Stent-Graft Sizing for AV Access Creation and Revision Procedures

Wall apposition is not necessary for quality results.

BY JOHN R. ROSS, MD

Creating and maintaining a functional vascular access in many hemodialysis patients remains a significant challenge due to an increasingly complicated end-stage renal disease patient population with significant comorbidities and multiple previous failed arteriovenous (AV) access attempts. Many of these patients may not be suitable candidates for creation of an AV fistula, and an AV graft (AVG) may be the preferred method of AV access creation.[1] Although it is essential to create a functional access and attempt to maintain that access as long as possible, it is also imperative to plan each patient's possible revision strategy.

This article describes sizing and positioning of the GORE VIABAHN Endoprosthesis and the GORE Hybrid Vascular Graft (Gore & Associates) for AV access creation and revision procedures. My experience, recent clinical data, and computational fluid dynamics (CFD) studies have demonstrated that a lack of vein wall apposition at the distal tip of stent-grafts placed in an outflow vein are not necessary in order to provide quality long-term results.

CREATION STRATEGIES: INFLOW, OUTFLOW, CONDUIT

When creating an access, there are three components that must be carefully considered: the inflow, the outflow, and the conduit. There must be adequate inflow to sustain flow in an access and, similarly, adequate outflow to accept the blood going through the conduit. When choosing a synthetic conduit, the patient must be evaluated in terms of anatomy, location, and size of their veins and arteries, previous access history, and the potential need for early cannulation. The configuration of the conduit must also be considered. One conduit of choice, especially for the complex patient, is the GORE Hybrid Graft.

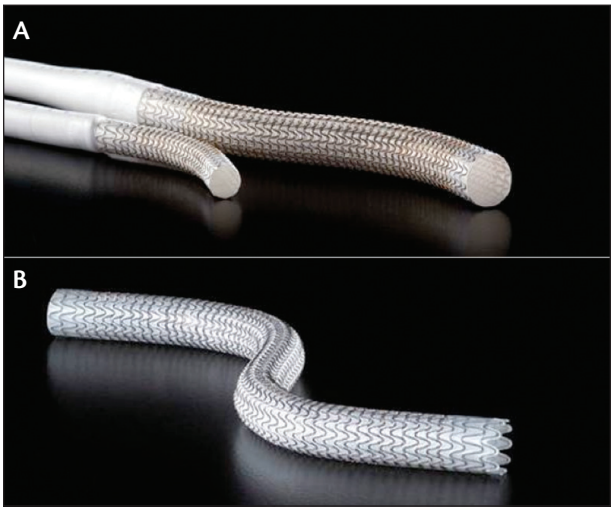

Figure 1. The GORE Hybrid Vascular Graft (A) and the GORE VIABAHN Endoprosthesis (B).

The GORE Hybrid Graft is an expanded polytetrafluoroethylene (ePTFE) graft with a Nitinol Reinforced Section (NRS) on one end (Figure 1A). The GORE Hybrid Graft includes the CBAS Heparin Surface, consisting of covalent end-point attached heparin on the luminal surface. The constrained NRS can be deployed into a vessel, resulting in a sutureless end-to-end anastomosis. The venous anastomosis can be performed with a minimally invasive, over-the-wire technique. This technique allows one to access the adequate outflow vein in patients with challenging anatomy and/or deep vessels.

REVISION STRATEGIES: ESTABLISHING A NEW OUTFLOW

Formation of neointimal hyperplasia at the venous anastomosis remains the most common cause of AVG failure, many times requiring multiple interventions to

