seal closure device with manual compression in the setting of contemporary PCI. How should the results of the ANGIOCARE study be interpreted? Being by design a prospective randomized, controlled trial aiming to provide the highest level of scientific evidence, this study is a valuable contribution to the current body of evidence on VCDs. However, there are a few limitations that should be considered in the interpretation of this study.

First, this was a single-center study; lower scientific weight is given to single-center versus multicenter trials.\(^12\)\(^,13\) Second, the definitions of access site-related vascular complications comprising the prespecified primary endpoint may be debated. This limitation is not specific to the ANGIOCARE study solely. Enormous heterogeneity in defining complications is a distinctive feature of all studies assessing VCDs, leading to difficulties in the interpretation of the results. That is why despite the numerous studies on VCDs published as peer-review publications, no major conclusion has been reached yet with regard to their safety.

Unification of standard definitions of major bleeding and vascular complications is therefore absolutely necessary in order to critically assess the results of future trials on VCDs and to avoid heterogeneity in outcomes. Consensus endpoint definitions should be created for the standardized assessment of vascular complications in a similar way where the interventional cardiology society have achieved an agreement to standardize endpoint definitions for clinical trials by arranging an academic research consortium (ARC).\(^14\) This will undoubtedly improve design and quality of future randomized, controlled trials on VCDs and their meticulous appraisal. Third, the duration of follow up should not be limited to in-hospital stay and should be extended to 30 days. The rate of late local complications is low but not negligible. Optimally, also, the data regarding patients’ viewpoints on the use of Angio-Seal as compared with mechanical compression should have been collected. It might be one of the endpoints where an advantage in favor of VCDs would be demonstrated. Figure 1 summarizes information to be collected in properly conducted randomized, controlled trials on VCDs, and Figure 2 summarizes the main criteria for the assessment of VCDs.\(^4\)

A finding of lower incidence of complications in the subgroup of patients with hypertension using Angio-Seal should be considered with care. The study was underpowered to reveal differences in the rare endpoints in this
subgroup, and therefore this outcome should be viewed as hypothesis-generating rather than conclusive. [5]

In the ANGIOCARE study, the use of femoral angiography as recommended by the Angio-Seal manufacturer has not been routinely performed. While subject for debate, we believe that an arteriogram preceding vascular closure is required to provide key information on the arterial puncture site in relation to the femoral artery bifurcation, inguinal ligament and femoral head, as well as the size of the femoral artery, presence of atherosclerotic disease and vascular calcification. Certain findings on the femoral angiogram including small (< 5 cm) diameter of the femoral artery, presence of peripheral vascular disease or high-grade dissection should preclude a vigilant operator from using a VCD.

In conclusion, the single-center, randomized, controlled ANGIOCARE study provided additional important evidence on safety of the 6 French Angio-Seal closure device compared with manual compression in the setting of PCI using contemporary antithrombotic therapies. However, despite achievement of quick hemostasis and shortening the time to ambulation with Angio-Seal, duration of hospitalization was similar regardless of the type of hemostasis. Therefore, the issue of earlier patient discharge in the setting of PCI after use of the Angio-Seal VCD is not supported here and continues to be unclear. To improve the design of future randomized, controlled VCD trials and to fully assess clinical outcomes across these trials, there is an imperative need for creating consistent endpoint definitions.

References


From Technion – Israel Institute of Technology and Rambam Health Care Campus, Haifa, Israel.

Address for correspondence: Eugenia Nikolsky, MD, PhD, Director, Cardiovascular Research Unit, Rambam Health Care Campus, Haifa, Israel. E-mail: e_nikolsky@rambam.health.gov.il

Click here to get important email news and updates

Commentary

Source URL: http://www.invasivecardiology.com/content/vascular-closure-devices-case-closed

Links:
[6] mailto:e_nikolsky@rambam.health.gov.il
APPARATUS AND METHOD FOR SEALING VASCULAR PUNCTURES

Inventors: Sew-Wah Tay, Plymouth; Kemal Schankereli, St. Paul; Thomas Holman, Minneapolis; Hans Mische, St. Cloud, all of Minn.

Assignee: Scimed Life Systems, Inc., Maple Grove, Minn.

Filed: Apr. 30, 1993

Related U.S. Application Data


References Cited

U.S. PATENT DOCUMENTS

Re. 33,925 9/1992 Bales et al. 606/50
1,596,004 8/1926 De Bengoa 604/900
1,731,069 10/1929 Herman .
1,983,669 12/1934 Kimble .
2,790,442 4/1957 Donaldson .
2,808,833 10/1957 August .
3,301,258 1/1967 Werner et al .
3,613,682 10/1971 Naylor .
3,636,943 1/1972 Balamuth .
3,858,586 1/1974 Lessen .

ABSTRACT

An apparatus for closing and sealing a vascular puncture is connected to an energy supply such that heat is generated in, or thermally conducted to, the tissue, thereby thermally fusing the vascular tissue together. The method for closing and sealing a vascular puncture comprises applying radio frequency or other energy to the tissue, the energy being sufficient to thermally fuse the tissue together, thus sealing the puncture. Embodiments of depth finding and guiding devices, as well as blood vessel occluders, are also disclosed.

