World J Surg
DOI 10.1007/s00268-008-9912-2

Patency Rates of Cuffed and Noncuffed Extended Polytetrafluoroethylene Grafts in Dialysis Access: A Prospective, Randomized Study

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Abstract

Background Although autogenous arteriovenous fistulae are the optimal route for dialysis access, extended polytetrafluoroethylene (ePTFE) grafts continue to be the preferred access for patients without suitable superficial veins. Among the common complications related to dialysis grafts, thrombosis due to graft outlet stenosis is the most frequently encountered clinical problem. A cuffed graft was designed to eliminate the outflow turbulence to reduce outlet stenosis and to enhance the clinical patency of ePTFE grafts. We conducted a prospective, randomized study to compare the clinical outcomes of cuffed ePTFE grafts and noncuffed grafts in dialysis access.

Methods Between November 2004 and October 2005, 89 ePTFE grafts were implanted for hemodialysis access in the upper extremities of end-stage renal patients. Graft selection was randomized, with patients receiving a cuffed graft (Venaflo) or a regular noncuffed graft (Stretch Gore-Tex). All patients were monitored for signs of thrombosis or other complications. Primary and secondary graft patency was analyzed by using a life-table analysis, and the log-rank test was applied to compare graft patencies.

Results Demographic data for both groups were similar without statistical difference. The primary patency rates and secondary patency rates at 12 months after implantation were 56% and 91% for cuffed grafts, and 41% and 78% for noncuffed grafts, respectively. The cuffed group outperforms the noncuffed group regarding primary and secondary patencies statistically. However, the incidence of other complications that required further surgery was similar in both groups.

Conclusions This investigation revealed that the cuffed ePTFE graft, which was designed to decrease graft outlet stenosis, may enhance the clinical patency rates of dialysis grafts.

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Introduction

Autogenous arteriovenous fistula is known to be the optimal route for hemodialysis treatment for patients with chronic renal failure. However, for patients who have no suitable superficial veins, artificial grafts are generally required. Currently, expanded polytetrafluoroethylene (ePTFE) grafts are the most extensively used artificial dialysis grafts. In contrast to autogenous fistulae, ePTFE grafts are easily subjected to graft outflow tract intimal hyperplasia, which may lead to graft outlet stenosis and graft thrombosis after a certain period of usage.

A cuffed design has been added to the graft-end configuration in a commercial ePTFE graft (Venaflo; Bard Inc., USA) to improve the hemodynamic performance and to reduce outlet stenosis in the long run. The unique cuffed geometrical design has successfully shown by computational analysis to reduce flow turbulence at the graft-venous junction [1, 2]. However, despite the improvement in the hemodynamic parameters, the long-term patency of dialysis grafts remains to be proved.

To evaluate the influence of cuffed ePTFE grafts on the long-term patency of dialysis access, we conducted a

Published online: 27 January 2009

prospective, randomized clinical trial among our dialysis patients. In this study, we compared the clinical patency and the complications occurring with the usage of the commercially available cuffed graft to that with standard noncuffed grafts in chronic renal hemodialysis therapy.

Methods

This prospective, randomized study was designed to examine the clinical performance of cuffed grafts as dialysis grafts. Institutional review board approval was acquired before the study was conducted. All the graft implantation procedures were completed during November 2004 through October 2005. According to the clinical practice guidelines for dialysis vascular access from the National Kidney Foundation, ePTFE grafts were used only for those patients without suitable superficial vein for fistula creation [3]. Patients without suitable superficial veins for access undergoing dialysis graft implantation during the above-mentioned study period were included for the investigation. All the subjects recruited were outpatient clinic patients with clear consciousness and stable hemodynamic status who were suitable for local anesthesia. Patients with small vein size (<3 mm), impalpable arterial pulsation, or low systolic arterial pressure (<90 mmHg) were excluded from the study.

