Current Status of Percutaneous Endografting

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Abstract

Totally percutaneous endovascular abdominal aortic aneurysm repair (PEVAR) using suture-mediated closure devices (SMCDs) has several well-established advantages over standard open femoral exposure as a direct consequence of being less invasive and having shorter times to hemostasis and procedure completion. The first multicenter randomized controlled trial designed to assess the safety and efficacy of PEVAR and to compare percutaneous access with standard open femoral exposure was recently published (the PEVAR trial). The PEVAR trial demonstrated that percutaneous endografting is safe, effective, and noninferior to standard open femoral exposure among trained operators. The study reaffirmed the results of several recent single center and nonrandomized studies, demonstrating that percutaneous access facilitated shorter procedures, shorter times to secure hemostasis, and improved quality of life for patients. As PEVAR has gained popularity among patients and physicians, refinements to the technique and patient selection process have been made. There has been growing interest in treating patients with anatomical characteristics previously thought to be unsuitable for PEVAR, such as common femoral artery (CFA) calcifications, scarred groins, small CFA diameter, and high patient body mass index (BMI). However, observance of strict procedural technique and consideration for patient selection criteria remain paramount in achieving acceptable technical success rates with PEVAR.

Keywords

- preclose
- PEVAR
- ProGlide
- interventional radiology

Objectives: Upon completion of this article, the reader will be able to discuss the percutaneous endografting technique as well as the importance of and factors affecting patient selection and outcomes.

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The first multicenter randomized controlled trial designed to assess the safety and efficacy of percutaneous endovascular aneurysm repair (PEVAR) and to compare percutaneous access with standard open femoral exposure was recently published (the PEVAR trial).¹ The PEVAR trial demonstrated that percutaneous endografting is safe, effective, and noninferior to standard open femoral exposure among trained operators.¹ Since 1999 when the technique was originally described utilizing Prostar XL² (Abbott Vascular, Inc.,

Redwood City, CA), totally PEVAR with an adjunctive suture-mediated closure device (SMCD)-specific “preclose” technique has steadily gained favor with vascular surgeons and vascular interventionalists with the greatest benefits afforded to patients. PEVAR utilizing the Perclose ProGlide (Abbott Vascular, Inc.) SMCD was introduced in 2007.³ Originally designed to achieve hemostasis following the use of much smaller sheaths, the “preclose” technique utilizing SMCDs following endovascular aortic aneurysm repair (EVAR) had up until very recently been an “off-label” application of both devices. Encompassing 20 U.S. academic and community institutions and 151 patients randomized in a 2:1 fashion to PEVAR versus open femoral exposure, the PEVAR trial was designed as a noninferiority study comparing percutaneous access with standard open femoral exposure. The study helped clarify the risks and benefits of PEVAR facilitated with an adjunctive preclose technique.¹ Prior to the PEVAR trial, several single-center experiences and nonrandomized trials had been published, but only one single-center randomized trial had been performed.⁴ These studies suggested favorable outcomes with PEVAR as compared with standard open femoral exposure in appropriately selected patients. Specifically, the ability to achieve common femoral artery (CFA) hemostasis following aneurysm exclusion in a more timely manner than possible with standard open femoral exposure was suspected, which directly contributed to shorter operative times. In addition, patients who underwent percutaneous access had shorter hospital stays, reduced blood loss and procedure-related complications, and overall improved patient satisfaction compared with those with open femoral access.

In the PEVAR trial, procedural technical success rate was 94% for the ProGlide-based closures, 88% for the ProStar, and 98% for open femoral exposures.¹ Failure rates in the access closure substudy analyses demonstrated noninferiority of ProGlide-based closures (6%; $p = 0.005$), but not of the ProStar system (12%; $p = 0.100$), versus open femoral exposures (10%).¹ Both percutaneous closure systems yielded significantly shorter times to hemostasis and procedure completion and favorable trends in blood loss, groin pain, and overall quality of life when compared with open exposures.¹ The PEVAR trial demonstrated that “...among trained operators, percutaneous endografting with an adjunctive preclose technique using the ProGlide closure device is safe and effective, with minimal access-related complications, and it is noninferior to standard open femoral exposure with respect to treatment success at both 1 and 6 months.¹” The PEVAR trial outcomes with the 6F Perclose ProGlide SMCD used in conjunction with the Endologix AFX 21F profile (outer diameter) sheath-based endograft system resulted in FDA approval for the percutaneous delivery of suture for closing the CFA access site of patients who have undergone diagnostic or interventional catheterization procedures (PEVAR included) using 5F to 21F sheaths.¹ Its application in totally percutaneous EVAR is currently FDA approved for use with the same Endologix AFX 21F sheath-based system used in the trial, though its formal broader approval for use in closure of any device with similar sheath sizes can most likely be anticipated.

