Novel Vascular Access Management

The Boomerang system facilitates manual compression while leaving nothing behind.

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We report our recent experiences with vascular access management utilizing a novel technology that simply and safely converts the existing arteriotomy sheath size from 4 F to 10 F to an arteriotomy the size of an 18-gauge needle without leaving anything behind. This vascular access management system greatly simplifies and facilitates manual compression from the standpoint of the patient, physician, cath lab, and hospital. The potential clinical importance of the novel Boomerang (Cardiva Medical, Mountain View, CA) vascular access management system is underscored when considering that after a plethora of vascular closure devices (VCDs) have been introduced during the last decade, it is estimated that 70% of all diagnostic and interventional cases still utilize traditional manual compression as their primary mode of vascular access management.

THE BOOMERANG WIRE SYSTEM

The Boomerang System is an 18-gauge (.051-inch) wire designed to address the shortcomings of current vascular access management tools, primarily VCDs (Table 1). The Boomerang Wire is not a VCD because it leaves nothing behind once it is removed. In comparison, VCDs are generally active fixation devices based on sutures, collagen plugs, staples, or clips. VCDs manipulate the arterial wall in ways that can cause trauma, scarring, and/or lead to a nidus for infection. Unlike VCDs, the Boomerang Wire employs a passive mechanism—a temporary collapsible polyurethane-sheathed nitinol disc—to tamponade the arteriotomy site and stop the pressurized pulsatile blood flow from escaping the access site hole. The Boomerang Wire can be used on a variety of sheath sizes (4-10 F).

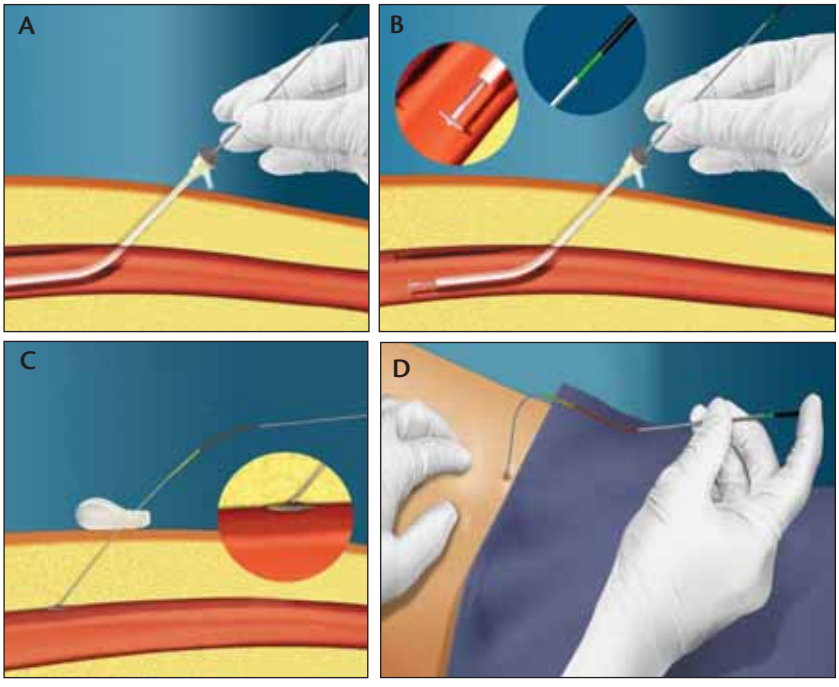

Figure 1. Step 1: The Boomerang Wire is inserted through the existing indwelling arterial sheath (A). Step 2: The Boomerang Wire tip is deployed and opens into a low-profile, biocompatible, conformable disc (B). Step 3: Sheath removal positions the disc against the arteriotomy for a tight seal and immediate tamponade of the arteriotomy (C). Step 4: In conjunction with facilitated manual compression, the device is removed leaving nothing behind, and light manual compression is applied to the 18-gauge arteriotomy until hemostasis is achieved (D).