All the patients were randomized into two groups. Randomization was made according to random numbers generated by a personal computer before entering the operation room. Grafts with a cuffed design (Venaflo) were used for the cuffed group and standard grafts with a regular shape (GORE-TEX Stretch Vascular Grafts; Gore Medical, USA) were used for the noncuffed group (Fig. 1). The subjects were blinded to the group assignments; however, operator and staff who assisted the procedures were not. All the implantation procedures were performed by the same surgeon (PJK) in department of thoracic and cardiovascular surgery of Chang Gung Memorial Hospital, using the same surgical principle and techniques for all patients. The sites of the graft implantations were chosen according to the "distal to proximal" principle and were begun from the patients' nondominant hands. The targeted outflow vein was gauged using sizing probes cautiously without overdilatation of the vessel walls. Only those patients with outflow veins >3 mm were included in the observation. Grafts in the forearm were implanted in a looped shape, whereas those in the upper arm were implanted in a curved shape. Patients' demographic data and the size of vessels were all recorded carefully. During the follow-up period, the complications concerning the dialysis grafts as well as the primary and secondary patency of grafts were tracked. Primary patency of the graft was defined as the interval between the implantation procedure and the first time of graft thrombosis, which was determined clinically by auscultation or inaccessibility of dialysis treatment clinically. Secondary patency represents the cumulative interval of patency, including all recannulization procedures, until the graft was abandoned.

Of the 98 subjects randomized into the study, 9 subjects had fallen into the exclusion criteria and were excluded from analysis. The remaining 89 subjects were analyzed (Fig. 2). We chose the primary patency time to determine the power of the study on the basis of data from the previous study, which showed that primary patency time was 168 days in the cuffed group compared with 68 days in the noncuffed group [4]. With 89 subjects and 38 months of

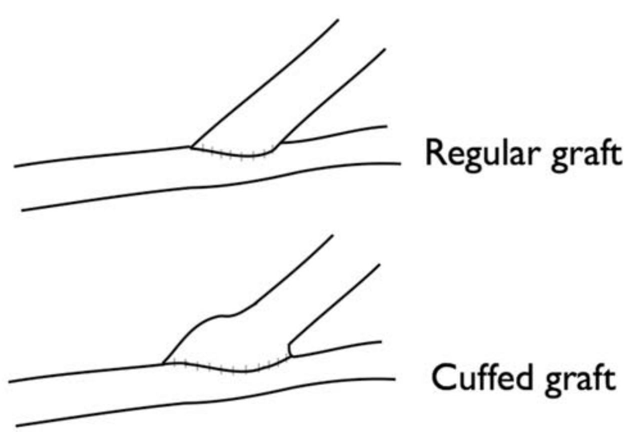

Fig. 1 In contrast to the regular graft, the cuffed graft has a cuffed-shape design on the graft end for venous anastomosis

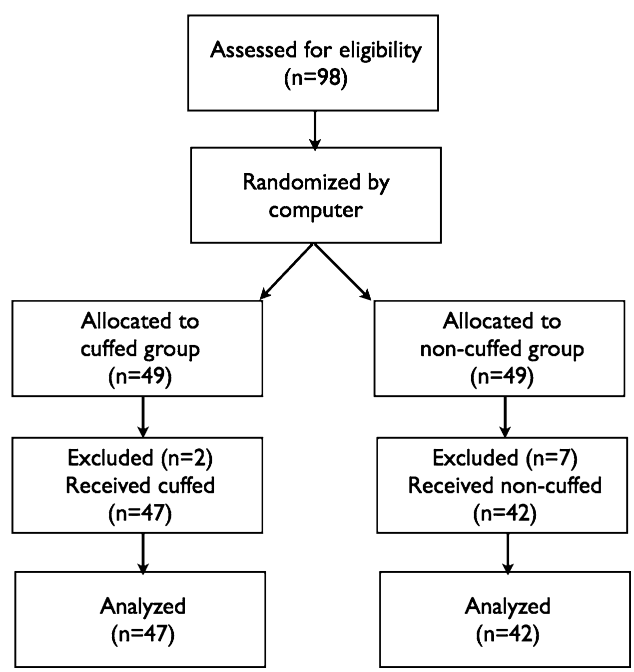

Fig. 2 Patient flow chart

study period, we had 82% power at a 5% level of significance to detect the difference of patency time between these two groups. SPSS 12.0 for Window (SPSS Inc., Chicago, IL) was used for statistical analysis. The χ^2 test and *t* test were used for analysis of continuous and category variables, respectively. Survival curves for primary and secondary patency in each group were calculated by the Kaplan–Meier method. Wilcoxon's test was applied to compare the primary and secondary patency of the two groups.

