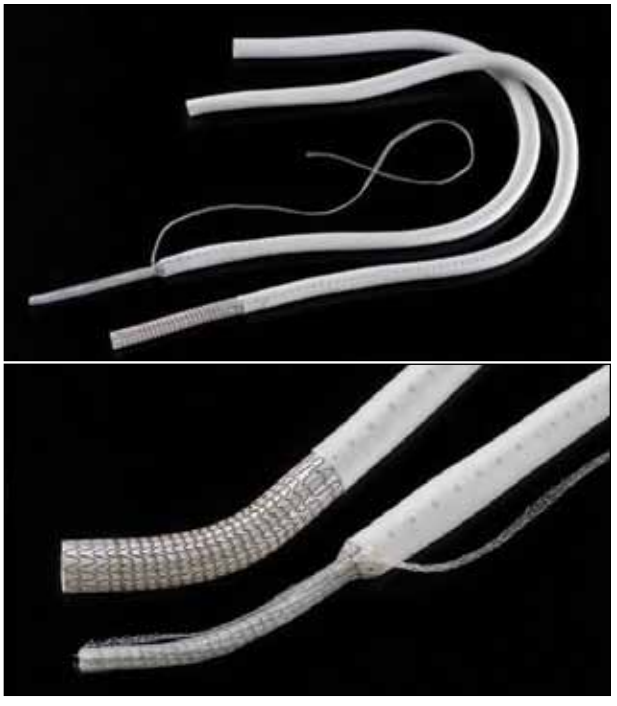
Percutaneous Venous Anastomosis With a Hybrid Vascular Graft

Treatment indications, percutaneous technique, and initial outcomes.

BY JOHN R. ROSS, MD

The creation of long-term hemodialysis access remains a significant challenge, especially in patients with multiple previously failed arteriovenous accesses, those with central venous stenosis due to previous catheter use, morbidly obese patients, and the elderly.[1-3] According to the 2011 United States Renal Data System Annual Report, 571,000 patients in the United States received treatment for end-stage renal disease (ESRD) in 2009, and since 2000, the incidence rate of ESRD has grown by 12% in patients who are 75 years of age and older.[4] As we continue to treat an older ESRD population with multiple comorbidities, an increase in the use of synthetic arteriovenous grafts (AVGs) may be required despite the Fistula First Breakthrough Initiative.[5]

Anastomotic stenosis of AVGs due to intimal hyperplasia is the major cause of failure in vascular access grafts used for hemodialysis, and there is a strong relationship between hemodynamic factors and the formation of intimal hyperplasia.[6] A conventional end-to-side venous anastomosis subjects the vessel wall to turbulent, nonlinear flow at the toe and heel of the anastomosis and where the flow impinges on the native vein wall—locations that have been shown to correspond to areas of the development of intimal hyperplasia.[6] In addition, spatial and temporal gradients in wall shear stress have been found at sites in which intimal hyperplasia tends to develop.[7] The new Gore Hybrid vascular graft (W. L. Gore & Associates, Flagstaff, AZ) (Figure 1) addresses the common failure of outflow stenosis, potentially reducing the number of interventions required to maintain AVG patency. This benefit, as well as the unique deployment system of the device, which allows for access to challenging anatomy, makes expanded polytetrafluoroethylene (ePTFE) grafts a more



(Courtesy of W. L. Gore & Associates.)

Figure 1. The Gore Hybrid vascular graft is an ePTFE vascular prosthesis that has a section that is reinforced with nitinol. The NRS is partially constrained to allow for easy insertion and deployment into a vessel.

