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TACKLING COMPLEX CASES IN

AV ACCESS

Providing durable access in challenging presentations.

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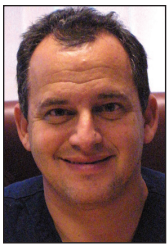
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High-Flow Versus Low-Flow Steal and the Hemodialysis Patient

A dialysis access expert weighs in on recognizing and managing this clinical presentation.

WITH SCOTT S. BERMAN, MD, MHA, FACS



Would you explain the concept of arterial steal?

Normal arterial flow down an extremity involves the high-resistance muscular arteries and arterioles distributing flow into the tissue bed through the capillaries. In addition to the main axial arteries, there are collateral pathways between the axillary and proximal brachial arteries in the upper arm and the radial, ulnar, and interosseous arteries (antebrachial arteries) in the forearm. The presence of an arteriovenous fistula (AVF) or arteriovenous graft (AVG) introduces an alternative, low-resistance pathway for the blood flow to take. Not only does a portion of the antegrade flow through the brachial artery get diverted through the AVF or AVG, but some flow that reaches the proximal antebrachial arteries via the collaterals is diverted through the AVF/AVG. This results in the actual reversal of flow in the artery distal to the arterial anastomosis of the AVG/AVF. This defines the physiology of arterial steal and is present in as many as 80% of patients with an AVF or AVG.

What are the symptoms?

Most patients with steal are asymptomatic. Symptoms can range from mild pain, numbness, or coldness during dialysis treatments (typically when systolic blood pressure trends lower than the patient's baseline) to severe pain, paralysis, and/or ischemic ulcers.

What are the degrees of arterial steal?

The most recent classification system for arterial steal was the product of the 2016 Charing Cross Vascular Access Master Class. This system uses a five-level grading classification based on signs, symptoms, and the results of investigations. Other published grading systems use four levels based on symptoms. The simplest classification is:

1. Mild pain, coolness, and/or paresthesia that occurs only during dialysis and is easily tolerated or controlled with a glove.

It is critical to make sure patients and their caregivers understand the urgency in the need for prompt and thorough evaluation of the symptoms of hand pain, paralysis, and/or severe paresthesia should they occur in the immediate postoperative period after AVF or AVG creation.

2. Moderate pain and/or paresthesia/weakness that requires pharmacologic management and occurrence is unrelated to dialysis treatments. These patients may improve with physical therapy and other conservative measures or may require surgical intervention if the symptoms are refractory to less invasive treatment.
3. Severe pain and/or neurologic symptoms that are debilitating to the patient. In the absence of these symptoms, the occurrence of ischemic tissue loss is also considered severe. Patients with this level of steal require surgical intervention to either relieve symptoms or preserve tissue/limb function.

What are the risk factors for developing arterial steal? Are there any preoperative criteria that can accurately predict the development of significant arterial steal?

The most consistent risk factors for the development of significant steal are diabetes, female gender, and having a brachial-artery–based AVG. In addition to these risk factors, any patient with arterial occlusive disease in the extremity planned to be used for the access would be at risk. Our group (S. S. Berman, MD, unpublished data, 2002)

and the Norfolk group also identified that a digital brachial index measured in the access extremity of < 0.45 at the time of construction has a correlation with the subsequent development of clinically significant steal.¹

How often does arterial steal require a surgical intervention?

Clinically significant steal requiring an intervention occurs in 5% to 10% of patients.

What diagnostic testing do you perform for arterial steal?

My approach to all patients who manifest steal symptoms includes a duplex scan of the AVF/AVG to measure flow and look for any possible abnormalities in the access circuit, measurement of digital brachial index with and without compression of the access to quantify the level of access-related ischemia, and a detailed arterial duplex scan of the extremity to evaluate and map out the arterial inflow and arterial runoff vessels.

In addition, catheter-based arteriography of the extremity and the access is performed at the time of surgical intervention to correct the steal to both verify the anatomy and document improved perfusion after the intervention.

How do you differentiate between high-flow and low-flow steal? Why is this so critical to the proper treatment choice?

Differentiating high-flow from low-flow steal is based upon the flow in the access. There is no consistent agreement concerning methodologies to measure flow. We use duplex scanning because modern imaging systems contain algorithms to measure volumetric flow. For an AVF, the threshold value that separates high flow from low flow is 600 mL/min. For an AVG, that value is 800 mL/min.

The reason to make this distinction is somewhat intuitive. Access patency is related to flow. Using a flow-reduction procedure such as banding or revision using distal inflow (RUDI) on an access that already has marginal flow may indeed correct the steal, but has a high likelihood to lead to access thrombosis. As part of the workup for steal, it is critical to rule out arterial inflow lesions that could not only be contributing to steal, but also be responsible for a low-flow access.

What are the best treatments for high-flow and low-flow steal?

The available treatments for steal include:

1. *Access ligation*: This is clearly the most effective treatment in reversing the ischemia independent of low flow or high flow, but it creates the secondary challenge of creating a new access for the patient.
2. *Distal radial artery ligation*: Indicated for distal

radiocephalic AVFs, where the steal is uniquely a result of flow reversal in the radial artery distal to the AVF.

3. *Distal revascularization interval ligation (DRIL)*: Because this procedure does not impact the access flow, it is the treatment of choice for low-flow–related steal. Additionally, because the DRIL includes a bypass into the forearm branches of the radial, ulnar, or interosseous arteries, it is also the treatment of choice for patients who have severe occlusive disease in the proximal portion of these vessels as a contributing factor.
4. *Banding of the access*: This technique is only effective in high-flow–related steal. There is a myriad of techniques reported, including a simple suture placed around the proximal AVF with a 4 mm balloon in place to act as a mandrel for sizing, and the use of expanded polytetrafluoroethylene cuffs. Banding is most consistently successful when performed concurrently with access flow measurements to minimize the risk of reducing the access flow below a critical threshold and thereby minimizing the risk of access thrombosis.
5. *RUDI*: This is an effective treatment for high-flow steal because it moves the inflow of the AVF/AVG to a smaller, more distal artery.
6. *Proximalization of the arterial inflow (PAI)*: This is also an effective treatment for low-flow or high-flow steal. PAI moves the inflow to the proximal brachial or axillary artery; therefore, there is no reduction of flow to the access. Moreover, by moving the inflow to the axilla, PAI also reduces the flow reversal in the distal forearm related to the proximity of these vessels and the elbow-based inflow.

If you band a low-flow steal, what is the consequence?

Banding a low-flow AVG/AVF has two potential consequences: too much banding, and the access will thrombose; or not enough banding, and the steal symptoms will persist.

If you DRIL a high-flow steal, what is the consequence?

Doing a DRIL procedure on a high-flow AVG/AVF is usually of no consequence because the access flow is unaffected; however, three factors are critical:

1. The inflow of the DRIL is positioned far enough away from the access (5 to 7 cm) to minimize steal physiology through the DRIL.
2. The distal anastomosis of the DRIL bypass goes to the dominant forearm artery feeding the hand.
3. The ligation component of the DRIL should be proximal to the termination of the radial/ulnar collaterals so that these vessels do not continue to demonstrate steal physiology during intraoperative imaging.

What are some other causes of diminished blood flow to the hand?

The most common cause of diminished blood flow to the hands in the renal failure population is arterial occlusive disease. The DRIL offers the opportunity to bypass these occlusions if there is an acceptable distal target (radial, ulnar, or interosseous artery) feeding the hand. Contemporary minimally invasive revascularization techniques (balloon angioplasty and atherectomy) are finding some application in this setting in improving blood flow to the hand by directly addressing the occlusive disease either alone or concurrently with other techniques to treat steal.

Are there any other questions we should have asked you? Are there any other tips to share?

In the context of vascular access–related steal, one of the most difficult problems is distinguishing that diagnosis from ischemic monomelic neuropathy. Ischemic monomelic neuropathy usually occurs immediately after access creation, and its symptoms are like steal in the absence of measurable ischemia. Unfortunately, in most cases, the only treatment is ligating the access. It is therefore critical to make sure patients and their caregivers understand the urgency in the need for prompt and thorough evaluation of the symptoms of hand pain, paralysis, and/or severe paresthesia should they occur in

the immediate postoperative period after AVF or AVG creation.

It is also imperative, given the incidence of diabetes, neuropathy, and peripheral artery disease in the renal failure population that access surgeons carefully evaluate and document preoperative vascular, motor, and sensory function of a patient's hand so that early detection of access-related pathology can be enhanced.

An additional pathology that can add to diagnostic confusion in this setting is carpal tunnel syndrome. Because access ligation or revascularization is not helpful in this setting and would result in the unnecessary sacrifice of the AVF/AVG, it is imperative to exclude the diagnosis of carpal tunnel syndrome in any patient who develops pain and/or neurologic symptoms in the hand after access creation. ■

1. Goff CD, Sato DT, Bloch PH, et al. Steal syndrome complicating hemodialysis access procedures: can it be predicted? *Ann Vasc Surg.* 2000;14:138-144.

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Dialysis Cannulation: Direction of Bevel and Blood Flow

Discussing tips and tricks to optimize cannulation.

WITH MATTEO TOZZI, MD



What are your tips for successful cannulation of a vascular graft?

Success in the cannulation process is achieved through close collaboration between nephrologists, nurses, and vascular surgeons. Convening on the discussion of complex cases is a necessity to make a step forward in immediate cannulation. The careful application of simple rules should reduce major complications such as infection, pseudoaneurysm, and hematoma.

What is the required training for a dialysis nurse or technician to perform duplex ultrasound cannulation?

In 2017, compact duplex ultrasound in the hemodialysis unit is essential for nurses and nephrologists. Training starts with a basic course that teaches how to evaluate the vascular access. Ultrasound cannulation is learned in a few hours of frontal teaching and some practice during hemodialysis sessions. Within 1 month of ultrasound evaluation of vascular accesses and cannulations, the nurses and nephrologists typically possess all the necessary skills.

Is it standard practice to use local anesthesia prior to vascular graft cannulation?

No, in our center, we currently do not have an extensive use of anesthesia. In cases of accentuated pain or special sensitivity, a patient may need a small dose of anesthetic gel on the skin before antiseptic preparation and cannulation.

What are the antiseptic options used to cleanse the patients' site prior to cannulation?

In our center, all patients' upper arms are cleansed with surgical soap before their dialysis session. The nurse disinfects the cannulation area with chlorhexidine 2% for 30 seconds.

Do nurses usually wear sterile gloves for vascular graft cannulations?

Yes. We prefer to use sterile gloves for all prosthetic vascular accesses because bacteria contamination from the skin to the needle increases the risk of subcutaneous tissue infection, hematoma, or infection of the graft. This is a crucial point, and we use sterile gloves for every cannulation for the life of the graft.

In what time frame is a non-early cannulation vascular graft typically needed for hemodialysis? What about for early cannulation?

The time to first cannulation of a standard arteriovenous graft is an average of 14 days. An early cannulation graft, such as the GORE® ACUSEAL Vascular Graft, has completely changed this. We can use the graft within 24 hours of surgery. In the case of the GORE ACUSEAL Vascular Graft, it is possible to perform immediate cannulation within a few hours after the surgery. However, with immediate cannulation, if the needle exit site is not held for 10 to 15 minutes to achieve hemostasis, there can be a higher percentage of periprosthetic hematoma.

Periprosthetic hematoma may complicate subsequent cannulations. Today, in centers that use early cannulation grafts, the percentage of periprosthetic hematoma is very low. In our center, the number of hematomas after immediate cannulation is greatly reduced by the experience of the nurses.

If cannulating within the early postoperative period, what needle gauge and blood flow rates are preferred?

With an early cannulation graft, we prefer using a 17 gauge needle for 2 weeks with a 200 mL/min blood flow rate.

Why do you prefer the small-gauge and low blood flow rates?

We prefer a smaller needle for first-time use of the graft because of the possibility of larger needles to cause hematoma, and this is problematic for subsequent cannulations of the graft. It is important to perform the first hemodialysis with a low blood flow rate (200 mL/min) to reduce complications in the vein near the anastomosis with the graft.

If the patient starts with a small-gauge needle and low blood flow rates, how do you increase to larger-gauge needles and higher blood flow rates?

It is possible to increase the flow and the needle size if necessary after 2 weeks. After 2 weeks, the needle can be increased from 17 to 16 gauge, and then after another 2 weeks, from 16 to 15 gauge. We also increase the flow from 200 to 300 mL/min after 2 weeks. The increase of the flow is mandatory with respect to the venous pressure. If the venous pressure is high, we maintain either low-flow hemodialysis or treat any areas of stenosis.

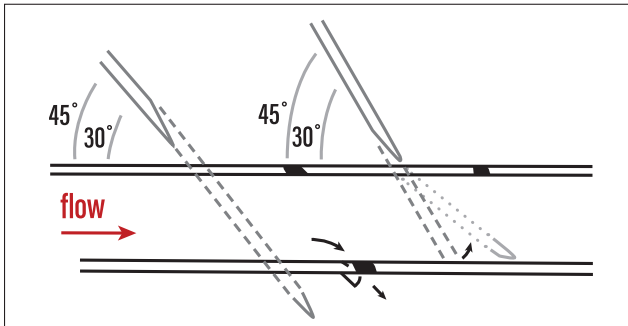


Figure 1.

Which direction is preferred for the bevel of the needle during cannulation?

The posterior wall of the graft is vulnerable to intragraft stenosis and the anterior wall to pseudoaneurysm, so we cannulate with the bevel down. When the needle is bevel up, it is possible to damage the posterior wall with the sharp part of the needle. With the bevel down, it is impossible to create this damage. If we reduce the damage to the posterior wall, we reduce the risk of intragraft stenosis (Figure 1).

After 1 year of utilizing the needle bevel-down technique, the rate of hematoma and pseudoaneurysm formation in our prosthetic vascular access grafts has decreased. The only change we made was the direction of the needle bevel, so this is a most important cannulation technique.

If a back wall puncture occurs during cannulation, what is the course of treatment?

