Artificial Organs
27(8):722–727, Blackwell Publishing, Inc.

A Polyurethane Vascular Access Graft and a Hybrid Polytetrafluoroethylene Graft as an Arteriovenous Fistula for Hemodialysis: Comparison with an Expanded Polytetrafluoroethylene Graft

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Abstract: Aim: We evaluated a polyurethane vascular access graft (TVAG), a hybrid polytetrafluoroethylene graft (hPTFEG), and an expanded polytetrafluoroethylene graft (ePTFEG) for postoperative complications and graft patency in their use as prosthetic devices of vascular access for hemodialysis. Methods: Between August 1993 and October 2001, we treated 200 patients in whom A-V fistulas were placed by the same surgeon. These were divided into the following four groups according to the type of blood access: 27 cases of ePTFEG, 23 cases of TVAG, 22 cases of hPTFEG, and 128 cases of an autogenous A-V fistula. We calculated the cumulative patency rates by the Kaplan-Meier method, including primary (problem-free) and secondary (revised or functional) patency rates. Results: The hPTFEG group experienced few thromboses. The absence of perigraft edema in the TVAG group permitted the early use of the TVAG within a few postoperative days for hemodialysis. Among the three graft groups, the primary patency was the best in the hPTFEG group (94.7% at 1 year and 86.1% at 2 years), with a significant difference versus the ePTFEG group. In regard to secondary patency, hPTFEG had an excellent patency of 100% at 1 year and 90.9% at 2 years, and TVAG had a comparable patency with that of ePTFEG. Conclusion: The hPTFEG was considered superior to ePTFEG in terms of being complication-free and had the excellent 2 year secondary patency of 90.9%. TVAG, with a patency equal to that of ePTFEG, could be used immediately after implantation due to the absence of limb edema. **Key Words:** Polyurethane graft—Hybrid polytetrafluoroethylene graft—Expanded polytetrafluoroethylene graft—Graft patency—Blood access—Hemodialysis.

The number of patients requiring dialysis therapy for end-stage renal disease has been increasing rapidly, whereas there have been very few cases of kidney transplant in Japan (1,2). The prolonged survival of patients on dialysis depends on a well-functioning and long-term patent vascular access for hemodialysis (HD). Furthermore, prosthetic vascular grafts are inevitably used for the increasing number of patients whose vessels are unsuitable for an autogenous arterio-venous (A-V) fistula due to diabetes mellitus-derived atherosclerosis. For those cases with vessels devastated by repeated surgical revision following long maintenance of HD, reconstruction of vascular access using synthetic grafts is essential. Therefore, the development of vascular grafts with high performance is very important.

At present, an expanded polytetrafluoroethylene graft (ePTFEG) is available and estimated to be a prosthetic graft with suitable patency and biocompatibility. However, it has some unresolved associated problems, such as postoperative perigraft edema and seroma, and cannot be regarded as ideal for vas-

Received December 2001; revised October 2002.
Presented in part at the 13th World Congress of the International Society for Artificial Organs held November 5–8, 2001 in Osaka, Japan.
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cular access (3). A new polyurethane vascular access graft (TVAG) and a hybrid polytetrafluoroethylene graft (hPTFEG) are among the most recent additions to the list of commercial graft materials used to create an A-V fistula for HD (4,5).

Here, we report our clinical use of ePTFEG, TVAG, and hPTFEG for vascular access and compare the postimplant complications and graft patency rates among the three graft groups.

PATIENTS AND METHODS

Graft materials

In this retrospective clinical study, we used three kinds of prosthetic vascular graft: an expanded polytetrafluoroethylene graft (ePTFEG, Gore-Tex EPTFE graft II/regular graft, nonstretch, straight thin wall type; W.L. Gore & Associates, Inc., Flagstaff, AZ, U.S.A.), a polyurethane vascular access graft (Thoratec vascular access graft, TVAG; Thoratec Laboratory Corporation, Pleasanton, CA, U.S.A.), and a hybrid polytetrafluoroethylene graft (hPTFEG, Atrium; Atrium Medical Corporation, Hudson, NH, U.S.A.). All the grafts were 6 mm in internal diameter and straight types with regard to configuration.