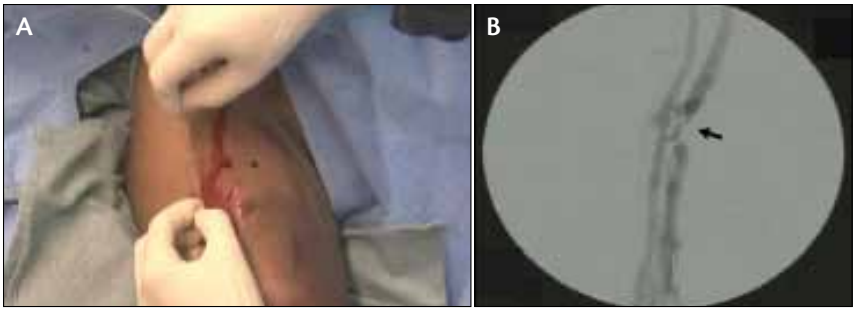


Figure 2. The failed ePTFE loop graft is cannulated, and a guidewire is advanced under fluoroscopy (A). The needle was exchanged for a 7-F introducer, and fluoroscopy was performed to visualize the occlusion in the failed ePTFE loop graft (arrow, B).

attractive therapy for arteriovenous access creation, especially in the aging dialysis population.

The Gore Hybrid vascular graft is an ePTFE graft with a nitinol-reinforced section (NRS) (Figure 1), and the continuous luminal surface is covalently bonded with the Carmeda bioactive surface (Carmeda AB, Upplands Väsby, Sweden), which consists of a stable, covalently bonded, reduced-molecular-weight heparin. Deployment of the NRS into a vessel results in a sutureless end-to-end anastomosis and can be performed with an over-the-wire, minimally invasive percutaneous technique.

The "endoluminal anastomosis" created with the Gore Hybrid vascular graft optimizes the hemodynamic profile at the outflow anastomosis, resulting in a reduction in intimal hyperplasia. Computational fluid dynamics studies with this device have shown improvement in hemodynamics and a decrease in variation of wall shear stress at the NRS of the device, as compared to a standard end-to-side anastomosis.[8] An in vivo porcine study has also demonstrated a reduction in stenosis and thrombosis with the Gore Hybrid vascular graft as compared to a conventional end-to-side anastomosis.[9]

We and others have reported on the creation of an arteriovenous anastomosis with either a vascular graft and a stent graft or a vascular graft alone in a manner that is similar to that of the Gore Hybrid vascular graft.[10-13] Our experience with a percutaneous sutureless anastomosis using a vascular graft and a stent graft to create conduits for long-term hemodialysis access spans over 175 patients and 10 years; we continue to observe excellent safety and effectiveness results from this procedure.

With the Gore Hybrid vascular graft now available, we can use a single device with a continuous lumen to create a sutureless venous anastomosis in a percutaneous fashion. The Gore Hybrid vascular graft also incorporates a low-permeability film within the wall of the graft that acts as a barrier to ultrafiltration and provides seroma resistance. This article describes a percutaneous approach for creating an endoluminal anastomosis with the Gore Hybrid vascular graft and the initial outcomes in 83 patients.

CASE REPORT

A 70-year-old woman with a history of hypertension, diabetes mellitus, obesity, and ESRD presented with a malfunctioning right upper arm looped arteriovenous ePTFE graft. Flow in the graft was pulsatile, and the patient was not able to undergo adequate dialysis. Angiography showed retrograde flow within the AVG and a complete occlusion within the loop graft near the outflow anastomosis (Figure 2). The occlusion could not be crossed with a wire.

The adequate outflow axillary vein was located deep within the axilla and would have been a challenging site for surgical creation of a new outflow anastomosis. Due to its ability to create an endoluminal anastomosis in a percutaneous fashion, the Gore Hybrid vascular graft was chosen to bypass the occlusion and create a new sutureless outflow venous anastomosis.