Currently, there is unfortunately no treatment for back wall injury. There is a direct correlation between damage of the posterior wall of the graft and posterior wall stenotic lesions. A graft with posterior wall damage has a very short life span; thrombosis occurs frequently due to the stenotic lesions. This is also why it is so important to cannulate with the needle bevel down.

In what direction is the venous needle placed?

In vascular grafts, we normally prefer the direction of the venous needle to be in the direction of venous flow. This is the same for an arteriovenous fistula. The needle direction is in the same direction as the blood flow in the vein, as this is important to reduce any resistance of the returning blood flow into the venous system.

In what direction is the arterial needle placed?

Needles placed with the flow of blood create a better flap for hemostasis, so the direction of the needle is with the flow in the vein and with the flow in the artery (Figure 2).

Is antibiotic ointment applied on the needle exit site?

No, we do not use a topical antibiotic. We cleanse the cannulation area with chlorhexidine, but we do not use a topical antibiotic after cannulation.

How do you secure the needles during dialysis?

We use medical tape to secure the needles to the skin. It is very important to secure the needles to the skin of the patient's arm to avoid accidental removal of the needle from the graft.

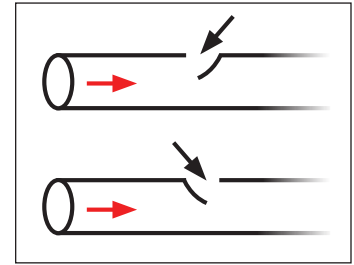


Figure 2.

After the dialysis treatment, which needle is removed first? Why?

We remove the arterial needle first because we continue to use the venous needle for the return of blood to the patient.

Is the pressure to the needle and vascular graft exit site held with fingers or clamps?

We do not use clamps because they may be traumatic to the grafts—in patients with low flow/pressure, it is possible to occlude the graft with the clamp. It is important to instead apply light pressure with the fingers. During the first treatment, the nurse will use a sterile gloved finger to achieve hemostasis. During the second treatment, the patient will be asked to hold the site himself using a sterile glove.

What type of bandage is used to cover the needle exit site?

Slight compression with a sterile 2 x 2 gauze is used to achieve hemostasis. Then, two wound dressings are placed over the needle exit sites.

Do you have any other tips to share?

Always listen with a stethoscope for the bruit in the prosthetic graft or feel the thrill with fingers before needle cannulation. This is important to avoid cannulating a thrombosed graft. I believe that the life of a vascular prosthetic access is preserved with this management, and it is the responsibility of each operator to reduce the complication rate and prolong the life of the graft for as long as possible. It is very important for all technicians, nurses, vascular surgeons, nephrologists, and interventional radiologists. ■

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CASE REPORT

An Anastomotic Technique for Small Arteries in Arteriovenous Graft Creation

BY MATTEO TOZZI, MD

A 35-year-old African woman presented to our institution with stage 4 chronic kidney disease and HIV-related nephropathy. Comorbidities were hypertension and dyslipidemia. In April 2016, she was admitted to our hospital for an acute abdomen. X-ray imaging documented pneumoperitoneum, and CT scan raised suspicion of a bowel perforation due to acute diverticulitis. Intravenous broad-spectrum antibiotic, anti-inflammatory, and hydration therapy were started immediately. Abdominal cavity exploration confirmed the descending colon perforation, which was treated successfully with segmental resection and immediate recanalization. Unfortunately, the postoperative course was characterized by rapid deterioration of her residual renal function.

PROCEDURE

The patient's compromised clinical conditions and medical history necessitated the nephrologists perform a joint evaluation with an anesthesiologist and vascular surgeon. An early cannulation arteriovenous graft creation was decided as a better option than a central venous catheter for urgent hemodialysis. Preoperative ultrasound examination documented a small, calcific artery (2.2 mm radial artery diameter) and a suitable venous network (4.3 mm average cephalic vein diameter). Locoregional anesthesia was performed with axillary brachial plexus block. A radio-antecubital forearm loop was created with a 6 mm polytetrafluoroethylene graft with CBAS Heparin Surface (GORE® ACUSEAL Vascular Graft) 18 days after the segmental resection and recanalization.

Because of the small caliber of the artery, a modified anastomosis (Varese technique) was performed (Figures 1 and 2) to reduce the anastomosis area and, consequently, the risk of steal syndrome. Operative time was 45 minutes, and exiguous blood loss (approximately 35 mL) was registered. No intraoperative complications were seen, and the patient started hemodialysis through the graft the day after implantation. Postoperatively, she started antiplatelet therapy with 100 mg of acetylsalicylic acid and 75 mg of clopidogrel per day. The patient was discharged after 2 days (postoperative day 20). Follow-up was closely conducted with clinical and ultrasound examination every 10 days for the first month and monthly thereafter.

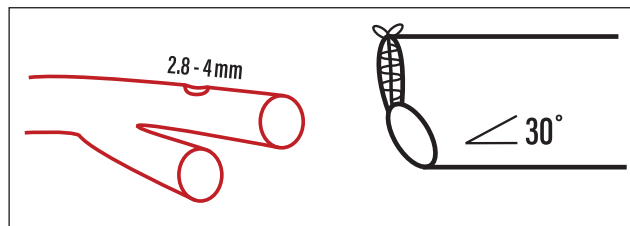


Figure 1. Arterial anastomosis (Varese technique): obliquely cutting the graft and suturing the straight part to obtain an opening of approximately 30° and 3 to 4 mm. Arteriotomy is performed with a 2.8 to 4 mm arterial punch, depending on the diameter of the vessel, and sutured with the parachute technique.

RESULTS

At the end of August 2016, after 3 months of hemodialysis, the patient suffered from severe posthemodialysis hypotension, and consequently, a graft thrombosis was registered. The patient was immediately admitted to our department. Ultrasound examination confirmed the clinical diagnosis but documented a significant increase in the diameter of the antecubital vein, the whole arm cephalic axis (average diameter, 6.4 mm), and the brachial and radial arteries (4.3 mm at the anastomosis site). Locoregional anesthesia was performed with axillary brachial plexus block, and 1 g of prophylactic vancomycin was administered intraoperatively. During the intervention, the graft was completely and gently removed, and a native fistula was created through a side-to-side anastomosis (approximately 4 mm) between the same radial artery and antecubital vein site as the prior graft anastomosis (Figures 3 and 4). Adequate hemostasis was performed to avoid bleeding during the subsequent hemodialysis conducted 4 hours after surgery to correct the electrolytic imbalance. Postoperatively, antiplatelet therapy with 100 mg of acetylsalicylic acid per day was continued preventively. The flow rate documented on the cephalic vein at discharge was 1,200 mL/min. In March 2017, after 6 months, the fistula was still functioning normally.

DISCUSSION

The idea of a prosthesis used as a bridge to vessel maturation in native fistulas is not new¹; however, early cannulation grafts have radically changed the perspective on bridge treatments. While a conventional graft needs

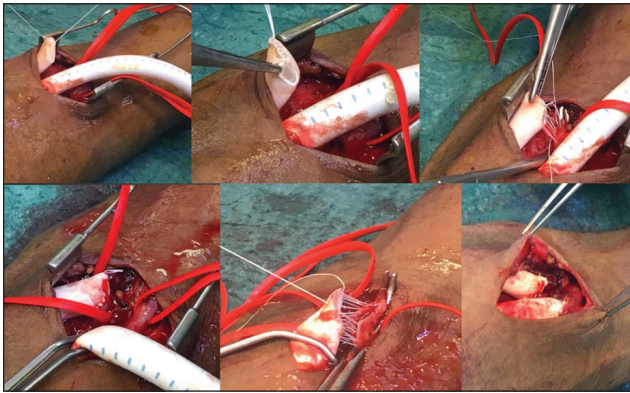


Figure 2. Forearm loop with the GORE® ACUSEAL Vascular Graft in the radio-antecubital vein.



Figure 3. Harvesting of the prosthetic loop after maturation of the basilic and cephalic veins in the upper arm.

at least 2 weeks before puncturing, an early cannulation graft permits an immediate cannulation, allowing the maturation of venous vessels and avoidance of central venous catheter placement.¹ The presented case emphasizes how accurate planning for vascular access does not need to start with the old paradigm of fistula first to achieve the same goal through use of allogenic material. Although this method appears to be intricate with multiple surgical interventions required, it is linear, allows the preservation of vascular assets, and avoids future central venous catheter-related complications.

In our department, we have also used an alternative technique. In the case of unsuitable cephalic veins, our target becomes the basilic vein, which can be transposed

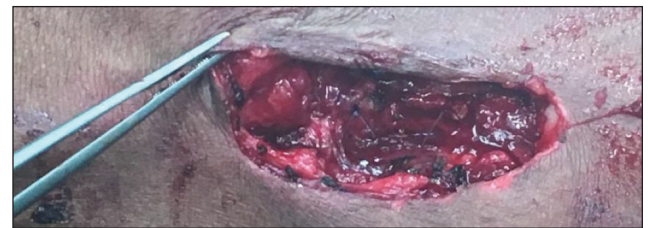
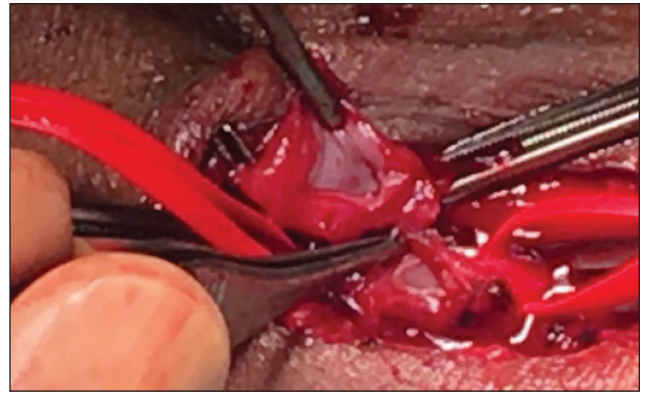


Figure 4. Side-to-side anastomosis in the radio-antecubital vein for proximal native fistula.

after maturation. Graft removal must be scheduled only after basilic vein—first cannulation (three-stage technique).

Additionally, the presented case documents another characteristic of the bridge approach: the aptitude to increase the diameter of small or calcific arteries. In fact, as reported in the literature, blood steal produced by the fistula induces an arterial hypertrophy.² Consequently, we started to set up temporary prosthetic access with a modified anastomosis to reduce the risk of arteriovenous access ischemic steal in the subsequent definitive fistula. The modified anastomosis technique (Varese technique, Figure 3) gave us encouraging results. Creation of an early cannulation graft with a standard 6 mm prosthesis on small vessels can prevent technical difficulties associated with the high risk of arteriovenous access ischemic steal. ■

1. Aitken EL, Jackson AJ, Kingsmore DB. Early cannulation prosthetic graft (Acuseal) for arteriovenous access: a useful option to provide a personal vascular access solution. *J Vasc Access.* 2014;15:481-485.

2. Miller GA, Hwang WW. Challenges and management of high-flow arteriovenous fistulae. *Semin Nephrol.* 2012;32:545-550.

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CASE REPORT

Combining Dialysis Access Technologies to Provide a Solution for a Complex Arteriovenous Access Problem

BY SCOTT S. BERMAN, MD, MHA, FACS

A 37-year-old African American woman with chronic kidney disease requiring hemodialysis presented to our institution. The etiology of her renal failure was multifactorial, including insulin-dependent diabetes mellitus, hypertension, and systemic lupus erythematosus. Additional significant comorbidities included morbid exogenous obesity with a body mass index of 37 kg/m² and active tobacco use. She is left handed and was initiated on hemodialysis 6 months prior to presentation using left-sided tunneled dialysis catheters (TDCs) by her nephrology team. She was deemed to not be a candidate for an autogenous arteriovenous fistula (AVF) due to inadequate upper extremity venous anatomy. Before transfer to our facility, she had recently completed a course of intravenous antibiotics for MRSA line sepsis, which also required removal of her left internal jugular vein TDC. Her current hemodialysis access consisted of a poorly functioning right femoral TDC.

TREATMENT OPTIONS

This challenging patient needed permanent hemodialysis access, preferably with an arteriovenous fistula or arteriovenous graft (AVG). She had already experienced the disadvantages of TDCs, including catheter sepsis and currently had a poorly functioning femoral TDC. Placement of a new upper body TDC should be a last resort in this type of patient, who has never had an upper extremity arteriovenous (AV) access. Repeat venous duplex imaging of her upper extremities verified inadequate venous anatomy for an AVF, although imaging of her arteries and veins was suboptimal due to her body habitus. Given these limitations, the initial treatment plan was to explore her right axilla (nondominant extremity) to directly evaluate the arterial and venous anatomy for suitability for an AVG. To further limit her exposure to TDCs, use of an early cannulation AVG (GORE® ACUSEAL Vascular Graft) was also part of the treatment strategy.

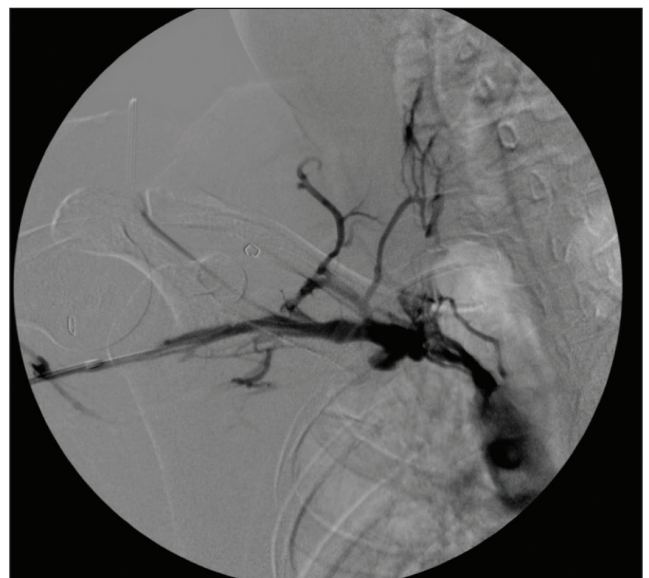


Figure 1. Venogram via a 5 Fr sheath in the basilica vein demonstrating diseased axillary, subclavian, and brachiocephalic veins.

