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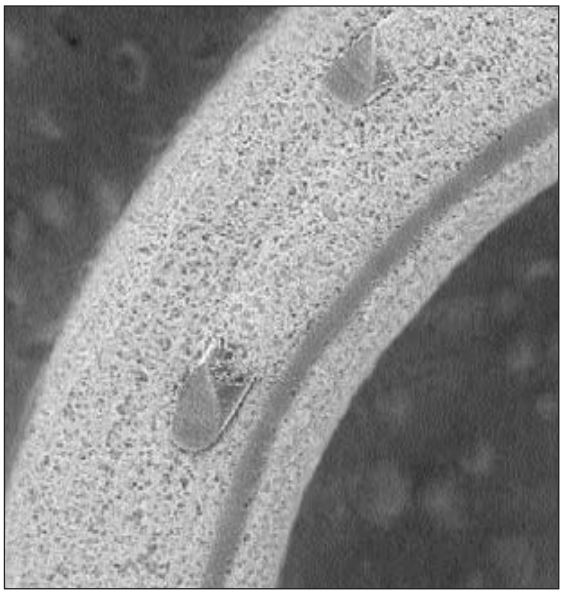
VECTRA® HEMODIALYSIS VASCULAR ACCESS GRAFT PROVIDES EARLY ACCESS WITHOUT COMPROMISING LONG-TERM PERFORMANCE

The overwhelming majority of patients suffering from kidney failure undergo hemodialysis. Easy and reliable access to the bloodstream is critical to the success of the treatment. Typically, this requires surgical creation of an arteriovenous (AV) fistula or implantation of an expanded polytetrafluoroethylene (ePTFE) vascular access graft connected between the patient's artery and vein. However, both of these accesses have a common limitation in that they require a period of time after implantation prior to use. Autogenous AV fistulas typically require a maturation period of 6 weeks to 6 months before first cannulation, whereas prosthetic grafts are not accessed for 2 to 4 weeks, to permit tissue incorporation. To provide immediate access in this large and growing patient population, most clinicians favor the placement of a temporary central venous catheter to provide access until the graft or fistula matures. In the United States, it is reported that approximately 250,000 hemodialysis catheters are inserted annually. However, use of these catheters contributes to a significant amount of complications including bacteremia, central vein strictures, lower flow rates, increased mortality and hospitalization rates, and decreased hemoglobin levels.



The **Vectra®** hemodialysis vascular access graft (VAG) is designed to provide early access without compromising long-term performance. It features an impermeable middle layer that allows the graft wall to seal rapidly after a needle puncture and removal, thus enabling the graft to be cannulated for dialysis within 24 hours of implantation. This ability may potentially eliminate the use of costly and complication-fraught central venous catheters. Additionally, patients with AV fistulas or ePTFE grafts often require additional time to stop the bleeding after the needles are removed, prolonging treatment time at the dialysis center. Vectra's self-sealing design has the potential to increase quality of life for patients by reducing treatment time and

decreasing bleeding time to one to five minutes after needle removal.

In December 2000, Thoratec Corporation received U.S. FDA clearance to market the Vectra VAG, based on the results of a multicenter randomized prospective clinical study. In the study, a total of 142 patients were randomized to receive either a Vectra or an ePTFE graft after meeting all eligibility requirements. All patients were followed prospectively to 12 months or to the end of secondary patency. Specifically, this study documented the performance of Vectra and ePTFE grafts by determining the patencies and complication for both grafts. Patient characteristics between the two grafts were similar with respect to risk factors and demographic characteristics ($p>0.05$). Subsequently, these same patients were followed for an additional 12 months, resulting in 2 years of follow-up data by a team of surgeons headed by Earl Schuman, M.D. of Oregon Surgical Consults (Portland, OR).

There were 63 grafts in the ePTFE group and 57 in the Vectra group available for analysis. Females comprised 62% of the Vectra group vs. 51% in the ePTFE group. Primary and secondary patencies are similar with both materials at 2 years. ePTFE had a primary patency at one year of 33% vs. Vectra at 35% ($p = 0.3$). The secondary patencies at one year are ePTFE = 78% and Vectra = 73%. Secondary patencies at 2 years are ePTFE = 70% and Vectra = 66% ($p = 0.19$).

The Vectra graft can be utilized immediately after implantation without degradation of patency rates. This can obviate the need for a dialysis catheter, a major goal of the DOQI criteria. In the ePTFE arm, 71% required a dialysis catheter before the graft was used versus 46% in the Vectra arm. The Vectra graft was utilized early (within 14 days) in 68% of those implanted versus 9.8% of the ePTFE grafts ($p = 0.001$). Nevertheless, life tables mean duration was 773 days for ePTFE and 737 for Vectra. Mean duration from time of first use of the graft was 778 days for ePTFE and 780 days for Vectra. There was no difference in patency rates between Vectra grafts used early and those accessed for the first time after more than 14 days.

Sealing time after dialysis was significantly different between the groups, with the ePTFE mean being 7.2 minutes and the Vectra mean being 3.4 minutes ($p = 0.0001$). The thrombectomy rate was higher in the Vectra graft than with ePTFE (0.9/yr vs. 0.53/yr). The total complication rate was also higher in Vectra. This was thought to be due to a learning curve in handling this new material.

In those patients who are not candidates for a native fistula, the Vectra polyurethane graft can provide immediate use, quick sealing times, and durability. Its characteristics were given favorable ratings by the dialysis staff and patients. This graft can help minimize the use of dialysis catheters and be an important part of the armamentarium of the access surgeon.

In the United States, the Vectra Graft is distributed exclusively by Bard Peripheral Vascular, Inc. For more information concerning the Vectra graft, call Bard Peripheral Vascular, Inc. at 1-800-321-4254; contact a Bard Peripheral Vascular representative at ASN booth, #2029; or visit Bard's Web site at www.bardpv.com.