Patients

Between August 1993 and October 2001, we treated 200 patients with chronic renal failure by placement of A-V fistulas. These consisted of the following four groups according to the type of blood access: 27 cases of ePTFEG, 23 cases of TVAG, 22 cases of hPTFEG, and 128 cases of autogenous A-V fistula. The ePTFEG, TVAG, and hPTFEG were used for patients who needed implantation of synthetic grafts between August 1993 and December 1997, between February 1998 and March 1999, and between April 1999 and October 2001, respectively.

Operation of graft implantation

All A-V fistulas were established using synthetic prostheses under regional anesthesia by the same skillful surgeon who had experience in blood access operations for more than 10 years. The grafts were implanted in either a straight or loop configuration in the arm or in a loop configuration in the thigh. In the cases of ePTFEG and hPTFEG, the grafts were anastomosed initially to the native artery in an end-to-side fashion and placed through the subcutaneous tunnel in the correct position. They were anastomosed to the native vein in a similar fashion. In the cases of TVAG, the grafts were first placed into the subcutaneous tissue in the optimal position and then anastomosed in an end-to-side fashion to the native artery and finally to the native vein. The ePTFEG was anastomosed at an angle of 30° between the graft and the peripheral portion of the native vein. On the other hand, the TVAG was anastomosed at an angle of more than 80° because of the elasticity of the TVAG. Following this, the hPTFEG was also anastomosed at an angle of more than 80° (Fig. 1). The anastomoses were performed using a continuous suture technique with 7-0 polypropylene or polytetrafluoroethylene atraumatic needles (Surgelene, United States Surgical Co., Norwalk, CT, U.S.A.; Gore-Tex suture, W.L. Gore, & Associates, Inc., Flagstaff, AZ, U.S.A.).

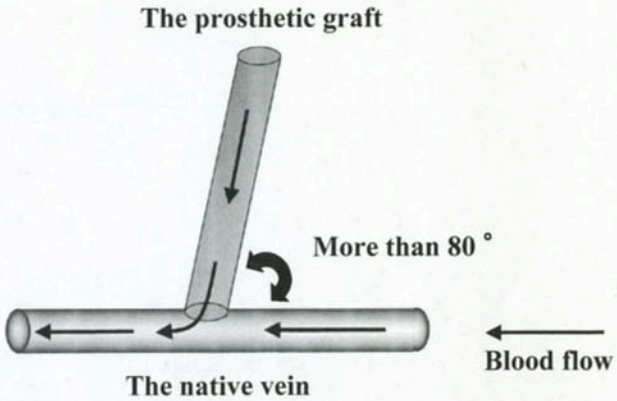

FIG. 1. The TVAG and the hPTFEG were anastomosed at an angle of more than 80° between the graft and the peripheral portion of the native vein.

Assessment

We evaluated the risk factors of the patients of each prosthetic graft group. The complications encountered after implantation were examined among the three synthetic graft groups, which were also compared with regard to the cumulative patency rates including primary (problem-free) and secondary (revised or functional) patency rates.

Statistical analysis was conducted using the Kruskal-Wallis test and chi-square test. Results are expressed as mean ± standard deviation (SD). Differences were considered significant at a P value of less than 0.05. The cumulative patency rates were analyzed by the Kaplan-Meier method and compared by the Logrank test.

RESULTS

Patient profile

The backgrounds of the patients in each group are shown in Table 1. There were no significant differences in the patients' age, sex, duration of HD, cause

TABLE 1. *Background of the patients in each group*

	ePTFEG (n = 27)	TVAG (n = 23)	hPTFEG (n = 22)
Age (years)	63.9 ± 13.3	60.5 ± 10.2	61.7 ± 11.6
Gender			
Male	12	13	14
Female	15	10	8
Duration of HD (years)	8.6 ± 7.5	9.8 ± 9.5	12.0 ± 8.5
Primary case	6	2	6
Cause of CRF			
CGN	14	15	14
DM	9	8	7
Others	4	0	1
Postoperative systolic blood pressure (mm Hg)	143 ± 25	139 ± 19	149 ± 18
Preoperative hematocrit (%)	25.3 ± 6.0	28.9 ± 5.5	29.7 ± 4.0

HD, hemodialysis; CRF, chronic renal failure; CGN, chronic glomerulonephritis; DM, diabetes mellitus.

of chronic renal failure, postoperative maximum blood pressure, and preoperative hematocrit among the three groups.

