Current Status of Percutaneous Endografting

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ABSTRACT

Significant advances in the technology and techniques in the field of endovascular thoracic and abdominal aortic aneurysm repair have been made since its introduction in the early 1990s. The low incidence of periprocedural complications combined with comparable early outcomes to open surgery have made the endovascular treatment option the first choice of therapy in patients whose aortic anatomy is suitable for endografting. All currently available endografts for aortic aneurysm repair have delivery systems at least 21-French in outer diameter and have traditionally been inserted via surgical cutdowns. More recently, attempts to validate a totally percutaneous approach to the placement of these devices have been introduced by utilizing suture-mediated closure devices. This article will provide an overview of suture-mediated closure devices, our experience with the off-label application of suture-mediated devices for percutaneous closure of arterial access sites during endovascular aneurysm repair, and a review of the literature on this topic.

KEYWORDS: Percutaneous, endograft, preclose

Objectives: Upon completion of this article, the reader should be able to explain the technique and outcomes of totally percutaneous endografting.

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Since the initial introduction of endovascular aneurysm repair by Parodi et al¹ in 1991, significant advances in endograft technology and delivery systems have been made. There are currently five Food and Drug Administration (FDA)-approved devices for endovascular abdominal aortic aneurysm (AAA) repair (Medtronic AneuRx [Minneapolis, MN], W.L. Gore Excluder [Flagstaff, AZ], Cook Zenith [Bloomington, IN], Endologix Powerlink [Irvine, CA], and Medtronic Talent) and three FDA-approved devices for thoracic aortic aneurysm (TAA) repair (W.L. Gore TAG, Cook TX2, and Medtronic Talent). As experience with use of

these devices has increased and the benefits of this technology have become more apparent, the use of endografts in an off-label application has also grown, especially in the treatment of symptomatic type B thoracic aortic dissections and traumatic aortic injuries. The profile of currently available components of endograft delivery systems ranges from 9-French to 25-French in inner diameter, which correlates to ~11-French to 27-French outer diameter (OD). In particular, the delivery systems for thoracic endografts are 22- to 27-French OD and are traditionally placed via femoral artery cutdowns or a surgically created conduits. Haas

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et al were the first investigators to describe the use of a suture-mediated closure device (Prostar XL 10) for percutaneous closure of a 16-French arterial access site during endograft placement.² The potential advantages of percutaneous closure of endograft access sites include less patient discomfort, shorter hospitalization, less tissue trauma, fewer surgery-related complications, and a reduced requirement for the level of anesthesia. We would like to provide an overview of suture-mediated closure devices and their potential off-label application for percutaneous closure of endograft access sites, present our experience with this technology, and provide an overview of the current literature on this topic.

AVAILABLE CLOSURE DEVICES

There are two suture-mediated percutaneous closure devices that are currently available for potential off-label use in the closure of endograft access sites (Perclose Prostar XL and Perclose Proglide, Abbott Laboratories, Abbott Park, IL). The Perclose Prostar XL device comes in two different sizes. The Prostar XL 8 is designed for closure of 6.5- to 8-French access sites and Prostar XL 10 is for closure of 8.5- to 10-French access sites. These devices have two sutures attached to four needles and are designed to deploy the two sutures in a crisscross fashion to facilitate closure of the percutaneous arteriotomy site.

The newer Proglide device (6-French) has only one suture deployed through two needles. The suture material is a monofilament, which has a high knotted tensile strength and is also designed to minimize tissue retraction. As compared with the Prostar XL device, the Proglide is a lower-profile device and relatively easier to use.

PRECLOSE TECHNIQUE

The preclose technique involves deployment of the sutures at the time of percutaneous access into the femoral artery prior to insertion of the endograft delivery system or the large sheaths.³ After the sutures are predeployed, they are organized and tagged with hemostats and set to the side. The subcutaneous tract is bluntly dissected to allow over-the-wire insertion of the endograft delivery system and the various sheaths. At the end of the endograft procedure, the predeployed sutures are used to close the arteriotomy by pushing the knots down to the level of the arteriotomy.