The Prostar XL SMCD was introduced in 1998 (with its PEVAR application following in 1999²), and had long been the sole device with approval for use in closure of large-size femoral artery puncture sites (8.5F–10F sheaths). Its application for larger access sites, as those necessary for EVAR, TEVAR, and TAVI, continues to be “off-label.” This single device places two sutures in the artery in a crossing pattern and was designed for the percutaneous delivery of sutures for closing the CFA access site following use of up to 10F sheaths. In its “preclose” application, the sutures are tagged and placed aside as the access site is upsized for device deployment; the sutures are then tied down at the end of the case.⁵

The Perclose ProGlide SMCD was introduced in 2004⁵ (with its PEVAR application following in 2007³), and was originally formally approved to facilitate closure of smaller size femoral artery puncture sites (5F–8F sheaths). Approval for use of the ProGlide device has been expanded to larger (up to 21F) sheaths provided; at least two devices and the “preclose” technique are utilized for sheath sizes greater than 8F. Two ProGlide devices are used to create the same crossing suture pattern achieved with a single Prostar XL device, and uses a single monofilament polypropylene suture instead of the two braided polyester sutures used for the Prostar XL device.⁵ Because of its relative popularity and ease of use, the Perclose ProGlide SMCD is the focus of the technical discussion at the conclusion of this review.

A systematic review of PEVAR was performed in 2010 to evaluate primary outcomes including success rate and locoregional complications, as well as secondary outcomes such as operative time, hospital stay, time to ambulation, blood loss, and cost for the time period between January 1991 and July 2009.⁶ Of the twenty-two studies reviewed, including one randomized trial, ten prospective nonrandomized studies, and eleven retrospective studies, the overall technical success rate was found to be 92%. Though the majority of the studies during that period of time were performed with the ProStar XL device, the success rate for use of ProGlide was better than the Prostar group (93.7 vs. 90%).⁶ The PEVAR group, as a whole, had fewer access-related complications (4.4%) and reduced operative times.⁶ The most common exclusion criteria were heavy femoral artery calcifications, scarred groins, and femoral artery aneurysms.⁶ Several nonrandomized studies have found that morbid obesity, femoral artery calcification, groin scars from prior interventions, and large sheath size are most commonly associated with percutaneous device failure.⁷ Thoughtful patient selection criteria are of utmost importance in maintaining the noninferiority of PEVAR as compared with standard open femoral exposure. The results of the PEVAR trial support noninferiority of totally percutaneous EVAR (with the Endologix 21F sheath-based system and likely generalizable to other comparably sized devices), provided that the patient selection criteria used in the study are followed. In addition to several demographic requirements and adherence to Endologix system anatomic eligibility requirements, the patient selection criteria used in the trial included parameters for the aneurysm being treated, several CFA characteristics, and restrictions with regard to prior groin access, groin infection, and obesity.¹ Patient

selection criteria will differ from institution to institution with requisite scrupulous attention to details of each patients anatomy and procedural history.

Technical Considerations When Attempting Percutaneous Endografting

Operator Experience

Physician inexperience (defined in several studies as <30 cases) has been predictably shown to be significantly correlated with early conversion to femoral cutdown.⁷ One of the predominant conclusions of the PEVAR trial was that “training, experience, and careful application of the preclose technique are of paramount importance in ensuring successful, sustainable outcomes.”¹ Investigators at each of the 20 U.S. institutions involved in the trial were required to have training and experience with both standard femoral exposure and SMCD preclose percutaneous techniques, including having completed an Endologix EVAR training program and certified on more than 20 PEVAR preclose cases prior to participation in the trial.¹ A recent meta-analysis of 17 published studies for a total of 2,447 femoral access sites demonstrated an overall technical success rate of PEVAR to be 93%, with success rates increasing over time.⁸ The technical success rate was lower in earlier studies, probably due to a relative lack of operator experience.⁸ **Table 1** lists the reported technical success rates in percutaneous endografting that have been published in the literature since the last review of this topic in *Seminars of Interventional Radiology*.⁵ Mechanical failure of percutaneous devices has also commonly been cited as a predictor for conversion. Mechanical failure is generally identified as an inability to place SMCD (i.e., unsuccessful needle capture) or with suture closure (i.e., suture breakage or premature locking of knot before its position at the vessel access). In our experience, mechanical failure can be mitigated with meticulous technique and careful initial vessel access. Operator experience clearly represents one of the most important determinants for technical success. Operator experience with this device can be enhanced with its use in closure of traditional access (6–8F sheath) during other arterial interventions.