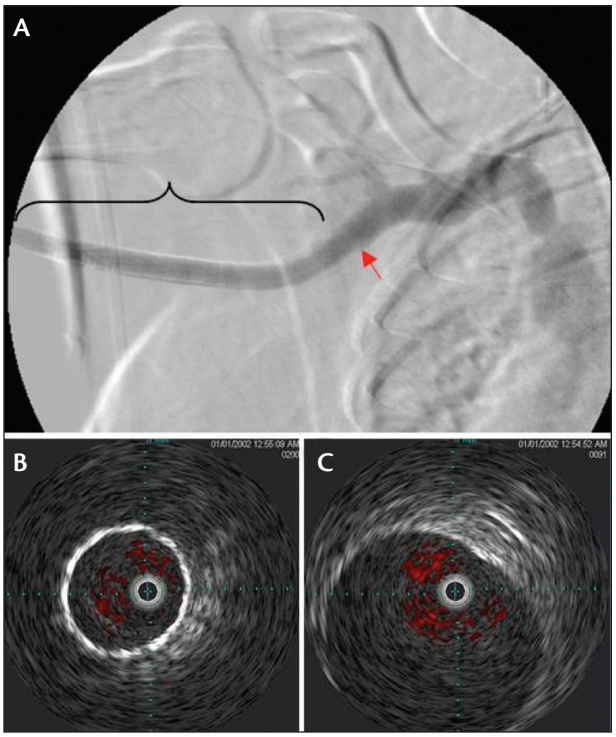

Figure 2. Case example of the GORE VIABAHN Device (bracket) extending an AV access graft into a larger outflow vein (arrow). The angiographic view demonstrates little-to-no backflow observed (A). Intravenous ultrasound visualizes the smaller-diameter cross-section of the GORE VIABAHN Device (B) as compared to the outflow vein (C).

maintain graft patency.[2] If an AVG fails due to outflow stenosis or thrombosis, the use of the GORE VIABAHN Device should be considered. The GORE VIABAHN Device is constructed with a durable, reinforced, biocompatible, ePTFE liner attached to an external nitinol stent structure (Figure 1B). It is indicated for the treatment of stenosis or thrombotic occlusion at the venous anastomosis of synthetic AV grafts.

STENT-GRAFT SIZING CONSIDERATIONS

The strategy for sizing a stent-graft, whether in the arterial system or the venous system, has historically been to oversize with respect to the recipient vessel. Data demonstrate that, in the arterial system, the GORE VIABAHN Device should be oversized by 5% to 20%, but that oversizing by more than 20% results in decreased patency rates.[3]

While it is recommended to oversize a stent-graft to the recipient vessel by 5% to 20% to ensure adequate anchoring, in the venous system, I always ensure that the size of the distal tip of the stent-graft (or NRS of the HVG) is smaller than the adequate outflow vein, providing robust flow through the device and good long term results (Figure 2). Of course for stent-grafts, I first ensure that I have adequately sized to

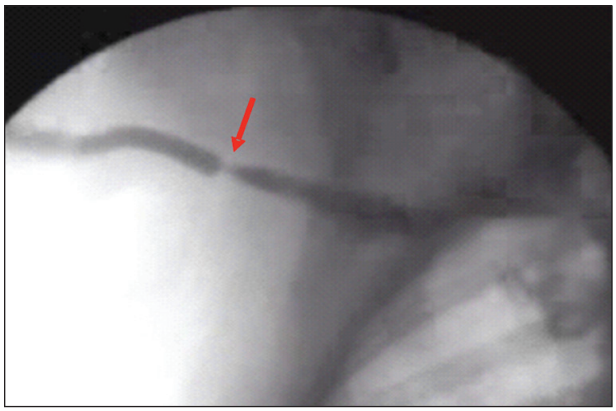

Figure 3. Example of oversizing a stent-graft in the venous system by more than 20%, resulting in acute spasm at the end of the stent-graft (red arrow).

the inflow in order to gain wall apposition for anchoring of the device and to prevent migration. In my experience, oversizing the outflow in the venous system can produce an acute spasm at the end of the stent-graft (Figure 3) and/or rapid end-stent stenosis, resulting in poor long-term outcomes. It is unclear whether this phenomenon is due to improved hemodynamics, lack of foreign body response, larger outflow considerations, and/or some other response.

