Crossing the Point of Flexion in the Antecubital Fossa

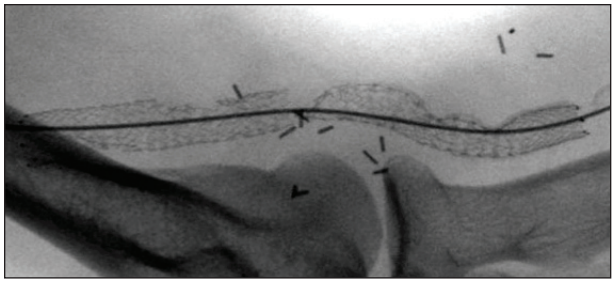
Using the GORE VIABAHN Endoprosthesis for long-term access patency.

BY WILLIAM DAVANZO, MD

Crossing the antecubital fossa with a stent or stent-graft to treat a dysfunctional or thrombosed graft can be a cause for concern for most interventionists. Some stent-grafts will kink when the arm bends, which can lead to a thrombotic occlusion.[1] Bare-metal stents tend to have enough flexibility to avoid kinking, but the mechanical strain from repeated flexion can potentially compromise the structure of the device (Figure 1). The only alternatives are frequent angioplasty or graft abandonment, neither of which is ideal for the patient.

The GORE VIABAHN Endoprosthesis (Gore & Associates) has proven to be both flexible and durable when crossing the antecubital fossa. The device resists kinking even when the arm is bent (Figure 2). Most importantly, I have not experienced any device fracture even under repeated flexion. My experience was validated by the absence of fractures reported over the entire 24-month study period of the Gore REVISE Clinical Study (REVISE), including the 25 subjects who required a device to cross the antecubital fossa. The data suggest that this device does not tend to fracture under repeated flexion, which results in a clinically significant issue.[2]

I describe a single case experience, as well as the population data from REVISE for the placement of the GORE VIABAHN Device across the antecubital fossa. The case highlights the direct impact the device can have on the life of a patient's arteriovenous (AV) access graft, while the REVISE data validate the decision to use the device across the elbow.



(Image courtesy of Thomas Vesely, MD.)

Figure 1. Bare-metal stent crossing the antecubital fossa, with fracture.

CASE STUDY

A 36-year-old woman with end-stage renal disease for just over 2 years was referred to our hospital for what was originally thought to be a thrombosed access. Upon examination, she was found to have a faint bruit and a weak thrill in her left forearm graft.

The patient was not diabetic, but she had a history of hypertension, which was thought to be the cause of her renal disease. Her current and only vascular access was a left forearm loop, expanded polytetrafluoroethylene, tapered 4 to 7 mm graft using the brachial artery for inflow and the cephalic vein for outflow. Before this visit, she had a history of three thrombotic events of the graft in 23 months, each of which were successfully treated interventionally with percutaneous thrombectomy and angioplasty of the venous anastomosis. The most recent event was 4 months before the visit.

The patient had a healthy cephalic vein for a potential upper arm fistula that could have provided a better working access with less frequent thrombosis. However, I wanted to attempt to alter the natural history of the current access through endovascular means to prevent the need for a central venous catheter while retaining future options. Also, prolonging the life of the current access was particularly important, given the patient's young age and potential need for long-term dialysis.

The patient was screened for the REVISE Study. She met all of the inclusion/exclusion criteria and consented for participation in the clinical trial.

The patient was then taken to the angiography suite, where she was prepped in the standard fashion. A 7 F short sheath was inserted into the venous section of the graft, and angiographic images were obtained with multiple views. The films revealed a clinically significant lesion of the venous anastomosis measuring 24 mm in length originating at the venous anastomosis and 75% stenosed (Figure 3A). She also had a distal cephalic arch