48 Claims, 18 Drawing Sheets
<table>
<thead>
<tr>
<th>Patent Number</th>
<th>Date</th>
<th>Inventor(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4,943,290</td>
<td>7/1990</td>
<td>Rexroth et al.</td>
</tr>
<tr>
<td>4,946,463</td>
<td>8/1990</td>
<td>Wright</td>
</tr>
<tr>
<td>4,953,559</td>
<td>9/1990</td>
<td>Salerno</td>
</tr>
<tr>
<td>4,960,133</td>
<td>10/1990</td>
<td>Hewson</td>
</tr>
<tr>
<td>4,961,729</td>
<td>10/1990</td>
<td>Vaillancourt</td>
</tr>
<tr>
<td>4,979,948</td>
<td>12/1990</td>
<td>Gedicke et al.</td>
</tr>
<tr>
<td>4,994,060</td>
<td>2/1991</td>
<td>Rink et al.</td>
</tr>
<tr>
<td>5,009,656</td>
<td>4/1991</td>
<td>Reimels</td>
</tr>
<tr>
<td>5,035,695</td>
<td>7/1991</td>
<td>Weber, Jr. etc.</td>
</tr>
<tr>
<td>5,047,028</td>
<td>9/1991</td>
<td>Qian</td>
</tr>
<tr>
<td>5,049,148</td>
<td>9/1991</td>
<td>Mehl</td>
</tr>
<tr>
<td>5,053,046</td>
<td>10/1991</td>
<td>Janes et al.</td>
</tr>
<tr>
<td>5,061,267</td>
<td>10/1991</td>
<td>Zeller</td>
</tr>
<tr>
<td>5,061,274</td>
<td>10/1991</td>
<td>Kensey</td>
</tr>
<tr>
<td>5,078,743</td>
<td>1/1992</td>
<td>Mikalov et al.</td>
</tr>
<tr>
<td>5,080,660</td>
<td>1/1992</td>
<td>Buehna</td>
</tr>
<tr>
<td>5,085,659</td>
<td>1/1992</td>
<td>Rydell</td>
</tr>
<tr>
<td>5,116,332</td>
<td>5/1992</td>
<td>Lottick</td>
</tr>
<tr>
<td>5,122,137</td>
<td>6/1992</td>
<td>Lennox</td>
</tr>
<tr>
<td>5,131,394</td>
<td>7/1992</td>
<td>Gehlbach</td>
</tr>
<tr>
<td>5,133,714</td>
<td>7/1992</td>
<td>Beane</td>
</tr>
<tr>
<td>5,141,515</td>
<td>8/1992</td>
<td>Eberbach</td>
</tr>
<tr>
<td>5,147,316</td>
<td>9/1992</td>
<td>Castillenti</td>
</tr>
<tr>
<td>5,147,357</td>
<td>9/1992</td>
<td>Rose et al.</td>
</tr>
<tr>
<td>5,151,098</td>
<td>9/1992</td>
<td>Loetscher</td>
</tr>
<tr>
<td>5,151,102</td>
<td>9/1992</td>
<td>Kamitzkam et al.</td>
</tr>
<tr>
<td>5,156,613</td>
<td>10/1992</td>
<td>Sawyer</td>
</tr>
<tr>
<td>5,158,261</td>
<td>10/1992</td>
<td>Rydell et al.</td>
</tr>
<tr>
<td>5,159,926</td>
<td>11/1992</td>
<td>Neuwirth et al.</td>
</tr>
<tr>
<td>5,188,634</td>
<td>2/1993</td>
<td>Hussein et al.</td>
</tr>
<tr>
<td>5,190,541</td>
<td>3/1993</td>
<td>Abele et al.</td>
</tr>
<tr>
<td>5,192,300</td>
<td>3/1993</td>
<td>Fowler</td>
</tr>
<tr>
<td>5,207,675</td>
<td>3/1993</td>
<td>Camady</td>
</tr>
<tr>
<td>5,217,024</td>
<td>6/1993</td>
<td>Dorsey et al.</td>
</tr>
<tr>
<td>5,217,458</td>
<td>6/1993</td>
<td>Parins</td>
</tr>
<tr>
<td>5,217,459</td>
<td>6/1993</td>
<td>Kemberling</td>
</tr>
<tr>
<td>5,217,460</td>
<td>6/1993</td>
<td>Knoeppler</td>
</tr>
<tr>
<td>5,221,259</td>
<td>6/1993</td>
<td>Weldon et al.</td>
</tr>
<tr>
<td>5,221,281</td>
<td>6/1993</td>
<td>Kilcock</td>
</tr>
<tr>
<td>5,222,974</td>
<td>6/1993</td>
<td>Kensey et al.</td>
</tr>
<tr>
<td>5,226,908</td>
<td>7/1993</td>
<td>Yoon</td>
</tr>
<tr>
<td>5,230,349</td>
<td>7/1993</td>
<td>Langberg</td>
</tr>
<tr>
<td>5,257,635</td>
<td>11/1993</td>
<td>Langberg</td>
</tr>
<tr>
<td>5,258,006</td>
<td>11/1993</td>
<td>Rydell et al.</td>
</tr>
<tr>
<td>5,269,780</td>
<td>12/1993</td>
<td>Roos</td>
</tr>
<tr>
<td>5,275,616</td>
<td>1/1994</td>
<td>Fowler</td>
</tr>
<tr>
<td>5,281,216</td>
<td>1/1994</td>
<td>Kliceck</td>
</tr>
<tr>
<td>5,282,799</td>
<td>2/1994</td>
<td>Rydell</td>
</tr>
<tr>
<td>5,290,310</td>
<td>3/1994</td>
<td>Makower et al.</td>
</tr>
<tr>
<td>5,292,332</td>
<td>3/1994</td>
<td>Lee</td>
</tr>
<tr>
<td>5,304,117</td>
<td>4/1994</td>
<td>Wilk</td>
</tr>
<tr>
<td>5,320,639</td>
<td>6/1994</td>
<td>Rudnick</td>
</tr>
<tr>
<td>5,415,657</td>
<td>5/1995</td>
<td>Taymor-Luria</td>
</tr>
</tbody>
</table>
APPARATUS AND METHOD FOR SEALING VASCULAR PUNCTURES

CROSS REFERENCE TO RELATED APPLICATION

The present application is a continuation-in-part of application Ser. No. 07/873,955, filed Apr. 23, 1992, abandoned, the disclosure of which is hereby incorporated by reference.

FIELD OF THE INVENTION

The present invention relates to an apparatus and method for closing and sealing vascular punctures. More particularly, the present invention relates to a novel apparatus and method for sealing a vascular puncture resulting from the use of a medical device, catheter system or the like by using radio frequency or other energy to effect closure and thermal fusing of a puncture.

BACKGROUND OF THE INVENTION

Many medical procedures require access into the vascular system of the patient. Although various means may be used to obtain access into a vein or artery, typically access is obtained by inserting a cannula or introducer sheath through the skin and into the selected blood vessel. A medical device or diagnostic instrument, such as a guide wire, guiding catheter, balloon angioplasty device, atherectomy device, or the like is then inserted into the vascular system through the cannula or introducer sheath.

In percutaneous transluminal coronary angioplasty, for example, it is customary to introduce a catheter into the femoral artery at an entry site in a patient's leg and to advance the catheter through the artery to the coronary region. The artery, which may be located one half inch or more beneath the skin, is punctured with a needle or similar device. A guide wire is inserted through the needle and the needle is removed. An introducer sheath and dilator together are threaded over the guide wire. The introducer sheath is often twisted and otherwise manipulated as it is inserted into the vessel, thereby causing further enlargement of the vascular puncture. The dilator is then removed and the catheter is inserted.

To permit the insertion of a medical device or instrument therethrough, the introducer sheath must be of a relatively large diameter. Introducer sheaths typically have a diameter in the range between one millimeter and six millimeters, thus creating a significant puncture in the artery. After the intravascular medical procedure is completed, this puncture must be closed and bleeding from the blood vessel stopped.

At present, such bleeding is stopped by the application of direct digital pressure over the puncture site by a trained physician or other suitably trained medical personnel. Such direct pressure must be applied for a sufficiently long time for hemostasis to occur so that the opening is effectively closed and further bleeding is prevented. In the case of punctures into the femoral artery, the pressure is generally applied for twenty to thirty minutes, but it may be necessary to apply pressure for as long as one hour. Further, twelve pound sandbags may then be placed on the puncture site for an additional two to six hours.

The time required to stop bleeding using digital pressure is not an efficient use of medical professional services. Not only is this direct digital pressure application procedure wasteful of time by highly skilled medical professionals, the procedure results in a substantial reduction, if not virtual arrest, of blood flow through the vessel. Since thrombosis is one of the major problems that can occur in the immediate post-operative period, any reduction in blood flow, caused by the application of digital pressure, is undesirable. Furthermore, when digital pressure is applied, an undesirable bruise or hematoma can form at the entry site, since internal bleeding of the punctured artery continues until clotting blocks the puncture. There is also a significant chance that upon movement by the patient, the puncture will reopen and begin bleeding again, resulting in a hematoma or other complications. In addition, when anticoagulants used in the medical procedure are left active in the body, the introducer sheath is generally left inside the patient for twelve to twenty four hours in order for the anticoagulants to clear from the blood. Because the patient may be required to remain immobile and because of the risk of complications, patients are usually required to remain overnight in the hospital for observation, thus greatly increasing the cost of the overall procedure.

One prior device for stopping bleeding from a puncture in a blood vessel is a type of expandable plug. An example of such a device is shown in U.S. Pat. No. 4,890,612 (Kensey). The plug is pushed through the puncture into the blood vessel and into the blood stream. Once exposed to blood, it expands. The expanded plug is then pulled back against the puncture where, because of its expanded size, it plugs the opening. A similar device is an expandable closure, such as that described in U.S. Pat. No. 4,852,568 (Kensey). Such devices may work satisfactorily, but require inserting and leaving a foreign object in the vessel for a period of time. It is usually medically preferable to avoid leaving objects in a vessel, even if they eventually biodegrade.

Another device for stopping bleeding from a puncture is disclosed in U.S. Pat. No. 4,929,246 (Sinofsky). This patent relates to a method for closing an artery using laser energy while simultaneously applying pressure directly to the artery through the use of a balloon placed on the exterior of the artery over the puncture site.

SUMMARY OF THE INVENTION

An apparatus for closing and sealing a puncture at a puncture site in a vessel located beneath the skin using radio frequency or other energy to cauterize the puncture has been developed. In one aspect, the invention constitutes a probe sized to be percutaneously inserted adjacent the vascular opening and a connector for connecting the probe to an energy supply source; the probe being configured to conduct energy directly to tissue adjacent the probe to cause heating of tissue surrounding the vascular opening to close the opening.