Results

A total of 89 patients were included in the investigation (cuffed group: 47 patients; noncuffed group: 42 patients). Table 1 summarizes the demographic data of the patients. No significant statistical difference was noted between the two groups in terms of sex, age, graft location, and size of vessels. Similarly, no difference was observed in the prevalence of diabetes, hypertension, or cardiac disease between the cuffed and noncuffed groups. During the observation period, a similar incidence of complications—other than thrombosis—that needed surgery was observed in both the groups. In the cuffed group, two cases had extensive graft infection and one case had vascular access steal syndrome, which required surgical intervention. In the noncuffed group, two cases had extensive graft infection and one case had localized graft infection, which required debridement surgery.

Table 2 shows the primary patency of the grafts, and Table 3 shows the secondary patency in the two groups.

Table 1 Demographic data of two groups

	Cuffed	Noncuffed	*P* value
Gender			
Male	15 (35.7%)	20 (42.6%)	0.524
Female	27 (64.3%)	27 (57.4%)	
Age (year)	61.17 ± 14.06	64.89 ± 11.48	0.173
Comorbidity			
HTN	23 (54.8%)	28 (59.6%)	0.673
DM	13 (31.0%)	22 (46.8%)	0.136
Cardiac disease	8 (19.0%)	5 (10.6%)	0.369
Location			
Upper arm	36 (85.7%)	32 (68.1%)	0.079
Forearm	6 (14.3%)	15 (31.9%)	
Vessel size (mm)			
Artery	4.5 ± 0.94	4.6 ± 0.88	0.4
Vein	5 ± 1.2	4.7 ± 1.1	0.18

χ^2 test was used for sex, comorbidities, and access locations; *t* test was used for age and vessel size

Table 2 Life table of the primary patency of two groups

Months	Cuffed	Noncuffed
0–3	0.9	0.8
3–6	0.85	0.59
6–9	0.79	0.56
9–12	0.63	0.5
12–15	0.56	0.41
15–18	0.49	0.37
18–21	0.45	0.32
21–24	0.45	0.32
24–27	0.45	0.27
27–30	0.39	0.27
30–33	0.31	0.27
33–36	0.31	0.27

Table 3 Life table of the secondary patency of two groups

Months	Cuffed	Noncuffed
0–3	0.98	0.95
3–6	0.98	0.88
6–9	0.98	0.88
9–12	0.98	0.85
12–15	0.91	0.78
15–18	0.88	0.72
18–21	0.84	0.64
21–24	0.84	0.61
24–27	0.79	0.61
27–30	0.79	0.55
30–33	0.73	0.48
33–36	0.73	0.48