Percutaneous Technique

After regional anesthesia, the patient's upper arm was prepared and draped in the usual fashion. The failed ePTFE loop graft was cannulated with an 18-gauge needle (Figure 2A), and a 180-cm guidewire was threaded

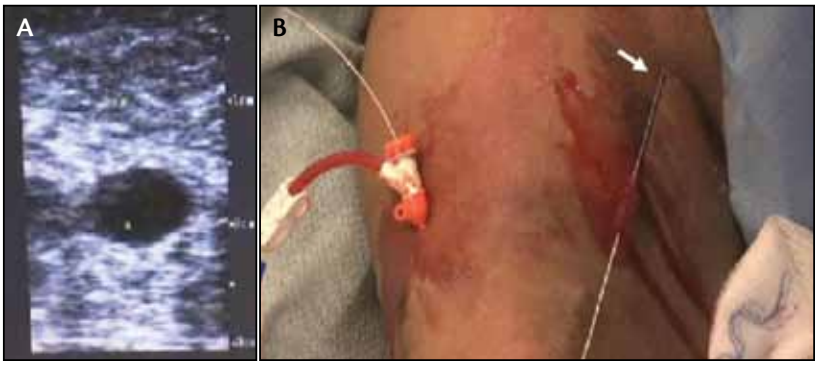


Figure 3. Ultrasound guidance (A) is used to cannulate the axillary vein proximal to the occlusion in the previously failed ePTFE loop graft (arrow, B).

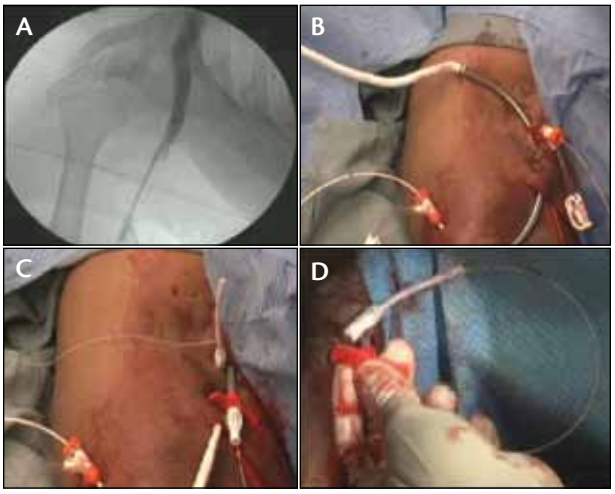


Figure 4. Fluoroscopic imaging of the axillary vein where the NRS of the Gore Hybrid vascular graft will be deployed (A). Tunneling of the Gore Hybrid vascular graft (B). The 7-F introducer sheath is exchanged for a 14-F peel-away sheath (C). The dilator of the peel-away sheath is removed, and the NRS is back-loaded over the wire into the peel-away sheath (D).

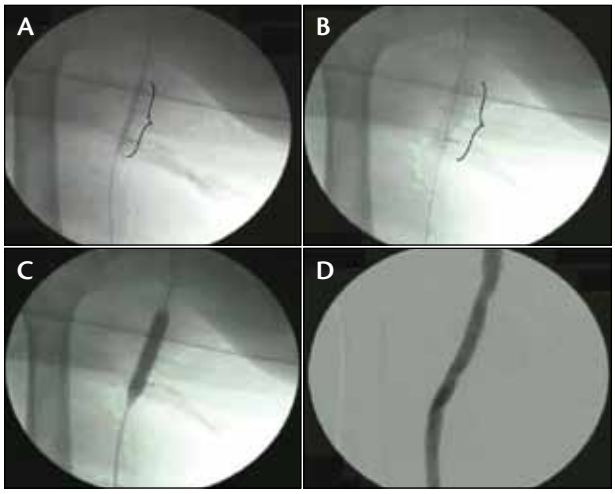


Figure 5. The peel-away sheath is peeled away, and the undeployed NRS is visualized under fluoroscopy (A). The deployment line of the Gore Hybrid vascular graft is pulled, and the NRS self-expands (B). The NRS is dilated with a percutaneous transluminal angioplasty balloon (C). A contrast agent is injected to visualize the placement of the NRS and the outflow vein (D).

through the prior AV loop graft under fluoroscopy. The needle was exchanged for a 7-F introducer, and angiography was performed to visualize the occlusion in the failed ePTFE loop graft (Figure2B). The axillary vein was visualized proximal to the occlusion using a portable ultrasound device (Figure 3A), and the axillary vein was cannulated under ultrasound guidance (Figure 3B).