In another aspect, the apparatus comprises a cautery device having a means for forcing together biological tissue surrounding a percutaneous vascular puncture and at least one electrode connectable to a radio frequency power source such that an electrical current may flow through the tissue, thermally fusing the tissue together.

In yet another aspect, the invention is an apparatus for the percutaneous medical treatment of biological tissue, comprising a plurality of electrodes connectable to a radio frequency power source, the electrodes adapted to engage biological tissue at points; and a lumen connected to the electrodes for guiding the electrodes to the biological tissue at said spaced points.

In one specifically disclosed embodiment, the apparatus comprises a radio frequency cautery device having forces
adapted to grasp vascular tissue surrounding the puncture site. The forceps, when connected to a radio frequency power source, also serve as bipolar electrodes for fusing the tissue surrounding the puncture.

A backstop element, such as a balloon occluder assembly or a T-shaped occluder, may also be used in conjunction with the cautery device. The balloon occluder assembly essentially comprises a balloon at the distal end of a balloon shaft and a means for inflating the balloon. The balloon occluder assembly temporarily occludes the puncture while providing a backstop against which the forceps may grasp the vascular tissue. The balloon occluder assembly also has utility separate from its use with the disclosed cautery device, as discussed more fully hereafter.

In another aspect, the invention is a method of sealing a vascular opening comprising the step of delivering energy to the vascular wall, resulting in local heating of bodily material external to the intima layer of the vessel to achieve hemostasis without substantially heating the intima layer of the vessel.

In yet another aspect, the method of the invention comprises the steps of percutaneously inserting a probe adjacent to the vascular opening; conducting energy from the probe directly to tissue adjacent the probe in an amount sufficient to coagulate the tissue to thereby close the vascular opening; and removing the probe. The invention in still another aspect is a method of sealing a vascular puncture comprising the steps of holding the vascular tissue surrounding the puncture site in a contacting position and applying energy to that tissue, the energy being sufficient to thermally fuse the tissue together, thus sealing the puncture. Preferably, this method of sealing a puncture includes the steps of advancing a balloon into the lumen of a vessel, inflating the balloon and withdrawing it to abut the puncture from within the vessel, inserting a cautery device having forceps connected to a radio frequency power source, grasping and bringing the vascular tissue into a contacting position, causing an electrical current to flow from one forceps, through the vascular tissue, to the other forceps, thus effecting a closure by thermally fusing the vascular tissue together.

In another aspect of the invention, a balloon occluder need not be used. Instead, pressure is applied to the vessel to restrict blood flow therethrough, an electrode is percutaneously inserted to a position proximate the puncture site, and radio frequency energy is used to cause thrombosis of the blood to seal the puncture site.

The present invention thus provides an apparatus which is simple to use and which overcomes the disadvantages of the prior art, including the need for the application of digital pressure for long periods of time and the possibility of a substantial reduction of blood flow through the vessel. The present invention also provides methods that are effective for closing off a puncture or other opening in a blood vessel by using radio frequency or other energy to thermally fuse the vascular tissue or form a seal by causing thrombosis of the blood. The puncture is hemostatically sealed almost immediately after the medical procedure is performed, thus avoiding any potential complications associated with re-opening of the puncture or long hospital stays while anticoagulants remain active in the body.

The forgoing has outlined rather broadly the advantages of the present invention. Additional benefits of the invention will be described hereinafter. These advantages, as well as the invention itself, are more easily understood in view of the attached drawings, a brief description of which follows.

**BRIEF DESCRIPTION OF THE DRAWINGS**

FIG. 1 is an exploded view of the first preferred apparatus embodiment of the present invention.

**FIG. 2** is an enlarged cross-sectional view of the distal portion of the device of the first preferred embodiment.

**FIG. 3** is an enlarged perspective view of the distal end of a forceps of the first preferred embodiment.

**FIG. 4** is an enlarged cross-sectional view of the distal end of a forceps of the first preferred embodiment.

**FIG. 5** is an enlarged cross-sectional view of a check valve assembly and hub used in conjunction with the inflation means of the first preferred embodiment.

**FIG. 6** through **FIG. 8** illustrate alternate embodiments of the actuating mechanism.

**FIG. 9** through **FIG. 18** are partial cross-sectional views illustrating the method of using the first preferred embodiment of the present invention.

**FIG. 9A** is a partial cross-sectional view taken along line 9A—9A of **FIG. 9** showing the relationship of the aneurysm sheath to the femoral artery and associated anatomy.

**FIG. 15A** is an enlarged cross-sectional view of the region of **FIG. 15** showing the various layers of the vascular tissue being contacted by the electrodes.

**FIG. 17A** is an enlarged cross-sectional view of the region of **FIG. 17** where the seal is made.

**FIG. 19A** and **FIG. 19B** illustrate an alternate embodiment of the backstop element of the present invention.

**FIG. 20** illustrates a second apparatus embodiment of the present invention.

**FIG. 20A** is an enlarged cross-sectional view taken along line 20A—20A of **FIG. 20**.

**FIG. 21** illustrates a third apparatus embodiment of the present invention.

**FIG. 21A** is an enlarged cross-sectional view taken along line 21A—21A of **FIG. 21**.

**FIG. 22** illustrates a fourth apparatus embodiment of the present invention.

**FIG. 22A** is an enlarged cross-sectional view taken along line 22A—22A of **FIG. 22**.

**FIG. 23** illustrates a fifth apparatus embodiment of the present invention.

**FIG. 23A** is an enlarged cross-sectional view taken along line 23A—23A of **FIG. 23**.

**FIG. 24** illustrates a sixth apparatus embodiment of the present invention.

**FIG. 25** is an exploded view of a first alternative vessel depth locating and occluding apparatus of the present invention.

**FIG. 26** is a partial cross-sectional view of the apparatus of **FIG. 25** in use.

**FIG. 27** is another partial cross-sectional view like **FIG. 26** showing the apparatus of **FIG. 25** ready for insertion of a cautery probe.

**FIG. 28** illustrates a second alternate embodiment of a vessel depth locating and occluding apparatus and one of the earlier described cautery devices of the present invention.

**FIG. 29** is an enlarged cross-sectional view disclosing a first alternative embodiment of the apparatus of **FIG. 28**.

**FIG. 30** is an enlarged cross-sectional view disclosing a second alternative embodiment of the apparatus of **FIG. 28**.

**DETAILED DESCRIPTION OF THE DRAWINGS AND PREFERRED EMBODIMENTS OF THE INVENTION**

Before describing the apparatus of the present invention, a brief description of a typical intravascular surgical proce-
actuation mechanism having a wedge which acts against an inclined plane for actuating said electrode from a first position to a second position.

19. An apparatus for the percutaneous treatment of a vascular puncture, said apparatus being adapted to percutaneously apply an electrical current to tissue proximate said vascular puncture to thermally seal said vascular puncture, comprising:

a) a cautery instrument for percutaneously sealing said vascular puncture, said instrument having
i) an elongated guide lumen for receiving an elongated shaft therethrough, and
ii) at least one electrode; and
b) an elongated shaft for percutaneously guiding said electrode to said vascular puncture, said elongated shaft having a distal end comprising a positioning mechanism insertable into a vessel lumen, said positioning mechanism configured to anchor the distal end of said elongated shaft inside said vascular puncture.

20. The apparatus of claim 19 wherein said elongated shaft further comprises markings thereon to measure a depth of said vascular puncture from a skin level.

21. The apparatus of claim 19 wherein the cautery instrument further comprises an elongated tubular retaining housing substantially surrounding said guide lumen and said electrode.

22. The apparatus of claim 19 wherein said electrode is an elongated electrode, external to and substantially parallel with said guide lumen.