Design of implantation surgery

Location and configuration of each graft are shown in Table 2. A straight configuration in the upper arm was the most favored implant procedure in all groups. Only one hPTFEG was implanted in the thigh using a loop configuration, compared with eight ePTFEGs and nine TVAGs.

Occasions of postoperative complications and revisions for malfunctioning grafts

Table 3 shows the complications observed after graft implantation. Thrombosis and stenosis occurred a total of 27 times in the ePTFEG group and 15 times in the TVAG group, but on no occasion in the hPTFEG group. Only stenosis occurred on one occasion each in the ePTFEG and hPTFEG groups and twice in the TVAG group. The stenosis often occurred at the venous anastomotic site, which was subclassified into the venous outflow site and the graft end site. The TVAG group experienced no episode of postoperative perigraft limb edema; however it occurred in all ePTFEG cases and in 72.7% (16/22) of the hPTFEG cases, leading to perigraft seromas in one case each in the ePTFEG and hPTFEG groups. In our cases, the absence of perigraft edema enabled the early first puncture of grafts within 4 days after surgery, with an average of 2.4 days in the TVAG group, compared with the ePTFEG and hPTFEG groups, which started HD over 14 days after implantation routinely. On four occasions in the TVAG group, a kink in the end-to-side anastomotic vein or in the middle of the graft of a straight configuration occurred. Pseudoaneurysms at the puncture site or the arterial anastomotic site developed in two cases with TVAG. Graft infection was seen in only one case each in the ePTFEG and TVAG groups.

We attempted to revise and salvage grafts with some complications by surgical and/or endovascular treatment, as shown in Table 4. Thirteen cases (48.1% of 27 cases) in the ePTFEG group and seven cases (30.4% of 23 cases) in the TVAG group received a repair once or repeatedly, whereas only one case (4.5% of 22 cases) in the hPTFEG group was salvaged. Two cases with TVAG underwent thrombectomy six times or more.

Patency

The primary patency rate of 128 cases with an autogenous A-V fistula was 81.8% at 1 year, 76.1%

TABLE 2. *Location and configuration of each graft*

Location	Configuration	ePTFEG (n = 27)	TVAG (n = 23)	hPTFEG (n = 22)
Forearm	Straight	4	1	2
	Loop	3	2	0
Upper arm	Straight	11	10	15
	Loop	1	1	4
Thigh leg	Loop	8	9	1

TABLE 3. *Episodes of postoperative complications in each group*

Complication (frequency)	ePTFEG (n = 27)	TVAG (n = 23)	hPTFEG (n = 22)
Perigraft edema	27	0	16
Thrombosis and stenosis	27	15	0
Stenosis only	1	2	1
Infection	1	1	0
Kink	0	4	0
Seroma	1	0	1
Pseudoaneurysm	0	2	0

TABLE 4. *Number of occasions to revise malfunctioning grafts in each group*

Number of times	ePTFEG (n = 27)	TVAG (n = 23)	hPTFEG (n = 22)
0	14	16	21
1	5	2	1
2	3	1	0
3	4	2	0
4	1	0	0
5	0	0	0
6 or more	0	2	0

at 2 years, 72.3% at 3 years, and 55.8% at 5 years, and the secondary patency rate was 90.0% at 1 year, 85.3% at 2 years, 81.6% at 3 years, and 74.4% at 5 years (Fig. 2).

The primary patency in the TVAG group was 74.1% at 1 year, 67.4% at 2 years, and 44.2% at 3 years, although that in the ePTFEG group was 52.6% at 1 year, 43.1% at 2 years, and 25.1% at 3 years. Moreover, the hPTFEG group showed improvement with a primary patency of 94.7% at 1 year and 86.1% at 2 years (14 of 15 cases were patent at 1 year, and six of eight cases were patent at 2 years). There was a significant difference in the primary patency rate between the ePTFEG group and the hPTFEG group ($P = 0.0016$; Fig. 3).