Body Mass Index

Obesity (body mass index [BMI] > 30) is often regarded as a significant predictor of SMCD failure. In the PEVAR trial, morbidly obese patients (BMI > 40) were excluded.¹ There has been evidence to support and refute this notion. Obesity, though not an independent predictor for SMCD failure in and of itself, has been attributed to technical failure in several studies; however, this relationship has also often not been statistically significant.⁶ Several recent retrospective study populations^{9–12} and a recent prospective study⁷ did not identify obesity as a significant predictor of failure. At least one single-center study suggests that PEVAR in the obese population is safe.¹² One retrospective study found that only one obese patient versus 11 nonobese patients experienced percutaneous failure¹²; another found the association between failed percutaneous suture-mediated closure (PSMC) and

obesity to be unclear, with a retrospective review of 101 PEVAR patients demonstrating no significant correlation.¹³ Ultimately, CFA depth may be a better way of predicting technical difficulty in obese patients.¹⁴ A resounding theme in recent literature is that obesity necessitates the use of ultrasound guidance as palpation of the artery is difficult or impossible, and may otherwise result in less than ideal puncture sites (such as the vessel sidewall), resulting in ineffective placement of the sutures of the closure device.

Vessel Diameter

With increased operator experience and improved device deployment techniques, the trend over the past several years has been for patients with smaller CFAs to be selected for the percutaneous technique, despite the fact that there has been evidence regarding the value of small vessel size (defined in many studies as < 5 mm) as a predictor for PSMC failure. One retrospective study reported that the minimum CFA diameter of patients undergoing percutaneous endografting decreased from an average of 7.3 mm in 2006 to 6.2 mm in 2010, while also reporting that smaller vessel diameter was predictive of technical failure.¹² Similarly, in a group of 168 patients undergoing PEVAR, a common femoral vessel diameter < 5 mm was found to be predictive of percutaneous failure (16.7% of vessels < 5 mm failed vs. 2.4% of vessels > 5 mm).¹² Also, women, with smaller arteries as a whole, experience a higher rate of percutaneous failure when compared with men.^{10,12} However, appropriately selected women fare well with PEVAR.^{1,15} It is worth noting that in the PEVAR trial, only 9.9% of the cohort was women.¹ Small CFAs may not allow room for proper function of the device, as the footplate may not have adequate clearance for proper function without disrupting plaque or even suturing the back wall of the artery to the anterior wall.¹²

Sheath Size

Decreases in sheath size and the ability to pass these devices through narrowed, diseased, and tortuous anatomy have greatly expanded the role for many of the stent grafts used in endovascular aortic repair. Many retrospective studies have demonstrated that there is no significant difference in patient populations treated percutaneously with regard to BMI or sheath sizes used.^{10,14} While some early studies found success rates to be higher with smaller French size sheaths, more recent studies have found that large sheath size (defined as > 20F) had no significant value in predicting PSMC failure.⁶ Similarly, a separate study found that there was no significant difference in success rates for larger sheath sizes (16–18F) as compared with smaller sheath sizes (<16F).⁹ The systematic review of PEVAR patients from January 1991 to July 2009 found decreased success rates with increasing sheath size.⁶ A prospective study in 2009 found that larger sheath sizes correlated with higher rates of failure, though to a lesser degree than severe CFA calcifications and operator inexperience.⁷ Interestingly, one study reported that smaller sheath sizes were associated with more failures (7.4%) than large sheath sizes (1.9%).¹² No conclusions were drawn from this finding, however, with the study concluding only that

Table 1 Review of recent literature reporting rates of technical success in percutaneous endografting