23. An apparatus for percutaneously sealing a vascular puncture with an electrical current, said apparatus being adapted to percutaneously apply an electrical current to tissue surrounding said vascular puncture for the purpose of thermally sealing said vascular puncture, said apparatus comprising:

a) a cautery instrument for percutaneously sealing said vascular puncture, said instrument having
i) at least two movable electrodes, each electrode having a proximal end adapted to connect to a radio frequency power source and a distal end adapted to engage vascular tissue surrounding said vascular puncture and being movable from a first position to a second position;
ii) an elongated interior guide lumen for receiving an elongated shaft to said electrodes to said vascular puncture;
iii) an elongated tubular retaining housing substantially surrounding said electrodes and said guide lumen, said tubular retaining housing having an open distal end to allow for movement of said electrodes from said first position wherein said electrodes are contained within said tubular retaining housing to said second position wherein the distal end of each of said electrodes extends beyond the open distal end of said tubular retaining housing;
b) an elongated shaft for percutaneously guiding said electrodes to said vascular puncture; and
c) a balloon occluder assembly which includes said elongated shaft, said elongated shaft having a proximal end and a distal end, said distal end of said elongated shaft comprising an inflatable balloon and said proximal end connected to an inflation mechanism, said balloon occluder assembly adapted to be inserted into said interior guide lumen and to percutaneously guide each of said electrodes to said vascular puncture.

24. The apparatus of claim 23 wherein said elongated shaft comprises a T-shaped occluder, said T-shaped occluder adapted to be inserted into said interior guide lumen for percutaneously guiding each of said electrodes to said vascular puncture.

25. The apparatus of claim 23 wherein said electrodes are bipolar electrodes.

26. The apparatus of claim 25 wherein said bipolar electrodes are outwardly biased forces for grasping tissue proximate the vascular puncture.

27. The apparatus of claim 26 wherein said outwardly biased forces have a serrated distal end for grasping tissue proximate said vascular puncture.

28. The apparatus of claim 23 further comprising a grounding pad to be positioned beneath a patient for completing an electrical circuit with said cautery instrument.

29. An apparatus for the percutaneous treatment of a vascular puncture using radio frequency energy, said apparatus comprising:

a) a pair of substantially parallel elongated bipolar electrodes, each of said electrodes having a distal end for engaging tissue proximate said vascular puncture and a proximal end connectable to a radio frequency power source;
b) an elongated tubular retaining housing substantially surrounding said electrodes and comprising an elongated interior guide lumen substantially parallel to said electrodes for receiving a guiding device therethrough to guide said electrodes to said vascular puncture; the housing having at least one internal wall separating said guide lumen from said electrodes, said apparatus being adapted to apply an electrical current to tissue surrounding said vascular puncture for the purpose of thermally sealing said vascular puncture.

30. The apparatus of claim 29 wherein said electrodes are movable from a first position to a second position and said tubular retaining housing has an open distal end to allow for movement of said electrodes from said first position wherein said electrodes are contained within said tubular retaining housing to said second position wherein the distal end of each of said electrodes extends beyond the open distal end of said tubular retaining housing.

31. The apparatus of claim 29 wherein said housing has an open distal end and an open proximal end, said apparatus further comprising a guiding device insertable into and through said interior guide lumen for percutaneously guiding said electrodes to said vascular puncture, said guiding device having a distal end extending beyond said open distal end of said tubular retaining housing and insertable into a vessel lumen and a proximal end extendable beyond a proximal end of said tubular retaining housing.

32. The apparatus of claim 29 wherein said housing comprises triple lumen tubing.

33. The apparatus of claim 29 wherein said internal wall comprises a separate elongated tube having said guide lumen therethrough.

34. The apparatus of claim 29 wherein said apparatus further comprises a proximal end having a gripping handle for grasping said apparatus.

35. The apparatus of claim 34 wherein said apparatus further comprises an actuation mechanism having an actuator element, movement of said actuator element causing each of said electrode to move from said first position to said second position.

36. A method for percutaneously sealing a vascular puncture using radio frequency energy comprising:

a) using an elongated shaft to percutaneously locate said vascular puncture;
b) percutaneously guiding a radio frequency energy cautery instrument to said vascular puncture using said elongated shaft; and
23. c) generating a cauterizing discharge from said cauterity instrument to tissue proximate said vascular puncture sufficient to thermally seal said vascular puncture.

37. The method of claim 36 wherein the step of using said elongated shaft to percutaneously locate said vascular puncture further includes the step of temporarily occluding said vascular puncture using said elongated shaft wherein said elongated shaft has a distal end comprising an inflatable balloon and wherein said balloon is inflated and retracted inside said vascular puncture until said balloon abuts said puncture, thereby preventing fluid loss from said puncture.

38. The method of claim 36 wherein the step of using an elongated shaft to percutaneously locate said vascular puncture further includes the step of determining the depth of said vascular puncture by advancing a distal portion of said elongated shaft into a vessel lumen, said shaft having a series of markings thereon for determining depth.

39. The method of claim 36 wherein the cauterity instrument comprises an interior guide lumen and the step of using an elongated shaft to percutaneously locate said vascular puncture further comprises using an elongated shaft having a proximal end and a distal end, said distal end of said elongated shaft comprising an inflatable balloon and said proximal end connected to an inflation mechanism, said balloon being adapted to be inserted into said interior guide lumen and to percutaneously guide said cauterity instrument to said vascular puncture.

40. The method of claim 36 wherein the step of percutaneously guiding a radio frequency energy cauterity instrument to said vascular puncture using said elongated shaft further comprises using a cauterity instrument having an elongated interior guide lumen for receiving said elongated shaft therethrough and at least one substantially parallel elongated electrode external said guide lumen for applying electrical current to said tissue proximate said vascular puncture.

41. A method for percutaneously sealing a vascular puncture comprising:

a) guiding a cauterity instrument to the vascular puncture, the cauterity instrument having
i) a distal end comprising a pair of forceps which act as electrodes for grasping tissue,
ii) a proximal end for gripping by a user,
iii) an elongated interior guide lumen between and substantially parallel to said forceps for receiving an elongate guiding device to guide said forceps to said vascular puncture; and
iv) an elongated tubular retaining housing surrounding said forceps and said guide lumen, and having an open distal end;
b) actuating said forceps from a first position wherein said forceps are contained substantially within said tubular retaining housing to a second position wherein said forceps extend beyond said tubular retaining housing and grasping tissue proximate said vascular puncture; and
c) generating a cauterizing discharge to said tissue proximate said vascular puncture to thermally seal said vascular puncture.

42. A method of using radio frequency energy to seal a vascular puncture comprising:

a) using a guiding assembly to locate said vascular puncture;
b) guiding a cauterity instrument having a cauterizing distal end to said vascular puncture using said guiding assembly;

c) engaging tissue proximate said vascular puncture with said cauterizing distal end;
d) energizing said instrument with said radio frequency energy to thermally seal said vascular puncture.

43. A combination of an apparatus for sealing a vascular opening and a guide to direct the apparatus to the vascular opening, wherein the combination comprises:
a) a probe sized to be percutaneously inserted adjacent the vascular opening;
b) a connector connected to the probe for connecting the probe to an energy supply source;
c) the probe comprising a conductor configured to conduct energy directly to tissue adjacent the probe to cause heating of tissue surrounding the vascular opening to close said opening; and
d) the guide comprising an elongated member with a lumen therein open at least on its proximal end and a port in a side thereof in fluid communication with said lumen.

44. A method of using radio frequency energy to close a vascular puncture surrounded by vascular tissue comprising the steps of:

a) providing a guiding element extending from the vascular puncture;
b) guiding a cauterity device comprising a lumen to the vascular puncture by passing the lumen over the guiding element extending from the vascular puncture, said cauterity device comprising at least one electrode connected to a radio frequency energy source, said electrode being guided into direct contact with the vascular tissue; and
c) supplying radio frequency energy to the electrode while the electrode is in contact with the vascular tissue, thereby delivering radio frequency energy to the vascular tissue, the energy being sufficient to cause the vascular tissue surrounding the puncture to fuse together to close the opening.

