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 interventionist.

BY PETER WAYNE, MD

Regardless of whether you are a vascular surgeon, general surgeon, interventional radiologist, or interventional nephrologist, the interventionist'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

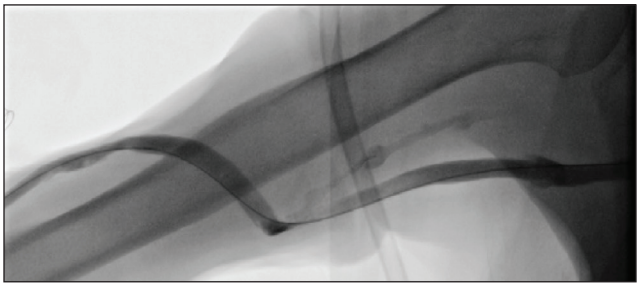

Figure 1. The initial shuntogram after thrombectomy demonstrating significant venous anastomotic stenosis as well as stenosis within the proximal aspect of the patient's right arm graft. Note the accessory vein at the site of the venous anastomotic stenosis.

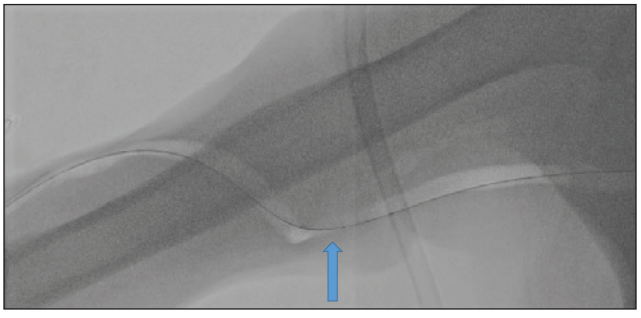

Figure 2. After several balloon angioplasties at the site of venous anastomotic stenosis, significant residual stenosis remained. The vascular surgeon elected to stent this area. Note that Figures 2, 3, and 4 are reversed images because they were the only saved radiographs from the intraoperative thrombectomy.

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

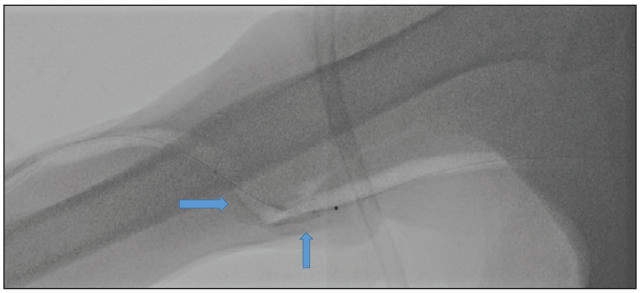

Figure 3. The residual stenosis noted at the venous anastomosis was ultimately stented with an 8 mm x 5 cm GORE® VIABAHN® Endoprosthesis. Arrows indicate deployed stent graft.

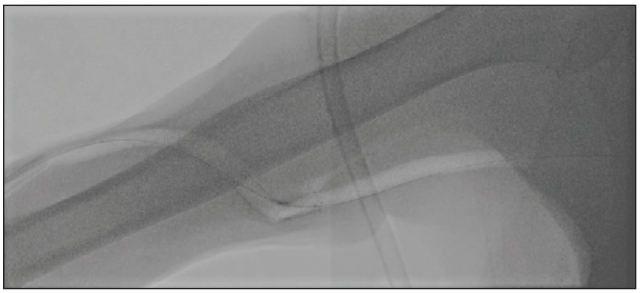

Figure 4. The deployed GORE® VIABAHN® Endoprosthesis was maximally expanded with an 8 mm x 4 cm Vaccess angioplasty balloon (Bard Peripheral Vascular).