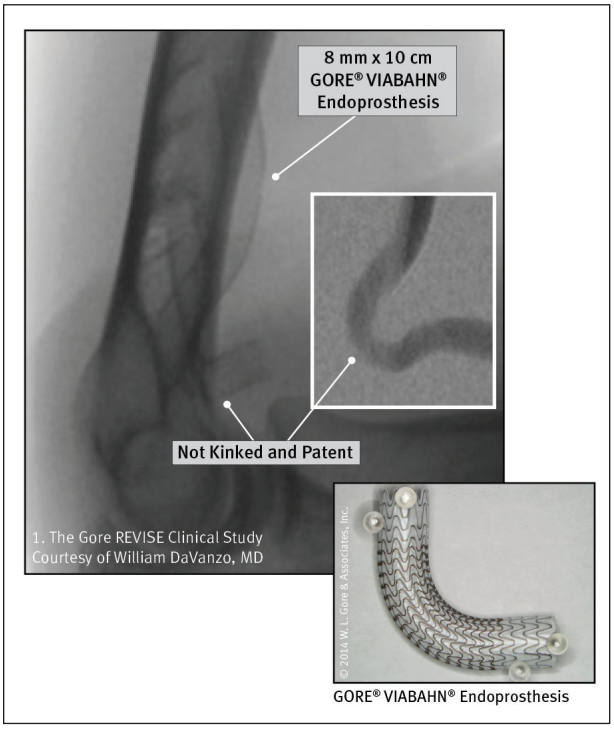


Figure 2. GORE VIABAHN Device crossing the antecubital fossa with flexion. Note patency of the device without kink.

stenosis of 53% that was 25 mm long. Angioplasty was performed with a 7 mm × 8 cm balloon, followed by an 8 mm × 4 cm balloon. Both balloons were inflated to 16 atm for 60 seconds, resulting in a 21% residual stenosis. This met the study requirement for successful treatment of a secondary lesion. The remainder of the dialysis circuit was patent; the arterial anastomosis was < 50% stenosed and was not treated.

The target lesion was then addressed. An 8 mm × 8 cm balloon was used to perform angioplasty on the lesion, requiring 26 atm of pressure for 60 seconds to remove the balloon waist. A 25% residual stenosis was seen, and the patient was randomized to the GORE VIABAHN Device group. The 7 F sheath was exchanged for an 8 F sheath, and an 8 mm × 5 cm GORE VIABAHN Device was used to treat the lesion. The 8 mm diameter device was chosen to ensure anchoring into the 7 mm outflow of the graft. The device crossed the antecubital fossa and landed in the cephalic vein, measuring 10.6 mm at the distal edge of the device (Figure 3B). The device crossed the flexion point of the vein by approximately 1 cm, and the lumen of the device remained open at that flexion point with the arm bent. The patient successfully dialyzed through the access the following day.

Three days later, she reported to the dialysis clinic with a thrombosed access. Thrombectomy was performed through the graft, the device, and the native cephalic vein. The arterial anastomosis was found to be > 50% stenosed. A 7 mm angioplasty balloon was used to perform angioplasty on the lesion. The GORE VIABAHN Device was found to be widely patent (Figure 3C).

At the 30-day follow-up interval, the patient was found to have been discharged from the dialysis unit after multiple missed treatments. We were unable to contact the patient, and she was terminated from the clinical trial as "lost to follow-up."

The patient was referred back to our clinic for decreased vascular access flow on hemodialysis, 33 months later. The access had not been intervened on in the interim. She was taken to the angiography suite and was found to have an arterial anastomosis stenosis, which was treated. The GORE VIABAHN Device crossing the antecubital fossa was found to be minimally stenosed (Figure 4A).

The patient was again referred back for poor access flow 39 months after initial implantation and was found to have a pulsatile access on exam. Angiography was performed, demonstrating advancement of the secondary cephalic arch lesion. The original implant was widely pat-