45. A method of sealing a vascular puncture comprising the steps of:
a) percutaneously inserting a probe having a lumen by inserting the lumen over a guiding element extending from the vascular puncture and placing a tip of the probe in direct contact with vascular tissue surrounding the vascular puncture;
b) conducting energy from said probe tip directly to vascular tissue adjacent the probe tip in an amount sufficient to coagulate said tissue to thereby close said vascular puncture; and
c) removing said probe.

46. The method of claim 45 wherein the step of conducting energy comprises conducting energy from the probe to the tissue while the guiding element extends from the vascular puncture.

47. The method of claim 46 wherein after the energy conduction and probe removal, the method further comprises the step of removing the guiding element from the vessel, leaving a hole sufficiently small such that clotting can finish closing the vascular puncture.

48. The method of claim 46 wherein after the energy conduction and probe removal, the method further comprises the step of removing the guiding element from the vessel, leaving a hole sufficiently small such that vessel tissue contraction and clotting can finish closing the vascular puncture.

* * * * *
ABSTRACT
A suture-applying device comprises a guide body having a needle guide at its distal end. Needles are reciprocably carried on a shaft so that they may be advanced through the needle guide and tissue into the guide body. The suturing device is used by placing the needle guide within a vascular puncture. A contact surface is provided on the guide body, and the needle guide is configured so that the vascular wall surrounding the puncture is fully exposed to the needles passing therethrough. The suturing device may be combined with a predilator to form a system for suturing vascular punctures.

62 Claims, 11 Drawing Sheets
1 APPARATUS AND METHOD FOR VASCULAR CLOSURE

This application is a continuation-in-part of application Ser. No. 07/989,611, filed Dec. 10, 1992 now U.S. Pat. No. 5,417,699 and of application PCT/US93/11864, with an international filing date of Dec. 8, 1993, which claimed priority and continuation-in-part status from application Ser. No. 07/989,611, now U.S. Pat. No. 5,717,699. Both of these applications are incorporated fully herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to apparatus and methods for the percutaneous closure of body lumens. More particularly, the present invention relates to apparatus and methods for the percutaneous closure of arterial and venous puncture sites, which are usually accessible only through a tissue tract.

A number of diagnostic and interventional vascular procedures are now performed transluminally, where a catheter is introduced to the vascular system at a convenient access location and guided through the vascular system to a target location using established techniques. Such procedures require vascular access which is usually established using the well known Seldinger technique, as described, for example, in William Grossman’s “Cardiac Catheterization and Angiography,” 3rd Ed., Lea and Febiger, Philadelphia, 1986, incorporated herein by reference.

When vascular access is no longer required, the introducer sheath must be removed and bleeding at the puncture site stopped. One common approach for providing hemostasis (the cessation of bleeding) is to apply external force near and upstream from the puncture site, typically by manual or “digital” compression. This approach suffers from a number of disadvantages. It is time-consuming, frequently requiring one-half hour or more of compression before hemostasis is assured. This procedure is uncomfortable for the patient and frequently requires administering analgesics to be tolerable. Moreover, the application of excessive pressure can at times totally occlude the underlying blood vessel, resulting in ischemia and/or thrombosis. Following manual compression the patient is required to remain recumbent for at least six and at times as long as eighteen hours under close observation to assure continued hemostasis. During this time renewed bleeding may occur resulting in bleeding through the tract, hematoma and/or pseudoaneurysm formation as well as arteriovenous fistula formation. These complications may require blood transfusion and/or surgical intervention. The incidence of these complications increases when the sheath size is increased and when the patient is anticoagulated. It is clear that the standard technique for arterial closure can be risky, and is expensive andonerous to the patient. While the risk of such conditions can be reduced by using highly trained individuals, such use is both expensive and inefficient.

To overcome the problems associated with manual compression, the use of bioabsorbable fasteners to stop bleeding has been proposed by several groups. Generally, these approaches rely on the placement of a thrombogenic and bioabsorbable material, such as collagen, at the superficial arterial wall over the puncture site. While potentially effective, this approach suffers from a number of problems. It can be difficult to properly locate the interface of the overlying tissue and the adventitial surface of the blood vessel, and locating the fastener too far from that surface can result in failure to provide hemostasis and subsequent hematoma and/or pseudoaneurysm formation. Conversely, if the fastener intrudes into the arterial lumen, intravascular clots and/or collagen pieces with thrombus attached can form and embolize downstream causing vascular occlusion. Also, thrombus formation on the surface of a fastener protruding into the lumen can cause a stenosis which can obstruct normal blood flow. Other possible complications include infection as well as adverse reactions to the collagen implant.

A more effective approach for vascular closure has been proposed in co-pending application Ser. Nos. 70989,611 now U.S. Pat. No. 5,417,699; 08/148,809 now U.S. Pat. No. 5,527,322; and PCT/US93/11864. A suture applying device is introduced through the tissue tract with a distal end of the device located at the vascular punctures. One or more needles in the device are then used to draw suture through the blood vessel wall on opposite sides of the punctures, and the suture is secured directly over the adventitial surface of the blood vessel wall to provide highly reliable closure.

While a significant improvement over the use of manual pressure, clamps, and collagen plugs, certain design criteria have been found to be important to successful suturing to achieve vascular closure. For example, it is important that the needles be properly directed through the blood vessel wall so that the suture is well anchored in tissue to provide for tight closure. It is also important that needle deployment within the suturing device be controlled to prevent accidental deployment before the device has been properly introduced to the puncture site in a blood vessel. Additionally, it is important that the vascular suturing device be introduced only to blood vessels which are in a condition to receive it. In particular, because of the expense of the device and potential trauma to the patient, it is important to ascertain whether or not the suturing device can be fully inserted and deployed prior to the actual introduction.

For these reasons, it would be desirable to provide apparatus, systems, and methods for suturing vascular punctures which meet all or some of the criteria discussed above.

2. Description of the Background Art

Devices capable of delivering pairs of needles to various tissue locations are described in the following patents and patent applications: U.S. Pat. Nos. 4,493,323 and 659,422; European patent application 140 557; and U.S.S.R patent applications 1174-036-A and 1093-329-A. A suturing device that carries a pair of needles having suture therewith is described in a brochure entitled “Innovation through Progress,” REMA-MEDIZINTECHNIK, GmbH, January, 1992. A suturing device having a partially flared cylindrical core for delivering needles to suture anastomoses is described in U.S. Pat. No. 4,553,543. Other suturing and ligating devices are described in U.S. Pat. Nos. 5,171,251; 5,160,339; 4,317,445; 4,161,951; 3,665,926; 2,959,172; 2,646,045; and 312,408. Devices for sealing percutaneous vascular punctures using various plugs and fastener structures are described in U.S. Pat. Nos. 5,222,974; 5,192,302; 5,061,274; 5,021,059; 4,929,246; 4,890,612; 4,852,568; 4,744,364; 4,587,969; and 3,939,820. Collagen fastener sealing devices are under commercial development by Data- scope Corp., Montvale, N.J., and Kensey Nash Corporation, Exton, Pa. Copending application Ser. No. 08/148,809, now U.S. Pat. No. 5,527,322 describes a vascular suturing device having a needle guide with a constant peripheral dimension.

SUMMARY OF THE INVENTION

The present invention provides improved apparatus, systems, and methods for suturing percutaneous luminal puncture sites.
ture sites, particularly vascular puncture sites located at the distal end of a percutaneous tissue tract. The improvements are most applicable to paired-needle suturing systems, such as those described in co-pending Application Ser. Nos. 07/989,611 now U.S. Pat. No. 5,417,699 and PCT/US93/11864. At least some of the improvements, however, will be equally applicable to single-needle suturing systems, such as those described in co-pending Application Ser. No. 08/148,809 now U.S. Pat. No. 5,527,322 as well as other types of suturing devices known and described in the medical and patent literature.