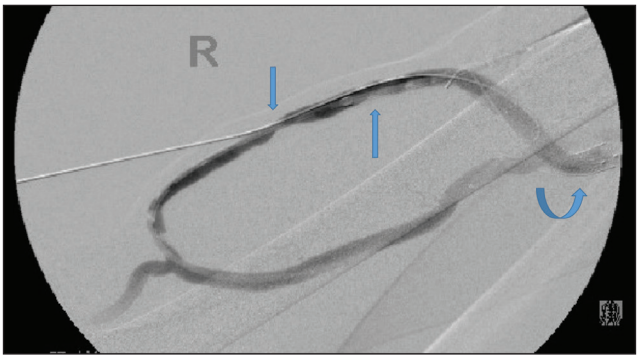

Figure 5. Shuntogram after percutaneous repeat thrombectomy. Residual thrombus remained within the graft. The previously placed 8 mm x 5 cm GORE® VIABAHN® Endoprosthesis at the venous anastomosis is indicated with a curved arrow. Recurrent areas of stenosis are indicated with straight arrows.

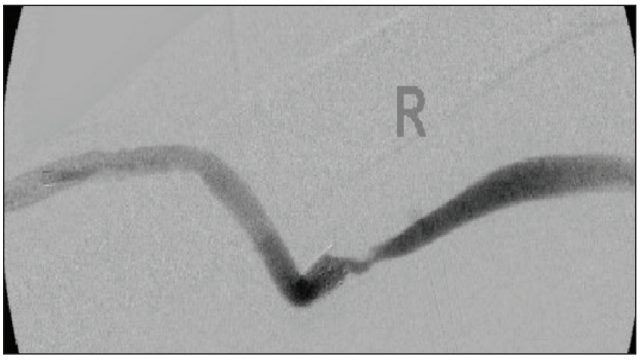

Figure 6. The shuntogram also revealed recurrent stenosis just distal to the previously placed 8 mm x 5 cm GORE® VIABAHN® Endoprosthesis.

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 accessary 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]

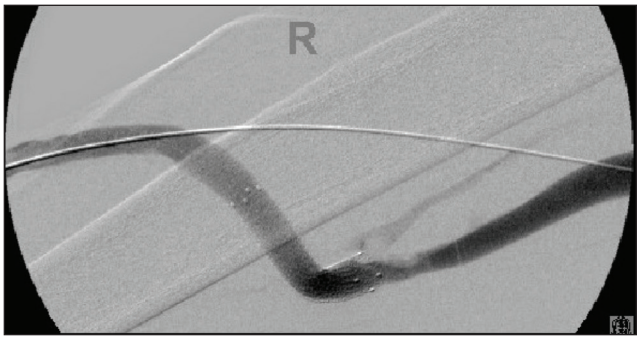

Figure 7. The accessory vein was once again noted at the site of recurrent venous anastomotic stenosis following the declotting procedure. This accessory vein was present on the initial examination. Failure to place a stent graft across this accessory vein and a potential valve can lead to future stenosis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

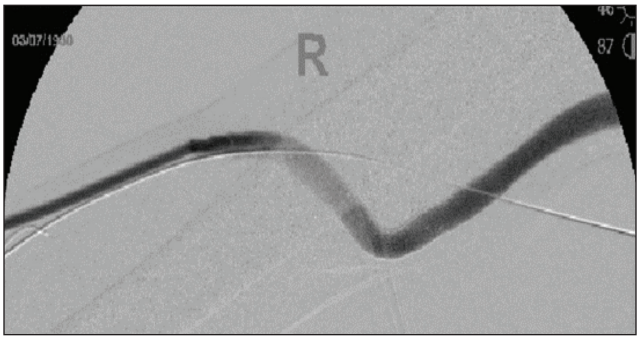

Figure 8. After placement of a 9 mm x 5 cm GORE® VIABAHN® Endoprosthesis with the previously placed stent and extending into the draining right axillary vein, prompt flow was reestablished through the patient's graft.