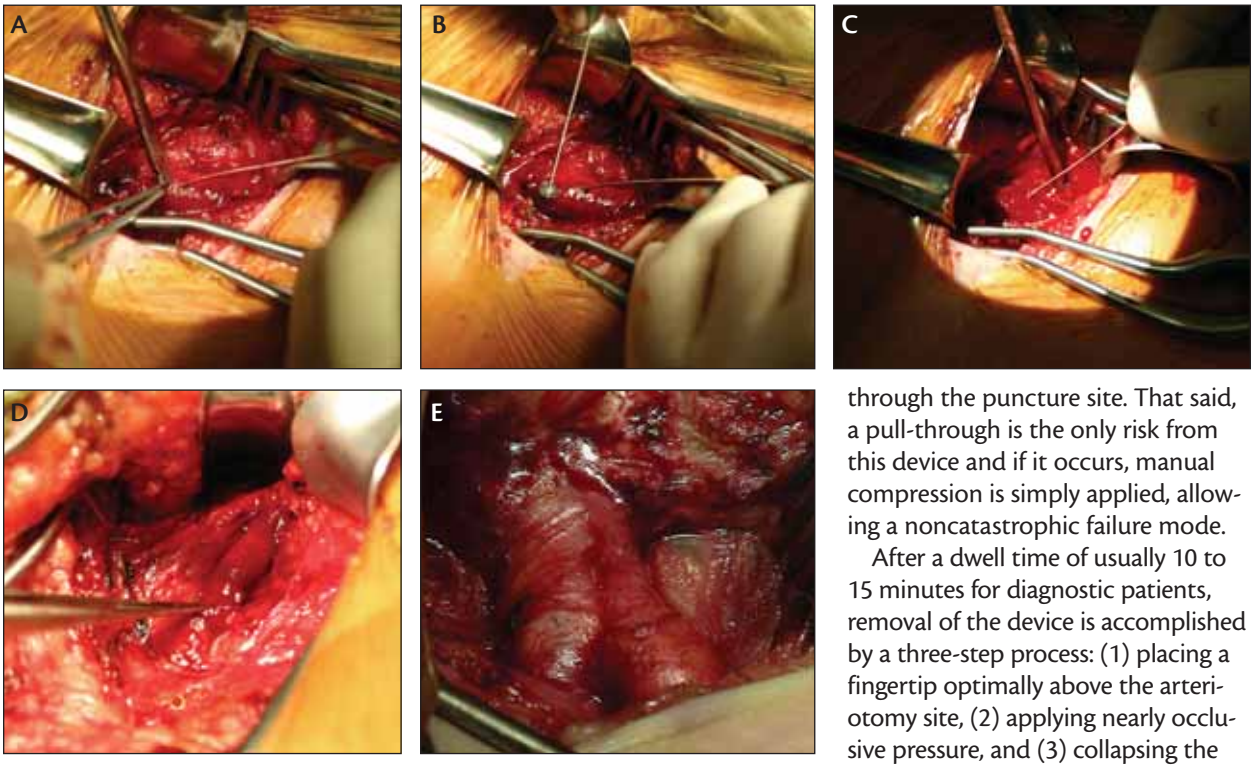

Figure 2. Common Femoral Artery (CFA) sequence from case 1 after direct intraoperative insertion of a 7-F sheath. CFA 3 minutes after 610 Boomerang Wire deployment demonstrating the "Boomerang effect," elastic recoil of the periarteriotomy tissue (A). The extraluminal 610 Boomerang disc is deployed at 5 minutes for intraluminal comparison (B). At 10 minutes, the disc is retracted demonstrating an 18-gauge needle stick spurt of blood converting the larger 7-F arteriotomy to an 18-gauge needle-sized arteriotomy (C). In case 2, the CFA 12 minutes after disc deployment and removal demonstrating complete arteriotomy site elastic recoil and sealing (D). In case 3, CFA and bifurcation 3 weeks after 7-F arteriotomy revealing minimal vessel wall scarring. Note vaso vasorum has remained intact (E).

