

Novel Access Technology Providing Implant-Free Femoral Artery Closure

An introduction to applying this Axera technology in your practice.

BY JAAFER GOLZAR, MD, FACC, FSCAI

An estimated 2.2 million cardiovascular catheterization procedures are performed annually in the United States alone.¹ The overwhelming majority (98%) of these procedures are accessed through the femoral artery.² While femoral access site management techniques and arterial closure devices continue to evolve, the research into the complications involved with many of these techniques begins to highlight the need to take into full consideration all periprocedural aspects of these access modalities. Sealing the arterial puncture site immediately after percutaneous coronary intervention is frequently accomplished at the expense of preservation of groin tissue and the integrity of the natural arterial tract. Among the shortcomings of so many closure platforms are complication rates—inherent in the processes of anchoring, plugging, clipping, and suturing—which approach 6% in some studies.³ As we observe an increasing range of cardiovascular interventions and with more patients returning to the catheterization lab multiple times for diagnostic and interventional procedures, we are motivated to adopt femoral access techniques that ensure that future arterial access is not compromised.

In this article, we report on the Axera access device (Arstasis, Redwood City, CA), which was initially cleared by the FDA in February 2011 for diagnostic femoral artery catheterization. We have used this current generation of the Axera device successfully in more than 385 procedures, including many that were crossed over to percutaneous coronary intervention.

THE CONCEPT

In the frequently used modified Seldinger access method, the sheath is placed through an arteriotomy made at a relatively steep angle (approximately 45°). Axial tension in the artery wall makes such an arteriotomy difficult



Jaaffer Golzar, MD, performing the Axera self-sealing access procedure.

to close, relying on clot formation for hemostasis. In contrast, the Axera access device creates an optimally predetermined shallow-angle arteriotomy, which allows the internal hemodynamic pressure to aid in closing the access channel (Figure 1).

Creation of this shallow-angle arteriotomy begins with the modified Seldinger technique. After the initial pilot stick with a 19-gauge needle, the Axera device is introduced into the vessel lumen. Employing an anchoring mechanism consisting of a heel apposed against the artery wall, the device is precisely placed relative to the vessel wall, and the vessel tissue is stabilized to allow for the

introduction of an integrated micropuncture needle. This needle cannulates the optimally engineered shallow-angle access tract in preparation for the guidewire and arterial sheath. This pathway is referred to by the manufacturer as a “self-sealing arteriotomy,” which is used as an adjunct to minimal manual compression.

The geometry of the Axera device ensures reliable deployment of the shallow angle needle for the creation of the self-sealing arteriotomy, thus consistently delivering the clinical benefit of increased tissue-upon-tissue overlap (Figure 2). In this way, the Axera device takes advantage of the coagulation cascade, facilitating more rapid clot formation and hemostasis as an adjunct to manual compression.

THE AXERA DEVICE

The Axera access device comes supplied with a latch-wire that is similar in function to a docking guidewire. A guidewire lumen extends through the handle and shaft. Accessories include a 0.018-inch nitinol guidewire (for delivery of an introducer sheath) and a 19-gauge access needle. A dilator adapter is also available to provide compatibility of