In a first aspect of the present invention, a suturing device comprises a guide body, a needle guide connected to and spaced-apart from a distal end of the guide body, and a tissue-receiving region therebetween. The needle guide includes at least one needle guide channel, usually including at least two guide channels for receiving a pair of reciprocable needles having a length of suture therebetween. A contact surface is provided at the distal end of the guide body and is oriented at an angle in the range from 30° to 80° relative to a central axis of the guide body. The angle is selected to offset the oblique angle at which the guide body typically approaches a vascular punctures site. The oblique angle is the result of the tissue tract which is formed using the well known Seldinger technique. The contact surface is thus able to lie generally flat over the adventitial surface of the blood vessel wall. In this way, the guide body is better positioned to receive needles passing from the needle guide through the tissue-receiving region and into the guide body.

In the second aspect of the present invention, a suturing device comprises a guide body and needle guide, generally as described above. A pair of needles are mounted on a reciprocable shaft, and the needles and distal portion of the shaft are preferably mounted in a flexible needle sheath. Prior to use, sharpened proximal ends of the needles are located in the guide channels of the needle guide, and proximal reciprocation of the shaft will draw the needles through the guide, through the tissue-receiving region, and to needle-receiving lumens within the guide body. The needle guide has a non-circular profile within the tissue-receiving region which disposes surrounding tissue to provide an improved target for the needles being advanced from the needle guide. In this way, the likelihood that the needles will pass through and become firmly anchored within the tissue surrounding the puncture is greatly increased. Preferably, the non-circular profile is elliptical and the distal end of the needle guide from which the needles emerge is generally circular. The circular profile helps direct the needles past a major face of the elliptical region of the guide, providing a good tissue target for the needles. The circular end of the needle guide also makes and forms a smooth transition with the flexible needle sheath which is preferably attached to the guide.

In a still further preferred embodiment, the needle guide will have a substantially uniform peripheral distance, i.e., total distance around the periphery of any normal cross-section, over the transition from the circular distal end to the elliptical tissue-receiving region. The uniform peripheral distance allows hemostasis at the vascular puncture and allows the puncture periphery to be shaped without distending the tissue to tear and damage the vessel.

In a third aspect of the present invention, a suturing device comprises a guide body, needle guide, pair of needles, and reciprocable shaft, generally as described above. The suturing device will further comprise a lock or other structure on the guide body for releasably securing the shaft to prevent relative reciprocation. The lock prevents accidental needle deployment while the suturing device is being introduced within the tissue tract. In a preferred embodiment, the lock comprises at least one slot formed at a proximal end of the guide body, preferably within a proximal handle, and at least one key disposed at the proximal end of the shaft. The key is engaged and disengaged in the slot by rotation of the shaft relative to the guide body.

The present invention still further comprises systems and methods for suturing vascular punctures at the distal end of percutaneous tissue tracts. In addition to a suturing device, which may be any of the devices described above, the system also includes a predator comprising a body, generally a cylindrical body having dimensions similar to the guide body of the suturing device, and a flexible tube attached to a distal end of the body, where the flexible tube has a diameter similar to that of the flexible needle sheath of the suturing device. A guide wire lumen will be formed continuously from the distal end of the flexible tube to the proximal end of the body, and the predator will further include at least one blood marker lumen extending from a mark port disposed on the flexible tube just distal of the distal end of the body.

According to the method of the present invention, the predator is first introduced through the tissue tract and into a blood vessel lumen prior to introducing a suturing device. In particular, the flexible tube of the predator is introduced fully into the blood vessel lumen so that the distal end of the predator body lies immediately over the adventitial surface of the blood vessel wall. Proper positioning of the predator can be determined by observing the appearance of blood through the marker lumen which extends to the proximal end of the predator body. Successful introduction of the predator dilates the tissue tract in preparation for the suturing device and is predictive of successful introduction of the suturing device. Thus, after the predator has been successfully introduced (and removed), the suturing device can be introduced and used to suture the vascular puncture, as will be described in detail hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of a suturing device constructed in accordance with the principles of the present invention, with portions broken away.

FIG. 2 is a detailed view of the needle guide of the suturing device of FIG. 1, taken along line 2—2 in FIG. 1.

FIG. 3 is an axial, cross-sectional view of the needle guide of FIG. 2, taken along line 3—3 in FIG. 2.

FIG. 4 is a left-end view of the needle guide of FIG. 3.

FIG. 5 is a right-end view of the needle guide of FIG. 3.

FIG. 6 is a perspective view of the proximal end of the suturing device of FIG. 1.

FIG. 7 is a side view of a predator device constructed in accordance with the principles of the present invention.

FIGS. 8—14 illustrate use of the suturing device of FIG. 1 and predator device of FIG. 7 in performing a vascular suturing procedure according to the method of the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENT

Referring to FIG. 1, a suturing device 10 constructed in accordance with the principles of the present invention comprises a guide body 12, a needle guide 14 secured to a distal end of the guide body 12, and a flexible needle sheath
United States Patent

Ratcliff et al.

[54] VASCULAR WOUND CLOSURE SYSTEM

[75] Inventors: Keith Ratcliff, Newton; Roberto Pedros, Seymour, both of Conn.

[73] Assignee: United States Surgical Corporation, Norwalk, Conn.

[21] Appl. No.: 09/092,430
[22] Filed: Jun. 5, 1998

[51] Int. Cl. A61B 17/04
[52] U.S. Cl. 606/213; 606/142, 606/143
[58] Field of Search 606/213, 142, 606/143, 139

[56] References Cited

U.S. PATENT DOCUMENTS
4,539,990 9/1985 Stivala 606/216
4,622,970 11/1986 Wozniak 606/153
5,383,896 1/1995 Gershony et al .
5,531,759 7/1996 Kensey et al .
5,545,178 8/1996 Kensey et al .
5,645,566 7/1997 Breneman et al .

[57] ABSTRACT

An apparatus for facilitating closure of an opening in a blood vessel, includes a closure instrument having an elongated member defining a longitudinal axis and proximal and distal ends. The elongated member has a vacuum lumen extending at least a portion of the length thereof for conveying a vacuum and terminating in a vacuum port adjacent the distal end of the elongated member. The distal end of the elongated member is dimensioned to be positioned proximal a vessel opening in a blood vessel whereby vessel edge portions defining the vessel opening arc at least drawn toward the vacuum port in response to a vacuum conveyed through the vacuum lumen. At least one surgical clip is mounted adjacent the distal end of the elongated member and is adapted to be formed to an at least partially formed condition thereof. The one clip is positioned with respect to the vacuum port to engage the vessel edge portions drawn toward the vacuum port upon movement of the one clip to the formed condition thereof to generally approximate the vessel edge portions to at least partially close the vessel opening. A method for facilitating closure of an opening in a blood vessel is also disclosed.

18 Claims, 17 Drawing Sheets
1 VASCULAR WOUND CLOSURE SYSTEM

FIELD OF THE INVENTION

The present invention relates to a system which assists in the closure of puncture or other wounds in the vasculature of a patient. Specifically, the invention relates to devices which aid in locating and isolating the wound in the vasculature and guiding an appropriate wound closure device to the site, so that the wound may be closed using surgical clips, sutures, or staples.

BACKGROUND OF THE INVENTION

Transluminal balloon angioplasty is used in the treatment of peripheral vascular disease to increase or restore blood flow through a significantly narrowed artery in a limb; it is also used in the treatment of blockage of the coronary arteries. In fact, coronary angioplasty has emerged as a major viable alternative to bypass surgery for revascularization of stenotic and occluded coronary arteries. Unlike bypass surgery, angioplasty does not require general anesthesia, opening of the chest wall, use of a heart-lung machine, or transfusion of blood. Angioplasty is not only less invasive and less traumatic to the patient, it is also less expensive because of the shorter hospital stay and shorter recovery time.

