The Value of the GORE® ACUSEAL Vascular Graft

Assessing the clinical and economic value of the GORE® ACUSEAL Vascular Graft for AV access in the office-based lab setting.

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In managing patients with end-stage renal disease (ESRD), it is common that the first treatment to prepare for dialysis begins with a tunneled dialysis catheter (TDC). This is mostly because a sustained surgical intervention is involved for the creation of an arteriovenous fistula (AVF) or arteriovenous graft (AVG). However, an AVF takes time to mature before it can be effectively used for hemodialysis, which often leads to dependence on TDCs. The incidence of TDC placement ranges from 75% to 80% and becomes pertinent in cases of delays in referral, noncompliance, or inability to ascertain timely intervention.

Reliance on TDCs in patients with ESRD for dialysis is often associated with complications due to infections with high rates of morbidity and mortality. It has been reported that patients who use a TDC for dialysis have a sevenfold risk of infection,1 emphasizing the need for an AVG that can be cannulated earlier to reduce or avoid dependence on a TDC for dialysis. The FDA-cleared GORE® ACUSEAL Vascular Graft is designed to be cannulated within 24 hours of implantation and represents a promising option to overcome the TDC challenges.

Our center is a nephrology practice with an office-based laboratory that serves the dialysis access needs of patients with renal disease in the Albuquerque metropolitan area as well as adjoining areas of New Mexico. We are focused on providing our ESRD patients with the best possible outcomes by using fluoroscopic- and angiography-guided techniques for dialysis access creation and maintenance. This article discusses the value of early cannulation vascular grafts and the nonsurgical perspective on such a vascular graft.

EARLY CANNULATION VASCULAR GRAFTS

In the past 15 years, the field of dialysis access has seen an emergence of early cannulation graft implantation to circumvent the problems associated with the use of TDCs. Frequent infections, occlusions, chronic venous stenosis, and exhaustion of the conventional access routes have led to adoption of the immediate-access AVGs.2,3 In their randomized clinical trial, Aitken et al found that the rate of infectious complications was 13% less with the use of immediate-access AVGs when compared with the AVF plus/minus TDC group.4

The GORE ACUSEAL Vascular Graft is designed to be cannulated within 24 hours of surgical implantation. The three-layer design incorporates an elastomer membrane between two layers of expanded polytetrafluoroethylene (ePTFE), where the inner luminal layer is bonded with the CBAS® Heparin Surface (Gore & Associates) (Figure 1). It is the elastomeric middle layer that imparts the capability of early cannulation by providing low bleed, removing the need for tissue incorporation before cannulation. Although thicker than conventional grafts, the GORE ACUSEAL Vascular Graft remains very flexible and resists kinking and compression.

Glickman et al reported that the GORE ACUSEAL Vascular Graft had overall patency rates comparable with those of historical control ePTFE grafts.5 More importantly, GORE ACUSEAL Vascular Grafts cannulated in the early phase (< 72 hours after implantation) had no statistically significantly different patency rates compared with those grafts that were cannulated after 21 days. Desai et al reviewed the health economic impact of the
GORE ACUSEAL Vascular Graft and showed a significant cost savings associated with the device as compared with TDCs.6

RECOGNIZED CLINICAL VALUE

In our practice, patients who have the GORE ACUSEAL Vascular Graft benefit from early cannulation of the access, thereby bypassing the use of TDCs. The clinical value of early cannulation to the patient is realized by the completely subdermal access, which lessens infection risk, and the graft can be effectively used for dialysis with 17-gauge needles as early as postoperative day 1. Postoperative edema and healing time are drastically reduced and allow for early cannulation.

The GORE ACUSEAL Vascular Graft also allows for arterialization of upper arm veins when placed in the forearm loop or straight configuration, which fosters the maturation process for a future AV access. The dialysis unit staff have been successful in cannulating the GORE ACUSEAL Vascular Graft very effectively with proper guidance. It is very helpful if the implanting surgeon outlines the graft location and marks the direction of blood flow for the dialysis unit cannulator to further optimize dialysis treatments.