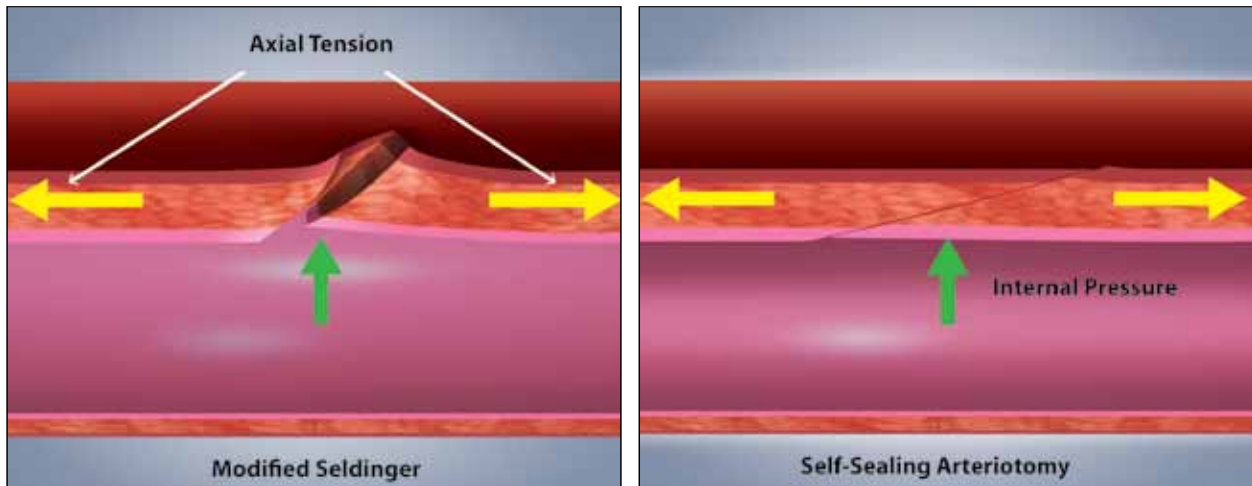


Figure 1. Axial tension forces a standard arteriotomy (left) to pull open. The image on the right illustrates tissue-upon-tissue apposition of the shallow angle arteriotomy produced by the Axera access device.



Figure 2. Blue stain used to illustrate a longer, shallow-angle arteriotomy versus a shorter, standard arteriotomy in a porcine aorta.

the 0.018-inch guidewire with standard 0.035- or 0.038-inch guidewire-compatible sheaths. Figures 3 through 5 illustrate the device and its primary components.

TECHNIQUE

The 19-gauge access needle is used to achieve the initial (pilot) access. Puncture of the common femoral artery is ideally performed at the level of the mid-common femoral artery and at least 1 to 2 cm below the inguinal ligament. Both ultrasound- and fluoroscopy-guided access methods have been studied and found useful for achieving access at the desired location.⁴⁻⁷ Once pilot access is confirmed, the Axera 0.035-inch latchwire is then threaded through the needle. A length of wire sufficient for handling (approximately 2 cm) should remain exposed above the access needle. The access needle is then removed. The device is held firmly at its distal tip as the latchwire is inserted into the distal end of the device. The device is then advanced into the artery until brisk blood return (first mark) is observed flowing from the marker port, confirming that the distal shaft of the device has entered the arterial lumen.

The device heel is then deployed by pulling back on the heel actuator until it stops. A neutral position is

assumed where the forces on the tissue are minimized, and the device is gently drawn back until blood mark ceases or is significantly reduced; this occurs as the device heel achieves purchase against the anterior vessel wall. If the blood mark does not cease, slightly raising or lowering the device angle relative to the tissue can provide remediation. A small amount of force, just beyond blood mark cessation, will satisfactorily appose the wall and anchor, tenting the artery into position (Figure 3).

The device is stabilized with the left hand to avoid jarring the artery. The device handle is held in this neutral position, maintaining gentle upward tension. The integrated, 21.5-gauge micropuncture needle is deployed through a fenestration in the distal shaft of the device by pressing the plunger. This action creates the shallow-angle, self-sealing arteriotomy that is used as an effective adjunct to manual compression (Figure 4). The second mark from the marker port again confirms the intraluminal position of the integrated needle. The 0.018-inch guidewire is inserted and advanced through both the plunger port and the integrated needle into the arterial lumen. The guidewire is advanced until only 3 to 4 inches of the wire remain outside the plunger. The guidewire should be advanced far enough to maintain access while removing the Axera device (Figure 5). The integrated micropuncture needle is withdrawn, and the heel is released by retracting the plunger. The Axera device is then removed, taking care to keep the guidewire in place.

The Arstasis dilator adapter is inserted into the distal end of the introducer sheath and dilator assembly. The adapter allows for the placement of 0.035- and 0.038-inch sheath sets over the Arstasis 0.018-inch nitinol guidewire. The sheath assembly can then be inserted over the guidewire into the vessel. The adapter, dilator, and guidewire are then carefully removed, leaving only the

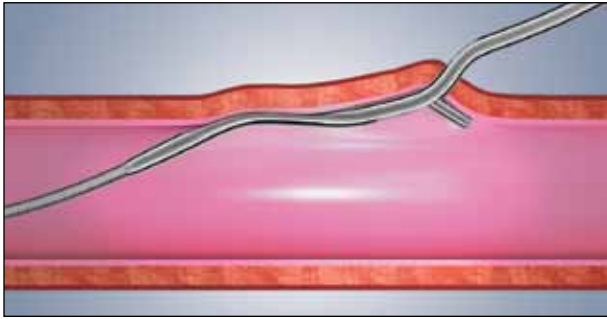


Figure 3. Retraction of the device to properly position the arterial wall for needle deployment.