Transluminal balloon angioplasty is performed by first inserting a hollow needle through the skin and into the patient’s femoral artery. A guidewire is advanced through the hollow needle and into the artery, then along the patient’s vasculature toward the site of the blocked blood vessel or heart valve to be treated. X-ray imaging is used to help move the guidewire through the vascular system and into position just past the stenosis to be treated. A balloon catheter is then threaded over the guidewire and advanced until the deflated balloon is within the stenosis. The balloon is then repeatedly inflated to widen the narrowed blood vessel. After the procedure is complete, the catheter and guidewire are withdrawn from the blood vessels and the patient.

Angiography, which is used to detect diseases that alter the appearance of blood vessels, is performed in a similar manner. A hollow needle is first inserted through the skin and into the femoral artery, and a guidewire is then inserted through the needle and into the affected blood vessel. A catheter is then threaded over the guidewire and into the blood vessel to be examined, using x-ray imaging to guide the catheter to the desired position. Contrast medium is then injected, and a rapid sequence of x-ray pictures are taken so that blood flow along the affected vessel can be studied. Once complete, the catheter and guidewire are removed from the patient’s body.

After the catheter and guidewire used during angioplasty or angiography are removed, the puncture wound in the femoral artery must be closed and the bleeding through the puncture site in the artery stops. Currently, ice packs and/or pressure are applied to the artery for a period lasting up to several hours in an attempt to stop the bleeding. There exists, however, a significant chance that upon movement by the patient, the wound will reopen and begin bleeding again. Although efforts have been made to close the puncture wound using staples, clips, and sutures, they have been unsuccessful, largely due to the inability to clearly locate and visualize the puncture wound in the femoral artery.

Other wounds in the vasculature of a patient can also be difficult to locate and access. Thus, a device and method to facilitate the closure wounds in the vasculature of a patient, such as femoral artery puncture wounds following transluminal balloon angioplasty and angiography, would be extremely beneficial. A device having the ability to aid in locating the puncture wound and facilitating the closure of the wound using staples, clips, or sutures would eliminate the prolonged bleeding currently associated with such wounds.

SUMMARY OF THE INVENTION

An apparatus for facilitating closure of an opening in a blood vessel, includes a closure instrument having an elongated member defining a longitudinal axis with proximal and distal ends. The elongated member has a vacuum lumen extending at least a portion of the length thereof for conveying a vacuum and terminating in a vacuum port adjacent the distal end of the elongated member. The distal end of the elongated member is dimensioned to be positioned proximal a vessel opening in a blood vessel whereby vessel edge portions defining the vessel opening are at least drawn toward the vacuum port in response to a vacuum conveyed through the vacuum lumen. At least one surgical clip, preferably, two, are mounted adjacent the distal end of the elongated member and is adapted to be formed to an at least partially formed condition thereof. The one clip is positioned with respect to the vacuum port to engage the vessel edge portions drawn toward the vacuum port upon movement of the one clip to the formed condition thereof to generally approximate the vessel edge portions to at least partially close the vessel opening.

The apparatus may further include a clip forming member mounted to the elongated member and engageable with the one clip. The clip forming member is movable relative to the elongated member to move the one clip to the formed condition thereof. Preferably, first and second clip forming members are mounted to the elongated member in diametrically opposed relation.

In another preferred embodiment, an apparatus for facilitating closure of an opening in a blood vessel, includes an elongated member having a vacuum lumen extending at least a portion of the length thereof for conveying a vacuum and terminating in an axial vacuum port, a source of vacuum connectable to the elongated member in communication with the vacuum lumen whereby vacuum forces conveyed through the vacuum lumen and vacuum port causes vessel edge portions defining the vessel opening to be at least partially drawn into the vacuum port such that the vessel edge portions assume a generally everted condition, and a pair of surgical clips releasably mounted to the distal end of the elongated member adjacent the vacuum port and positioned to engage the vessel edge portions drawn into the vacuum port upon movement of the surgical clips to respective formed conditions thereof to thereby approximate the vessel edge portions to at least partially close the vessel opening. The apparatus may further include a manually actuable clip forming mechanism mounted to the elongated member. The clip forming mechanism is movable to move the surgical clips to respective formed conditions thereof.

A method for closing a vessel opening in a blood vessel is also disclosed. The method includes the steps of applying a vacuum to the blood vessel adjacent the vessel opening such that vessel edge portions defining the vessel opening assume an everted condition, and deploying a surgical clip adjacent the vessel opening whereby the surgical clip generally approximates the vessel edge portions to at least partially close the vessel opening.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of a portion of a human body, showing the site where the femoral artery is typically accessed and punctured during angioplasty or angiography.
FIG. 2 is a perspective view of one embodiment of the wound closure device of the present invention.

FIG. 3 is an exploded perspective view of the wound closure device of the present invention.

FIG. 4 is a cross-sectional view of a portion of a human body, showing the femoral artery accessed via a hollow needle, and a guidewire having an inflatable balloon attached, inserted through the hollow needle and into the femoral artery.

FIG. 5 is a side view of the distal end of a surgical clip applicator to be used in conjunction with the wound closure device of the present invention.

FIG. 6 is a partial cross-sectional view of a portion of a human body, showing the femoral artery having a guidewire positioned therein, and a perspective view of the retractor of the present invention positioned over the guidewire, with its distal tip at the site of the puncture in the femoral artery.

FIG. 7 is a side view of the retractor with its cap removed and the wings of the surgical clip applicator inserted into the grooves within the retractor.

FIG. 8 is a cross-sectional view of the clip applicator and retractor taken along line 8—8 in FIG. 7.

FIG. 9 is a perspective view of an alternate embodiment of a femoral artery closure device in accordance with the present invention.

FIG. 10 is an exploded perspective view of the alternate embodiment of the femoral artery closure device illustrated in FIG. 9.

FIG. 11 is a side view of the 2 halves of the retractor of FIGS. 9 and 10 separated slightly and having a dilator inserted therethrough.

FIG. 12 is a cross-sectional view of the distal end of the retractor having a dilator and a guidewire inserted therethrough.

FIG. 13 is a side view of the components of the femoral artery localization and closure assembly.

FIG. 14 is a side view of the 2 halves of the retractor separated slightly and having a surgical clip applicator with an applicator guide and a guidewire inserted therethrough.

FIG. 15 is a top view of the surgical clip applicator guide of the present invention.

FIG. 16 is a side view of the clip applicator guide, having a guidewire inserted therethrough.

FIG. 17 is an enlarged perspective view of a dilator having a removable double-sleeved balloon at its distal end.

FIG. 18 is an enlarged perspective view of the dilator of FIG. 17 with the sleeves of the balloon inflated.

FIG. 19 is an enlarged perspective view of the dilator of FIG. 18 having the retractor inserted between the sleeves of the balloon.

FIG. 20 is an enlarged perspective view of the dilator and retractor of FIG. 19 with the dilator removed, illustrating the tunnel formed by the retractor and the outer sleeve of the balloon.

FIG. 21 is a perspective view of another alternate embodiment of a retractor in accordance with the present invention.

FIG. 22 is an exploded perspective view of the alternate embodiment of the retractor illustrated in FIG. 21.

FIG. 23 is a perspective view of an alternate embodiment of a dilator having a double-sleeved balloon and a distal balloon mounted thereon in accordance with the present invention.

FIG. 24 is a top view of another embodiment of the double-sleeved balloon, illustrating the 1-shaped inner sleeve.

FIG. 25 is a perspective view of the alternate embodiment of the dilator of FIG. 23, showing the balloons inflated.

FIG. 26 is a cross-sectional view of the dilator of the present invention, illustrating the various lumens in the dilator.

FIG. 27 is a side view of the distal end of a surgical clip applicator with an indicator tube mounted thereon.

FIG. 28 is a perspective view of an alternate embodiment of a retractor of the present invention, shown in a closed position.

FIG. 29 is a perspective view of an alternate embodiment of a retractor of the present invention, shown in an open position.

FIG. 30 is a side view of a dual-lumen indicator tube of the present invention, having a guidewire inserted through its central lumen.

FIG. 31 is a side view of the dual-lumen indicator tube of the present invention, with the retractor mounted thereon.