CLINICAL OUTCOMES OF LANDING IN A LARGE OUTFLOW VEIN

I choose to use the GORE VIABAHN Device as a de novo treatment for strictures > 2 cm long or those that do not respond well to percutaneous transluminal angioplasty (PTA). In my experience, the longer strictures tend to have a high recurrence rate. Short strictures that either have a high-grade stenosis or that immediately rebound after PTA also tend to have a high recurrence rate. In those instances, the natural history of the AV access has declared itself to be unresponsive to PTA, and that patient is destined for frequent visits to the operating room unless an alternative treatment method is chosen. The GORE VIABAHN Device will change the natural history of that access by excluding the compromised vein from the AV access circuit. In my experience, the outcomes of the device tend to be more durable than other endovascular techniques and should work for the majority of patients with large outflow veins for at least 9 to 12 months before recurrence.

The durability of the GORE VIABAHN Device, however, can be affected by the choice of landing zone. Often, I will seek to not only overcome the stricture but also reach an outflow vein > 9 mm or at least 1 mm greater than the device, as demonstrated in Figure 2. The longer length options of the GORE VIABAHN Device allow the device to reach larger healthy vessels without the need for placing multiple devices.

The GORE Hybrid Vascular Graft adds significant options, particularly when creating an access in a patient with a violated axilla. This is a patient with an axilla that has had multiple explorations with multiple grafts in place and/or a patient with a massively obese arm. The GORE Hybrid Graft is also a valuable tool when a patient does not have an adequate target vein in the axilla but has an adequate outflow vein higher up toward the chest wall.

The GORE Hybrid Vascular Graft comes with an NRS of four different diameters (6, 7, 8, and 9 mm) and in two lengths (5 and 10 cm). The appropriate diameter and length of the NRS should be chosen based on where the tip of the NRS will land in the adequate outflow vein. If the vein where the tip of the NRS will land is > 9 mm in diameter, I will use the 9 mm Hybrid configuration. If the vein (where the tip of the NRS will land) is 9 mm in diameter, I will choose an 8 mm diameter NRS, and so on. It is important to recognize that, while the tip of the NRS may be undersized to the vein and not have wall apposition, the majority of the length of the NRS of the GORE Hybrid Vascular Graft is typically sized to the vein according to the Instructions for Use (IFU) recommendation of 5% to 20% oversizing, ensuring adequate anchoring to the vessel wall. The 10 cm length NRS is usually chosen for deep axillary procedures in order to reach the adequate outflow.

OTHER POSITIONING AND LANDING ZONE CONSIDERATIONS

When the GORE VIABAHN Device and the GORE Hybrid Graft are used in the axillary region, some may have concerns that blocking the venous return with the stent-graft (or NRS of the GORE Hybrid Graft) may cause edema or arm swelling. Due to the rapid and extensive collateralization of the venous system, I do not hold this concern and have not had any significant problems with arm swelling or edema after placing these devices in the axillary region.

In addition to diameter sizing, it is also critical to position and land the stent-graft (or NRS of the GORE Hybrid Graft) properly within the vein. This positioning consideration includes the concentricity of the vessel with the device. It is important to attempt to ensure that positioning of the stent-graft (or NRS) is straight into the larger vein, centered down the "barrel" of the large vein (Figure 2), so that the outflow is directed "inline" with the host vein. If the tip of the stent-graft is directed at an angle, the high-pressure arterial flow will impinge on the native vein and may cause significant vessel trauma and/or intimal hyperplasia development.

Valves are another critical consideration in selecting an adequate landing zone for the device. In my experience, landing inside or within 1 cm proximal to the valve can lead to rapid endothelial buildup at the edge of the device. I choose to cross the valve by at least 1 cm to avoid this potential failure mode (Figure 4).

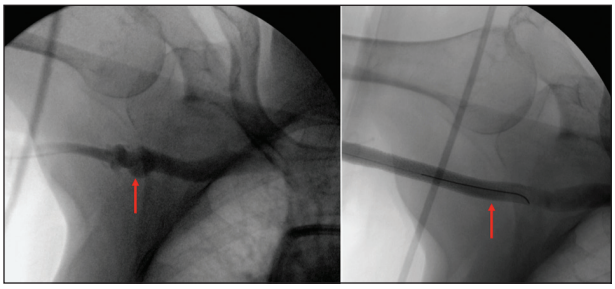

Figure 4. Example of appropriate landing of the NRS of the GORE Hybrid Graft beyond a vein valve. The red arrows indicate the valve and tip of the NRS.