A guidewire was threaded into the axillary vein under fluoroscopy, and the needle was exchanged for a 7-F introducer. Angiography was performed to visualize the central venous system and the axillary vein where the NRS of the Gore Hybrid vascular graft was deployed (Figure 4A). The outflow axillary vein was approximately 8 mm in diameter, and a Gore Hybrid vascular graft with an 8-mm-diameter NRS was chosen. The graft was tunneled in the usual manner (Figure 4B), and the 7-F introducer was exchanged over the wire for a 14-F tearaway introducer (Galt Medical Corporation, Garland, Texas) (Figure 4C). The 14-F peel-away introducer was necessary to accommodate the vascular graft with the 8-mm-diameter NRS. The dilator of the peel-away sheath was removed, and while keeping a thumb over the open end of the sheath to prevent back-bleeding, the guidewire was threaded into the constrained NRS and through the vascular graft section (Figure 4D). As the wire was pulled through the device, the constrained NRS was introduced into the end of the peel-away sheath.

As the peel-away sheath was split, the NRS of the Gore Hybrid vascular graft was advanced into the axil-

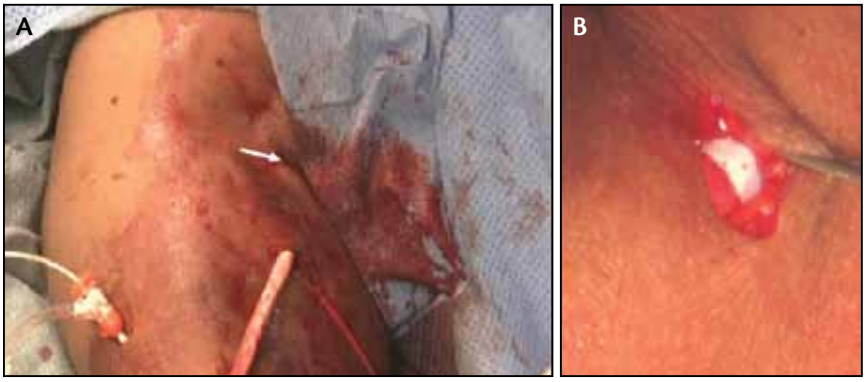


Figure 6. The venous anastomosis (arrow) in the deep axilla created with the Gore Hybrid vascular graft requires minimal dissection and simplifies a difficult surgical procedure (A). A close-up view of the percutaneous venous anastomosis created with the Gore Hybrid vascular graft (B).

lary vein to approximately 4 cm. The position of the NRS was verified under fluoroscopy prior to deploying the NRS (Figure 5A). The deployment line was pulled parallel to the vascular graft section, and the NRS was deployed from the tip toward the vascular graft section to a final diameter of 8 mm (Figure 5B). Angiography was performed to visualize the areas in need of angioplasty. A high-pressure 8-mm X 4-cm percutaneous transluminal angioplasty balloon was used to postdilate the NRS, open a constriction at the NRS vein exit location, and to seat the NRS against the vein wall (Figure 5C). Repeat angiography confirmed an acceptable result (Figure 5D). An end-to-end graft-graft anastomosis was then performed with the prior ePTFE loop graft to provide arterial inflow to the Gore Hybrid vascular graft.

RESULTS

The vascular graft maintained primary unassisted patency at 12-month follow-up. The over-the-wire implantation technique described in this case allowed minimally invasive, percutaneous creation of the venous anastomosis (Figure 6). The Gore Hybrid vascular graft is a valuable tool, especially for the creation of hemodialysis access in dialysis patients with a centrally located outflow vein.

Since September 2010, the Gore Hybrid vascular graft has been implanted in challenging dialysis access patients (n = 83), of which, the majority only had centrally located outflow veins available. Technical success was accomplished in all cases (100%). Mean follow-up was 245 days (range, 28–391 days), with a functional graft patency at 6 and 12 months of 82% and 69%, respectively. As described in this case report, implants were performed over-the-wire in a percutaneous fashion.