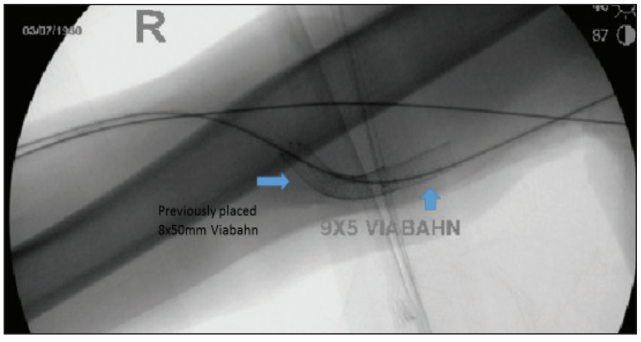

Figure 9. The newly placed GORE® VIABAHN® Endoprosthesis is in good position and is centrally placed within the draining vein. The tip of the stent is not angulated as it enters the draining vein, which improves flow and decreases the incidence of vessel trauma and/or the development of neointimal hyperplasia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

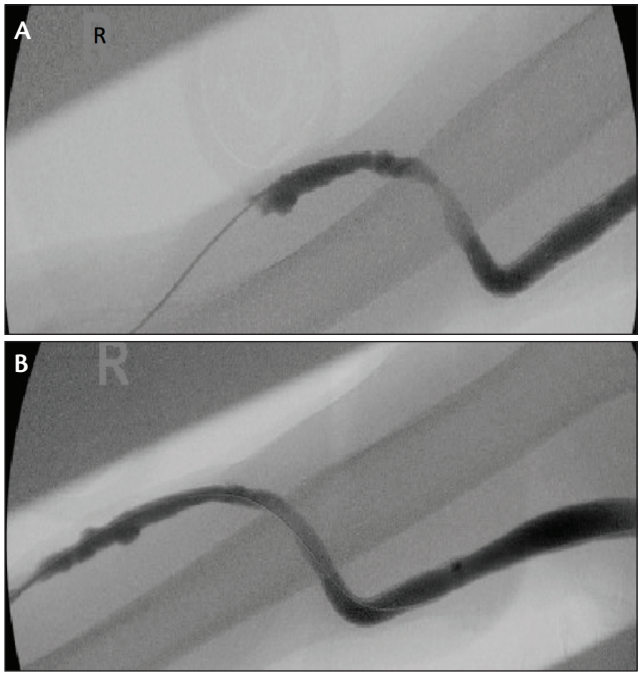

Figure 10. Follow-up shuntogram revealed an area of stenosis within the distal aspect of the right upper arm AV graft (A). There remained wide patency of the previously restented venous anastomosis (B).

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 sheer 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 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

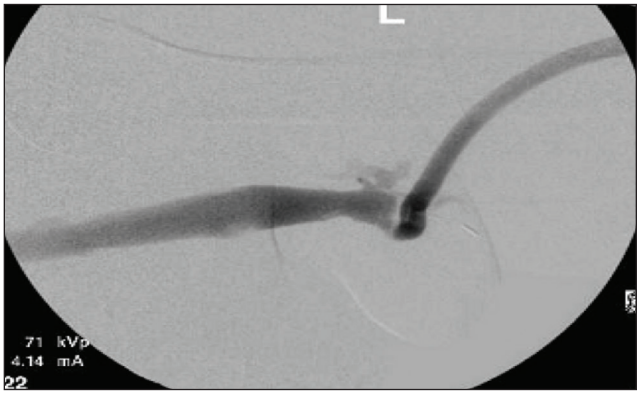

Figure 11. The patient presented because of prolonged bleeding upon removal of the hemodialysis needles at the completion of hemodialysis. Note the acute angle between graft and the native draining vein.