Author (year)	Study period	Suture-mediated closure device type	Sheath sizes used	Common femoral arteries accessed	Technical success rate of percutaneous arterial closure	Study description
Arslan et al (2009) ⁵	1999–2008	Prostar XL and ProGlide	12–25F	926	84.5% (range: 46–100%)	Summary of 9 retrospective studies from 1999 to 2008
Eisenack et al (2009) ⁷	January 2004–December 2005	Prostar XL	14–24F	903	96%	Prospective study
Smith et al (2009) ¹⁴	March 2005–April 2007	Prostar XL and ProGlide	18F (median)	38	100%	Retrospective study
Malkawi et al (2010) ⁶	January 1991–July 2009	Predominantly Prostar XL; also ProGlide	12–24F	1,751	92%	Systematic review of PEVAR prospective randomized and controlled nonrandomized trials and case series
Georgiadis et al (2011) ⁸	January 1999–August 2010	Predominantly Prostar XL and ProGlide (also Perclose AT and Closer S)	12–26F	2,447	93%	Meta-analysis of randomized trials, retrospective and prospective observational studies
Etezadi et al (2011) ⁹	March 2003–January 2010	Prostar XL and ProGlide	12–18F	100	85%	Retrospective study
Sarmiento et al (2012) ¹³	January 2005–July 2009	ProGlide	12–24F	202	90%	Retrospective study
Bensley et al (2012) ¹²	January 2005–December 2010	ProGlide	12–24F	296	96%	Retrospective study
Mousa et al (2013) ¹⁰	January 2009–June 2011	ProGlide	12–24F	267	88%	Retrospective study
Bechara et al (2013) ¹¹	March 2009–August 2011	Prostar XL or ProGlide	12–24F	198	82%	Retrospective study
Nelson et al (2014) ¹	July 2010–February 2012	ProGlide and Prostar XL	21 F	101	94% ProGlide 88% Prostar XL	Prospective, randomized trial

Abbreviations: OD, outer diameter.

“even small sheaths can cause serious complications when placed into diseased arteries and care needs to be taken when performing percutaneous access.”¹² Not in question is the necessity for use of more than one ProGlide closure device when utilizing larger delivery systems.

Ultrasound Guidance

The benefit of using ultrasound guidance during access of the CFA is widely accepted, and its use is now virtually mandated when performing PSMC, with one author stating “there is no doubt that the main adjunct and gatekeeper for percutaneous access is utilizing ultrasound guided needle puncture.”¹⁰ The idea that perfect access yields optimal outcomes is supported by lower rates of conversion to surgical cutdown and complications, with up to a 90% reduction in the risk of conversion.¹³ Gaining access to the CFA at the 12-o'clock position, approximately 1 cm proximal to the CFA bifurcation, is now regarded as a requisite for success. High puncture is associated with an increased risk of severe life-threatening hemorrhage on ambulation due to incorporation of the inguinal ligament into the suture. Low punctures can lead to ischemia from vessel damage and occlusion. One study sought to determine the effect of ultrasound-guided access on conversion to open repair by femoral cutdown and found that it influenced successful PEVAR, with only 1 of 49 (2%) patients who underwent the procedure with ultrasound-guided access necessitating conversion to open cutdown compared with 9 of 52 (17.3%) patients performed without ultrasound-guided access.¹³

Vessel Calcifications

Severe calcifications of the CFA and iliac vasculature have been attributed to significant complications with the percutaneous approach.¹⁰ There is some conflicting evidence in the literature regarding the effect of CFA calcification on PSMC failure, largely due to the lack of uniformity in defining access vessel calcifications. Several studies^{9,11,14} surmised that calcifications were not a reliable predictor of PSMC failure, though one of these studies describes a single significant complication requiring intervention due to distal embolization following PSMC attempt in a highly calcified vessel.⁹ Indeed, some of the credit for increased rates of PEVAR success must be attributed to the fact that, with increased operator experience and more refined patient selection, attempts at a percutaneous approach for severely calcified vessels have decreased over time. In a study that attempted a standardized approach to assessing access vessel calcifications, it was the location of the calcification that had the greatest impact on success, concluding that “severe vessel calcification, as defined by more than half of the circumference in the target access vessel on computed tomographic (CT) scan, was found to be the most predictive factor of conversion” and that the “extent of the arc of the calcium appears to be more important than the calcium location.”¹⁰ A prospective study also found that severe calcification of the CFA was significantly correlated with early conversion to femoral cutdown.⁷ As an adjunct to the utility of ultrasound for all PEVAR access, many authors have noted that ultrasound

allows for avoidance of anterior calcium deposits, possibly confounding the effect of access vessel calcifications on success in those studies. In the PEVAR trial, ultrasound guidance for CFA puncture was strongly recommended but not protocol mandated.¹

There are additional considerations with regard to patient selection. Several factors that seem not to be associated with PSMC failure include hypertension, age (>66), current smoking, past smoking, diabetes, and BMI.¹³

Operative Time, Length of Stay, and Procedural Complications

As discussed earlier, patient satisfaction and decreased periprocedural complications are some important advantages to a percutaneous approach, as well as shorter overall procedure time, decreased hospital stay, and potentially decreased cost.

