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Dacron or ePTFE for Femoro-popliteal Above-Knee Bypass Grafting: Short- and Long-term Results of a Multicentre Randomised Trial

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Abstract *Objectives:* To compare expanded polytetrafluoroethylene (ePTFE) prosthesis and collagen-impregnated knitted polyester (Dacron) for above-knee (AK) femoro-popliteal bypass grafts.
Design: A prospective multicentre randomised clinical trial.
Patients and Methods: Between 1992 and 1996, 228 AK femoro-popliteal bypass grafts were randomly allocated to either an ePTFE ($n = 114$) or a Dacron ($n = 114$) vascular graft (6 mm in diameter). Patients were eligible for inclusion if presenting with disabling claudication, rest pain or tissue loss.

Follow-up was performed and included clinical examination and duplex ultrasonography at all scheduled intervals. All patients were treated with warfarin.

The main end-point of this study was primary patency of the bypass graft at 2, 5 and 10 years after implantation. Secondary end-points were mortality, primary assisted patency and secondary patency. Cumulative patency rates were calculated with life-table analysis and with log-rank test.
Results: After 5 years, the primary, primary assisted and secondary patency rates were 36% (confidence interval (CI): 26–46%), 46% (CI: 36–56%) and 51% (CI: 41–61%) for ePTFE and 52% (CI: 42–62%) ($p = 0.04$), 66% (CI: 56–76%) ($p = 0.01$) and 70% (CI: 60–80%) ($p = 0.01$) for Dacron, respectively. After ten years these rates were respectively 28% (CI:18-38%), 31% (CI:19-43%) and 35% (CI: 23-47%) for ePTFE and 28% (CI: 18-38%), 49% (CI: 37-61%) and 49% (CI: 37-61%) for Dacron.
Conclusion: During prolonged follow-up (10 years), Dacron femoro-popliteal bypass grafts have superior patency compared to those of ePTFE grafts. Dacron is the graft material of choice if the saphenous vein is not available.

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Introduction

Femoro-popliteal bypass grafting has been shown to be an effective treatment for arterial occlusive disease in patients with severe claudication or critical ischaemia. Autogenous venous conduits are associated with improved patency for both above- and below-knee femoro-popliteal bypass.[1,2] Prosthetic graft material is still a frequently used alternative to venous conduits due to the absence of a good-quality long saphenous vein in many patients.[3] The choice of prosthetic graft material, such as expanded polytetrafluoroethylene (ePTFE) or Dacron, for femoro-popliteal bypass grafts has been controversial over the past decade.[4] Seven randomised clinical trials have been conducted to compare the outcome of ePTFE or Dacron for femoro-popliteal bypass.[5–13] However, interpretation of these studies is difficult due to a number of problems in the design of the investigations, including short follow-up time, the inclusion of both supra- and infrageniculate bypasses and the inclusion of different graft diameters. Consequently, no firm conclusions have been reached on whether ePTFE or Dacron is preferable.[14,15]

The present study was conducted to answer the question whether an ePTFE or a Dacron prosthesis should be used for supragenicular femoro-popliteal allograft bypass grafting.

Patients and Methods

Recruitment for this multicentre randomised trial was carried out from July 1992 until August 1996. The follow-up was extended until June 2007. The protocol followed the rules of the Helsinki declaration and the Consolidated Standards of Reporting Trials (CONSORT) reporting standards have been used. Patient consent was obtained in all cases. Patients were eligible for inclusion if they presented with symptoms of disabling claudication, rest pain or tissue loss and supragenicular femoro-popliteal bypass was feasible. Exclusion criteria were previous ipsilateral femoro-popliteal procedures, contraindication to long-term anticoagulant therapy, life expectancy less than 1 year and current treatment with chemotherapy or radiotherapy.

The preoperative assessment followed The Society for Vascular Surgery/International Society for Cardiovascular Surgery (SVS–ISCVS) risk score,[16] including detailed evaluation of patient history, cardiovascular risk factors, physical examinations, ankle–brachial index (ABI) and intra-arterial digital subtraction angiography (DSA).

Randomisation was stratified for each centre using sealed envelopes. The physician treating the patient could not be blinded to the treatment allocation.