PROCEDURAL DESCRIPTION

The procedure was performed in the hybrid endovascular operating room under general anesthesia. An axillary incision was used to gain exposure of the proximal brachial artery and the basilic-axillary vein junction. The axillary artery was soft and patent, but extremely small in diameter (3 mm). The junction of the basilic-axillary vein junction was sclerotic. Using a 5 Fr micropuncture sheath system, a venogram was performed (Figure 1). This demonstrated diffuse disease in the axillary and subclavian veins with a chronic, recanalized-appearing brachiocephalic vein emptying into a normal-looking superior vena cava. This finding was unexpected given the absence of any

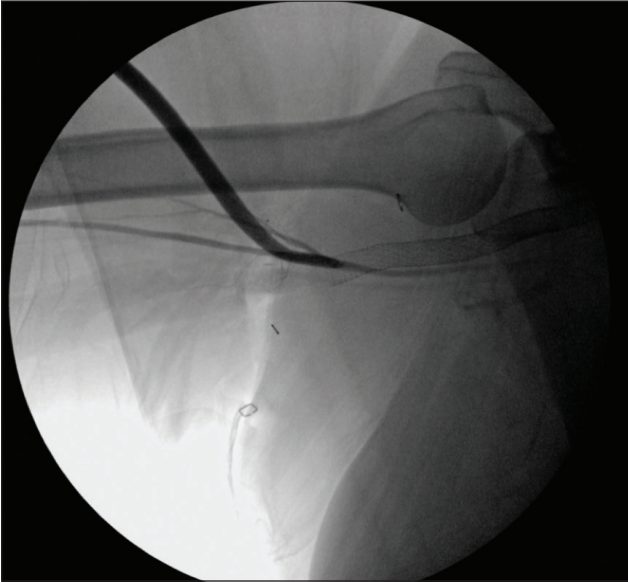


Figure 2. A 4 mm to 7 mm GORE® ACUSEAL Vascular Graft connected to the proximal brachial artery.

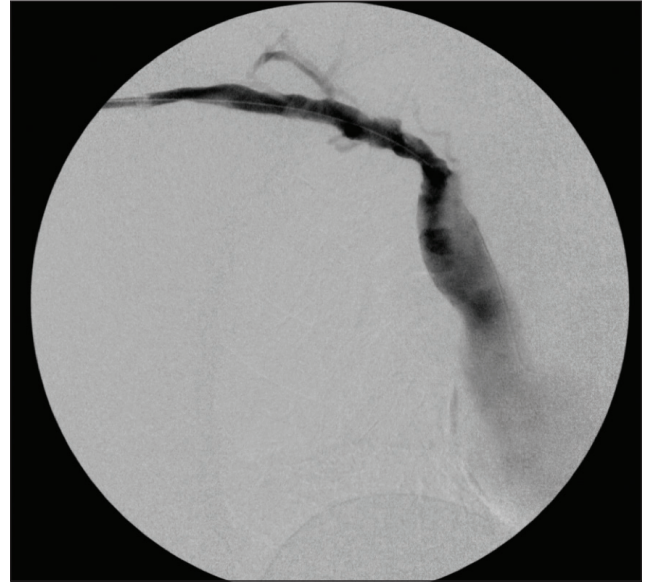


Figure 3. Venogram after 9 mm balloon angioplasty of the subclavian vein–brachiocephalic vein. Residual disease noted at the sheath entry site.

history of venous occlusive disease in the right upper extremity along with the absence of any clinical signs of upper extremity central vein occlusive disease. Given the small size of the brachial artery and the chronic occlusive disease in the axillary and subclavian vein, the treatment plan had to be altered to accommodate these challenges. It was decided to address the small brachial artery by using a 4 mm to 7 mm tapered GORE ACUSEAL Vascular Graft to create the AVG stick zone on the dorsolateral surface of the bicep. The 4 mm end of the GORE ACUSEAL Vascular Graft was anastomosed end-to-side to the proximal brachial artery (Figure 2). The axillary-subclavian vein disease would be treated using a GORE® Hybrid Vascular Graft, which incorporates a nitinol-reinforced segment (NRS) on one end of a 6 mm expanded polytetrafluoroethylene (ePTFE) graft.

After crossing all the venous occlusive disease with a guidewire, the microsheath was replaced with a 9 Fr sheath, and balloon angioplasty of the subclavian-brachiocephalic vein disease was accomplished with a 9 mm ultra-high-pressure balloon with a very acceptable result (Figure 3). The 9 Fr sheath was then exchanged for a 14 Fr peel-away introducer sheath. A GORE Hybrid Vascular Graft with a 9 mm x 10 cm NRS was threaded over a 9 mm angioplasty balloon and then introduced over the wire through the 14 Fr peel-away sheath, advancing the NRS segment under fluoroscopy beyond the point of disease in the subclavian vein. The NRS segment was deployed and immediately expanded with the preloaded 9 mm balloon. The procedure was completed by performing an end-to-end anastomosis between the GORE ACUSEAL Vascular Graft and the GORE Hybrid Vascular Graft through a

counterincision just proximal to the antecubital fossa to create the apex of the upper arm loop AVG. A completion fistulagram demonstrated brisk flow through the AVG and a widely patent venous anastomosis created with the NRS of the GORE Hybrid Vascular Graft (Figure 4).

RESULTS

The patient had an uneventful recovery and was discharged home on postoperative day 3. She underwent dialysis through her right upper arm loop AVG using the GORE ACUSEAL Vascular Graft portion as the cannulation zone on postoperative days 1 and 3 and had her right femoral TDC removed on postoperative day 1. She has been dialyzing now for 2 months without incident. Recent duplex imaging of her right upper arm AVG demonstrated a flow rate of 2,500 mL/min with spiral flow noted throughout the graft (Figure 5).

DISCUSSION

This patient presented significant challenges for hemodialysis access, including the need for immediate access, the need to avoid TDCs, and disadvantaged anatomy that included small arterial inflow and diseased venous outflow. Before the GORE ACUSEAL Vascular Graft and GORE Hybrid Vascular Graft were available, management of this patient would have likely required the use of a standard PTFE AVG combined with a HeRO® Graft (Merit Medical Systems, Inc.) to overcome the venous outflow pathology. In addition, the lack of a US Food and Drug Administration (FDA)–approved early cannulation graft would have necessitated the patient to have further



Figure 4. Completion fistulagram shows wide patency of the 9 mm x 10 cm nitinol-reinforced segment of the GORE® Hybrid Vascular Graft emptying into the proximal subclavian vein.

TDC contact time while the upper extremity AVG healed. This time frame is quite variable, ranging from 2 to 6 weeks.

The GORE ACUSEAL Vascular Graft is the only FDA-cleared early cannulation graft for AV access in the United States. It was only logical to use this technology in this patient given her prior history of TDC complications. Use of the GORE ACUSEAL Vascular Graft eliminated the immediate risk of further TDC complications, as the patient's AVG could be used on the first postoperative day, and her TDC could be removed. The unexpected finding of venous outflow disease created a secondary challenge that highlights the advantage of the GORE Hybrid Vascular Graft. The 10 cm NRS segment allows for the simultaneous creation of a sutureless venous anastomosis and treatment of venous outflow disease using ePTFE-encapsulated self-

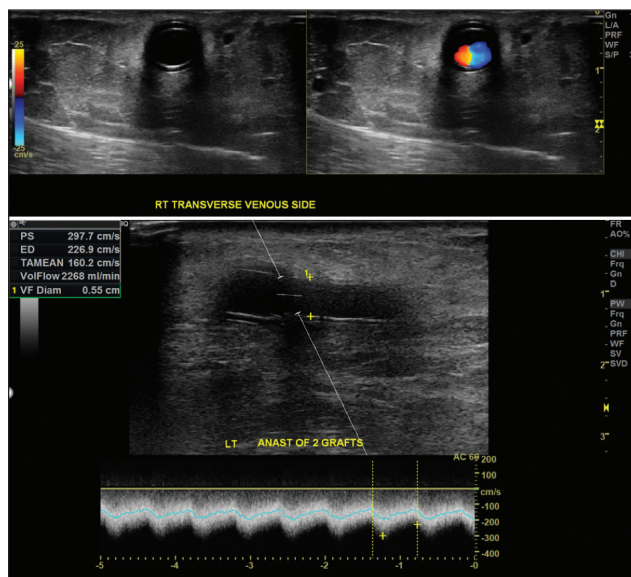


Figure 5. Postoperative duplex scan of the right upper arm loop arteriovenous graft demonstrating spiral flow with a flow rate of 2,200 mL/min.

expanding nitinol stent technology. Combining the GORE ACUSEAL Vascular Graft and the GORE Hybrid Vascular Graft took full advantage of the unique attributes of each device to specifically target this patient's need for early cannulation, a tapered graft to accommodate small arterial inflow, and a durable solution for her venous outflow disease. ■

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CASE REPORT

Creating a Sutureless Anastomosis at the Venous Outflow

BY JOHN R. ROSS, MD

A properly functioning dialysis access requires three things: (1) good arterial inflow, (2) a patent conduit (eg, native venous fistula, synthetic graft, in-dwelling central venous catheter), and (3) unobstructed outflow. Patients with chronic end-stage renal disease (ESRD) and a history of various accesses often suffer from venous occlusion and stenosis somewhere within the entire circuit. The introduction of arterial flow into the venous system often results in the formation of stenotic lesions. This is the primary failure mechanism of arteriovenous fistulas and grafts.

Because of this, adequate outflow veins (appropriately sized, accessible, free of stenosis, and not having valves) are often difficult to locate and often force accesses to be placed in dominant arms, thighs, or elsewhere. A patient with challenging veins who requires placement of a new access is often challenged with compromised, inaccessible veins, veins with valves present making anastomosis placement a challenge, or preexisting stents or stenoses. ESRD patients also often present with obese arms, making surgical dissection to adequate veins challenging.

The GORE® Hybrid Vascular Graft (HVG) allows percutaneous creation of an endoluminal, end-to-side anastomosis. The HVG is a single-lumen surgical graft composed of two structural components, an expanded polytetrafluoroethylene (ePTFE) vascular graft, and a constrained ePTFE section supported with nitinol, known as the Nitinol Reinforced Section (NRS). The NRS is designed to be inserted into the outflow vessel, allowing the creation of an end-to-end anastomosis deep into a vein that may not be otherwise accessible to allow performance of conventional anastomosis. In the following case, a patient with multiple failed accesses benefited from the placement of a HVG, which allowed percutaneous placement of the venous outflow of the graft deep in the axilla.

CASE REPORT

A 62-year-old elderly man with ESRD presented with complications associated with a violated axilla concomitant with multiple failed accesses, including basilic vein transposition and one upper arm graft placement. The patient was currently dialyzing through a catheter placed on the left side, suggesting that there was a problem in the central venous system on the right side. Preoperative ultrasound

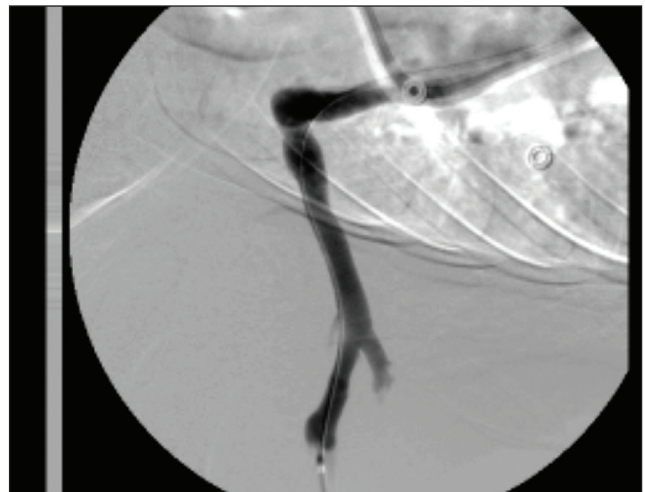


Figure 1. Initial angiogram.



Figure 2. Deployed GORE® Hybrid Vascular Graft prior to balloon angioplasty.

vessel mapping showed adequate brachial and radial arterial flows and pressures, but inadequate veins in the upper arm.

Needle access was gained, and an 8 Fr introducer (Merit Medical Systems, Inc.) was placed in the proximal basilic vein without difficulty using sonographic guidance. A 0.035-inch Roadrunner® PC guidewire (Cook Medical) was introduced all the way into the superior vena cava. Venography showed

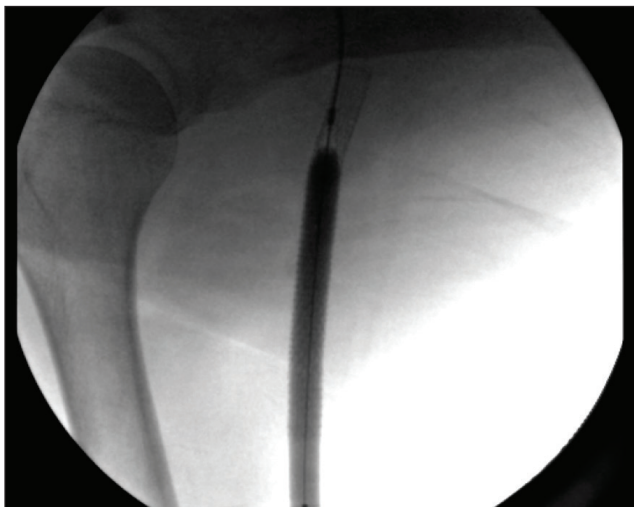


Figure 3. Balloon angioplasty of the NRS.

that there was no evidence of high-grade central stenosis, and the location of valves was noted, as is paramount to determine the landing zone of the tip of the NRS (Figure 1). The optimal landing zone of the NRS should be at least 2 cm lateral to (or beyond) the valve.