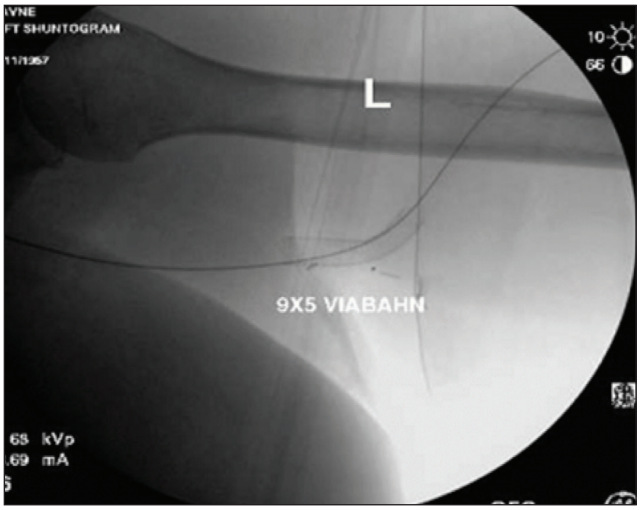

Figure 13. The position of the GORE® VIABAHN® Endoprosthesis across the venous anastomosis.

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

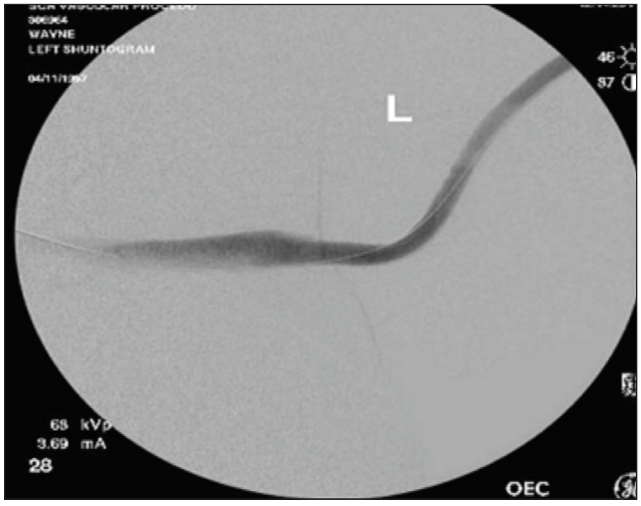

Figure 12. Angioplasty was performed on the high-grade stenosis; however, this was the third intervention on this lesion, and a stent was placed. The completion shuntogram demonstrates the flexibility of the GORE® VIABAHN® Endoprosthesis and the resulting improved flow through the newly stented venous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

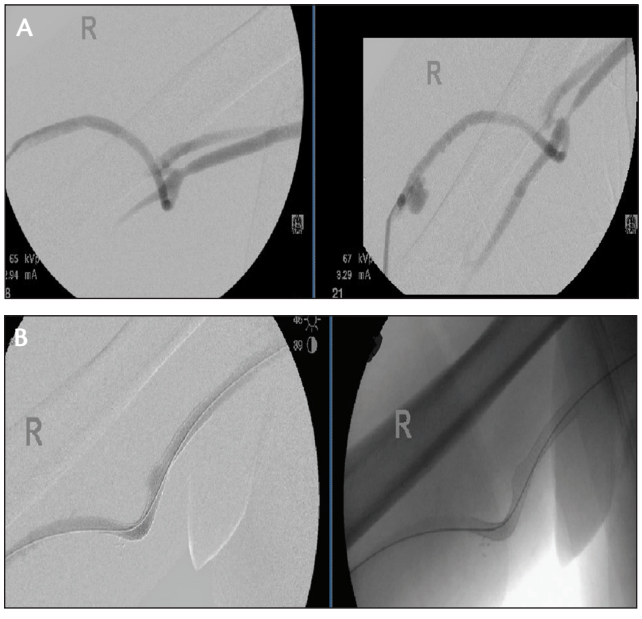

Figure 14. This patient presented because of decreased flow rates noted at the dialysis center. The shuntogram revealed not only tortuosity at the venous anastomosis but also acute angles between graft and native vein (A). The GORE® VIABAHN® Endoprosthesis easily negotiated the tortuosity and acute angle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