The operation was performed with general or regional anaesthesia. All patients received antibiotic prophylaxis

Table 1 Patient characteristics

Parameter	ePTFE *n* (%)	Dacron *n* (%)	df	Test value	*p*-value
N	114	114			
Gender limbs M/F	74/40	73/41	1	$\chi^2 = 0.02$	0.89[a]
Age (yrs) mean, (range)	66 (43–89)	67 (39–92)	226	$t = -0.60$	0.99[b]
Co-morbidity (%)					
DM	37 (32.5)	30 (26.3)	1	$\chi^2 = 1.04$	0.31[a]
Hypertension	45 (39.5)	38 (33.3)	1	$\chi^2 = 0.93$	0.34[a]
Cerebrovascular disease	19 (16.7)	8 (7.0)	1	$\chi^2 = 5.08$	0.02[a]
Cardiac disease	41 (36.0)	33 (28.9)	1	$\chi^2 = 1.28$	0.26[a]
Smoking			3	$\chi^2 = 5.94$	0.12[a]
Never	21 (18.4)	16 (14.0)			
<10 per day	26 (22.8)	18 (15.8)			
>10 per day	35 (30.7)	31 (27.2)			
Quit	32 (28.1)	49 (43.0)			
Ischaemia category (Rutherford classification)			4	$\chi^2 = 0.82$	0.94[a]
1	3 (2.6)	5 (4.4)			
2	44 (38.6)	40 (35.1)			
3	42 (36.8)	42 (36.8)			
4	10 (8.8)	10 (8.8)			
5	15 (13.2)	17 (14.9)			
No. patent crural vessels[c]			3	$\chi^2 = 2.04$	0.56[a]
0	1 (0.9)	0 (0.0)			
1	31 (27.2)	27 (24.1)			
2	38 (33.3)	45 (40.2)			
3	44 (38.6)	40 (35.7)			

[a] For categorical variables Pearson's chi-square test were used.
[b] For continuous variables Student's *t*-test was used.
[c] A vessel was still 'patent', even if a significant stenosis was present.

consisting of Cefazoline according to local guidelines. Before arterial clamping, 5000 units of heparin were given intravenously. Anastomoses were performed end-to-side, with 6/0 Prolene (Johnson & Johnson; Ethicon, St Stevens-Woluwe, Belgium), proximal to the common femoral artery and distal to the above-knee popliteal artery. Post-operatively, all patients were given Warfarin.

The grafts used were either 6-mm expanded, stretched, thin-walled PTFE (Goretex®, W.L. Gore & Ass., Flagstaff, AZ, USA) or a 6-mm collagen-impregnated Dacron (Hema-shield®, Meadox, Oakland, NJ, USA) (Boston Scientific, Maquet). The patients were scheduled for follow-up after 3 and 6 weeks, 3, 6, 9, 12, 18 and 24 months, and yearly up to 10 years. Review consisted of clinical consultation, a physical examination, ABI and a duplex scan. After surgery and at 1 year a DSA was performed.

The main end-points of this study were primary patency rates of the bypass 2, 5 and 10 years after implantation. Secondary end-points were mortality, primary assisted patency and secondary patency.

In accordance with the SVS—ISCVS[16] guidelines, primary patency was defined as uninterrupted patency without any manipulation of the graft. Primary assisted patency was defined as uninterrupted graft patency, but maintained by prophylactic intervention like angioplasty, patch angioplasty or small graft interpositions. Secondary patency was defined as restored patency after occlusion with or without revision of the graft.