After obtaining initial fluoroscopic imaging and deciding that there was an adequate venous landing zone for the NRS, a surgical cutdown was performed on the supra-antecubital brachial artery. A HVG with an 8 mm x 10 cm NRS was selected and was passed through a 14 Fr COOK® PEEL-AWAY® Sheath Introducer fluoroscopically and deployed per the instructions for use. There is always a stricture at the entrance of the NRS into the vein (Figure 2), and this is immediately remedied when ballooning the entire NRS with an 8 mm x 8 cm BARD® CONQUEST® PTA Dilatation Catheter (Figure 3).

After the NRS is deployed in the outflow vein, a tissue tunnel is created for the vascular graft component using a BARD® IMPRA® Kelly-Wick Tunneler followed by retrograde pullback of the graft through the tunnel. Special attention is given to ensure that there is no pleating, twisting, or kinking of the graft, especially at the transition zone (where the NRS meets the vascular graft component). A final angiographic run is performed by introducing contrast directly into the distal end of the HVG (Figure 4). The arterial anastomosis is conducted, and a simple end-to-side anastomosis in the usual fashion is accomplished.

CONCLUSIONS

There are many applications of the HVG in patients with complex anatomies. The NRS allows for the creation of outflow deep into the axilla and through obese arms. The NRS also allows placement through preexisting stents, stenotic lesions, and valves. By going percutaneously, the procedure is very efficient and can take approximately 20 to 30 minutes to complete. More importantly, the precision is far greater than surgically cutting down high in the axilla. In this case, we present the utility and

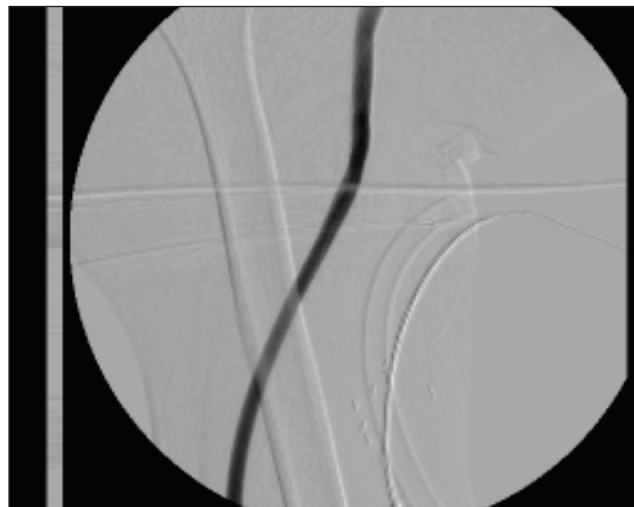


Figure 4. Final angiogram.

extraordinary usefulness of the HVG in a violated axilla, where conventional venous anastomotic techniques would have been extremely challenging, if not impossible.

The instructions for use for the HVG suggest oversizing the distal section of the NRS to the vein by 5% to 20%, which is consistent with other stents and stent grafts. In our experience, improved clinical outcomes have been obtained if the distal end of the NRS is undersized. Also, per the manufacturer's instructions for use, the placement of two stay sutures through the NRS is recommended to further anchor the NRS into the vein to avoid displacement of the NRS. Our experience has been that proper sizing of the NRS within the vein, with subsequent percutaneous transluminal angioplasty using a balloon to seat the NRS, obviates the need for these stay sutures. We have not experienced any migration or pulling out of the NRS.

Based on our historical results of the expectation of patency of the deployed HVG, the violated axilla is comparable, if not superior to conventional dialysis access vascular grafts. The HVG allows for the creation of dialysis access in patients with complicated anatomies and is a worthy alternative procedure to central venous catheter dependency. ■

Learn more about this case and the value of the GORE® Hybrid Vascular Graft in complex dialysis cases by visiting goremedical.com/hybridcase

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Disclosures: Physician training for Gore & Associates.

CASE REPORT

Extending the Range of Vascular Access in Anatomically Challenging Patients With the GORE® Hybrid Vascular Graft

BY PATRICIA ROSENBERRY, MS, BSN; SOO YI, MD; SILKE NIEDERHAUS, MD;
AND DAVID B. LEESER, MD, MBA

The GORE® Hybrid Vascular Graft (HVG) was approved for use in the United States in 2010¹ and was first used in 2011. One year later, the HVG with the 10 cm Nitinol Reinforced Section (NRS) was introduced in the United States. The device uses a deployable stent to achieve a percutaneous and sutureless venous anastomosis. This has provided many novel ways to maintain vascular access in some of the most challenging patients.¹⁻⁴ The HVG with 10 cm NRS has further extended the reach of the access surgeon to a landing zone at the border of or even within the thorax.

We present two cases of patients with poor axillary veins of small caliber and previously failed upper extremity accesses who underwent successful dialysis graft placement using the HVG with 10 cm NRS with the tip of the nitinol-reinforced stent graft within the distal axillary/proximal subclavian vein.

CASE 1

A 73-year-old right-hand-dominant woman with a history of hypertension, diabetes mellitus, morbid obesity, and end-stage renal disease presented for access placement. The patient had previously failed peritoneal dialysis. In addition, the patient also had a previous attempt at a percutaneous and open hybrid graft placement by another surgeon. Vein mapping showed no suitable veins for fistula creation, but did show a patent axillary vein on the left upper extremity. The patient was therefore scheduled for an axillary venogram and possible hybrid graft placement.

The patient was taken to the operating room, and a venogram showed that the axillary vein was small in caliber and did not open into a suitable vein to support a graft until close to the thoracic wall (Figure 1). Because the suitable vein was so high in the axilla and close to the chest wall, a HVG with 5 cm NRS would not have reached the appropriate landing zone within the outflow vein.

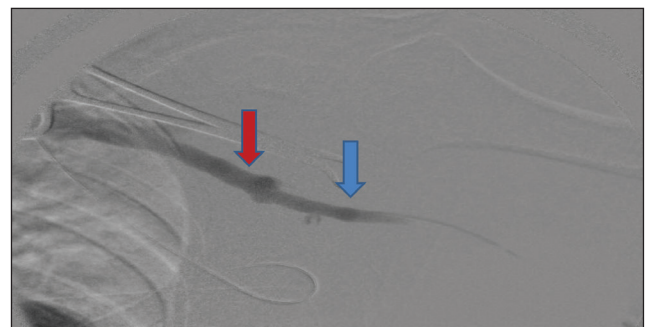


Figure 1. Venogram showing a small-caliber vein (blue arrow) and larger vein near the thoracic cage margin (red arrow).

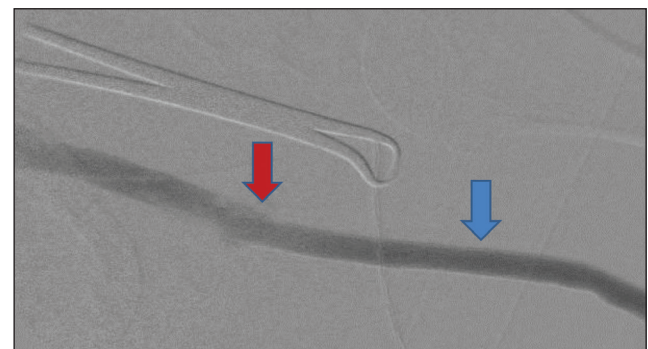


Figure 2. Deployed HVG.

Therefore, a graft with 10 cm x 8 mm NRS was placed with a landing zone that was in a vein of a suitable caliber (Figure 2). The patient was seen 2 weeks postoperatively, and the graft had a palpable thrill and audible bruit. The graft was used shortly after the postoperative visit without difficulty.

CASE 2

A 41-year-old right-hand-dominant woman with a history of hypertension, diabetes mellitus, obesity, and end-stage renal disease presented for access placement. The

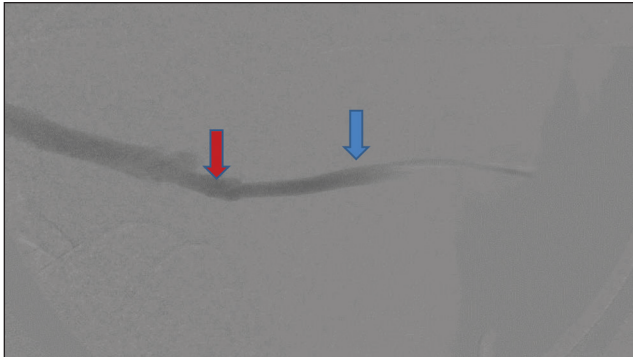


Figure 3. Venogram showing small-caliber vein (blue arrow) and larger vein near the thoracic cage margin (red arrow).

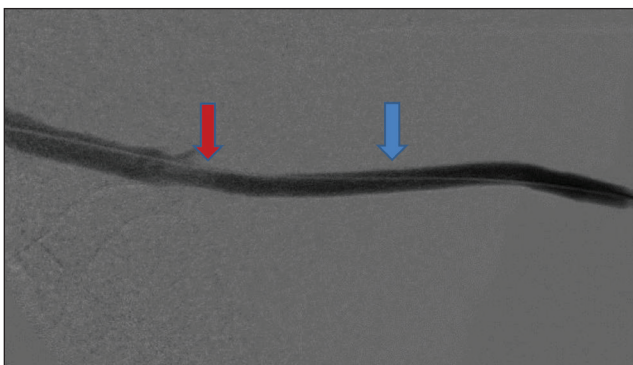


Figure 4. Deployed HVG.

patient had previously had a peritoneal dialysis catheter and a left upper extremity brachial-to-cephalic vein fistula that failed to mature. Because of the patient's obesity, she was scheduled for a left arm venogram and hybrid graft placement.

The patient was taken to the operating room, and a venogram again showed a poor outflow vein that was small in caliber and opened into an appropriate vein near the chest wall (Figure 3). In this case, a HVG with 10 cm x 7 mm NRS was placed, again to reach a more proximal suitable landing zone for the end of the stent portion of the graft (Figure 4).

The patient was seen postoperatively and had an audible bruit and a palpable thrill. The graft was used shortly after the postoperative visit.

DISCUSSION

The HVG is an important tool for all access surgeons to have in their toolbox. As seen in the previously described clinical scenarios, which support other published literature regarding the use of the HVG, this device allows for the preservation of upper arm access in patients with failing or failed upper arm grafts, morbid obesity, or previously stented venous outflow.⁴ This graft can avoid morbidity in obese patients (due to a smaller axillary incision) who present difficult access challenges with a secondary patency of over

60% at 1 year.⁵ The HVG allows for the creation of a sutureless anastomosis in cases where a standard graft could not be successfully placed. In these cases, the newer graft with the extended 10 cm stent portion allows for the creation of a graft with adequate outflow in a patient with a small-caliber or diseased axillary vein that does not open into a good outflow vein until very close to the thorax, where the vein becomes the subclavian.

Surgeons who develop the required skills to create access options using the HVG will become essential members of their access team and provide life-preserving care for patients with end-stage renal disease. As we all know, it is not the first access placed that is the most important; maintaining access in patients with decreasing options is the challenge. Access numbers four, five, six, seven, and beyond are the ones that sustain a patient's life line. The HVG with 10 cm NRS has an important role to play in the ongoing access challenge. ■

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CASE REPORT

Complex Vascular Access

BY FILIPPO BENEDETTO, MD, PhD; DAVID BARILLÀ, MD; NARAYANA PIPITÒ, MD, PhD;
AND DOMENICO SPINELLI, MD, PhD

In the past, one of the major problems and causes of failure in hemodialysis (HD) has been the lack of suitable vascular access (VA) options. Over the last few decades, the advent of prosthetic arteriovenous grafts (AVGs) and central venous catheters (CVCs) has given physicians the opportunity to choose the most appropriate VA for HD patients. However, the native arteriovenous fistula (AVF) remains the first choice for VA, especially because of the infectious and thrombotic complications more frequently associated with AVGs and CVCs.¹ Due to improved HD technique and treatment of comorbidities, dialysis patients now have a longer life expectancy. Because HD patients are now living longer, they require improved performance from their VAs so that the access can potentially last for decades. Prosthetic AVGs consist of an AVF made with prosthetic interposition between an artery and a vein and serves two purposes: (1) to be able to link two vessels that cannot be connected due to their distance,² and (2) to interpose a high-capacity prosthetic segment (between an artery and a vein) that can also be used for the insertion of HD needles. AVG creation is the second step of treatment, following AVF creation with native vessels.³

In selected cases, an AVG is indicated as the first line of treatment, such as in cases of paucity of autologous material; for those only needed for a short, predictable period of hemodialytic treatment (eg, in children)⁴; in patients with short obese limbs, in which the superficial veins are deep in the subcutaneous tissue; and finally, in patients with extreme vascular fragility (thrombocytopenic purpura), in whom a simple venous puncture produces wounds and serious hematomas.⁵ In the following case report, we describe a patient who underwent GORE® Hybrid Vascular Graft (HVG) implantation for HD access placement.

CASE REPORT

A 65-year-old man presented with end-stage renal disease and had significant comorbidities, including obesity (body mass index, 42 kg/m²), hypertension, type 2 diabetes, dyslipidemia, coronary artery disease (48%

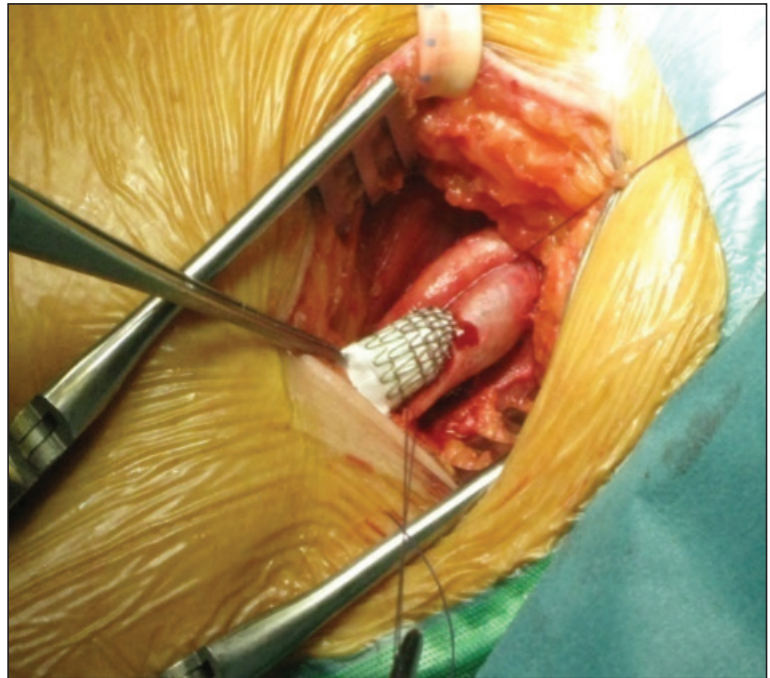


Figure 1. Venous anastomosis between the nitinol-reinforced section and the axillary vein.

left ventricular ejection fraction), and advanced chronic obstructive and restrictive pulmonary disease. He was also grade IV on the American Society of Anesthesiologists classification scale. A preoperative ultrasound scan demonstrated no available autologous veins for native AVF creation; thus, the patient was clearly unfit to receive a native AVF and underwent implantation of a 7 mm x 10 cm HVG in axillo-axillary configuration.

