

GORE[®] ACUSEAL Vascular Graft and Early Cannulation

Perspective on the potential patient care paradigm shift.

BY MARC H. GLICKMAN, MD

The number of patients starting dialysis with a central venous catheter (CVC) has not appreciably changed in the last decade; the percentage ranges from 78% to 82%.¹⁻³ There are many reasons for this lack of change in the CVC incident rate, including lack of early referrals, patient noncompliance, and an inability to undergo adequate and timely surgical intervention. Although attempts have been made to change these factors, the incidence of CVCs still remains high in the United States. The high morbidity and mortality rates associated with catheter dialysis are often noted within the first 90 days of starting dialysis.⁴ Infection is the second most common cause of death in the hemodialysis population.⁵ For this reason, the possibility of using an early cannulation graft for dialysis is intriguing in that reducing the time to catheter removal or avoiding catheters could have a positive impact on the dialysis population. This impact could result in a reduction in infections, improving mortality and morbidity in these patients, and possibly reducing the incidence of central vein stenosis.

A new graft developed by Gore & Associates is a trilayer expanded-polytetrafluoroethylene (ePTFE) graft composed of an inner layer of ePTFE bonded with CBAS Heparin Surface, a middle elastomeric layer, and an outer layer of ePTFE (Figure 1). Although there are reported cases of early cannulation with standard ePTFE grafts, hematoma formation and excessive bleeding are the major reasons that these standard grafts should not be cannulated within hours or days of implantation.

The GORE ACUSEAL Graft allows for early cannulation and is provided in three lengths. This includes a 6 mm × 40 cm graft for primary graft implant and a 6 mm × 10/20 cm graft for arteriovenous graft revisions. The use of the GORE ACUSEAL Graft for revisions due to infection or pseudoaneurysmal formation allows for extensive repair without the need for placement of temporary catheters, as this new graft may be accessed immediately without any increase in infection or hematoma formation (Figure 2).

A new 4 to 7 mm tapered GORE ACUSEAL Graft is on the horizon. The hope, as with any tapered graft, is that the incidence of steal will be reduced and allow for use in very high-risk steal patients.

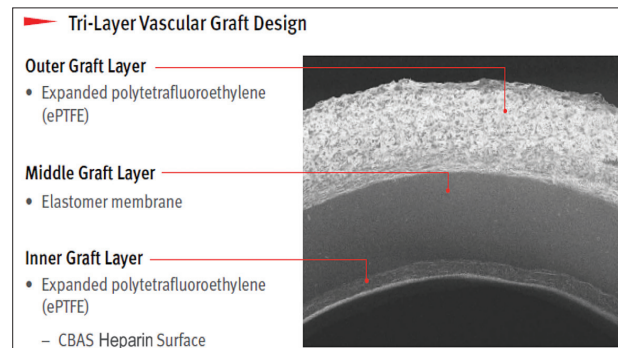


Figure 1. This is a scanning EM of the GORE ACUSEAL Graft demonstrating the three layers of the graft. The middle elastomer layer provides the “low-bleed” state of the graft.

SURGICAL IMPLANTATION

As opposed to other early cannulation grafts, the GORE ACUSEAL Graft does not have any particular tunneling needs. A Kelly Wick Tunneler (Bard Peripheral Vascular) or Sheath Tunneler (Bard Peripheral Vascular) may be used to tunnel the graft into position. Due to the slightly larger outer diameter (8.8 mm), a slightly larger sheathed tunneler needs to be used rather than the standard, commonly used devices.

The GORE ACUSEAL Graft has a strong radial force, and there has been no evidence to date of any kinking or compression of the graft. Sewing of this graft to the vessels is not mechanically different from sewing standard ePTFE grafts. Care should be taken to ensure that the arterial anastomosis is not overly large, staying within the 5 mm size. No special care is needed for the venous anastomosis. Surgeons find this graft easy to use and quite malleable in its handling properties, including a reduction in suture line bleeding (Figure 3).

One observation is how these grafts incorporate into the subcutaneous tissue. There are two different types of tissue incorporation. The majority of grafts become incorporated into the surrounding tissues like other ePTFE grafts. A subset of grafts, upon dissection, does not appear to be completely incorporated. This nonincorporation does not mean the graft is infected. To date, none of the nonincorporated



Figure 2. Tunneling of the graft and bypassing a large infected cannulation site.

grafts has become infected. Therefore, if there are no signs of infection (ie, sepsis or purulence), then the nonincorporation does not mean infection, and the graft should remain in place. This is a new concept and a very important observation seen primarily in African American women.

EARLY CANNULATION GUIDELINES

Educating and working with the dialysis unit is an important first step in achieving good results with an early cannulation graft. Many of the staff members in dialysis units are not familiar with cannulating grafts in the early postoperative period, and educating the nursing staff is important for success. Many of the units' staff members may be resistant, but once they have experience, they will accept the concept of early cannulation, knowing the catheter will be able to be removed sooner.