Prostar XL (8 and 10)

After obtaining access to the common femoral artery, a 1-cm skin incision is made and the subcutaneous tract is bluntly dissected with a hemostat to facilitate insertion of the various devices. Subsequently, the arteriotomy is dilated with 8- or 10-French dilators to allow the

advancement of the Prostar XL 8 or 10 device, respectively. Over a 0.035-inch guide wire, the Prostar device is advanced into the artery until the guide wire exit port is just above the skin line. At this point the guide wire is removed and the hub of the Prostar device is unlocked by depressing the interlocks with the thumb and forefinger. After unlocking the hub, the device is gradually rotated back and forth while advancing the barrel of the device at a 45-degree angle, relative to the skin. A steady continuous drip of blood from the hypotubing lumen signifies a proper intraluminal position of the device to allow deployment of the sutures and needles. All four needles are deployed, and the sutures with needles affixed to them are removed from the hub using a pair of needle drivers. The needles are cut off from the ends of the sutures, and the delivery catheter is retracted to allow visualization of the sutures at the skin entry site. The two separate sets of sutures are identified and secured without putting any traction on the sutures. The delivery catheter is pulled further back to allow the insertion of a 0.035-inch guide wire back into the artery lumen. Some investigators will then insert and predeploy a second Prostar XL device if the arteriotomy is going to be larger than 16-French. A single Prostar XL 10 device has been successfully used for sheaths up to 24-French at our institution; however, most clinical sites will use a Prostar XL 10 plus a Prostar XL 8 device to optimize the chance for hemostasis when using sheaths up to 25-French.

Proglide

Although a single Proglide device has been successfully used for achieving hemostasis for 12-French sheaths, most clinical sites use at least two Proglide devices for ensuring adequate hemostasis after use of sheaths 12-French in size or larger. Two devices are sequentially advanced at a 45-degree angle to the skin and deployed ~60 degrees opposite in orientation (i.e., 10 o'clock and 2 o'clock positions relative to each other) to create more of a crisscross suture closure. The device itself has number marks to identify the deployment sequence, which make it easier to remember the procedural steps.

After obtaining access to the common femoral artery and dilating the subcutaneous tract to 8-French over a 0.035 guide wire, a 1-cm skin incision is made at the skin entry site. The first Proglide device is advanced into the artery at a 45-degree angle to the skin until the guide wire exit port is at the skin level (Fig. 1A). The guide wire is removed and the device is further advanced into the artery until pulsatile flow is achieved from the plastic translucent marker lumen located on the right side of the device (Fig. 1B), indicating proper positioning of the device inside the artery lumen. The device is rotated to the 10 o'clock position and the lever (#1) is lifted, deploying the needle foot plates inside the artery.

Figure 1 Preclosure procedure using the Proglide device. (A) The device is inserted over a guide wire. (B) The guide wire is removed and device further advanced in to the artery until pulsatile blood flow seen at the translucent marker lumen. (C) The device is rotated to the 10 o'clock position, the lever is pulled to expose the intra-arterial foot plates, and the plunger is fully depressed to deploy needles and capture the sutures. (D) The blue, longer suture is cut and the sutures are clamped with a small hemostat and set to the side. (E) A guide wire is advanced back in to the artery through the guide wire port marked with two white arrows and a second Proglide device is deployed in the 2 o'clock position. (F) An 8-French sheath is inserted to seal the access site. (G) A 22-French sheath is placed over a Lunderquist guide wire.

The device is then gently retracted until bleeding from the marker lumen has stopped and some resistance to retraction is appreciated. The needles are deployed and sutures are captured by fully depressing the plunger (#2) until a click is heard (Fig. 1C). The device is held firmly with one hand and the plunger (#3) is pulled back completely from the device, exposing the sutures from the back end of the delivery catheter. There are two sutures: one white and one blue. The blue one is longer and attached to the plunger mechanism. The suture attachment is cut by using the Quickcut mechanism attached on the device (Fig. 1D). The retraction tension on the device is relaxed and the lever is returned to its original position (#4) to return the foot plates to their undeployed position. The device is pulled back until the guide wire exit port, which is marked with two white arrows, is exposed at the skin entry site. The two sutures should also be visible on the outside of the delivery catheter just outside the skin entry site and grasped at this point and pulled downward, retracting the sutures from the backend of the delivery catheter. Once free from the delivery device, the sutures are clamped with a small hemostat and set to the side (Fig. 1D). At this point, a guide wire (author B.A. prefers an extra stiff 80-cm-long Amplatz wire [Cook, Inc., Bloomington, IN]) is readvanced through the guide wire port (Fig. 1E), and same procedure is completed for the second device, which is deployed at 2 o'clock position. We then routinely place an 8-French sheath over a guide wire. The working guide wire is appropriately positioned for the intended endograft procedure (Fig. 1G). Some operators recommend sequential dilation of the arteriotomy site. As long as the delivery device has a good taper, we do not perform sequential dilations and have not experienced a problem in our first 61 cases (86 access sites).