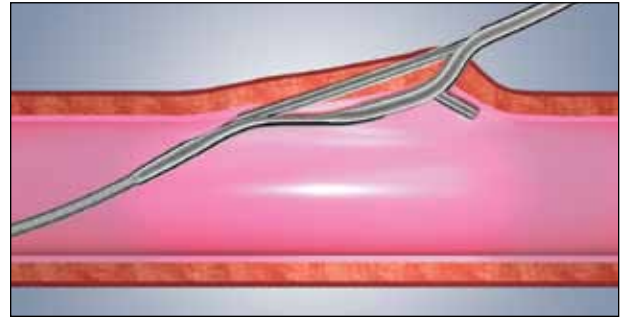


Figure 4. Deployment of micropuncture needle to create the self-sealing arteriotomy.

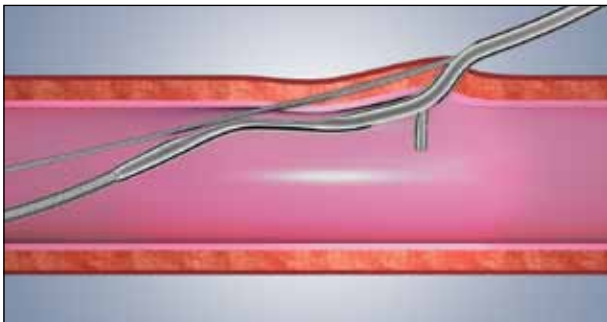


Figure 5. Advancement of the guidewire through new access channel.

introducer sheath in the vessel. At the conclusion of the catheterization procedure, if no anticoagulation has been used, the introducer sheath is slowly withdrawn. Hospital protocol for monitoring activated clotting times is followed in which heparin, bivalirudin, or glycoprotein IIb/IIIa inhibitors have been administered.

The recovery team pulling the sheath is trained to palpate the vessel, applying moderate compression two finger breadths above the puncture site, placing the gloved hand directly in contact with skin, while continually observing the puncture site. Intra-arterial pressure works in conjunction with manual compression to seal the arteriotomy. Manual compression is applied for 3 to 6 minutes in most diagnostic cases. In cases that have proceeded to intervention, a hold of 7 to 10 minutes is typical. The time to hemostasis will inevitably be longer than without use of the Axera device. The self-sealing arteriotomy used adjunctively with manual compression lends ample tissue-upon-tissue contact where clot formation occurs—in effect up to 10 times more surface area than in the case of a conventional arteriotomy.

Patients who undergo diagnostic cardiac catheterization at our hospital are able to sit up at a 45° angle within 30 minutes and ambulate at 1 hour (peripheral vascular catheterization patients ambulate at 2 hours). Hospital discharge for both groups of patients typically occurs within 1 hour postambulation at our hospital.

DISCUSSION

Use of the Axera access device can be significantly facilitated through attention to detail at several key steps during the deployment sequence. First, as with any other type of femoral arterial access, it is important to locate the femoral head before deployment to minimize complications. This is best achieved angiographically by placing the hemostats over the medial, lower one-third of the femoral head. Second, aligning the device within the artery is important. Misalignment can reduce the chance of successfully accessing the lumen. The device is self-aligning due to the curvature of its design; easing up on the hold of the device allows it to align itself within the vessel. Should misalignment cause the needle to fail to enter the artery, the plunger can be retracted (maintaining the heel in position) and redeployed, taking extra care to allow the device to align itself within the artery.

Furthermore, we have found it helpful to administer brief fluoroscopic imaging throughout the procedure to ensure that the device is not only in situ but also correctly aligned within the vessel. It is not uncommon to proceed under the assumption that the device is placed in the vessel, only to find via fluoroscopy, that this is not the case. Especially in procedures in which the first or second mark has not been achieved, brief fluoroscopic imaging can provide insight into the possible reasons.