The procedure was performed under locoregional plexus block in a dedicated operating room equipped with a mobile fluoroscopic C-arm (BV Pulsera, Philips Volcano), because contrast angiography was required. Antibiotic prophylaxis with cephalosporin was given before the surgical incision.

The device implantation technique has previously been reported in detail.⁶ Briefly, the selection of graft size and access configuration is made by the surgeon,⁷ keeping in mind that because the graft, by design, occludes the distal venous outflow, the Nitinol Reinforced Section (NRS) should be placed as distal as is reasonable, based on vein diameter. The aim is to allow the chance for

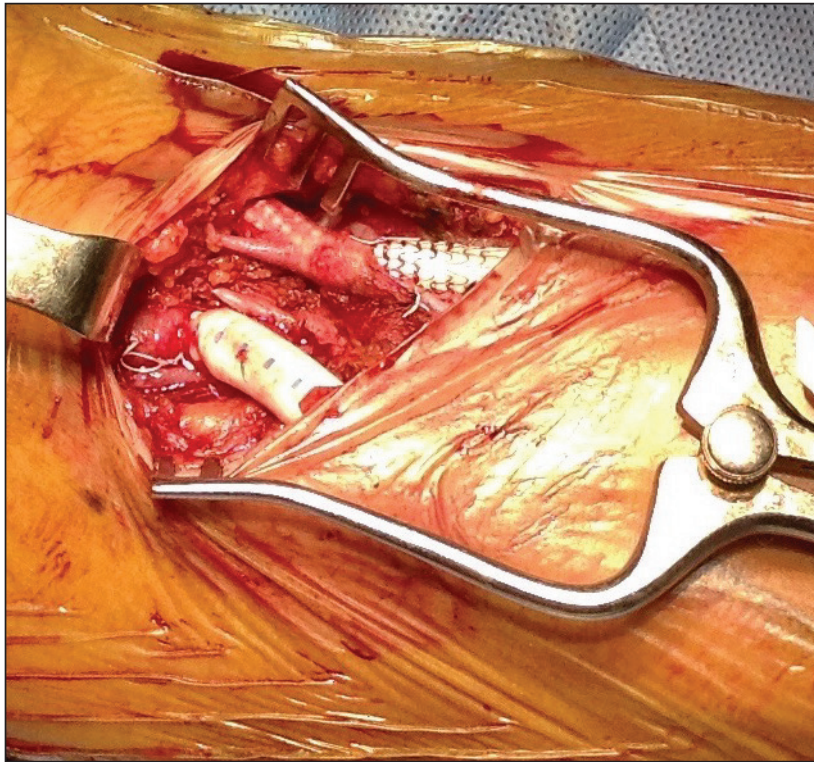


Figure 2. The axillo-axillary loop of the AVG.



Figure 3. Final angiogram.

future access placements and to preserve the confluence of venous branches whenever possible. Optimal NRS oversizing is considered to be 5% to 20%, as suggested in the instructions for use. In the reported case, an

axillo-axillary loop AVG was implanted through an axillary incision in the armpit. The nonstented part of the device was stretched and tunneled in the subcutaneous tissue. The NRS was inserted into the axillary vein through a venotomy. The NRS was then positioned into the vein, leaving the last 2 cm outside. It was then deployed and secured to the vein with two 6-0 polypropylene stitches (Figure 1) to prevent graft dislocation during the procedure, as suggested by the manufacturer. The arterial anastomosis was performed in an end-to-side fashion, as with traditional grafts. As a final step, balloon dilation of the stent was performed through direct puncture of the prosthesis. Completion control imaging was performed at the end of the procedure via contrast angiography (Figure 2) and confirmed technical success (Figures 3-5). The patient had an uneventful recovery.

CONCLUSION

The unique aspect of the HVG is its 5 or 10 cm NRS, instead of the sewn venous anastomosis. Because of this feature, the venous anastomosis is easier to perform and presents a straight geometry, which in turn might theoretically reduce the amount of turbulent flow.

Turbulence is a well-established factor in the development of intimal hyperplasia. Fillinger et al⁸ demonstrated a significant correlation between Reynolds number and intimal medial thickening at the venous anastomosis. The influence of the anastomotic angle on flow was studied using a porcine model.⁹ This consisted of an aortic graft interposition with an end-to-side configuration. Distal anastomoses were performed with angles of 90°, 45°, or 15°. The anastomoses of both 90° and 45° showed a recirculation zone, whereas no turbulence of the flow was documented in the 15° anastomoses. Nonetheless, the occurrence of intimal hyperplasia with HVG cannot be totally excluded, and

further studies are necessary for any conclusion to be drawn in this regard.

The duration of intervention is comparable to that of standard AVG implantation. Time spared by sutureless

anastomosis offsets the additional angiographic time. The HVG seems to be safe and effective and represents an improvement compared to standard polytetrafluoroethylene AVGs. ■

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CASE REPORT

The GORE® VIABAHN® Endoprosthesis for AV Access Revision

BY JOHN R. ROSS, MD

A 74-year-old patient presented with a thrombosed graft and outflow stenosis at the venous anastomosis approximately 6 months after receiving an upper arm arteriovenous (AV) graft for hemodialysis access. The graft was originally required to be placed in the patient's upper arm after it was determined that he was not a suitable candidate for AV fistula creation due to inappropriate venous vasculature. In this case, placement of an AV graft was the preferred method for AV access creation.

Upon returning with graft thrombosis and outflow stenosis, a superior venacavogram, axillary venogram, subclavian venogram, shuntogram, and a selective brachial arteriogram were performed. Thrombectomy was performed with the AngioJet (Boston Scientific Corporation) device to clear the clot within the graft. Severe outflow stenosis of approximately 90% was noted and initially treated with balloon angioplasty using a 7 mm x 8 cm angioplasty balloon. The high-grade stenosis was refractory to this treatment, which persisted even after further balloon inflation of the lesion with an 8 mm x 4 cm angioplasty balloon. The results were suboptimal with rebounding of approximately 50% after use of the second angioplasty balloon. We identified that the stenosis on the graft vein anastomotic and perianastomotic area was going to be compromised. As a result, placement of a GORE® VIABAHN® Endoprosthesis was selected to prolong functionality of the AV graft circuit.

To ensure good long-term results, careful selection of appropriate landing zones and device sizing was performed. In this case, a valve was present near the venous anastomosis. The GORE VIABAHN Endoprosthesis should be landed well before a valve, or if a sufficient landing zone with at least 1 cm of healthy vein prevents landing before the valve, the device should cross the valve completely. Landing immediately before a valve increases the likelihood of compromised patency. With respect to diameter selection, the GORE VIABAHN Endoprosthesis is sized to the venous outflow end of the graft to ensure sufficient wall apposition for anchoring and reducing the risk of migration. The recommendation is oversizing by 5% to 20%. Wall apposition to the vein at the outflow of the GORE VIABAHN Endoprosthesis is not required,



Figure 1.



Figure 2.

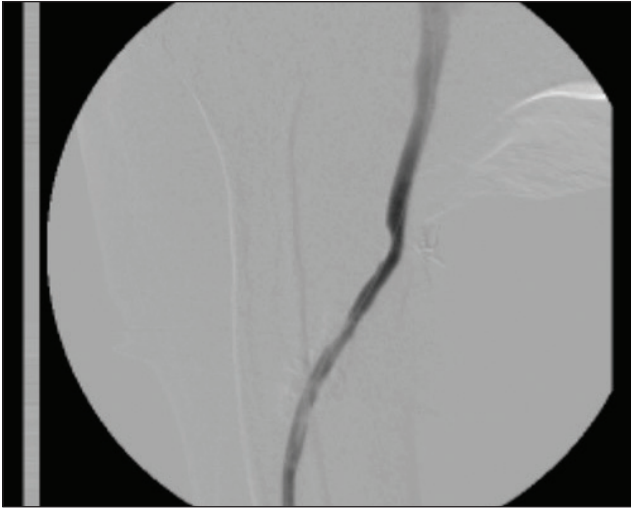


Figure 3.

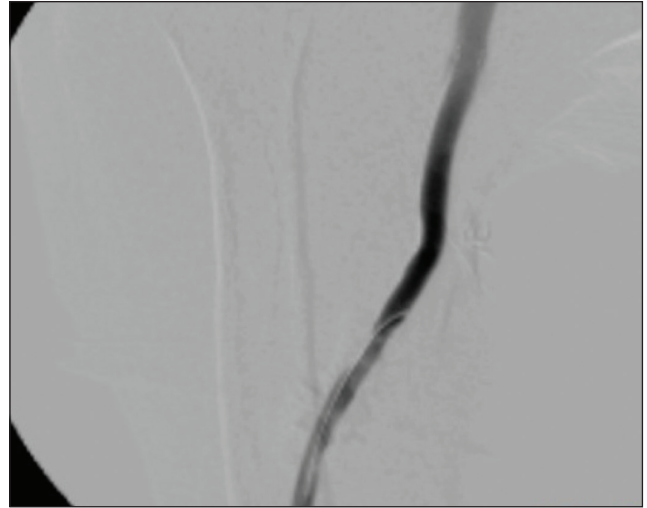


Figure 5.

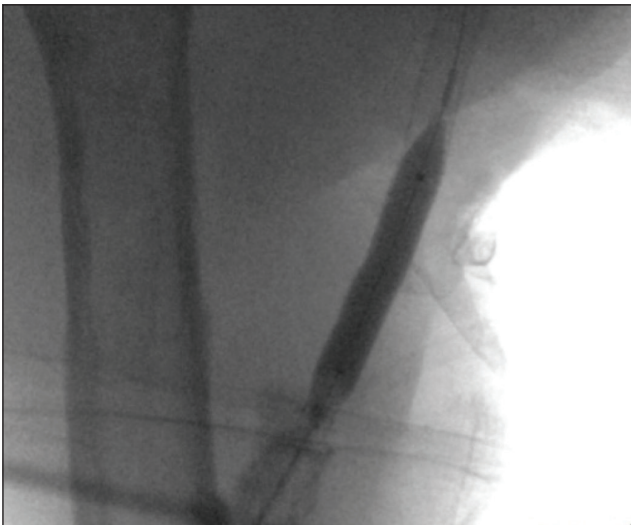


Figure 4.

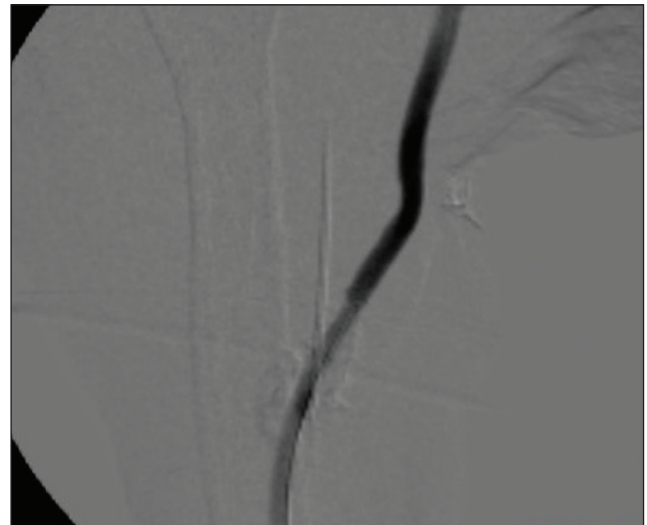


Figure 6.

and the device can be smaller in diameter than the outflow vein. A smaller device than the outflow vein allows for excellent flow through the device and better outcomes. In this case, an 8 mm x 10 cm GORE VIABAHN Endoprosthesis graft was selected and then placed across the outflow stenosis, which provided sufficient length to cover the outflow stenosis as well as extending to a landing zone that was not compromised by a valve. Postdilation was performed following successful device placement. A plug was pulled and macerated. An excellent thrill and bruit were restored to the access with excellent circulation to the hand.

DISCUSSION

This case illustrates the type of patient who can most benefit from the use of a stent graft for the treatment of venous outflow stenosis, such as those with recurrent problems or refractory type issues associated with

balloon angioplasty of the graft-vein anastomosis. These patients seem to respond very well to the use of stent grafts. In the current case, this is the characteristic vein-graft anastomotic stricture or perianastomotic stricture, where stent grafts can be expected to provide very good outcomes over a longer period compared with simple balloon angioplasty. ■

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CASE REPORT

Endovascular Salvage of an Abandoned AV Graft

Restoring and maintaining access patency using the GORE® VIABAHN® Endoprosthesis.

BY DANIEL V. PATEL, MD

Hemodialysis vascular access is vital for the life of dialysis patients. Although arteriovenous (AV) fistulas and grafts are preferred over dialysis catheters, many patients still rely on catheters until access maturation. Those with challenging anatomy may further require prolonged catheter dependence if an access cannot be created or maintained, and this can lead to catheter infections and sepsis. Here we describe the salvage of an abandoned AV graft and show the particular advantages of the GORE® VIABAHN® Endoprosthesis in dialysis access management.