Once endograft deployment is completed, closure of the access site is relatively straightforward. The operator needs to wrap the longer blue string around his or her index finger and gently retract the suture while applying pressure on the groin with the other hand. Retraction on the blue string will advance the slipknot down the subcutaneous tract to the arteriotomy site. It is important to moisten the monofilament suture material and to free it from any adherent clot or debris so that the slipknot can freely "slide down" to the arteriotomy site. At this time, an assistant can remove the sheath or the endograft delivery device from the artery, leaving the guide wire in place to maintain arterial access. Prior to removal of the delivery device, it is very important to ensure that the delivery device has been "reset" to its undeployed, smooth transition, low profile; otherwise, the exposed "edges" of the delivery system may lacerate the arteriotomy site, making it difficult to obtain hemostasis. The blue string from the second closure device should be immediately retracted at this time (Fig. 2A).

By placing retraction on the two blue strings at the same time, the arteriotomy site will be almost closed and the manual pressure above the artery can be released. Bleeding should be minimal at this point. If the bleeding is still of concern, another Proglide can be deployed. If there is more bleeding than expected, a sheath can be advanced into the artery and a surgical exposure and closure can easily be performed.

If bleeding from the access is minimal after removal of the delivery system or sheath, the guide wire is removed and the knots are further advanced to the artery surface by using the knot pusher. The preferred technique of advancing the knot is by rolling the blue string around the index finger and, while maintaining retraction pressure on the suture, using the thumb to advance knot pusher toward the artery surface (Fig. 2B). The sutures are cut using the red suture cutter lever positioned on the right side of knot pusher (Fig. 2C). Using this technique, the suture ends are buried in the subcutaneous tract, thereby reducing the risk for an infection. If oozing of blood persists, mild pressure over the groin is maintained for 3 to 5 minutes, as these patients are anticoagulated and oozing is often due to bleeding from the tract itself (Fig. 2D).

UNIVERSITY OF VIRGINIA EXPERIENCE

At our institution, the Prostar XL device for percutaneous access site closure during endograft procedures was initially used to close the access sites. However, due to its relatively simple deployment technique, the Proglide device is currently being used. Between July 2006 and August 2008, we performed 42 AAA and 19 TAA endovascular repairs using the Proglide device for percutaneous closure of the access sites. The endograft devices used included the W.L. Gore Excluder, Cook Zenith, Medtronic AneuRx, Medtronic Talent Abdominal and Thoracic, and Cook TX2. The device diameters ranged from 12-French to 25-French. The criteria utilized in the selection of patients for a percutaneous approach included: at least 1-cm segment of midcommon femoral artery without anterior calcification, absence of severe scarring at the groin, no graft material at the access site, a favorable common femoral bifurcation (i.e., not a high bifurcation), and an arterial diameter that would allow insertion of the delivery device or sheath. Computed tomographic angiographic evaluation is essential in helping to determine which patients are appropriate for a percutaneous approach. Previous use of a Proglide, a single prior femoral artery cutdown, or obesity were not considered contraindications for a percutaneous approach. We have successfully employed this technique in patients up to 350 pounds. However, we have chosen not to use a percutaneous approach in patients who weigh less than 300 pounds with other features that are borderline. Our success rate

Figure 2 Closure of the arteriotomy using the previously deployed sutures. (A) After clearing the suture material of debris and moistening them, both blue, longer sutures from the two Proglide devices are retracted to allow the slipknot to move down toward the arteriotomy site. (B) The knot pusher is used to advance the knot to the surface of the artery using index finger to retract the suture and the thumb to advance the knot. Note that minimal bleeding is seen despite the absence of manual pressure at the puncture site. (C) After hemostasis is demonstrated, the sutures are cut with the red cutter placed on the knot pusher so that the suture material is buried in the subcutaneous tract. (D) Several minutes of additional manual pressure may be applied if necessary. (E) The arteriotomy site should be dry and hemostasis should be visible immediately after the procedure.

in these 61 patients was 100% for effective closure of the arteriotomies. We had no immediate complications related to the closure or at clinical follow-up.

DISCUSSION

The indications for the use of a percutaneous approach to endograft procedures is not well defined. However, we have found that suture-mediated closure of femoral arteriotomies during endograft procedures is feasible with a high technical success rate in appropriately selected

patients. In addition, our experience suggests that patients have less pain and ambulate much sooner using percutaneous closure. We have applied this technology in a variety of endograft procedures, and it has also been described in the repair of elective AAAs and TAAs,³ ruptured AAAs,⁴ and traumatic thoracic aortic injuries.⁵

Haas et al² first described this suture-mediated technique in 1999 using a first-generation Perclose device. Their experience included 13 closures in 12 patients. Nine of the closures were performed for 16-French sheaths. One of their patients had a 22-French sheath