The Boomerang Wire is exchanged for the existing sheath at the end of the diagnostic or interventional procedure, making this a simple, easy-to-use technology. The 18-gauge wire is passed through the existing sheath, and the temporary nitinol disc is deployed. Without touching the groin with any compression, the sheath is removed over the Boomerang Wire. The operator then gently grasps the green marked portion of the wire and exerts light pressure upward to allow the disc to seat in the artery, thereby sealing the arteriotomy site. While holding the green gripper and exerting gentle upward pressure on the spring wire, temporary hemostasis is achieved. A small plastic, atraumatic skin clip is placed on the unique spring portion of the wire to maintain an occlusive tamponade until the device is removed. The disc has been designed so that no traumatic damage to the artery results from the disc if inadvertently pulled through the puncture site. That said, a pull-through is the only risk from this device and if it occurs, manual compression is simply applied, allowing a noncatastrophic failure mode.

After a dwell time of usually 10 to 15 minutes for diagnostic patients, removal of the device is accomplished by a three-step process: (1) placing a fingertip optimally above the arteriotomy site, (2) applying nearly occlusive pressure, and (3) collapsing the disc by clicking the exposed end of the Boomerang Wire (Figure 1). The wire is then removed and light manual compression is applied to the arteriotomy site for 5 to 10 minutes in diagnostic nonanticoagulated patients and for 10 to 15 minutes in previously anticoagulated interventional patients. A light dressing is then applied to the site. Because manual compression times are shorter after removing the Boomerang Wire, physical staff effort and injury potential are reduced, and patient comfort is improved. In addition, bed rest for patients is typically less than 2 hours after using the Boomerang Wire, compared with 4 to 6 hours for patients receiving only manual compression.

In the interventional patient, the Boomerang Wire is managed similarly to a sheath awaiting removal, with the Boomerang Wire being removed after the same period of time as the sheath would normally be removed. Because the distal limb continues to receive unobstructed blood flow during this period (unlike an indwelling sheath patient), optimal perfusion can be achieved. This becomes important in patients with antegrade or brachial sticks, small arteries, or in patients who require larger sheaths, especially in patients with PVD in whom blood flow is already compromised.

TABLE 1. POTENTIAL LIMITATIONS OF CURRENT VCDs

Compatible primarily with 5-6–F sheath technology
Not well proven in a >7-8–F technology
High financial costs
Noninert, reactive, permanent, and absorbable device components (prone to infection and CFA scarring)
"Leaves something behind"—sutures, metal clips, or staples, plugs, anchors, collagen, etc. (prone to infection and reaccess complications)
Endoluminal device components (prone to thrombosis)
Small vessel size (<4-5 mm); a contraindication to use
Non-CFA "high or low sticks"; a contraindication to use
PVD; a relative contraindication to use
Often requires long, complex learning curve
Impaired or delayed CFA re-entry (reaccess concerns)
May still require manual compression and bed rest after closure
Marked obesity; a relative contraindication to use
Upsizing the existing sheath size may be required
Catastrophic failure mode (infection, thrombosis, embolization, massive hemorrhage, etc.)

VCDs, vascular closure devices; CFA, common femoral artery; PVD, peripheral vascular disease.

The Boomerang Wire system harnesses the natural elastic recoil of the tunica elastica found in muscular arteries, while simultaneously excluding pressurized blood from trying to escape through the arteriotomy site, thus allowing the perivascular arterial tissues and space to return safely to their presheath states and avoid unnecessary subcutaneous hemorrhage, therefore decreasing the potential for scarring. This elastic recoil phenomenon has been coined the "Boomerang effect" (Figure 2). The Boomerang operator (usually a physician but possibly a trained staff member with appropriate training and demonstrated competence) can deploy the Boomerang Wire in less than 1 minute (usually in <30 seconds). Once the Boomerang Wire is removed, managing the small, 18-gauge arteriotomy hole is much easier on the staff and the patient than is postprocedure site management through manual compression of a much larger arteriotomy site. Keep in mind that the introducer sheath is sized by its internal diameter, but the opening that a sheath makes in the artery is nearly 1 mm larger. The average 6-F (2-mm) sheath creates nearly a 9-F (3-mm) arteriotomy.