Regarding procedural times, length of hospital stay, and time to ambulation, several recent studies have shown that these parameters are slightly more favorable in the PEVAR population, though the differences are not drastic. In the PEVAR trial, there were significantly reduced times to procedural completion as well as a trend (though not significant) favoring PEVAR with respect to time to hospital discharge.¹ Cost savings due to decreased average length of stay is likely offset and balanced by an increased cost of the closure devices. Several studies have attempted to evaluate this, however, with different accounts of operative time, length of hospital stay, and cost of closure devices. Prostar XL may truly be cheaper due to the necessity for only one device even for larger sheath sizes as compared with the two devices required for the preclose technique with the ProGlide device. Sound conclusions pertaining to cost savings currently are difficult to make.

As stated previously, many of the periprocedural complications associated with cutdown of the femoral artery are also seen with the percutaneous technique, though to a lesser degree. PEVAR predictably results in formation of less scar tissue at the access site, and thus may be regarded as the approach of choice when subsequent common femoral access or procedures are anticipated.⁷

How We Do It: The Step-By-Step MCW Version of “Preclose” Technique

For a list of materials, please see ►Fig. 1.

1. Obtain Access into the Common Femoral Artery:

After sterile preparation of the patient has been performed, a line should be drawn on the patient's skin between the anterior superior iliac spine and the pubic tubercle to mark the position of the inguinal ligament. The inferior margin of the femoral head is marked under fluoroscopy; this is correlated by defining the CFA bifurcation with ultrasound. A micropuncture system (21-gauge access needle, 0.018-in. wire, 4F–5F microsheath) is highly recommended in case the puncture site is too high or too low. The CFA is accessed under ultrasound guidance, puncturing the artery at a 45-degree angle precisely at the 12-o'clock position and proximal to the CFA bifurcation but below the inguinal

Fig. 1 Materials necessary for percutaneous suture mediated closure: 6F sheath; 8F sheath. Micropuncture wire and transitional dilator. Two ProGlide devices. Two suture tags.

ligament (► **Fig. 2a**). Care should be taken to avoid areas of anterior wall calcification or plaque, as this access technique is one of the main predictors of success.⁵ The micropuncture wire is advanced and the needle exchanged for a micropuncture sheath. At this point, confirmatory angiography is recommended through the micropuncture sheath to verify that access is not too low or too high. Low punctures near or at the femoral bifurcation (within 1 cm) can lead to occlusive problems if the footplate of the SMCD catches the profunda femoris artery; high punctures can lead to bleeding complications if the sutures are deployed through the inguinal

ligament, which can disrupt the closure once the patient becomes mobile. If access is deemed unsuitable based on the aforementioned criteria, then the access is removed, manual pressure applied until hemostasis, and a new access is obtained. If access is deemed suitable, then the micropuncture wire and inner dilator are removed and an 0.035-in. guidewire is advanced to the T12–L1 level of the aorta.

2. Dilate the Subcutaneous Tract:

Having confirmed acceptable access under fluoroscopy, the skin and subcutaneous tract is prepared for eventual delivery of a large profile device. A vertical skin incision at the

Fig. 2 (a) Access the common femoral artery with a micropuncture needle under ultrasound guidance at the 12-o'clock position of the vessel. (b) Dissect the subcutaneous tissues down to the anterior wall of the common femoral artery using blunt technique, shown here using a finger. (c) Predilate the tract and arteriotomy with a 6F sheath over a 0.035-in. guidewire.

puncture site is made and is extended to approximately 1.5 cm (enough to insert the tip of the little finger). The tract is then gently dilated with a hemostat or finger down to the depth of the artery (**►Fig. 2b**). Care is taken to eliminate any skin bridges that may be present. These steps will prevent the subcutaneous tissues from impeding the slip knot of the SMCD from advancing to the wall of the CFA at the time of deployment.⁹

3. Dilate the Arteriotomy with Vascular Access Sheath:

The arteriotomy is predilated with a 6 or 7F vascular access sheath over a 0.035-in. guidewire (**►Fig. 2c**). This will help facilitate passage of the Perclose ProGlide device, as it has a fairly blunt tip compared with the tapered tip of a vascular sheath with dilator.

4. Advance the First of Two Perclose ProGlide Devices and Remove the Guidewire:

The arteriotomy dilating sheath is removed over the guidewire as manual pressure is held over the arteriotomy site. The first Perclose ProGlide device is advanced over the guidewire until the guide wire exit port of the device is just above the skin line (**►Fig. 3a**). The device lever marked #1 and the Perclose ProGlide logo should be facing the ceiling. At this point, the guide wire is removed.

5. Advance the Perclose ProGlide Device into the Artery until Blood Flow Is Observed:

The device is advanced at a 45-degree angle until brisk, pulsatile blood flow is noted at the clear plastic marker lumen on the right side of the device.