The secondary patency was almost equal between the ePTFEG group (87.2% at 1 year, 63.0% at 2 years, and 56.7% at 3 years) and the TVAG group (86.6% at 1 year, 73.7% at 2 years, and 63.1% at 3 years). The secondary patency in the hPTFEG group was 100.0% at 1 year and 90.9% at 2 years (all 15 cases were patent at 1 year, and six of seven cases were patent at 2 years), which was a superior result relative to that in the other groups with no significant difference (Fig. 4).

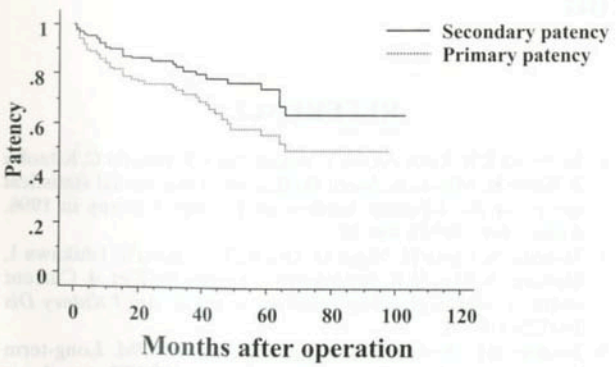

FIG. 2. The primary and secondary patency rate of 128 cases with an autogenous A-V fistula is shown.

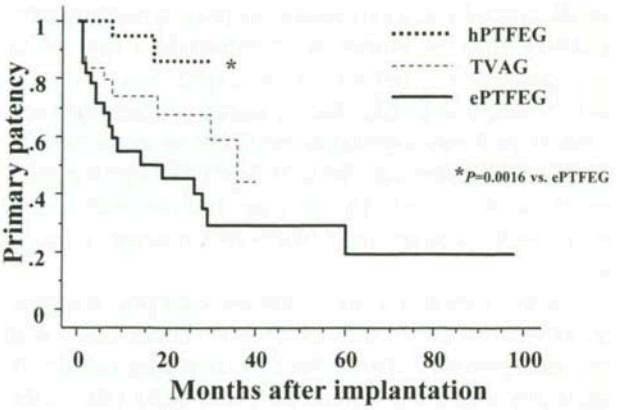

FIG. 3. The primary (problem-free) patency rate in each group is shown. Each graft was considered patent until a graft revision was performed due to complications.

DISCUSSION

Blood access on HD is a lifeline for patients suffering from end-stage renal disease. Several factors are considered to influence blood access patency: (1) blood pressure, blood viscosity, condition of the blood vessel wall, and the duration of HD as patient factors, (2) pre- and postoperative management of vascular access, the surgical technique, and synthetic graft material as operation factors, and (3) graft puncture technique, hemostasis technique, prevention of graft infection, and water balance of patients as HD factors. In particular, a prosthetic graft plays a key role in the creation of an A-V fistula for patients with devastated native vessels. However, considering that a vascular graft, a foreign body in

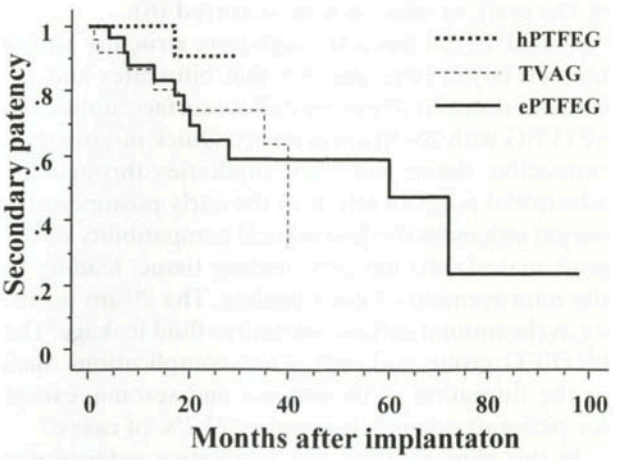

FIG. 4. The secondary (revised or functional) patency rate in each group is shown. Each graft was considered patent if a malfunctioning graft was salvaged and became functional as vascular access for hemodialysis. There was no significant difference among the three groups.

itself, is implanted in patients in poor conditions, the patency may be worsened compared to that of an autogenous A-V fistula. In our experience, even the widely used ePTFEG had a poorer primary and secondary patency compared with autogenous fistulas. Regarding complications in the ePTFEG group, perigraft edema occurred in all cases and thrombosis and stenosis were seen most frequently among the graft groups.