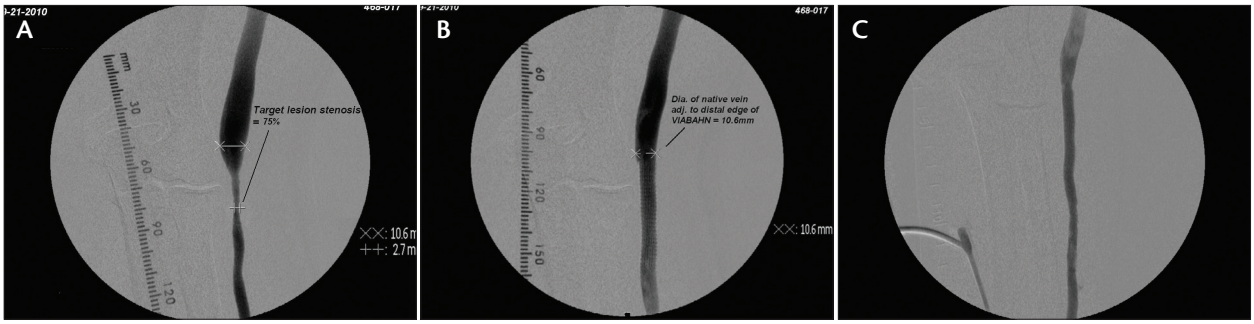


Figure 3. Prestent angiography (A). Note the anastomosis is with the cephalic vein, and the target lesion crosses the antecubital fossa. Poststent angiography showing 8 mm × 5 cm GORE VIABAHN Device placed across the antecubital fossa (B). Note the large-caliber cephalic vein (10.6 mm) for the landing zone. The patient returned with thrombosed AV access (C). The GORE VIABAHN Device was unremarkable.

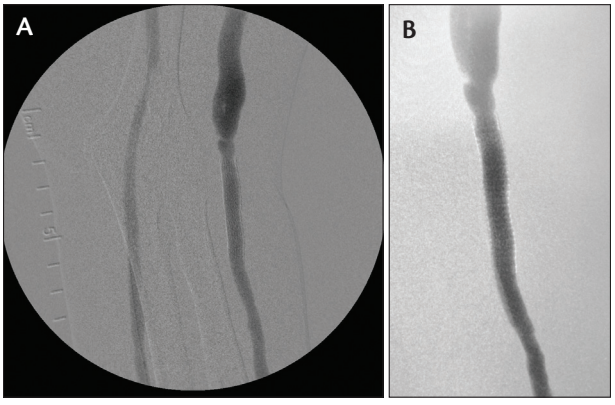


Figure 4. The patient was referred back at 33 months (A) and 39 months (B). Note the GORE VIABAHN Device was minimally stenosed.

ent (Figure 4B), and the cephalic arch lesion was successfully treated with an off-label placement of a stent-graft.

CHOOSING THE LANDING ZONE

The location of the outflow edge of the device is an important consideration when crossing the elbow. The placement can affect both outcomes and future potential access opportunities. In this procedure, many options are available to the operator, such as crossing the median cubital vein as a means for using the basilic vein or placement in the cephalic vein crossing the elbow completely or landing at the elbow crease. Each decision can provide a successful outcome for the patient with the GORE VIABAHN Device but can also come at the cost of preventing a future access.

The interventionist must also consider which vein is being used as the landing zone for the stent-graft when addressing the best scenario for the patient's future. If the anastomosis is within the cephalic vein past the median cubital, the only consideration for device choice becomes the size of the vein distal to the anastomosis. When considering the basilic vein, it is useful to evaluate the entire vein to determine whether it may be more appropriate than the cephalic for a future fistula. If so, crossing the median cubital vein and diverting the access to the basilic vein with a stent-graft may serve the patient well in the future.

In this case, an 8 mm device was used in the initial procedure to size 5% to 20% larger than the graft, per the instructions for use. However, the GORE VIABAHN Device was landed in a vein measuring 2.6 mm larger than its nominal diameter (Figure 3B). I believe this scenario contributes to the long-term patency of the device and reduction in the progression of stenosis at the outflow. When possible, I choose to land the device in a larger outflow vein, provided future access sites will not be compromised. My personal experience with this sizing strategy is in fact supported as safe and effective by the REVISE Study data.[2]

In the case described, I opted for a shorter device in the patient to maintain as much venous real estate as possible for a future upper arm cephalic fistula. This decision resulted in the device landing only a centimeter past the flexion point (Figure 3). Alternatively, a longer device would have more completely extended past the flexion point of the elbow (Figure 2). However, the patient in Figure 2 received the shorter device due to the characteristics of the stenosis, not in order to cross the flexion point. If the shorter device had landed in the point of flexion, a longer device would have been more appropriate. In such a case, I would choose to land the device only 1 cm past the flexion point while preserving as much healthy vein as possible. Excess length would have been extended distally into the graft, provided that cannulation zones could be avoided. In this location, the GORE VIABAHN Device still retains excellent flow and does not kink, despite the proximity of the flexion point to the end of the device.