6. Rotate the Perclose ProGlide Device to the Medial Position and Deploy the Device Footplate:

By convention, the authors always deploy the first SMCD in the medial position and the second SMCD in the lateral position. For the right groin, medial is at 2 o'clock and lateral is at 10 o'clock. Conversely for the left groin, medial is at 10 o'clock and lateral is at 2 o'clock. The device is rotated 30 degrees to the medial clock position of the vessel wall, and the 45-degree angle is maintained to introduce the device. The footplate is deployed using the black lever marked #1 on the device (**►Fig. 3b**). The footplate should never be deployed without having first rotated the device 30 degrees to the medial clock position.

7. Bring the Footplate into Contact with the Vessel Wall:

Gentle backward force is applied to the device to bring the footplate into contact with the vessel wall. Footplate-vessel wall apposition is indicated by the combination of a tactile resistance to further backward force and cessation of blood flow from the clear plastic marker lumen on the right side of the device. It is important to not put so much traction on the device so as to pull the footplate through the vessel wall.

8. Deploy the Suture:

The device is stabilized with the free hand while gentle traction is maintained. Pulsatile flow from the clear plastic tubing at the side of the device should have stopped at this point. As back tension is maintained on the device against the artery, the needles are deployed by pushing the plunger on the back of the device in the direction of the arrow marked #2 on the device. The plunger should be advanced until the black collar of the plunger makes contact with the purple body of

the device (**►Fig. 3c**). Excessive force or pushing on the plunger repeatedly should be avoided. Note that damage to the access vessel most often occurs due to suboptimal initial needle access, such as sidewall, suprainguinal, or posterior wall punctures.

9. Retract the Suture by Withdrawing the Plunger, and Cut It:

The device is stabilized with the free hand as the suture is retrieved. This is accomplished by retracting the plunger marked #3 on the device to disengage the suture needles (**►Fig. 3d**). Retraction of the plunger is continued until the suture is taut, confirming that the entirety of suture has been retracted from the body of the device. The quick cut mechanism on the device is used to cut the suture from the needle (**►Fig. 3e**). If no sutures have been captured, the needles have not engaged correctly and the device will need to be removed (note the footplate will need to be closed prior to removal), and the aforementioned steps will need to be repeated with a new device.

10. Return the Footplate to the Closed Position and Withdraw the Perclose ProGlide Device:

After relaxing traction on the device, the lever marked #4 on the device is pushed to return the footplate to the closed position (**►Fig. 3f**). This is a critical step; the device should not be removed without first closing the lever. Retracting the device will release the suture knot. The device is gently withdrawn until the guide wire exit port is visible at the skin line (**►Fig. 3g**).

11. Set the Suture Limbs Aside:

The two suture limbs are grasped adjacent to the sheath and pulled through the proximal guide. Note that the longer of the two sutures is the "rail" and is used to advance the knot. The shorter, white tipped suture is the "non-rail" suture and will eventually be used to lock the knot. Both sutures should be set aside after clamping the sutures together at the distal aspect of the "non-rail" suture limb to prevent the suture from advancing or locking prematurely. Excess suture is removed from the tissue tract by retracting the clamp until the sutures are taut. The clamped sutures are placed off to the side of the access site for completion of closure at the end of the procedure and covered with a damp towel. By convention, the sutures placed at the medial position are clamped together and placed medial to the access. Subsequently, the sutures placed at the lateral wall will be clamped and placed lateral to the access. This will be critical for determining the order of suture closure at the end of the case.

12. Reinsert the Guidewire and Remove the First Perclose ProGlide Device:

Enough guidewire is advanced through the exit port as necessary for a guide wire exchange. As the device is being removed, manual pressure is maintained over the arteriotomy site to prevent formation of a hematoma (**►Fig. 3h**).

13. Advance the Second of Two Perclose ProGlide Devices and Remove the Guidewire:

The second device is advanced over the guidewire until the guidewire exit port is just above the skin line. The lever marked #1 on the device and the Perclose ProGlide logo should be facing the ceiling. At this point, the guidewire is removed.