THE GORE REVISE CLINICAL STUDY

Results from the Gore REVISE clinical study support the previously described process of care strategy for my practice. A subset of the subjects in the study had an outflow vein with a diameter at least 1 mm greater than the implanted GORE VIABAHN Device (n = 49). For those subjects, the target lesion and circuit primary patency was 62% and 48% at 6 months, respectively, with an access secondary patency of 77% at 2 years.[4] These outcomes represent an improvement over the rest of the study cohort, albeit not statistically significant. These results demonstrate that similar clinical success, similar to what I have experienced with the GORE VIABAHN Device, can be achieved without stent-graft wall apposition to the outflow vein.

OBJECTIONS TO SIZING METHODOLOGY

Migration, the ability to declot, and flow disturbance are three common objections to placing a device at a graft anastomosis that is smaller than the outflow vein. These three objections, however, have not been demonstrated to be a clinically significant issue with either the GORE Hybrid Graft or the GORE VIABAHN Device when landing in a large outflow vein.

Migration is a logical objection because the opportunity to gain wall apposition is reduced if the stent-graft "jumps" forward during deployment. This is not a concern for the GORE Hybrid Graft because the NRS is attached to the graft. The unique design and deployment system of the GORE VIABAHN Device relies on a single pull of a deployment line as opposed to a push-pull mechanism. The result is highly accurate and consistent placement of the device that does not lend itself to jumping forward during deployment. Proper upstream sizing as well as accurate delivery are tantamount to preventing migration. Once deployed, both the graft and

the stenosis provide enough vessel wall surface area to allow the device to anchor in place and prevent spontaneous migration. No device jumping or spontaneous migration was reported for the entire Gore REVISE clinical study, including a subset of the subjects who had an outflow vein with a diameter at least 1 mm greater than the implanted GORE VIABAHN Device.

Standard declotting techniques are still applicable for devices that are smaller in diameter than the outflow vein. However, care should be taken with mechanical thrombectomy when transitioning from the device to the vein. Catching the exposed edge of the GORE VIABAHN Device with the mechanical thrombectomy device can lead to an adverse event and potential device destruction.

Flow disturbance is observed when there is an increase in turbulence associated with high velocity flow exiting the stent-graft into the larger open vein. However, the presence of disturbed flow is not enough to result in access dysfunction. The disturbed flow has to result in a significant increase in wall shear stress (WSS) for a hyperplastic and/or thrombotic response to be initiated.[6-11] In the next section, the impact of wall apposition on WSS of the outflow vein will be explored via a CFD model.

COMPUTATIONAL FLUID DYNAMICS

WSS Generated By a Stent-Graft Without Wall Apposition Versus With Wall Apposition

Elevated WSS has been correlated with remodeling of the vasculature in the form of neointimal hyperplasia as well as the formation of thrombus.[6-11] The remodeling is thought to be a mechanism to restore the WSS within the veins to the physiological range between 1 to 6 dyn/cm^2.[7] Thus, by creating a stenosis, the blood flow can be reduced and with it the WSS. The development of neointimal hyperplasia is confounded by the variability associated with the oscillatory nature of blood flow between the WSS of 15 to 75 dyn/cm^2.[10] However, beyond 75 dyn/cm^2, the impact of WSS on both neointimal hyperplasia and the activation of thrombosis pathways becomes significant.[6,7,11]

Engineers at Gore & Associates created a computational fluid dynamics (CFD) model study to understand the impact of flow disturbances on WSS. In this study, AV access hemodynamics in two outflow geometries (Figure 5) were compared using three-dimensional CFD simulations. Both geometries—generated using SolidWorks (Dassault Systèmes, S. A.)—had a graft inlet diameter of 7 mm and a vein outlet diameter of 11 mm, as illustrated in Figure 5. It was assumed that the upstream venous return was completely occluded by a stenosis such that the flow at the graft inlet was equal to the flow at the vein outlet. Also, the simulated placement of the stent-graft across the anastomosis was down the "barrel" of the vein, as shown in Figure 2.