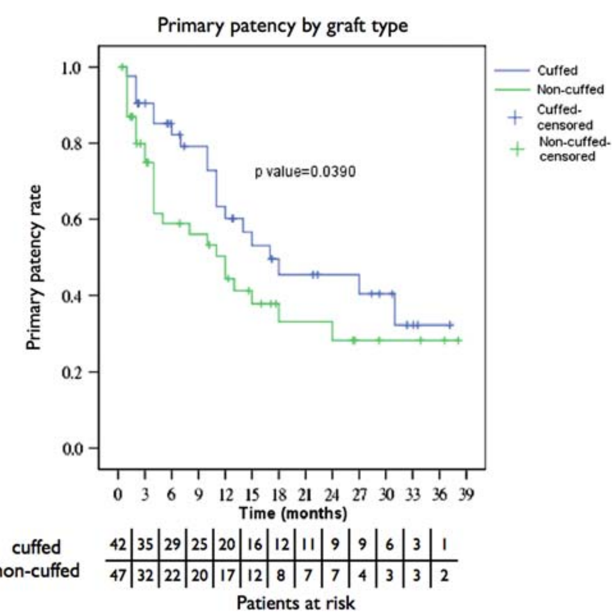

Fig. 3 Cumulative survival curve of primary patency

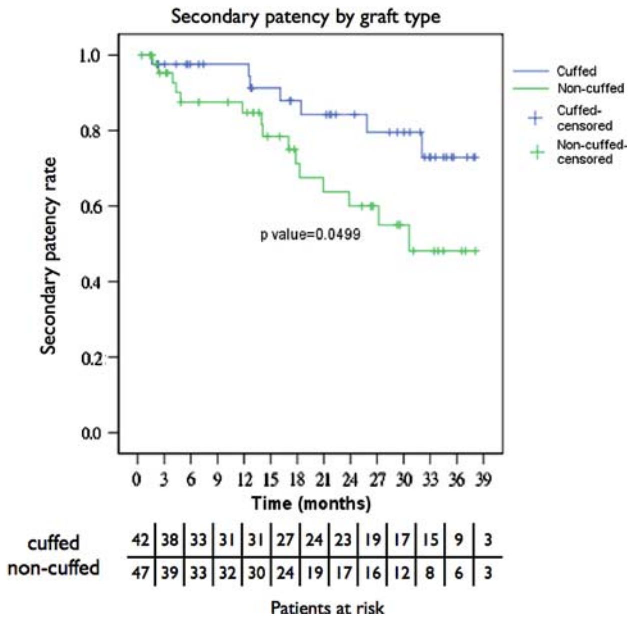

Fig. 4 Cumulative survival curve of secondary patency

Figures 3 and 4 demonstrate the cumulative survival curve of the primary and secondary patencies, respectively. The cuffed grafts had a primary patency of 63% and 45% at 1 and 2 years after graft implantation, respectively. Meanwhile, the noncuffed grafts had a primary patency of 50% and 32% after the same intervals. The secondary patency rate of the cuffed grafts was 98% and 84% at 1 and 2 years, respectively. The secondary patency rate of the noncuffed grafts was 85% and 61% at 1 and 2 years, respectively. Thus, a statistically significant improvement was observed for the cuffed group in the primary as well as the secondary patency rates compared with the noncuffed group.

Discussion

Graft thrombosis resulting from ePTFE graft outlet stenosis is the Achilles tendon of dialysis grafts [5]. In this prospective and controlled investigation, we have demonstrated the superiority of cuffed design ePTFE grafts to regular grafts used for dialysis access in terms of both primary and secondary patency rates. The implanted cuffed dialysis grafts achieved a lower thrombosis rate and yielded better long-term survival compared with the grafts without a cuffed design in our investigation period. Moreover, the occurrence of the other complications that needed surgical treatment during the follow-up period was roughly equivalent (3/47 in the cuffed group and 3/42 in the noncuffed group). The cuffed design had prolonged the life expectancy of dialysis grafts without increasing related complications.

It is important to prevent and treat artificial graft outlet intimal hyperplasia to enhance the longevity of dialysis grafts. Modifications in ePTFE grafts and the recent development of alternative graft materials for hemodialysis access have yielded encouraging early results in efforts to improve the patency of dialysis grafts [6, 7]. Cuff shape configuration of dialysis grafts may produce favorable hemodynamic conditions at the dialysis graft outlet and thus decrease the degree of graft outlet stenosis in the long run. In the event of thrombosis and/or occlusion at the graft outlet, the wider diameter of the graft outlet of cuffed grafts might enhance the ease of recanalization for dialysis access. This may explain the reason for the improved primary and secondary patency rates in the cuffed group in our study.

A cuffed design of dialysis grafts has been demonstrated in studies to create favorable local hemodynamics at the dialysis graft junctions by particle image velocimetry [8]. Graft outlet stenosis is the most common cause of dialysis graft thrombosis; the geometry of the cuffed graft may delay the onset of graft outlet stenosis, delay the progression of the stenosis, and reduce the degree of stenosis [9]. In our preceding study, we successfully showed that application of the cuffed ePTFE graft delays the occurrence of graft outlet intimal hyperplasia and decreases the degree of stenosis in chronic dialysis patients [10]. Other researchers also have demonstrated favorable outcomes for cuffed dialysis grafts in retrospective observations [11]. Sorom et al. conducted a prospective, randomized study in which the superior performance of cuffed grafts compared with that of standard grafts was demonstrated [4]. However, they had only 48 subjects in their investigation. In the current study, we further clarified the correlation of cuffed grafts with improved dialysis graft patency in a controlled, prospective observation in a relatively larger population. Both the primary and secondary patency of both groups are apparently better than those in studies by Tsoulfas et al. [11] and Sorom et al. [4]. This may attribute to the difference in selection of the study subjects. In our investigation, we choose only patients with relatively larger outflow veins (>3 mm, which was suggested by the instruction for use by the manufacture for cuffed grafts) and stable hemodynamics, to eliminate the effect of small veins and poor graft inflow on cuffed grafts. This also may suggest that, with cautious selection of patients with favorable anatomies and hemodynamic condition, we may further enhance both the primary and secondary patency of dialysis grafts (Table 4).