CASE PRESENTATION

A 63-year-old woman with end-stage renal disease, chronic obstructive pulmonary disease, and hypertension was seen for an exchange of her nonfunctioning dialysis catheter. Upon further history, it was revealed that she had previously been on peritoneal dialysis until failure of the peritoneal membrane. She had converted to hemodialysis 1 year before her presentation to our institution and had remained dependent on dialysis via a right internal jugular tunneled catheter.

Over the course of the previous year, repeated attempts at an AV access creation had failed. Her left arm options were exhausted, and she had a right upper arm brachial artery to brachial vein polytetrafluoroethylene (PTFE) graft created 4 months before presentation.

One month after creation, the graft thrombosed. An endovascular thrombectomy was performed at an outside institution with a 6 mm balloon angioplasty at the venous anastomosis of the graft. Although there was initial restoration of flow, the graft rethrombosed within 24 hours. A surgical thrombectomy was then performed, and no discernible etiology for thrombosis was identified. The patient subsequently had successful dialysis for two treatments before the graft rethrombosed again. Another surgical thrombectomy was performed, with brisk flow reestablished after antegrade and retrograde sweeps with a Fogarty catheter. Fluoroscopy did not reveal an etiology for the graft failure during the second surgical

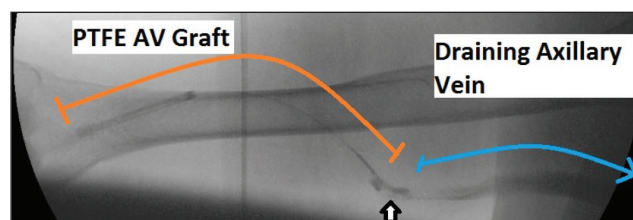


Figure 1. Pullback angiogram demonstrating thrombus and stenosis at the venous anastomosis (arrow).

thrombectomy. Flow was initially reestablished, but the access rethrombosed again shortly thereafter. The patient had maintained a right internal jugular vein catheter for dialysis access through this time.

Given failure of three separate thrombectomy attempts, the graft was abandoned at this point. Having exhausted upper extremity access options, the lower extremities were examined for a potential access. However, the patient had decreased pedal pulses bilaterally, and there was a concern for limb ischemia with femoral access.

When the patient presented to our center for her catheter exchange, she was contemplating placement of a femoral graft versus continued long-term catheter dependence. The catheter was exchanged without any issues.

The thrombosed graft was studied under Doppler ultrasound. The graft had organized thrombus present, and an apparent venous anastomosis stenosis was seen leading to a patent 9 mm axillary vein. At that time, the graft had been thrombosed for 3 months.

After a discussion with the patient and her nephrologist, we chose to attempt an endovascular salvage of the thrombosed graft, given the limited access options and continued catheter dependence. The thrombus volume appeared relatively small on Doppler through the graft. Given the apparently patent draining vein and intact graft, an endovascular salvage seemed feasible.

We initially cannulated the graft in a downstream direction. There was difficulty in passing a wire beyond the venous anastomosis, and an imaging catheter was used to pass a hydrophilic wire (0.035 inch Roadrunner wire,

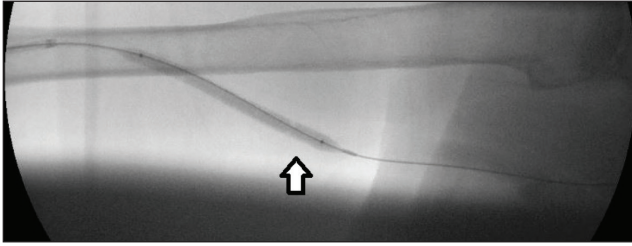


Figure 2. Angioplasty with a 7 mm x 8 cm balloon at the venous anastomosis stenosis (arrow) and thrombus.

Cook Medical) beyond the venous anastomosis and to the central veins. The patient was given 5,000 U of heparin and sedation. A pullback angiogram was performed, confirming a venous anastomosis stenosis and thrombus through the graft (Figure 1).

A 7 mm x 8 cm angioplasty balloon was advanced to the stenosis. The lesion was angioplastied open, and the rest of the graft thrombus was macerated with the balloon (Figure 2). Given the organized thrombus, a consideration was made to lace the graft with tissue plasminogen activator (tPA); however, the thrombus was initially easily macerated with the balloon, and tPA was not used in this case.

A second sheath was placed in an upstream direction, and a 4 Fr Fogarty thrombectomy balloon was used to aspirate the arterial plug. Several repeated intragraft angioplasties were performed with the 7 mm balloon to macerate remnant thrombus, and flow was restored to the graft. Despite angioplasty, ongoing recoil was seen at the venous anastomosis (Figure 3).

Given the recoil and repeated thrombosis history, the decision was made to place a stent graft at the venous anastomosis. The GORE VIABAHN Endoprosthesis diameter was selected based on the graft diameter. An 8 mm x 10 cm GORE VIABAHN Endoprosthesis was placed at the venous anastomosis. The distal end was placed within the graft, while the proximal portion extended to the draining axillary vein, which had measured 9 to 11 mm on Doppler.

During deployment, a small embolized fragment of thrombus was seen at the draining vein and venous anastomosis (Figure 4). This thrombus fragment was

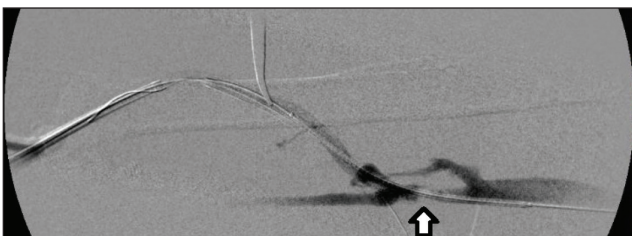


Figure 4. An 8 mm x 10 cm GORE® VIABAHN® Endoprosthesis lined up for deployment at the venous anastomosis stenosis. Note the thrombus fragment seen at the venous anastomosis (arrow).

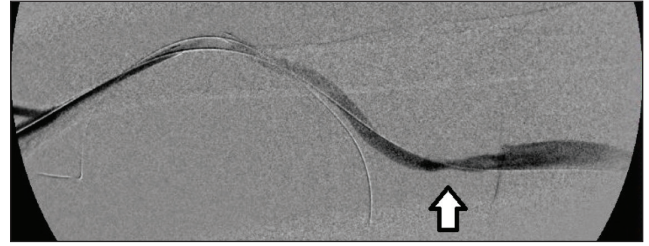


Figure 3. Recoil at the venous anastomosis after angioplasty.

excluded from the access by placement of the stent graft, trapping the thrombus between the stent graft and the vessel wall. More proximally, the 8 mm diameter GORE VIABAHN Endoprosthesis floated in the larger vessel wall without vessel wall apposition. The distal end of the 8 mm stent graft was securely anchored in the graft, and the stent graft was postdilated with the 7 mm balloon (Figure 5). A strong thrill was present, and flow was restored in the access.

Postprocedure, the graft was marked for cannulation. The patient underwent successful hemodialysis for 2 weeks, and the tunneled dialysis catheter was removed.

FOLLOW-UP

After restoration of flow, the patient had two further episodes of graft thrombosis. The first episode occurred 8 months after initial stent graft placement, and a second episode occurred 2 weeks afterward. This was initially managed with further endovascular thrombectomy and intragraft 7 mm balloon angioplasty. A more proximal calcified venous valve was identified as the culprit of recurrent stenosis during the second thrombectomy. A proximal overlapping 8 mm x 10 cm GORE VIABAHN Endoprosthesis was necessary to maintain access patency

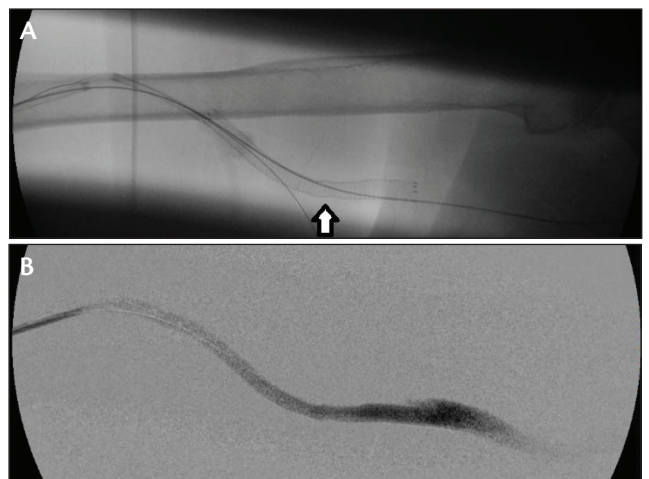


Figure 5. An 8 mm x 10 cm GORE® VIABAHN® Endoprosthesis deployed through the venous anastomosis (arrow indicates venous anastomosis) (A). Restoration of flow through the GORE® VIABAHN® Endoprosthesis (B).

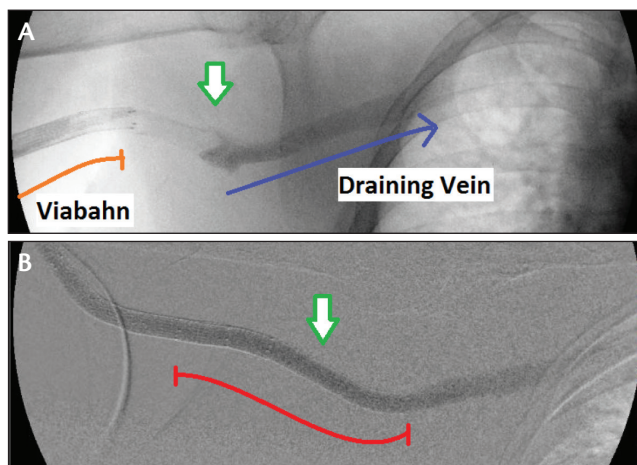


Figure 6. Recurrent thrombosis due to apparent proximal venous valve stenosis 8 months after previous salvage with a GORE® VIABAHN® Endoprosthesis (arrow indicates site of valve stenosis, with thrombus seen distally leading to the GORE® VIABAHN® Endoprosthesis) (A). After second proximal overlapping 8 mm x 10 cm GORE® VIABAHN® Endoprosthesis placement through the recurrent valve stenosis (B).

through this valve stenosis after failure of angioplasty to provide a durable result (Figure 6).

Placement of this second GORE VIABAHN Endoprosthesis stopped the cycle of recurrent thrombosis. To date, the patient has continued to use this graft for the last 12 months without any further dialysis catheter placement.

DISCUSSION

The Bard FLAIR study first showed the superiority of stent graft placement at the venous anastomosis versus treatment with balloon angioplasty alone in patent AV grafts.¹ The RENOVA trial demonstrated additional long-term advantages.² The GORE REVISE study reinforced the efficacy of stent grafts at the venous anastomosis and established the GORE VIABAHN Endoprosthesis as a durable treatment option. The REVISE trial went even further in demonstrating the superiority of the GORE VIABAHN Endoprosthesis over angioplasty during episodes of graft thrombosis.³

At the venous anastomosis, treatment with angioplasty alone often results in eventual restenosis with aggressive neointimal hyperplasia growth. In our experience, bare-metal stents offer limited further improvement and experience aggressive stenosis through bare-metal struts. With the advent of stent grafts, we now have a barrier to this neointimal hyperplasia growth—excluding this pathophysiology of stenosis from the venous anastomosis. Based on the evidence and our own experience, stent grafts have now become the standard of care for venous anastomosis stenosis in hemodialysis

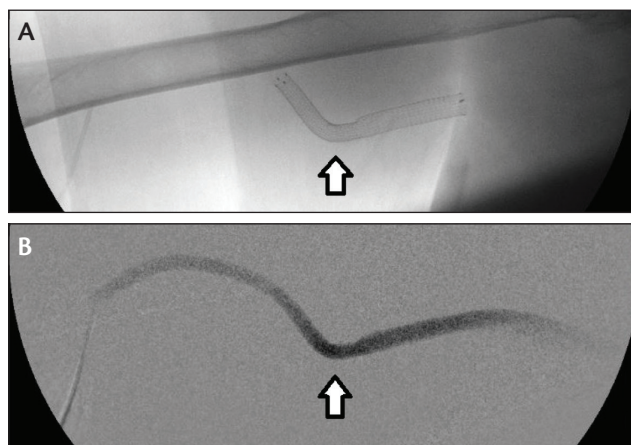


Figure 7. Angulation of the graft vein junction noted with removal of the wire (arrow indicates venous anastomosis) (A). Patent flow after GORE® VIABAHN® Endoprosthesis placement (B).

access. The decision to pursue an attempt at salvaging the graft in this case came from the recognition that earlier attempts did not involve stent graft placement.

Flexibility of the GORE VIABAHN Endoprosthesis

The ability of the GORE VIABAHN Endoprosthesis to bend and turn with the natural contours of the body is unmatched among other stent graft options. The REVISE trial uniquely demonstrated efficacy of the GORE VIABAHN Endoprosthesis at the antecubital fossa of forearm grafts, and the axilla is underappreciated as another site of flexion for upper arm graft venous anastomosis lesions.

Often, we study patients with a wire in place and with their arms extended on the procedure table. An angiogram of this patient, with the arm straight but without a wire, showed significant angulation at the venous anastomosis (Figure 7). It is possible that this unrecognized angulation contributed to the initial episodes of recurrent thrombosis. The ability of the GORE VIABAHN Endoprosthesis to conform and flex with patient movements while maintaining patency is a key advantage in this situation (Figure 8). This may minimize vessel kinking and potential for further neointimal hyperplasia.

GORE VIABAHN Endoprosthesis Sizing and Deployment Considerations

Slight oversizing of the anchored distal end of the stent graft allows for secure and reliable GORE VIABAHN Endoprosthesis placement without migration. The recommendation in the GORE VIABAHN Endoprosthesis instructions for use is for 5% to 20% oversizing. We regularly oversize GORE VIABAHN Endoprosthesis within ePTFE grafts. We anchor at least 2 to 4 cm of the GORE VIABAHN Endoprosthesis within the ePTFE graft and allow the proximal end to float in the outflow vein.