DISCUSSION

Lesions that are found near the antecubital fossa can be difficult to manage. Angioplasty has been the therapeutic modality of choice for lesions in this area. When angioplasty has failed, the options to maintain a working access are limited to stents or surgical revision of the venous anastomosis. The choice for using stents for repair of the venous anastomosis has been debated. Bare-metal stents have not been adequate solutions for the venous anastomosis or crossing the antecubital fossa, as they are prone to stent fracture (Figure 1) and in-stent tissue growth.[3,4] Use of other stent-grafts across the antecubital fossa has typically been avoided based on clinical data[5] or warned against in the device's instructions for use.

Alternatively, the GORE VIABAHN Device has the flexibility, durability, and the indication to successfully treat lesions across the antecubital fossa. In my experience, the device does not compress or kink when the extremity is flexed (Figure 2) as compared with other stent-grafts, which kink under the same anatomic manipulations.[1] Also, I have not experienced a GORE VIABAHN Device fracture when placed across the elbow, and no fractures were reported in the REVISE Study.[2] The device is a valuable tool in maintaining access function in even the most challenging lesions.

This case study highlights how the GORE VIABAHN Device can be effectively placed across the elbow to restore and maintain long-term access function. Typically, a patient who is thrombosing at this frequency does not

have much hope for long-term durability of his or her AV graft. However, the treatment of the venous anastomosis with the GORE VIABAHN Device seems to affect the successful outcomes for these patients. For the described patient, the only intervention in 33 months was for thrombosis due to dysfunction at the arterial anastomosis. The GORE VIABAHN Device was unremarkable at the time of that intervention (Figure 3C). Only a minimal stenosis was found at 33 months and 39 months (Figure 4).

My single-center experience was validated by the effectiveness outcomes of the REVISE Study. The GORE VIABAHN Device group included 25 patients who required a device to be placed across the antecubital fossa. Of those patients, three were protocol deviations, and 22 were analyzed for effectiveness. The outcomes for those patients were 72% for target lesion primary patency at 6 months and 83% for access secondary patency at 24 months.[2] These outcomes compare favorably to the overall outcomes reported in the REVISE Study and support the use of the device across the antecubital fossa.

Choosing the correct intervention for access preservation for failed AV accesses in patients undergoing hemodialysis has been difficult in the past. The use of stent-grafts has increased our ability to improve on the previous standard of care—angioplasty. However, the need for flexibility and durability is essential to the long-term benefit of therapy with an implantable device, especially in difficult anatomical locations. The mechanical properties of the GORE VIABAHN Device have been attractive for AV access applications across flexion points and have now been validated by the outcomes of the REVISE Study in areas where other devices have failed. ■

William DaVanzo, MD, is an interventional nephrologist at Phoebe Putney Memorial Hospital in Albany, Georgia. He has disclosed that he is a consultant for W. L. Gore & Associates and Bayer. Dr. DaVanzo may be reached at (912) 634-7714; wdavanzo123@gmail.com.

1. Funaki B, Slaby J. Covered stent compression in dialysis access. *Semin Intervent Radiol*. 2011;28:128–130.
2. W. L. Gore & Associates, Inc. Gore REVISE (VasculaR AccEss ReVision with GORE VIABAHN EndoproSthesis vs PercutanEous Transluminal Angioplasty) Study. ClinicalTrials.gov. Bethesda, MD: National Library of Medicine; 2013. http://clinicaltrials. gov/show/NCT00737672. Published August 15, 2008. Updated May 14, 2013. Accessed January 13, 2014. NLM Identifier: NCT00737672.
3. Vogel PM, Parise C. SMART stent for salvage of hemodialysis access grafts. *J Vasc Interv Radiol*. 2004;15:1051-1060.
4. Dolmatch B, Dong YH, Heeter Z. Evaluation of three polytetrafluoroethylene stent-grafts in a model of neointimal hyperplasia. *J Vasc Interv Radiol*. 2007;18:527-534.
5. Dolmatch BL, Duch JM, Winder R, et al. Salvage of angioplasty failures and complications in hemodialysis arteriovenous access using the FLUENCY Plus Stent Graft: technical and 180-day patency results. *J Vasc Interv Radiol*. 2012;23:479-487.