Fig. 3 (a) Advance the first Perclose ProGlide device over the guidewire until the guide wire exit port is just above the skin line. Remove the guidewire and then advance the device at a 45-degree angle until brisk, pulsatile blood flow is seen at the clear plastic marker lumen on the right side of the device. (b) Rotate the device to the medial position while maintaining a 45-degree angle and deploy the footplate using the black lever marked #1 on the device (shown here with the footplate deployed). (c) Apply gentle backward force to the device to bring the footplate into contact with the vessel wall. Deploy the needle by pushing on the plunger in the direction of the arrow marked #2 on the device until the black collar of the plunger makes contact with the purple body of the device (image inset). (d) Maintain gentle retraction on the device to stabilize it as the suture is retrieved by retracting the plunger marked #3 on the device to disengage the suture needles. (e) Continue pulling back on the plunger until the suture is taut, confirming that the entirety of suture has been retracted from the body of the device. Use the quick cut mechanism on the device to cut the suture from the needle. (f) Push the lever (marked on its undersurface with #4) on the device to return the footplate to the closed position after relaxing retraction on the device. (g) Gently withdraw the device until the guide wire exit port is visible at the skin line. Grasp the two suture limbs adjacent to the sheath and pull the suture limbs through the proximal guide. Re-advance the 0.035-in. guidewire through the guidewire exit port. (h) As the first Perclose ProGlide device is being removed, maintain manual pressure over the arteriotomy site to prevent formation of a hematoma. (i) Steps are repeated with the second Perclose ProGlide device delivered in the lateral position. Once completed, set aside both pairs of sutures under a damp towel during the EVAR procedure.

14. Advance the Perclose ProGlide Device into the Artery until Blood Flow Is Observed:

The device is advanced at a 45-degree angle until brisk, pulsatile blood flow is noted at the clear plastic marker lumen on the right side of the device. The device should be rotated approximately 30 degrees to the lateral clock position of the vessel wall (—Fig. 3i).

15. Repeat Steps 6 to 11 with the Second Perclose ProGlide Device, Deploying THE Suture at the Lateral Position.

16. Reinsert the Guidewire and Replace the Second Perclose ProGlide Device with a Vascular Sheath:

Enough guidewire as necessary should be advanced for a guide wire exchange. As the device is being removed, manual pressure is maintained over the arteriotomy site. An 8F

vascular access sheath should be placed after the second set of sutures has been clamped and set aside under a damp towel. The 8F sheath will eventually be replaced by the device delivery sheath; serial dilatation of the tract is not usually necessary.

17. Repeat Steps 1 to 16 on the Contralateral Groin:

When completed there will be two sets of untied Perclose ProGlide sutures at each groin. Wet towels are placed at the base of the CFA sheaths, and the clamped sutures are positioned underneath the towels. This functions to keep the sutures out of the way during necessary exchanges that occur during EVAR as well as to keep the polypropylene sutures moist during the aneurysm repair.

18. EVAR:

Obvious consideration is given to iliac size, tortuosity, and calcification, but generally it is wise to deliver the main body through the larger access vessel. Endovascular aneurysm repair is performed in standard fashion.

19. Irrigate the Secured Sutures:

At the completion of aneurysm repair and prior to closure, thorough irrigation of the sutures and subcutaneous tissue around the sheath will remove debris, tissue, or dried blood that may otherwise impede advancing the knots (►Fig. 4a).

20. Closure of Medially Placed Suture (Advance the Knot to Approximate the Arteriotomy, Lock the Knot, and then Cut the Suture):

For femoral sheaths that are of unequal size, it is the authors' preference to remove and initiate closure of the arteriotomy accommodating the larger of the two sheaths. The suture knots must be advanced in the order that they were placed (i.e., the medial suture is always placed first and is also the first suture to be closed). The longer of the two suture limbs acts as the "rail," while the shorter, white-tipped suture limb is used to lock the knot. The knot pusher is placed on the medial rail suture and the free end of this suture is wrapped around the index finger low and close to the skin level. The operator's thumb is positioned at the top of the knot pusher (►Fig. 4b). The suture should be aligned coaxially with the tissue tract; this is accomplished by positioning the knot pusher toward the access site in the course of the tissue tract. Gentle traction is maintained on the rail suture coaxial to the tissue tract as the sheath system from the procedure is removed over a guidewire. Gentle manual pressure is applied to the proximal CFA to maintain hemostasis as the sheath is removed over the guidewire (►Fig. 4c). Once the sheath system is removed, increasing tension to the rail suture is applied slowly while avoiding quick or jerky movements with the suture limb. Manual pressure is released over the arteriotomy site to allow the knot pusher to advance properly through the subcutaneous tissue, and cinches down the preformed knot of the suture. It is at this stage that the operator must be careful to avoid damaging the access vessel by tearing through the arterial wall. Additionally, knot failure due to air knot formation or suture breakage can occur at this juncture.¹⁶ The snared knot pusher is used to approximate the tissue edges. At this point, the knot is tightened by pulling the shorter, white tipped suture limb, keeping it coaxial to the tissue tract (►Fig. 4d). While maintaining gentle pressure on

the knot pusher and the suture limbs taut, manual pressure is removed to assess the degree of hemostasis (►Fig. 4e). Both limbs of the first suture set are held together and loaded into the suture trimmer. The suture trimmer is advanced to the arterial surface. The suture limbs are kept taut and the red lever is used on the suture trimmer to cut the suture limbs (►Fig. 4f).