Figure 8. The unique flexibility of the GORE® VIABAHN® Endoprosthesis.

In this case, the proximal end of the 8 mm GORE VIABAHN Endoprosthesis freely floated within the 9 to 11 mm draining vein. The relative undersizing of the proximal portion allows for permissive mobility of the stent graft within the outflow vessel. This undersized proximal portion of the stent graft has minimal contact with the vessel wall, which potentially could decrease development of edge stenosis (Figure 9).

The technique of GORE VIABAHN Endoprosthesis deployment is key to stent graft placement from a smaller graft diameter to the larger-diameter outflow vein. We straighten out the deployment device and reduce all slack from the wire, which usually involves taking several steps back from the procedure table and having an assistant stabilize the shaft near the sheath insertion site. The markers on the edges of the GORE VIABAHN Endoprosthesis are easily visible under fluoroscopy, and the GORE VIABAHN Endoprosthesis may be precisely positioned within the graft and the outflow vein for deployment.

Occult Venous Anastomosis Stenosis

In the era of angioplasty alone for treatment of venous anastomosis lesions, we often achieved successful initial results with graft thrombectomy procedures. However, we did encounter cases with recurrent thrombosis, sometimes within hours after restoration of flow. These were often perplexing, especially when our initial angiographic results with angioplasty were excellent. We suspected a delayed recoil that was not appreciated during initial procedures, but this was challenging to prove.

In problematic cases of short-term recurrent thrombosis, we tried a variety of antiplatelet agents and anticoagulants, initiated hypercoagulable workups, and tried to limit any hypotension at dialysis to potentially manage or treat recurrent graft thrombosis. Many times, our attempts to address these issues were futile. This often resulted in a frustrating cycle of recurrent thrombectomy attempts until the decision was made to ultimately abandon an access and place a catheter for access.

With the data from the REVISE clinical study supporting the benefits of the GORE VIABAHN Endoprosthesis over

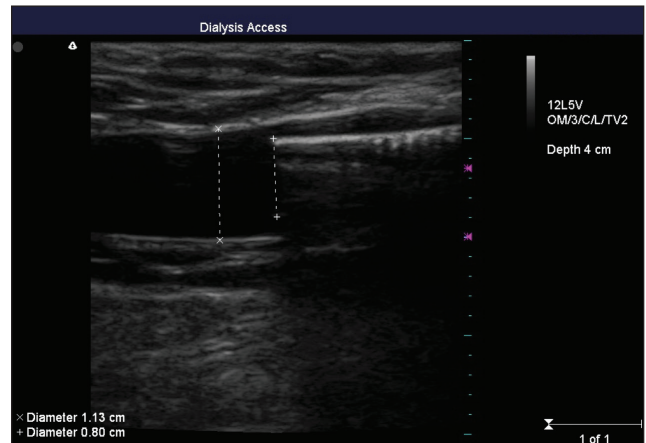


Figure 9. Ultrasound image demonstrating the 8 mm GORE® VIABAHN® Endoprosthesis floating in the larger draining outflow axillary vein. Note the lack of any stent graft edge wall apposition.

angioplasty in thrombosed grafts, we began to approach these lesions differently. We utilized the GORE VIABAHN Endoprosthesis at the venous anastomosis for these recurrent thrombosis cases, and we found that we could usually break the cycles of recurrent thrombosis. It stands to reason that we were able to eliminate all postangioplasty recoil with stent graft placement. This, along with exclusion of the neointimal hyperplasia, appears to be the key to maintaining patency.

Expanding our GORE VIABAHN Endoprosthesis use more consistently at patent and thrombosed venous anastomosis lesions, we've noted longer graft patency rates and reduced incidence of access thrombosis, which reflects the findings in the REVISE trial.

Approach to Abandoned Grafts

This patient originally presented for a tunneled dialysis catheter exchange. As part of comprehensive patient care, it is important to determine why a patient relies on catheter access. If there are no immediate plans for an AV access, we often help to facilitate mapping and planning for an access. This requires collaboration with the dialysis staff and the referring physicians, and ultimately can help to diminish catheter dependence for dialysis patients.

Most abandoned grafts are not reinvestigated for salvage. Small studies in the literature have shown occasional resuscitation of chronically thrombosed "dead" or "mummy" grafts.^{4,5} Often, the thrombus strongly organizes and cannot be passed with wires. Thrombosed pseudoaneurysms further complicate this, as chronic, adherent thrombus may be impossible to pass. Collapsed grafts with minimal luminal diameter are also a sign of compromised graft patency, and these are generally not candidates for salvage.

In this case, we had a relatively little-used graft with limited previous cannulation. There was apparent integrity

of the graft without collapse, and the thrombosed lumen was easily visualized with Doppler. There were no pseudoaneurysms present, and the vessel just proximal to the venous anastomosis appeared patent. Although organized thrombus was present, the overall thrombus volume was minimal in the graft.

Usually, resuscitation of abandoned grafts is a futile endeavour. However, in cases where there appears to be relatively little thrombus burden, otherwise-intact outflow veins, and preserved graft integrity, consideration can be made to attempt an endovascular salvage. Key here is the ability to pass a guidewire through the venous anastomosis. Stent grafts may be beneficial in achieving a more durable patency at the venous anastomosis, and they may have the added advantage of excluding organized thrombus from the access outflow.

Long-Term Considerations With Venous Anastomosis Stent Grafts

To manage long-term access patency with stent grafts, it is important to recognize the pathophysiology of venous anastomosis neointimal hyperplasia. With the placement of stent grafts at the venous anastomosis, the proximal edge of the newly placed stent graft now becomes the new venous anastomosis. This may potentially instigate further development of upstream neointimal hyperplasia, with the more proximal draining vein now being closer in proximity to the high flows from the access.

Although larger vein diameters more proximally seem to have less incidence of thrombosis, upstream stenosis may still develop. Venous valves can also be prone to stenosis, as demonstrated in this case. Usually, this can be managed with angioplasty alone, but further proximal stent graft placement may be necessary to maintain patency.

In our experience, we have not encountered significant development of in-stent restenosis with the GORE VIABAHN Endoprosthesis. The end-to-end ePTFE lining acts as a barrier to neointimal hyperplasia. The technique of placing a freely floating proximal end of the GORE VIABAHN Endoprosthesis in a larger diameter outflow vein may also further minimize edge stenosis and in-stent occlusion.

Although higher up-front costs may be associated with stent-graft placement versus angioplasty, the long-term benefits of durable access patency outweigh the costs of repeated angioplasties and thrombectomy procedures.⁶ It stands to reason that further savings can be realized

with avoidance of potential catheter infections and hospitalizations, as well as further surgical access placements and revisions.

A Breakthrough in Dialysis Access Care

With stent graft usage in dialysis access, endovascular salvage of failing accesses can now succeed where angioplasty alone has failed. Although salvage of long-abandoned grafts is rare, the techniques and approaches described here can apply to conventional dialysis graft thrombectomy procedures.

In this patient, an abandoned access was salvaged, and the catheter was removed. Secondary patency has been maintained for well over a year and counting for a patient who had limited other access options. This would have been unachievable in the era when balloon angioplasty was the only treatment choice.

The flexibility and full end-to-end ePTFE lining of the GORE VIABAHN Endoprosthesis makes it a key component for success when dealing with endovascular management of dialysis access. This has been nothing short of revolutionary for our patients, extending the lifespan of AV accesses and minimizing catheter dependence. We truly are in a new era of dialysis access management. ■

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CASE REPORT

The Versatility of the GORE® VIABAHN® Endoprosthesis

Several case reports highlighting its unique design and why it is a valuable tool for the interventionalist.

BY PETER WAYNE, MD

Regardless of whether you are a vascular surgeon, general surgeon, interventional radiologist, or interventional nephrologist, the interventionalist's role is to manage the dialysis patient's access. This is achieved by maintaining adequate patency with resulting satisfactory blood flow volumes and ensuring that the fistula or graft has developed the integrity to tolerate multiple large-bore needle sticks at least six times per week, as well as confirming the fistula or graft is of the appropriate depth to avoid infiltrations, which could be disastrous to the longevity of the access.

With the recent advent of the ESRD Seamless Care Organization (ESCO), the financial burden for caring for the end-stage renal disease (ESRD) patient population will be the responsibility of nephrology groups, large dialysis organizations, and potentially non-nephrologist health care organizations. The role of the ESCO is not only to organize and coordinate care of the dialysis patient and demand improved outcomes, but also to seek improvement in the cost of the care of that dialysis patient.¹ In the United States, 468,000 people undergo hemodialysis, and this number is expected to exceed 700,000 by 2020. The cost of hemodialysis is approximately \$85,000 per patient per year.²

With the recent significant decrease in Centers for Medicare & Medicaid Services reimbursement, many vascular access centers will be forced to close, which will only increase patient visits to the remaining vascular access centers and/or emergency departments. Independent vascular access centers will require interventional equipment that not only successfully repairs diseased accesses but is also cost-efficient. Roy-Chaudhury recently stated that the ESCO model could "incentivize innovation."³ The benefit of using the GORE® VIABAHN® Endoprosthesis at the venous anastomosis is one of those innovations. The success of the GORE VIABAHN Endoprosthesis at the venous anastomosis was detailed in the GORE REVISE trial. The stent graft

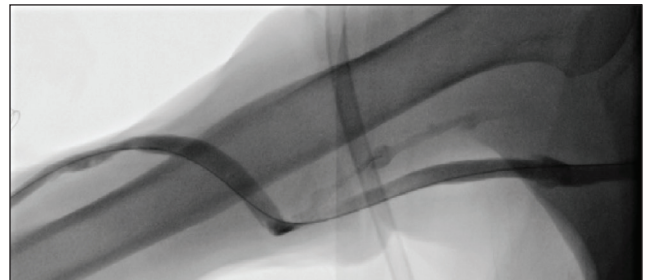


Figure 1. The initial shuntogram after thrombectomy demonstrating significant venous anastomotic stenosis as well as stenosis within the proximal aspect of the patient's right arm graft. Note the accessory vein at the site of the venous anastomotic stenosis.



Figure 2. After several balloon angioplasties at the site of venous anastomotic stenosis, significant residual stenosis remained. The vascular surgeon elected to stent this area. Note that Figures 2, 3, and 4 are reversed images because they were the only saved radiographs from the intraoperative thrombectomy.

group had a target lesion primary patency rate of 64.6% at 6 months, which exceeded the reasonable goal of 50% established by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative guidelines as well as exceeded the primary patency rate reported in a previous trial using a different stent graft.⁴ In addition, the number



Figure 3. The residual stenosis noted at the venous anastomosis was ultimately stented with an 8 mm x 5 cm GORE® VIABAHN® Endoprosthesis. Arrows indicate deployed stent graft.



Figure 4. The deployed GORE® VIABAHN® Endoprosthesis was maximally expanded with an 8 mm x 4 cm Vaccess angioplasty balloon (Bard Peripheral Vascular).

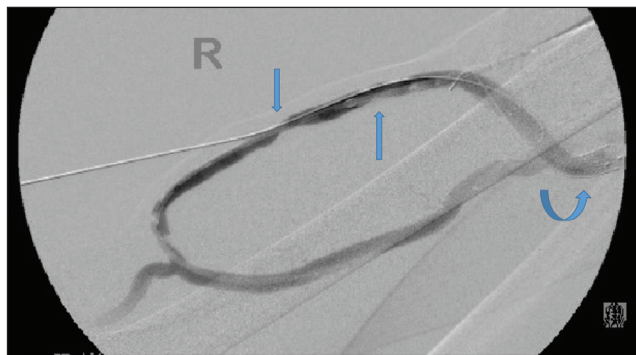


Figure 5. Shuntogram after percutaneous repeat thrombectomy. Residual thrombus remained within the graft. The previously placed 8 mm x 5 cm GORE® VIABAHN® Endoprosthesis at the venous anastomosis is indicated with a curved arrow. Recurrent areas of stenosis are indicated with straight arrows.

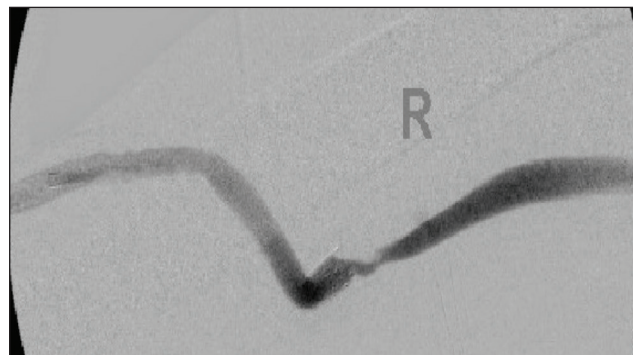


Figure 6. The shuntogram also revealed recurrent stenosis just distal to the previously placed 8 mm x 5 cm GORE® VIABAHN® Endoprosthesis.

of interventions was reduced by 27% over a 2-year period.³ These results will only improve outcomes and decrease the number of procedures, which will ultimately lower cost—one of the major goals of the ESCO model. The following two cases demonstrate the value and versatility of the GORE VIABAHN Endoprosthesis at a stenotic venous anastomosis.

CASE 1

The patient presented to a local emergency department with a thrombosed right arm graft. The graft had been created approximately 1 year previously, and the patient began dialysis once it had matured. No previous interventions had been performed. The patient was taken to the operating room, where a vascular surgeon performed open thrombectomy and a shuntogram. The graft was declotted, flow was reestablished, and a high-grade stenosis was noted at the venous anastomosis (Figure 1). Several balloon angioplasties were performed; however, significant elastic recoil and residual stenosis remained (Figure 2).

The surgeon elected to place an 8 mm x 5 cm GORE VIABAHN stent graft at the venous anastomosis, and

balloon angioplasty was performed to maximally expand the newly deployed stent graft. Prompt flow was reestablished (Figures 3 and 4). The patient was immediately dialyzed and was discharged the following morning.

The patient was seen approximately 1 month later in our outpatient endovascular center because of a rethrombosis right upper arm arteriovenous (AV) graft. The graft was declotted, and the initial shuntogram revealed a patent right arm graft (Figure 5) with an area of recurrent stenosis just distal to the outflow tip of the previously deployed GORE VIABAHN Endoprosthesis (Figures 6 and 7).