Table 1 Literature Review of Retrospective Studies on Percutaneous Endografting

Lead Author, year	Number of Arteries	Sheath Sizes (French)	Success Rate (%)	Device Type
Haas, 1999 ²	13	16–22	100	Prostar XL
Traul, 2000 ⁶	29	16–24	46.2	Prostar XL
Teh, 2001 ⁷	82	16–22	73.8	Prostar XL
Howell, 2001 ⁸	148	16	94.4	Prostar XL
Kennedy, 2003 ⁹	15	16	80	Prostar XL
Torsello, 2003 ¹⁰	27	14–24	86.6	Prostar XL
Morasch, 2004 ¹¹	94	12–18	85.1	Prostar XL
Lee, 2008 ¹²	432	18–24	94.4	Proglide
UVA (unpublished)	86	12–25	100	Proglide

UVA, University of Virginia.

in which two Perclose devices were used. They had no surgical conversions and no significant complications. Since this initial report, several retrospective series have been published with demonstrated success rates from 46 to 100% (Table 1).^{1,3,6–12} The largest series, by Lee et al, involved 292 patients and 432 access sites in which the Proglide technique was used.¹² A 94.4% technical success rate and a late complication rate of 1.92% (3/156) for sheath sizes ranging from 18- to 24-French were reported.

There are several prospective studies utilizing the Prostar XL device for percutaneous closure of access sites during endograft procedures. To our knowledge, there have been no prospective studies evaluating the Proglide device for this application. Watelet et al evaluated the feasibility of the percutaneous closure by prospectively enrolling all AAA and TAA patients for this option.¹³ Exclusion criteria included aorto-uni-iliac endografts in which femoral-to-femoral bypass grafts were planned, heavy anterior calcifications, heavily scarred groins, and presence of an inguinal arterial prosthesis. Thirty-nine successful closures at 47 access sites (83%) in 29 patients were achieved. The ODs of devices used were 21- to 25-French. Periprocedural access complications occurred in seven cases. Four of these patients underwent surgical repair, and the other three were managed by manual compression. Overall, percutaneous closure was achieved in 25 of 29 patients. No late complications were detected. Jean-Baptiste et al performed a prospective study to compare the percutaneous closure technique using the Prostar XL versus a surgical cutdown.¹⁴ Outcomes of their study are summarized in Table 2 and reveal a 92% technical success rate and shorter hospital stay as compared with the surgical arm. One case of death in their

percutaneous group was due to iliac artery rupture after excessive balloon expansion of an endograft limb.

In a review of the literature, Jean-Baptiste et al identified factors that contribute to the occurrence of a technical failure.¹⁴ There were a total of 585 attempts at percutaneous closure, with 57 failures (9.7%). Device malfunction or suboptimal technical expertise with use of the device was the most common ($n = 19$) reason for failure of the closure device, followed by obesity ($n = 8$) and poor puncture site anatomy ($n = 8$).

In another manuscript, Arthurs et al reviewed the role of ultrasound (US) for guidance during percutaneous endografting.¹⁵ US guidance for arterial access significantly reduced access related complications in patients requiring larger sheaths. With US guidance, a technical success rate of 98% was achieved as compared with a success rate of 94% with manual palpation for arterial access. Complications were 0% in the US group and 7% in the palpation group. With sheath sizes of 20-French or less, both groups had 97% a technical success rate. However, with sheath sizes larger than 20-French, the US group experienced a 100% technical success rate ($n = 24$) as compared with an 82% success rate ($n = 18$) in the manual palpation group. This difference in success rates was statistically significant. A limitation of the study is a lack of consideration of operator experience with each technique and whether or not fluoroscopic guidance was employed with the manual palpation technique. In our institution, fluoroscopic guidance is the main imaging tool used to complement manual palpation during arterial access for endografting. Ultrasound guidance is used in select cases by select operators for cases in which the femoral artery anatomy is borderline or somewhat challenging.

Table 2 Prospective Comparison of Percutaneous Endografting to Surgical Cutdown

	Number of Access Sites	Success Rate (%)	Overall Perioperative Complications (%)	Operative Mortality	Mean Hospital Stay (d)
Percutaneous	38	92	16	1	5.8
Surgical	42	90	14	0	7.8

CONCLUSION

In summary, totally percutaneous endografting using the suture-mediated preclose technique is a feasible procedure already being preferentially performed in many institutions. The more experienced the institution in this procedure, the better the outcomes appear to be. In one isolated study, the percutaneous technique was comparable, if not better, than open surgical access. Potential advantages of percutaneous endografting include faster patient recovery and earlier ambulation, less patient discomfort, fewer groin-related complications, less time to perform access site closure, and absence of a scar in the groin. Patient selection is very important for optimizing procedural success. Most technical failures have been shown to be due to inexperience with the closure device and inappropriate patient selection. Technical success rates are excellent after the learning curve with the preclose technique has been overcome.

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