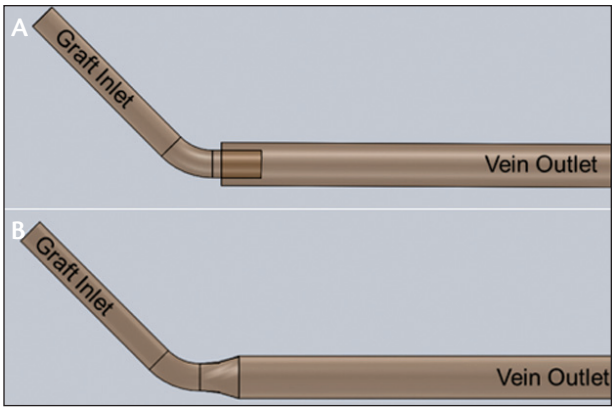

Figure 5. Two access geometries associated with AV access were modeled computationally. The two outflow geometries utilized for the CFD: one without wall apposition (A) and the other with wall apposition (B).

Ansys Fluent software (Ansys, Inc.) was used to obtain the numerical solution for the two cases. The simulated fluid was blood under Newtonian conditions with a density of 1,050 kg/m^3 and a dynamic viscosity of 3.7 cP. The CFD analyses used a prescribed pulsatile inlet flow waveform.[12] The inlet flow rate waveform had a peak flow rate of 1.6 L/min, a mean flow rate of 1.2 L/min, and a time period of 0.85 seconds.

Velocity vector plots are presented at four time points in the cardiac cycle (at 0.1, 0.4, 0.55, and 0.7 seconds) on the central plane for both the geometries (Figure 6). These time points include peak systole (0.4 seconds) and diastole (0.55 seconds), which correspond to the highest and lowest inlet velocities, respectively.

In Figure 6A, it was observed that the higher velocities occur on the bottom of the outflow, distal to the bend the stent-graft takes into the vein. It was seen that a recirculation region exists downstream of the stent-graft, mainly at peak systole and diastole. At the other time points (0.1 and 0.7 seconds), it was observed that the recirculation region was smaller comparatively. The recirculation region varies in intensity over the cardiac cycle, which is an indicator that little to no fluid is retained or pooled in that region past a single cardiac cycle. Figure 6B shows the result for a stent-graft with wall apposition to be similar to the straight stent-graft without wall apposition. Recirculation regions were observed in Figure 6B, and the intensity of the recirculation zones vary over the cardiac cycle. However, the recirculation region was observed to extend closer to the center of the vein, leading to a greater region of recirculation as determined qualitatively.

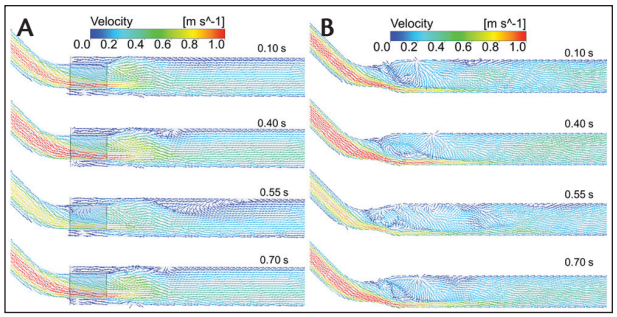

Figure 6. CFD outputs of velocity vector plots on the central plane at four representative time points in the cardiac cycle: outflow without wall apposition (A) and outflow with wall apposition (B).

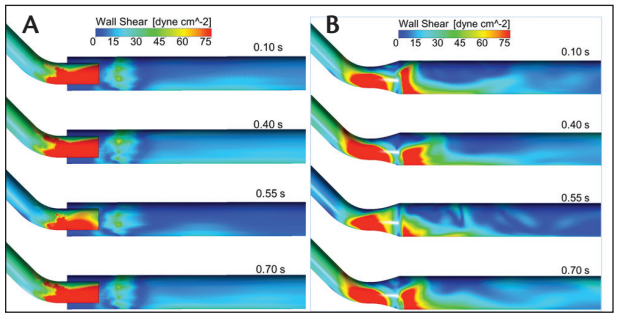

Figure 7. CFD outputs of the WSS contour plots at four representative time points in the cardiac cycle: outflow without wall apposition (A) and outflow with wall apposition (B).