TVAG, which is a three-layered cast polyurethane graft reinforced by spiral polyester fibers, has a wall of zero porosity. This structure features durability, elasticity, and a self-sealing property (4,5). One of the advantages of the TVAG over the ePTFEG is the absence of perigraft edema, which enables the early use of the TVAG after implantation. Therefore, TVAG could be used selectively for patients with an urgent need for HD and enabled shorter hospitalization. Another benefit of TVAG is its prompt hemostasis at the puncture site, which facilitates hemostasis and prevents the formation of a perigraft hematoma. A negative effect of TVAG was its elasticity, which characteristically caused a kink in the native vein and a pseudoaneurysm at the arterial anastomotic site by pulling them upward at the end-to-side venous and arterial anastomosis, respectively. Other causes of a kink were the high surface friction between the wall of the TVAG and the surrounding tissue, and the sequential minimal tissue adhesion of the graft after implantation. Once the TVAG was implanted through the subcutaneous tissue, it fixed the graft strongly in place. This resistance gradually lessened during the period of several months after the operation, and the graft shifted little by little. Consequently, its distortion focused on a weak point of the graft, at which a kink occurred (6).

The hPTFEG has a through-pore structure with a tapered 60 μm pore channel that bifurcates and trifurcates down to 20 μm on its flow surface, unlike the ePTFEG with 20–30 μm porosity. Quick in-growth of connective tissue and even capillaries through the adventitial pores of 60 μm in the early postoperative period enhances the histological compatibility of the graft material to the surrounding tissue, leading to the improvement of graft healing. The 20 μm porosity at the intimal surface minimizes fluid leakage. The hPTFEG group had only a few complications, such as the formation of thrombosis and seroma, except for perigraft edema observed in 72.7% of cases.

In this clinical study, the cumulative patency was the most noticeable parameter for evaluating graft capacity. The process of grouping was based on sequential usage of three different grafts from the ePTFEG in the earliest use to the hPTFEG in the latest use. The graft patency improved in a time-dependent manner, but the gain in experience with time for the surgeon had little influence on the graft patency, as he already had more than 10 years of experience in blood access operations before the beginning of the study. The results showed that the hPTFEG group had notably better primary and secondary patency rates than the other three groups including the autogenous A-V fistula group, though it was observed for only 2 years. The TVAG group had a better primary patency rate and an equal secondary patency rate compared to the ePTFEG group. We predicted that graft patency could depend on the properties of the graft materials and the anastomotic angle between the graft and the peripheral venous portion. Stenotic intimal thickening occurred mainly at the venous anastomotic site, which was subclassified into the venous outflow site and the graft end site (7). The grafts were anastomosed in an end-to-side fashion to the native vein at an angle of 80° or more, with the peripheral venous portion in the TVAG group and the hPTFEG group. The patencies of these two groups were better than that of the ePTFEG group, with an anastomotic angle of 30° to the peripheral vein. We assumed that an anastomotic angle of over 80° potentially reduced the velocity of the jet stream against the venous outflow segment and prevented intimal thickening due to vascular injuries. The change of the venous anastomotic angle might have affected the hemodynamic status around the anastomosis. Further investigation will be necessary to elucidate the mechanism by which venous anastomotic stenosis occurs and develops.

In conclusion, the hPTFEG was considered to be superior to the ePTFEG in terms of being complication free and had an excellent 2 year secondary patency rate of 90.9%. TVAG, with a patency equal to ePTFEG, did not induce limb edema, thereby allowing cannulation immediately after implantation, making it suitable for cases requiring an urgent HD.

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