The Boomerang 610 Data

The first-generation, 56 Boomerang Wire received FDA clearance in November 2004, but recently, the 610 Boomerang Wire has become available, allowing vascular access management of up to 10-F sheath sizes utilizing the same small 18-gauge needle size wire system. The 610 system is now utilized almost exclusively by all active, high-volume Boomerang labs.

To date, a Boomerang 610 real world registry from five major US sites has enrolled 415 patients (diagnostic, 272 patients; interventional, 143 patients). The average dwell time and average hold time for the diagnostic cases were 19.1 minutes and 8.2 minutes, respectively, and 120 minutes and 13 minutes, respectively, for the interventional cases. There was only one (0.25%) major complication (nonsurgical retroperitoneal hematoma) and two (0.49%) minor complications (both small hematomas). Fewer than 5% (4.7%) of the cases required an additional 5 to 10 minutes of hold time.

POTENTIAL ADVANTAGES

There are multiple potential advantages of the Boomerang vascular access management system (Table 2). Several clinical observations have become readily obvious, especially in treating our complicated critical limb ischemia (CLI) patients who may require nontraditional vascular access (brachial or antegrade CFA approach). We also treat our CLI patients with bivalirudin and a 12-hour to 18-hour GP IIb/IIIa infusion, much like acute coronary syndromes, and we have had to develop a vascular access management system to limit potential bleeding complications.[1] Our experience with all current VCDs, especially in PVD, is that the risks of complications far outweigh any potential benefits of VCDs, therefore, we have all but eliminated VCDs from our lab.

Prior to the Boomerang device, we historically would wait several hours for the effects of heparin to subside before sheath removal and would apply longer-duration manual compression with a C-clamp to achieve vascular access management in the CLI patient while GP IIb/IIIa infusions were continued. The Boomerang system has significantly improved vascular access management in this CLI clinical setting by eliminating the C-clamp and the longer-duration, strenuous manual compression often required to attain adequate hemostasis. The Boomerang can be comfortably left in place as long as clinically indicated until limited manual com-

ONE CENTER'S EXPERIENCE

By Ron Smalling, MD

At St. John's Regional Medical Center, we perform a high volume of complex percutaneous coronary interventions (PCIs) and percutaneous peripheral interventions (PPIs), therefore, throughput is always a high priority for maximizing staff resources. Vascular closure devices (VCDs) are used in a minority of patients. Some physicians are reluctant to use VCDs due to reports and personal experiences with procedural failures resulting in significant complications. Even when manual compression is employed, however, bleeding complications after sheath removal have been demonstrated at our institution, as have been described in the literature. Many manual compression patients experience significant hematomas, similar to complications resulting from VCD use, despite a committed and attentive staff. Recently, we began using the 610 Boomerang Wire system for vascular access management.

The Boomerang Wire system is the size of an 18-gauge needle with a temporary deployable nitinol disc on one end of a short 12-inch wire. Because a 6-F sheath is used in most diagnostic catheters, the Boomerang Wire device is easily passed through the existing sheath at the end of the procedure. Deployment of the nitinol disc, with subsequent removal of the sheath over the Boomerang Wire, is easily accomplished, usually in less than 30 seconds. The wire is then handled at the mid-dilator level and gentle, continuous pressure is exerted upward, allowing the disc to temporarily tamponade the arteriotomy. An external clip is then applied to the wire at skin level to maintain this hemostasis. We have learned that it is important to use a "no-touch technique" when removing the sheath over the wire.

The Boomerang Wire is then secured between two small sterile towels and taped to the leg. The patient is taken to the holding room (diagnostic, nonanticoagulated patients) or cardiac catheter lab recovery unit (anticoagulated patients). After approximately 10 to 15 minutes, the holding room staff removes the Boomerang Wire by collapsing the disc, removing the wire, and applying pressure for 7 to 10 minutes. The staff at St. John's has been instrumental in refining postdeployment care and has carefully coached each other in managing patients to optimize results. After approximately 2 hours of bed rest, patients are ambulated and generally can then be discharged from the outpatient catheter lab. Rebleeds have been infrequent and have not led to any major bleeding problems or significant hematomas. Boomerang Wire use has decreased the time staff spends at the bedside and has reduced wrist and arm strain from less compression time compared to the standard 25 to 30 minutes of manual compression. In addition, patients generally have 4 to 6 hours of bed rest with manual compression.