Additionally, in cases in which the Arstasis 0.018-inch guidewire will not advance into the vessel, it can be useful to ease up somewhat on the negative pressure (tenting). If the second mark has been achieved, but the 0.018-inch guidewire still does not advance, it could be due to the device needle touching the roof of the artery. When calcium is present, the guidewire can easily come up against plaque; easing the tenting will take the device off the superior wall of the artery such that the wire can then be advanced intraluminally.

As with any new medical device technology, there is considerable scrutiny of the device and procedural steps to minimize any technical complications. As previously described, the Axera device uses a secondary micropuncture needle to create a very shallow angle for the procedural

sheath to be inserted. The question then becomes, what happens to the initial puncture site used to insert the Axera device? The outside diameter of the Axera device is 0.06 inches, which is smaller than the 0.065-inch outer diameter of a standard 3-F sheath. During insertion of the procedural sheath, the primary puncture, which shares the same entry point as the secondary micropuncture needle at the adventitia, is mechanically compressed by the sheath for the duration of the procedure. Our experience with the device has not resulted in any bleeding or oozing in the area of the access site.

Finally, the self-sealing arteriotomy can be described as a next-generation modified Seldinger technique. The ultra-shallow angle into the arterial wall does not present, what some may question as, a dissection plane. The shape of the device and trajectory of the secondary micropuncture needle does not create a linear plane between the intima and media. The micropuncture needle traverses through the adventitia, media, and intima, providing a precise surgical path into the artery. Upon completion of the case, rapid hemostasis and ambulation are achieved without the necessity of very long hold times or any foreign material implant.

LIMITATIONS

One limitation of the Axera device is in cases of chronic total occlusion of the iliac artery because the attached latchwire is often not stiff enough to traverse such an obstruction. Another limitation presents itself in excessively tortuous anatomy, in which the J-tipped latchwire is not as easily maneuverable as some other wires.

ADVANTAGES FOR THE PHYSICIAN AND PATIENT

Furthermore, because the device leaves no footprint, reaccess has not been compromised in any way should it become necessary acutely or in the future. Many postoperative complications inherent in the introduction of foreign bodies into the artery and/or arterial tract are avoided, resulting in fewer surgeries to treat infection, thromboembolic events, or to remove migrated implants. Although many other closure implants are contraindicated when calcium is present, the Axera device is not, and we have used the device successfully in calcified and diseased vessels. It is also possible to use the Axera device for access near the bifurcation of the profunda and the superficial femoral artery.

ADVANTAGES FOR THE HOSPITAL

Because a hospital's ability to optimize capacity is largely determined by how efficiently their processes and operations are managed, use of the Axera device can improve throughput in several ways.

First, savings in staff time are realized immediately because minimized manual compression times (while preserving the safety profile of manual compression) and early ambulation and discharge free personnel for other duties.

Second, improved patient comfort translates into a positive patient satisfaction profile for the institution. Third, implant-free procedures translate into fewer complications requiring treatment and less complicated reaccess in the future when patients return for follow-up procedures, which again enhances the safety profile of the facility.⁸

CONCLUSION

The encouraging results of the first United States registry of the Arstasis access system have been reported by Wortham et al.⁹ The advantages of the Axera device's minimally disruptive self-sealing vascular access adjunct to manual compression are most readily apparent in its preservation of tissue integrity at the femoral access site. No harm is done to the arterial tract, as is the case with most other devices when foreign-body implants are left behind in the arterial tree. The strategically engineered, ultra-low-angle, self-sealing arteriotomy requires only minimal compression to provide rapid hemostasis, resulting in marked increases in patient comfort levels as a consequence of decreased bed rest and improved ambulation and discharge timelines.

It remains our conviction that the long-term implications of each vascular access and closure must be borne in mind as we witness increasing rates of reintervention brought about by a continually broadening range of emerging therapies. In our experience, the innovative advantages of this minimally disruptive approach are significant, with substantial decreases in complication rates and maintenance of the safety profile of manual compression alone, but without the staff burden of traditional manual compression. With the added benefit of the Axera arteriotomy's applicability to calcified and diseased vessels and the ability to access at bifurcations, this enabling procedure constitutes a promising addition to the resources available to the physician. ■

Jaafer Golzar, MD, FACC, FSCAI, is with MidAmerica

Cardiovascular Consultants in Chicago, Illinois. He has dis-

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Golzar may be reached at jaafer.golzar@advocatehealth.com.

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