CONCLUSION

The percutaneous implantation technique using the Gore Hybrid vascular graft simplifies difficult arteriovenous access creation and revision procedures. The device enables additional access sites for patients who have exhausted all sites with a conventional AVG. Without the use of this device, many cases would have been time-intensive, invasive surgical procedures, resulting in abandonment of the access site. The unique design and deployment of the Gore Hybrid vascular graft allows us to overcome multiple problems at once and opens up more time for patients to undergo dialysis. Six- and 12-month functional patency rates suggest that this graft decreases the incidence of outflow stenosis, decreases the incidence of infection and seroma, and improves outcomes in the most challenging patient populations. ■

John R. Ross, MD, is the Medical Director of the Dialysis Access Institute at the Regional Medical Center in Orangeburg, South Carolina. He has disclosed that he receives research funding from W.L. Gore & Associates. Dr. Ross may be reached at (803) 533-7488; jrrsurgery@aol.com.

1. Roy-Chaudhury P, Kelly BS, Zhang J, et al. Hemodialysis vascular access dysfunction: from pathophysiology to novel therapies. Blood Purif. 2003;21:99-110.
2. Lee T, Roy-Chaudhury P. Advances and new frontiers in the pathophysiology of venous neointimal hyperplasia and dialysis access stenosis. Adv Chronic Kidney Dis. 2009;16:329-338.
3. Lok CE, Allon M, Moist L, et al. Risk equation determining unsuccessful cannulation events and failure to maturation in arteriovenous fistulas (REDUCE FTM I). J Am Soc Nephrol. 2006;17:3204-3212.
4. The United States Renal Data System. USRDS 2011 Annual Data Report: atlas of chronic kidney disease and end-stage renal disease in the United States, National Institutes of Health, National Institute of Diabetes, and Digestive and Kidney Diseases. http://www.usrds.org/atlas.aspx. Published November 22, 2011. Accessed May 20, 2012.
5. Lynch JR, Mohan S, McClellan WM. Achieving the goal: results from the Fistula First Breakthrough Initiative. Curr Opin Nephrol Hypertens. 2011;20:583-592.
6. Haruguchi H, Teraoka S. Intimal hyperplasia and hemodynamic factors in arterial bypass and arteriovenous grafts: a review. J Artif Organs. 2003;6:227-235.
7. Ojha M. Spatial and temporal variations of wall shear stress within an end-to-side arterial anastomosis model. J Biomech. 1993;26:1377-1388.
8. Anaya-Ayala JE, Adams MK, Bavare CS, et al. Early experience with a novel "hybrid" graft used for hemodialysis access. Abstract presented at: the 40th Annual Symposium of the Society for Clinical Vascular Surgery (SCVS); March 14–17, 2012; Las Vegas, NV.
9. Roy-Chaudhury P, Wang Y, Mistry MJ, et al. "Hybrid" graft reduces venous stenosis in a pig arteriovenous graft model. Presented at: ASN Kidney Week 2011; October 30–November 4, 2011; San Diego, CA.
10. Moossavi S, Ross JR. Percutaneous sutureless venous anastomosis. Endovasc Today. 2007;6:54-56.
11. Ross J. Expanded polytetrafluoroethylene and nitinol stent-graft for salvage treatment of vascular access sites: initial experience. In: Henry ML, ed. Vascular Access for Hemodialysis-IX. Los Angeles, CA: W.L. Gore & Associates, Inc. & Bonus Books, Inc.; 2005:23:229-234.
12. Masuda EM, Kistner RL, Eklof B, et al. Stent-graft arteriovenous fistula: an endovascular technique in hemodialysis access. J Endovasc Surg. 1998;5:18-23.
13. Coulson A, Singh J, Moya J. Modification of venous end of dialysis grafts: an attempt to reduce neointimal hyperplasia. Dial Transplant. 2000;29:10-19.