21. Closure of Laterally Placed Suture (Advance the Knot to Approximate the Arteriotomy, Assess for Hemostasis):

Again, at this point the knot should not be locked or excessively tightened as the guide wire is still in the vessel. The same technique is followed as utilized in step 20. Prior to locking and cutting the knot, the authors assess for hemostasis. With the guidewire still in position, the rail suture is pulled (►Fig. 4g). This will function to advance the knot down to the arteriotomy and approximate the arteriotomy edges. With constant gentle traction held on the rail suture, manual compression is released from the proximal CFA to assess for hemostasis. At this stage, some slow nonpulsatile bleeding may be observed due to the guide-wire remaining in position. The knot pusher is used to cinch down the preformed knot of the suture.

22. Remove the Guidewire, Lock the Knot, then Cut the Suture:

If adequate hemostasis is not achieved, the guidewire is not removed.¹⁶ In the event of pulsatile blood flow or brisk hemorrhage, one of the two adjunctive closure techniques may be considered and applied. A third ProGlide device can be advanced over the wire and deployed at the 12-o'clock position (again, assessing for hemostasis while pulling up on the rail suture and advancing the knot to the arteriotomy). Alternatively, an 8F AngioSeal device (St. Jude Medical, Minnetonka, MN) can be deployed over the wire, followed by manual pressure over the arteriotomy for a period of 10 minutes. Even after deploying a third ProGlide device or AngioSeal hemostasis is still not achieved, then a large vascular access sheath (7–12F) can be reinserted into the vessel and an open repair performed with the sheath left in place to maintain hemostasis.¹⁰ The guidewire should be thought of as the safety net, and should always be the last thing removed with any access.¹⁶ Once the wire has been removed, the knot pusher can again be used to cinch down the preformed knot of the suture, then both limbs of the second suture set are held together and loaded into the suture trimmer. The suture trimmer is advanced to the arterial surface. The suture limbs are kept taut and the red lever on the suture trimmer is used to cut the suture limbs (►Fig. 4h).

23. Assess for Hemostasis and Sterile Dressing Applied:

Manual pressure can be applied for approximately 10 minutes (►Fig. 4i). Subcuticular closure of the skin incision is performed. The pedal pulses should be checked and compared with the preoperative pulse examination.

24. Repeat Steps 19 to 26 at the Contralateral Groin.

Discussion

Percutaneous EVAR has distinct advantages over open femoral access, which are primarily related to patient

Fig. 4 (a) Irrigate the sutures to remove debris or dried tissue and blood before advancing the knots. (b) The knot pusher is placed on the medial rail suture. The thumb is positioned at the top of the knot pusher. The suture should be aligned coaxial with the tissue tract. (c) Apply gentle manual pressure to the proximal CFA to maintain hemostasis as the sheath is removed over a guidewire. (d) Tighten the knot by pulling the shorter, white tipped suture limb, keeping it coaxial to the tissue tract. (e) While maintaining gentle pressure on the knot pusher and the suture limbs taut, manual pressure over the common femoral artery is removed to assess the degree of hemostasis. (f) Use the red lever on the suture trimmer to cut the suture limbs. Manual pressure is applied over the common femoral artery as the suture limbs are cut. Note that the 0.035-in. guidewire remains in position. (g) Repeat with the second set of suture limbs. The snared knot pusher is used to approximate the tissue edges. With the guidewire still in position, pull up on rail suture, advancing the knot down to the arteriotomy. With gentle traction held on the rail suture, manual compression is released from the proximal CFA to assess for hemostasis (shown). (h) Following guidewire removal, the knot is locked and then the second set of suture limbs are cut and removed. (i) Manual pressure should be held for approximately 10 minutes.

satisfaction and decreased rates of femoral complications. However, successful PSMC of large vessel access is predicated on careful patient selection and by skilled operators with sufficient experience with SMCDs. When selecting candidate patients, the vascular team should concern itself with the quality of the CFA and iliac vasculature (vessel size and calcifications). Consideration should be given to sheath size, the patient's surgical history (scarred groins), and distance from the skin to the CFA. It is critical to perfect

the CFA access technique with ultrasound guidance. These measures will significantly improve technical success and reduce procedure-related complications. However, the ability to convert to open femoral repair is also crucial. At the authors' institution, all PEVAR is performed with two skilled operators, one interventional radiologist and one vascular surgeon, which allows for the ability to convert to open femoral repair in case Preclose technique fails.

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