We have found that the cuffed graft outperforms regular grafts in both primary and secondary patency rates. That is, cuffed grafts, compared with standard grafts, are less likely to have graft thrombosis and can maintain long-term patency for dialysis access with greater ease. Intimal hyperplasia of graft outlets was proposed to be related to hemodynamic conditions, compliance mismatch, and surgical injuries at the graft outlets [12]. The cuffed grafts

Table 4 Different studies on cuffed grafts versus standard grafts

	Primary patency (1 year)	Secondary patency (1 year)	Type of study	Case no.
Cuffed				
Tsoulfas et al. [10]	38%	82%	Retrospective	41
Sorom et al. [11]	35%	64%	Prospective randomized	22
Our study	63%	98%	Prospective randomized	47
Noncuffed				
Tsoulfas et al. [10]	26%	56%	Retrospective	26
Sorom et al. [11]	10%	32%	Prospective randomized	21
Our study	50%	85%	Prospective randomized	42

were designed to produce a favorable hemodynamic condition at the graft outlets to decrease the degree of neointimal hyperplasia at the outlet. The development of intimal hyperplasia in cuffed grafts was less severe than that in regular grafts. As a result, the cuffed grafts develop fewer outlet stenosis and lead to fewer thrombotic occlusions than do regular grafts in the same observation period. Even if the cuff grafts become occluded, a considerably number of the grafts can be salvaged and kept patent for a reasonable period of time. The secondary patency of cuffed grafts at 2 years (84%) was still significantly higher than that of regular grafts (64%). The unique spacious geometry of cuffed grafts ensures a lack of extra difficulties during the revascularization procedures of the grafts. On the contrary, the widely open graft outlet may help to make the thrombectomy procedures more effective and lead to a better secondary patency rate.

We have successfully demonstrated the superiority of cuffed grafts (Venaflo from Bard Inc.) compared with noncuffed grafts (Gore-Tex Stretch from Gore Medical) regarding the long-term patency on dialysis access by this prospective study. Meticulous control of the surgical implantation method by a single surgeon was used to reduce the possible noise arising from discrepancies in surgical technique among different surgeons. The grafts used in both the study group and the control group are made of ePTFE, and the main difference between the two grafts lay in the configurations of the grafts (with or without a cuffed shape). However, the two grafts that we used in this study were from two different manufacturers. Therefore, although they were made from the same material, there must have been certain minor differences in graft characteristics, such as graft compliance, ability of soft-tissue incorporation, kinking resistance, puncture resistance, etc., which may interfere with the longevity of the dialysis grafts. Because no reports have concluded that grafts from a certain manufacturer are definitively better than those from another, we hope that these differences do not interfere with the validity of this study. Further studies using grafts from the same manufacturer may confirm the results of our investigation.

In this controlled, randomized, and prospective study, we compared the performance of cuffed and noncuffed ePTFE grafts in new implants for dialysis access. Although cuffed grafts are not perfect for dialysis access compared with autogenous fistulae in terms of patency, the improvement in graft outlet hemodynamic conditions by the cuffed design enhanced the clinical survival of these dialysis grafts. Although the suturing time and anastomosis length required for implanting a cuffed graft are greater than those for standard noncuffed ones, the cuffed design did decrease the incidence of thrombotic occlusion without increasing the incidence of graft-related surgical complications. Our study indicated that cuffed ePTFE grafts, which were designed to decrease the development of graft outlet stenosis, might enhance the clinical patency rates, including the primary and secondary patency rates, of dialysis access grafts.

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