Suggested guidelines for accessing early cannulation grafts include prepping the cannulation site with a bacteriostatic solution, having the nurse/technician wear sterile gloves, and using a 17 gauge dialysis needle for the first three sessions within the first 2 weeks of implantation, whichever comes first. The literature suggests using lower flows up to 250 mL/min as opposed to high flows up to 400 mL/min that are used later in a graft's history.⁶ This means after a graft has been cannulated successfully three times, the higher normal flow rates can be used. However, our experience has shown that using near-normal flow does not increase any complication rate of early access with this device. The suggested lower flows are thought to reduce both turbulence and stresses on the venous anastomosis.⁴ Some European dialysis units use the sterile glove technique, and this has resulted in an overall lower infection rate in their graft population.

It is important to note that the GORE ACUSEAL Graft is a low-bleed graft. This means that light pressure needs to be placed on the decannulation site for 10 to 15 minutes. The GORE ACUSEAL Graft is not a no-bleed graft; therefore, this light, constant pressure is needed to avoid any hematoma

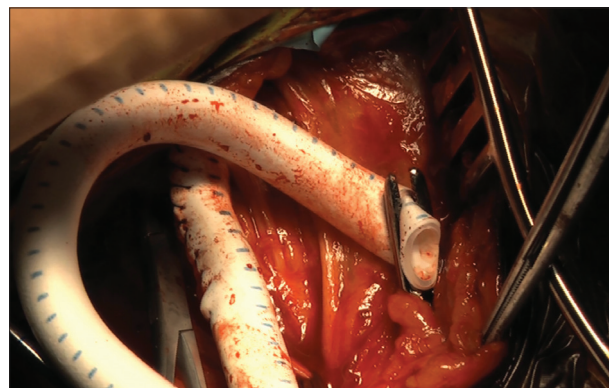


Figure 3. This graft is easy to use and malleable in its handling properties. Tunneling with a large clamp/forcep may be less traumatic.

formation, particularly in the first weeks after implantation. Educating the dialysis unit staff is important regarding these patients in order to achieve excellent and successful results.

Catheter removal protocols vary from institution to institution. In certain European institutions, a slightly different and more aggressive approach is used than in most centers in the United States. For patients who already have catheters, these are removed the evening before the placement of the GORE ACUSEAL Graft. The graft is then cannulated within 24 hours of placement. These patients have a reduced incidence of seeding of the graft by an indwelling catheter. However, most centers in the United States use a slightly more conservative approach. If a patient already has a catheter, most centers wait for three consecutive dialysis sessions before removing it.⁷ Although this is not totally "catheter avoidance," it does allow for a marked reduction in catheter dialysis days. This is still important and does shift the paradigm to reduce catheter-dependent dialysis days. As one obtains more experience with this new graft, we may be able to be more aggressive in avoiding long-term catheter placement by using temporary catheters for urgent dialysis and then switching promptly to this early cannulation graft.

PATIENT SCENARIOS WITH THE GORE ACUSEAL GRAFT

Case 1

A 76-year-old African American man presented to the emergency department with congestive heart failure and an elevated creatinine level. This patient was in stage 4 end-stage renal disease but was reluctant to undergo placement of any permanent access. The patient received a temporary dialysis catheter, 3 days of aggressive dialysis, and venous mapping. Venous mapping did not show any evidence of suitable veins.

The patient underwent placement of an upper arm straight GORE ACUSEAL Graft from the brachial artery to

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the axillary vein. Access of the graft was within 24 hours after placement, and removal of the temporary catheter was 12 hours after the first cannulation of the GORE ACUSEAL Graft. The graft has been functioning without any problems.

Case 2

A 58-year-old man with tunneled dialysis catheter placement for hemodialysis presented after venous mapping demonstrated no adequate veins for fistula creation. The patient had a catheter for 70 days and already experienced one infection. He underwent a left arm GORE ACUSEAL Graft placement with removal of the catheter 8 days after graft placement. The graft is functioning in this patient with no evidence of infection.

Case 3

This patient is a 68-year-old woman with patent ePTFE forearm loop graft of 3 year duration. She presented with a large pseudoaneurysm along the entire length of the graft. The patient underwent a jump graft around the pseudoaneurysm with a GORE ACUSEAL Graft. The graft was accessed 24 hours after placement, and no catheter was utilized in this patient.

SUMMARY

The GORE ACUSEAL Graft is a new trilayer graft that has been cleared by the US Food and Drug Administration

for vascular access and has the claim of early cannulation. The use of this graft has the potential to shift the paradigm of catheter usage. This may be done by either early access of the graft after implantation and removal of the present catheter or with catheter avoidance by cannulating the graft immediately after placement. Education of the dialysis facility is imperative in order to achieve excellent results with this new graft. Continued experience with this graft allows for a more aggressive approach to these very complex patients. ■

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