Our continued use of the GORE ACUSEAL Vascular Graft has repeatedly shown a reduction in both the placement and the duration of TDC use. The TDC is used as a bridge access to allow healing from the implantation procedure up to 2 months postsurgery prior to use of the GORE ACUSEAL Vascular Graft. Additionally, we have noticed the rates of catheter use continue to drop, which is reflected by better long-term central vein preservation, consequently improving dialysis and patient quality of life.

Figure 2. Laminar flow at graft vein anastomosis of the GORE® ACUSEAL Vascular Graft.

Figure 3. Minimal clot burden in the GORE® ACUSEAL Vascular Graft that needed repair with aspiration and angioplasty.

ECONOMIC BENEFITS

By lowering the prevalence and duration of TDCs, the GORE ACUSEAL Vascular Graft has had an economic impact on both our practice and the health care system by decreasing hospitalization rates from catheter-related bacteremia, sepsis, and need for long-term antibiotics for the treatment of these catheter-related events. The benefits are also felt at the dialysis units with lower catheter rates and decreased use of antibiotics. Reimbursement rates are positively impacted by decreased TDC prevalence at outpatient dialysis units and home dialysis programs. Furthermore, reimbursement rates are potentially increased if patients have fewer days with a TDC.

ENDOVASCULAR INTERVENTION

In our practice, the GORE ACUSEAL Vascular Graft has rarely required thrombectomy as compared with other grafts. The clot burden of the GORE ACUSEAL Vascular Graft is minimal and relatively easy to remove with the help of commonly available endovascular tools (Figures 2 and 3). Graft vein anastomosis is usually not as stenosed and does not require stent graft placement as often as other grafts. However, I have stented the graft vein anastomosis as with any other graft that is clotted with an appropriately sized covered stent after angioplasty. Intragraft stenosis has been even rarer, but should it arise, a 6- to 7-mm medium- or low-profile balloon is recommended. A low inflow, either from a patient’s low blood pressure or stenosis at the graft arterial anastomosis, can be a reason for early thrombosis of the GORE ACUSEAL Vascular Graft; in these rare instances, addressing them is paramount.
When gaining access for an intervention with the Gore ACUSEAL Vascular Graft, I recommend the standard micropuncture Seldinger technique under ultrasound guidance, which allows visualization through the thick three-layer wall while introducing and advancing sheaths. Once the needle and wire are in, larger devices including balloons, catheters, stents, and stent grafts easily slide through the wall layers, which tolerate the interventions very well. The triple layer of the graft allows fewer chances of pseudoaneurysm formation or wall damage. I have not seen a single case of pseudoaneurysm thus far. The thick layer also allows for quicker hemostasis after needle or interventional apparatus withdrawal. I typically hold manual pressure or apply a temporary purse-string suture to achieve hemostasis.

At the dialysis access unit, initial cannulation into the graft is easy with small 17-gauge needles. As with any AVG, avoid the anastomoses (arterial and venous) by a three-finger breadth distance. In my opinion, it is better to rotate from a bevel-up needle position at skin entry to a bevel-down position while going through the Gore ACUSEAL Vascular Graft wall. Once there is blood return, move the needle again to the bevel-up position by going through a rotating action. When good blood flow is obtained, connect the lines to the dialysis machine.

CONCLUSION

The Gore ACUSEAL Vascular Graft is clinically proven to be cannulated in the early postoperative period, which allows for earlier TDC removal or outright avoidance of TDCs. In our practice, the Gore ACUSEAL Vascular Graft has effectively proven to be a viable early cannulation access graft with undoubted long-term reliable use. In the future, I see increased prevalence of the Gore ACUSEAL Vascular Graft in renal failure patients requiring hemodialysis.


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