FIG. 32 is a perspective view of an apparatus for facilitating closure of an opening in a vascular organ illustrating the vascular closure instrument and a vacuum source connected to the closure instrument.

FIG. 33 is an enlarged isolated view of the distal end of the closure instrument illustrating the pair of clips releasibly mounted to the instrument.

FIG. 34 is a cross-sectional view of the closure instrument in a non-actuated condition illustrating positioning of the distal end of the closure instrument proximal the vascular opening.

FIG. 35 is an enlarged isolated view of the distal end of the closure instrument in the non-actuated condition proximal the vascular opening.

FIG. 36 is a cross-sectional view of the closure instrument illustrating the closure instrument in an actuated condition.

FIG. 37 is an enlarged isolated view of the distal end of the closure instrument in the actuated condition illustrating the surgical clips formed to close the vascular opening.

FIG. 38 is a perspective view of an alternate embodiment of the vascular closure instrument of FIG. 32.

FIG. 39 is an enlarged isolated view of the distal end of the closure instrument of FIG. 38.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Introduction

Although the description which follows details the closure of a puncture wound in a femoral artery, the present invention is not intended to be limited to use only with the femoral artery. Rather, the description which follows is exemplary only, and those of skill in the art can readily modify the method described below to use with other types of wounds to the vascular system.


Referring first to FIG. 1, there is shown a side view of a portion of a human body, showing a site 5 where a femoral artery 10 is typically accessed and punctured during angio-
BIOLOGICAL SEALANT MIXTURE AND SYSTEM FOR USE IN PERCUTANEOUS OCCLUSION OF PUNCTURE SITES AND TRACTS IN THE HUMAN BODY AND METHOD

Inventors: Gordon H. Epstein, Fremont; Todd E. Lempert, Piedmont; Brian B. Martin, Boulder Creek, all of Calif.

Assignee: Biointerventional Corporation, Pleasanton, Calif.

[54] PATENT DOCUMENTS
4,061,731 12/1977 Gottlieb ........................................ 424/448
4,600,574 7/1986 Lindner et al. ................................ 424/448
5,258,000 11/1993 Giansuroe .................................. 606/151
5,282,827 2/1994 Kensey et al. .................................. 608
5,290,552 3/1994 Sierra et al. ................................. 424/448
5,349,633 8/1996 Evans et al. ................................. 606/151
5,591,004 1/1997 Janzen et al. ................................. 608
5,626,601 5/1997 Gershony et al. ............................... 606/213
5,838,896 1/1995 Gershony et al. ............................... 606/213

OTHER PUBLICATIONS

Primary Examiner—Michael BuiZ
Assistant Examiner—Vikki Trinh
Attorney, Agent, or Firm—Flehr Hohbach Test Albritton & Herbert

ABSTRACT
A biological sealant comprising a gelatin slurry. The slurry contains gelatin, saline or water and thrombin.

42 Claims, 17 Drawing Sheets
BIOCHEMICAL SEALANT MIXTURE AND SYSTEM FOR USE IN PERCUTANEOUS OCCLUSION OF PUNCTURE SITES AND TRACTS IN THE HUMAN BODY AND METHOD

This is a continuation-in-part of prior application Ser. No. 09/126,963 filed Jul. 31, 1998 which is a continuation-in-part of application Ser. No. 08/972,583, filed Nov. 18, 1997 now U.S. Pat. No. 5,922,009 which is a continuation-in-part of application Ser. No. 08/798,870, filed Feb. 11, 1997 which issued as U.S. Pat. No. 5,782,860 on Jul. 21, 1998.

This invention relates to an expandable device and tension application device for use therewith, for use in vascular and non-vascular tracts in the human body and method and more particularly for percutaneous occlusion of vascular access sites in the human body.

Percutaneous access to the blood vessels and organs of the human body for diagnosis and treatment of disease processes has heretofore been accomplished. Percutaneous vascular procedures are performed involving the coronary, peripheral and cerebral vasculature. These procedures include coronary and peripheral angioplasty, angiography, arterectomies, coronary retroperfusion and reinfusion, cerebral angiograms, treatment of strokes, cerebral aneurysms and the like. Patients undergoing such procedures are often treated with anti-platelet drugs, anticoagulants such as heparin, thrombolytics, or a combination thereof, all of which interfere with coagulation making it more difficult for the body to seal a puncture site. Various devices and methods have heretofore been utilized, however, they all have had deficiencies, including the use of complicated devices and methods. In addition, difficulties are still encountered in obtaining good seals. There is therefore a need for a device and method for percutaneous access and occlusion of vascular access sites and other puncture sites and natural tracts in the human body which overcome the deficiencies of prior art devices and methods.

In general, it is an object of the present invention to provide a closure device and method for percutaneous access and occlusion of vascular access sites, other puncture sites and natural tracts in the human body which will make possible a positive seal of the puncture site or tract promoting rapid and effective sealing of the puncture site.

Another object of the invention is to provide a closure device and method of the above character which can be easily and reliably used.

Another object of the invention is to provide a closure device and method of the above character in conjunction with which a biological sealant is used by introduction into the puncture site or natural tract.

Another object of the invention is to provide a closure device and method of the above character which leaves a small enough opening after removal of the closure device so that the biological sealant will seal the remaining opening.

Another object of the invention is to provide a closure device and method of the above character which enables continued substantially unobstructed blood flow during deployment and use of the closure device.

Another object of the invention is to provide a closure device and method of the above character in which no foreign body remains in the blood vessel.

Another object of the invention is to provide a closure device and method of the above character that permits early ambulation of patients and avoids prolonged bed rest.

Another object of the invention is to provide a closure device and method of the above character which reduces the risk of bleeding, formation of arteriovenous fistula, formation of pseudoaneurysm, thrombosis with distal embolization and infection.

Another object of the invention is to provide a closure device and method of the above character that reduces the risk of causing ischemia of an extremity.

Another object of the invention is to provide a closure device and method of the above character that is inexpensive, quick, safe, easy to use and is disposable.

Another object of the invention is to provide an expandable device and method of the above character in which the configuration of an expandable assembly is determined by countervailing mechanical forces of an expandable member and a membrane.

Another object of the invention is to provide an expandable device and method of the above character in which tensioning means is provided for reversibly maintaining engagement of the expandable assembly against the vessel wall of a puncture and to free the operator’s hands from having to hold the device after it is correctly deployed in the puncture.

Another object of the invention is to provide an expandable device and method of the above character in which tensioning means is provided for reversibly maintaining engagement of the expandable assembly against the vessel wall of a puncture by applying a substantially constant force of tension over a range of motion.

Another object of the invention is to provide an expandable device and method of the above character in conjunction with which a solid biological sealant is used by introduction into the puncture site or natural tract.

Another object of the invention is to provide an expandable device and method of the above character wherein a sealant placement member is utilized for advancing said sealant into the body and placing the sealant external to the lumen of the vessel.

Another object of the invention is to provide an expandable device and method of the above character which provides a capsule or casing for compressing and delivering a solid sealant into the body and placing the sealant external to the lumen of the vessel.

Another object of the invention is to provide a biological sealant in the form of a gelatin slurry containing saline, thrombin and calcium.

Another object of the invention is to provide a biological sealant in the form of a Gelfoam® slurry containing saline, thrombin and calcium.

Another object of the invention is to provide a process for making a gelatin slurry biological sealant.

Another object of the invention is to provide a system and method for using a gelatin slurry biological sealant in conjunction with other vascular closure devices.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments and the methods using the same are described in conjunction with the accompanying drawings.

FIG. 1 is a side-elevational view partially in section of a closure device for obtaining percutaneous access and occlusion of puncture sites in the human body incorporating the present invention and having closure means in a de-deployed or retracted position.

FIG. 2 is a cross-sectional view taken along the line 2—2 of FIG. 1.

FIG. 3 is a side-elevational isometric view of the distal end of the device shown in FIG. 1 with the closure means in a deployed or extended position.