> "Many manual compression patients experience significant hematomas, similar to complications resulting from VCD use, despite a committed and attentive staff."

In initial results for 100 patients, 63% were taking aspirin and 21% received heparin. The high activated clotting time or bivalirudin patients, PCI or PPI patients (23% had an intervention) were also effectively managed. In 83 of the cases, 6-F sheaths were used; additionally, 7- and 8-F sheaths were used for 17 of the interventional and endovascular cases. The procedural success rate was 100%. Our initial device success was 94%, with only six device failures, five of which occurred in the first 55 cases—one case was a pull-through when too much tension was applied; one device was dislodged, and one device was pulled out with the sheath when the sheath was removed, probably due to ineffective disc deployment past the end of the sheath. Three devices did not achieve complete hemostasis, and the six failures were simply converted to manual compression demonstrating the Boomerang noncatastrophic failure mode and high safety profile.

Our initial 100 patients had no major complications. There were four small hematomas (<4 cm) and eight rebleeds requiring additional manual compression time (but less than 20 minutes). The physicians and staff continued to refine deployment and postprocedure management of these patients, and in the subsequent cohort, many of the minor problems were rectified. Our results are impressive when one considers that our data start with our first Boomerang Wire patient and that five physicians have placed the devices reflected in our results. Keeping patients' best interests in mind, the 610 Boomerang Wire system achieves most of the desirable features of the ideal vascular closure system. It is safe and effective, easy to use, and leaves nothing behind to precipitate complications while facilitating preservation of the patients' vascular access.

TABLE 2. POTENTIAL ADVANTAGES OF THE BOOMERANG SYSTEM

Rapid, simple deployment (often <20 seconds)
Short learning curve (applicable to trained tech deployment)
Utilizes the existing sheath (no arteriotomy "upsizing")
High safety profile, "Noncatastrophic" failure mode…just convert to manual compression!
Painless to deploy (patient and operator)
A redeployment (reaccess) sheath mechanism exists, if needed…
"Leaves nothing behind" therefore… (no sutures, metal, anchors, etc.)
Less infection, thrombosis, and overall complications
Reduces a large arteriotomy to 18-gauge needle size "hole" ("Boomerang effect")
Allows excellent distal vessel flow after deployment
Applicable to antegrade and brachial artery "sticks"
Applicable to non-CFA "high or low" sticks
Less patient and staff discomfort
Less staff and hospital resource utilization
Decreases and facilitates manual compression–our "gold standard"
Allows earlier ambulation and discharge
Potentially less late complications (less perivascular scarring)
Potentially allows safer and earlier reaccess
Better healing and preservation of the CFA
Small vessel size and PVD not a contraindication to use
No luminal narrowing
Applicable in 4-10–F arteriotomies (most VCDs not in to >7-8 F)
Less expensive than most VCDs
More optimal ergonomics–less work-related injury to physicians and staff
Optimal long-term management of vascular access for future procedures

VCDs, vascular closure devices; CFA, common femoral artery; PVD, peripheral vascular disease.

pression is applied. This strategy has allowed us to decrease complications, avoid VCD deployment, and improve our patient and staff satisfaction. We believe that leaving a Boomerang device to dwell in the artery is always better for the patient than having any sheath dwelling in the vessel.

CONCLUSION

The 610 Boomerang vascular access management system is a novel method of achieving vascular access hemostasis that is not a true VCD and greatly facilitates and minimizes manual compression. The potential to decrease vascular access management complications by greatly facilitating manual compression without leaving anything behind and decreasing work-related musculoskeletal injuries to our health care staff are but several advantages of this system. The Boomerang vascular access management system appears ideal for the long-term management of the cardiovascular patient by helping preserve the integrity of vascular access sites for successful procedures today and in the future. ■

For additional reading, see the article "Manual Compression May Not Be Benign" in the April 2003 issue of Endovascular Today.

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