A review of the radiographs from the previous thrombectomy procedure revealed the presence of a collateral or accessory vein immediately adjacent to the site of the previous venous anastomotic stenosis (Figure 1). Lane et al noted that the most common location of any valve is immediately distal to the point of entry of a venous tributary.⁵ Taking this information into consideration, a more precise location for the deployment of the original GORE VIABAHN Endoprosthesis would have been to place the stent graft across the accessory vein, thus ensuring stent placement across a potential valve. Ross noted that landing the stent inside or within 1 cm proximal to a valve can lead to rapid endothelial buildup at the edge of the device,⁶

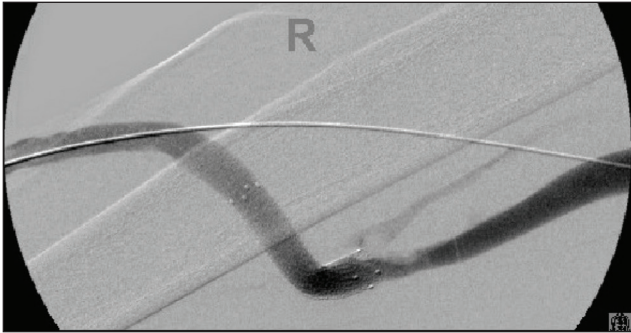


Figure 7. The accessory vein was once again noted at the site of recurrent venous anastomotic stenosis following the declotting procedure. This accessory vein was present on the initial examination. Failure to place a stent graft across this accessory vein and a potential valve can lead to future stenosis at this site.

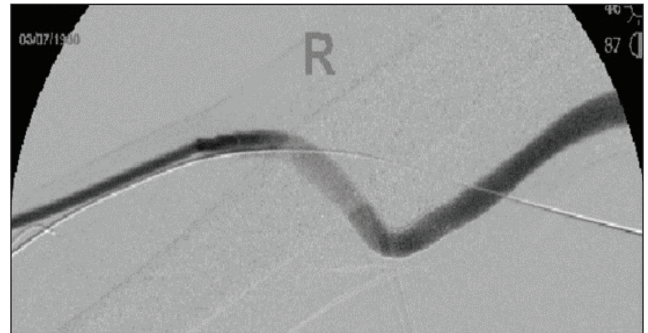


Figure 8. After placement of a 9 mm x 5 cm GORE® VIABAHN® Endoprosthesis with the previously placed stent and extending into the draining right axillary vein, prompt flow was reestablished through the patient's graft.

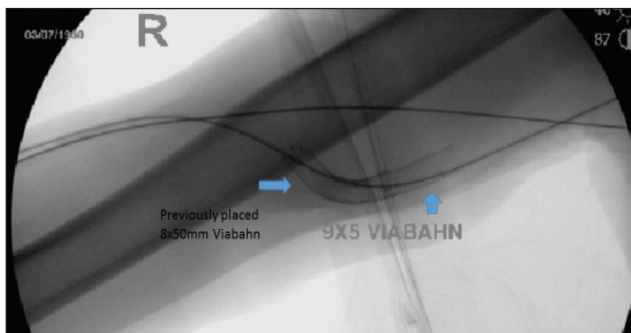


Figure 9. The newly placed GORE® VIABAHN® Endoprosthesis is in good position and is centrally placed within the draining vein. The tip of the stent is not angulated as it enters the draining vein, which improves flow and decreases the incidence of vessel trauma and/or the development of neointimal hyperplasia within the outflow vein because of elevated wall shear stress.

which was demonstrated on the follow-up shuntogram (Figures 6 and 7). In our experience, potential recurrent stenosis can be avoided by placing the stent graft across the valve by at least 1 cm.

Angioplasty was performed on the recurrent stenosis, and a new 9 mm x 5 cm GORE VIABAHN Endoprosthesis was deployed within the previously placed GORE VIABAHN Endoprosthesis, and the outflow end was placed in "good vein" (Figures 8 and 9). There was no wall apposition with the newly placed stent in the right axillary vein. Centering the stent in the outflow vein is important so that wall apposition is avoided with an angled stent. Previous studies have shown that if the tip of the stent graft is directed at an angle and opposes the outflow vein and impinges on the native vein, the high-pressure arterial flow causes significant vessel trauma and/or the development of neointimal hyperplasia because of the elevated wall shear stress.⁶

The patient was seen 7 months later because of difficulty accessing his right arm AV graft. The initial shuntogram revealed an area of recurrent stenosis within the proximal limb

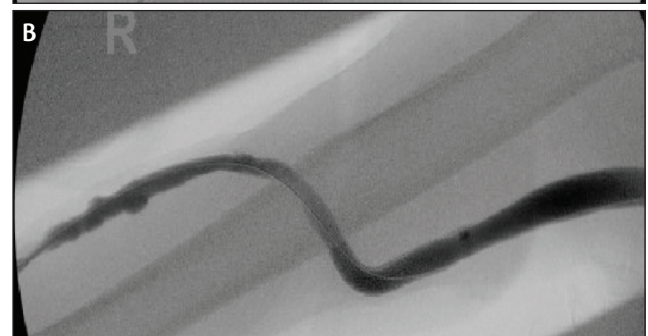
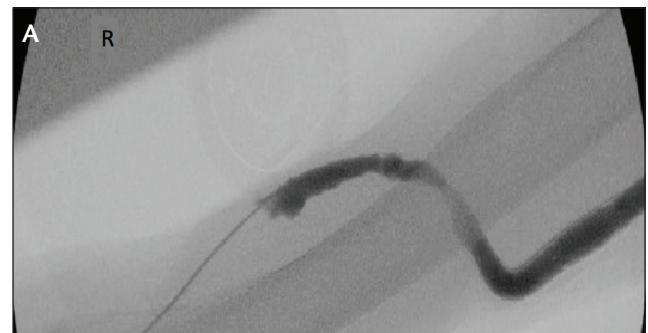


Figure 10. Follow-up shuntogram revealed an area of stenosis within the distal aspect of the right upper arm AV graft (A). There remained wide patency of the previously restented venous anastomosis (B).

of the right arm graft (Figure 10A); however, the previously placed 9 mm x 5 cm GORE VIABAHN Endoprosthesis at the venous anastomosis had remained widely patent without evidence of irregularity or stenosis (Figure 10B).

It is important to remember that stent graft placement should be as precise as possible because it is critical to the correct performance of the patient's stent and AV graft, as well as to the longevity of the patient's access.

CASES 2 AND 3

The versatility of the GORE VIABAHN Endoprosthesis includes its ability to be placed across joints, as well as its

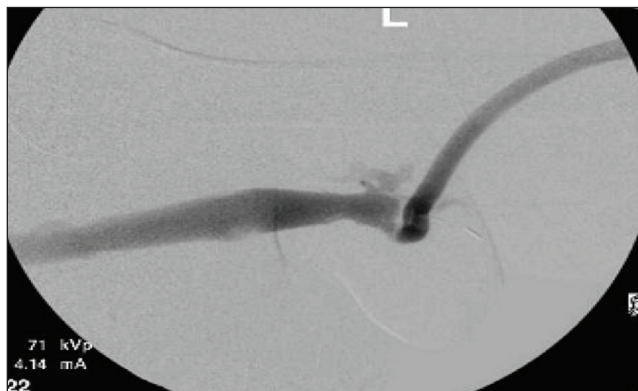


Figure 11. The patient presented because of prolonged bleeding upon removal of the hemodialysis needles at the completion of hemodialysis. Note the acute angle between graft and the native draining vein.

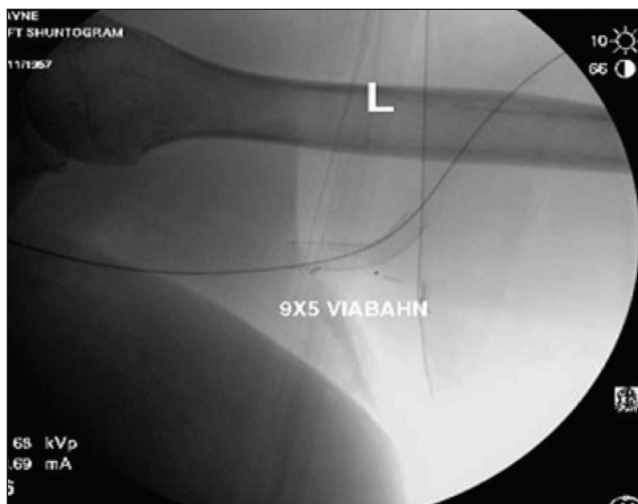


Figure 13. The position of the GORE® VIABAHN® Endoprosthesis across the venous anastomosis.

ability to be placed across a stenotic venous anastomosis that resulted in an acute angle at the anastomosis. The GORE VIABAHN Endoprosthesis is ideal for this particular situation because of its unique flexibility. There was a not-uncommon stenosis at the venous anastomosis with a markedly acute angle between the graft and the native vein (Figure 11). Angioplasty was unsuccessful, and because this was the second intervention in the same area on this patient, it was decided to place a stent in this region.

The GORE REVISE clinical trial showed that when treating a patient with a venous anastomotic stenosis and with no prior intervention, there was only a small percentage difference between percutaneous transluminal angioplasty (44%) and GORE VIABAHN Endoprosthesis placement (51%). However, when managing a recurrent venous anastomotic stenosis in a patient who has undergone prior interventions, target lesion patency was 54% at 6 months for GORE VIABAHN Endoprosthesis

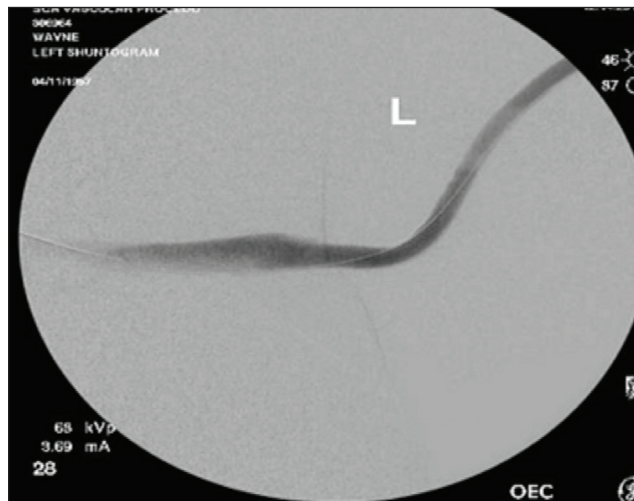


Figure 12. Angioplasty was performed on the high-grade stenosis; however, this was the third intervention on this lesion, and a stent was placed. The completion shuntogram demonstrates the flexibility of the GORE® VIABAHN® Endoprosthesis and the resulting improved flow through the newly stented venous anastomosis.

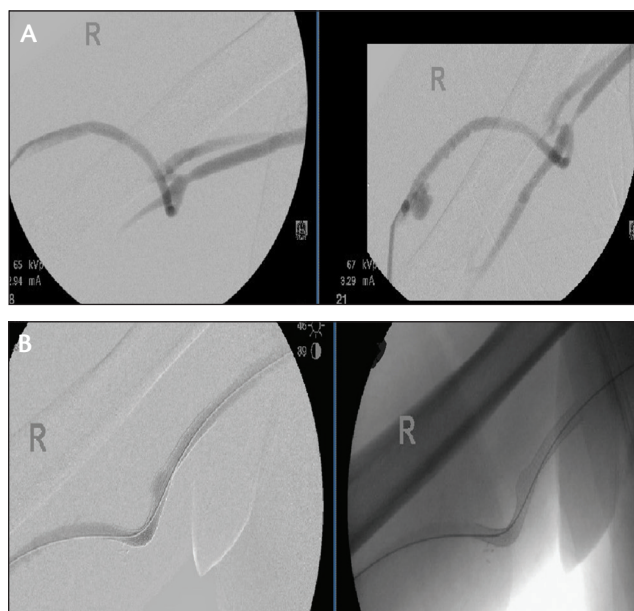


Figure 14. This patient presented because of decreased flow rates noted at the dialysis center. The shuntogram revealed not only tortuosity at the venous anastomosis but also acute angles between graft and native vein (A). The GORE® VIABAHN® Endoprosthesis easily negotiated the tortuosity and acute angle at the venous anastomosis with a result that improved flow and avoided any kinking postplacement (B).

compared to 29% patency for angioplasty alone.⁴ For the patient in this case, angioplasty was initially performed, and because this was a repeat intervention, it was decided to deploy a GORE VIABAHN Endoprosthesis

across the area of the angled stenosis and dilated with an appropriate angioplasty balloon with excellent results (Figures 12 and 13).

Other stent grafts do not have the flexibility to perform this task without potential complications, such as kinking. The GORE VIABAHN Endoprosthesis is a unique stent graft because of its ability to maintain patency when placed across an acute angle. An additional example is seen in Figure 14.

SUMMARY

The GORE VIABAHN Endoprosthesis is a very versatile, operator-friendly stent graft that can be used across a stenotic anastomosis without hesitation because of its flexibility, radial force, and ease of deployment. Because of unique innovations created by Gore & Associates, ESCO challenges may be better addressed (eg, cost containment, improved outcomes), and we will have the necessary tools to complete our role and address the daily problems we see with our dialysis patients. ■

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Disclosures: Consultant and speakers bureau for Gore & Associates.

GORE® VIABAHN® Endoprosthesis

INTENDED USE / INDICATIONS: The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery de novo and restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0 – 7.5 mm, in superficial femoral artery in-stent restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0 – 6.5 mm, and in iliac artery lesions up to 80 mm in length with reference vessel diameters ranging from 4.0 – 12 mm. The GORE® VIABAHN® Endoprosthesis is also indicated for the treatment of stenosis or thrombotic occlusion at the venous anastomosis of synthetic arteriovenous (AV) access grafts. Refer to Instructions for Use at goremedical.com for a complete description of all contraindications, warnings, precautions and adverse events. Rx Only

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