WSS contour plots are presented at the four representative time points in the cardiac cycle for both the geometries in Figure 7. The plots show that the highest WSS is found along the bottom of the stent-graft, distal to the bend the graft takes into the vein for both configurations.

As expected, the highest WSS (> 75 dyn/cm^2) corresponded to the location that had the highest velocity gradients and primarily occurs within the stent-graft. However, in Figure 7A, the WSS dissipated below 75 dyn/cm^2 once the flow transitioned from the stent-graft without wall apposition to the larger outflow vein. By comparison, the configuration with wall apposition in Figure 7B demonstrated high WSS both in the stent-graft and the vein. In this scenario, the maximum WSS was 185 dyn/cm^2, and high WSS was maintained throughout the entire cardiac cycle. The results suggest that a device with a diameter less than the outflow vein may actually reduce the WSS experienced by the vein relative to devices that match the vein diameter.

CONCLUSION

More and more patients are presenting with multiple failed AV access attempts, and these complex patients pose significant challenges when we try to create a functional access. Once a functional access has been created, it is important to strive to keep that access patent as long as possible while also planning the future revision strategy. Whether creating a new access in the violated axilla with the GORE Hybrid Graft or using a GORE VIABAHN Device to revise the outflow vein of a failed AVG, my experience, clinical data, and CFD studies suggest that vein wall apposition of the stent-graft outflow component is not necessary for successful long-term results of the AV access circuit. ■

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

Acknowledgement: Sudeep Sastry, PhD, engineering analyst, for developing the computational fluid dynamics model.

1. Lok CE, Davidson I. Optimal choice of dialysis access for chronic kidney disease patients: developing a life plan for dialysis access. *Semin Nephrol*. 2012;32:530-537.
2. Miller PE, Carlton D, Deierhoi MH, et al. Natural history of arteriovenous grafts in hemodialysis patients. *Am J Kidney Dis*. 2000;36:68-74.
3. Saxon RR, Chervu A, Jones PA, et al. Heparin-bonded, expanded polytetrafluoroethylene-lined stent graft in the treatment of femoropopliteal artery disease: 1-year results of the VIPER (Viabahn Endoprosthesis with Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease) trial. *J Vasc Interv Radiol*. 2013;24:165-173.
4. 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.
5. Haskal ZJ, Trerotola S, Dolmatch B, et al. Stent graft versus balloon angioplasty for failing dialysis-access grafts. *N Engl J Med*. 2010;362:494-503.
6. Van Tricht I, De Wachter D, Tordoir J, Verdonck P. Comparison of the hemodynamics in 6 mm and 4-7 mm hemodialysis grafts by means of CFD. *J Biomech*. 2006;39:226-236.
7. VanBavel E. Effects of shear stress on endothelial cells: possible relevance for ultrasound applications. *Prog Biophys Mol Biol*. 2007;93:374-383.
8. Meyerson SL, Skelly CL, Curi MA, et al. The effects of extremely low shear stress on cellular proliferation and neointimal thickening in the failing bypass graft. *J Vasc Surg*. 2001;34:90-97.
9. Haruguchi H, Teraoka S. Intimal hyperplasia and hemodynamic factors in arterial bypass and arteriovenous grafts: a review. *J Artif Organs*. 2003;6:227-235.
10. Goldman J, Zhong L, Liu SQ. Negative regulation of vascular smooth muscle cell migration by blood shear stress. *Am J Physiol Heart Circ Physiol*. 2007;292:H928-H938.
11. Anand M, Rajagopal K, Rajagopal KR. A model for the formation and lysis of blood clots. *Pathophysiol Haemost Thromb*. 2005;33:472-475.
12. Shu MCS, Noon GP, Hwang NHC. Phasic flow patterns at a hemodialysis venous anastomosis. *Biorheology*. 1987;24:711-722.