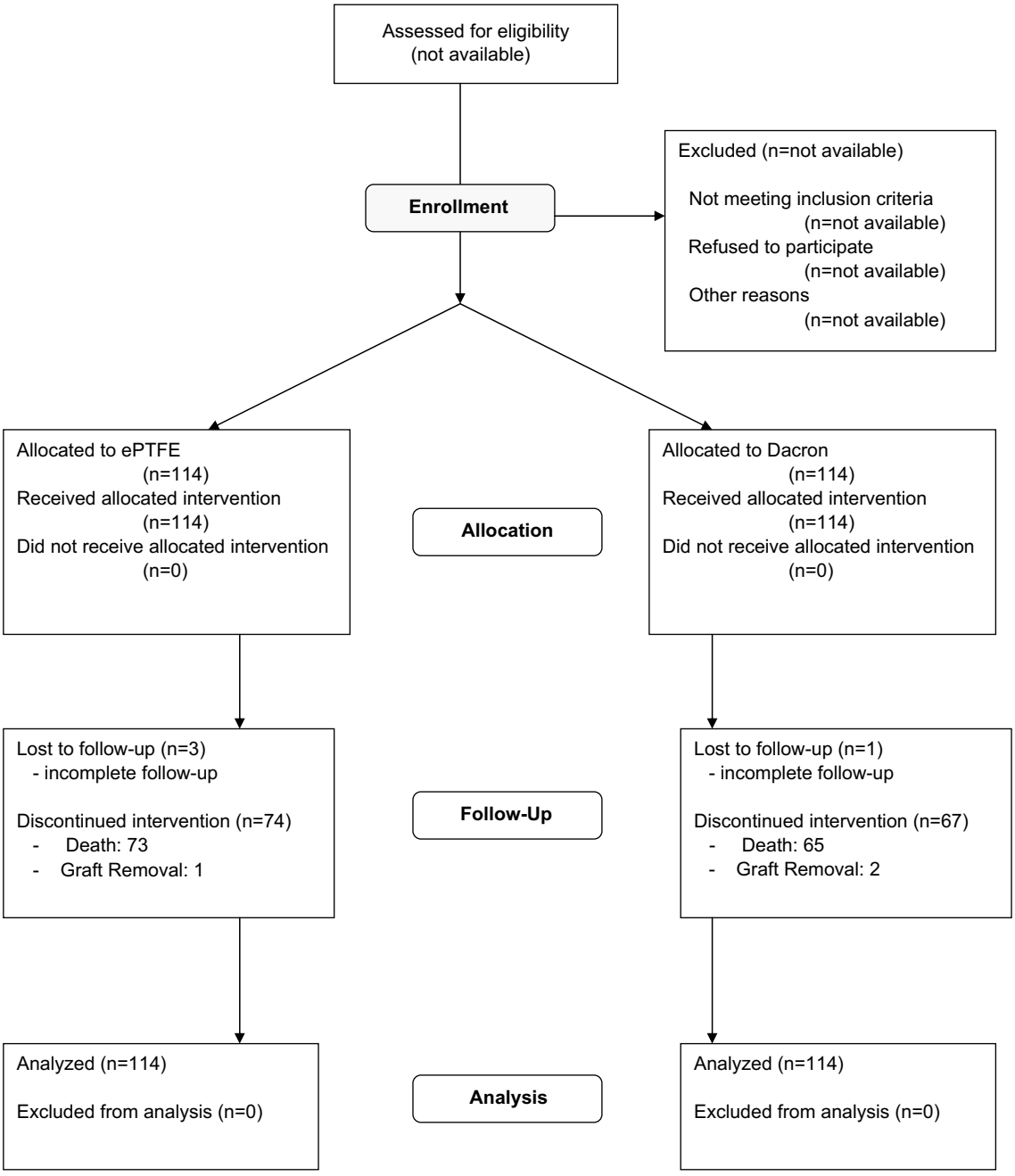

Figure 1 CONSORT-flowchart of participants in the study.

Table 2 Cumulative patency rates (%)

Patency	Follow-up time (years)	ePTFE (%)	SE	95% CI (%)	Dacron (%)	95% CI (%)	SE	df	χ^2	*p*-value
Primary[a]	2	64	0.05	54–74	70	62–78	0.04	1	0.78	
	5	36	0.05	26–46	52	42–62	0.05	1	4.39	**0.04**
	10	28	0.05	18–38	28	18–38	0.05	1	2.39	0.12
Primary assisted [a]	2	72	0.04	72–80	77	69–84	0.04	1	0.93	
	5	46	0.05	36–56	66	56–76	0.05	1	6.64	**0.01**
	10	31	0.06	19–43	49	37–61	0.06	1	7.45	**0.01**
Secondary[a]	2	78	0.04	70–86	84	76–92	0.04	1	1.04	
	5	51	0.05	41–61	70	60–80	0.05	1	6.50	**0.01**
	10	35	0.06	23–47	49	37–61	0.06	1	6.10	**0.01**

[a] Based on life-tables, corrected for censored patients at the respective end of each interval.

Statistics

Patients could be included in the study twice for operations performed on different legs. Analyses of the end-points were performed per limb.

When testing the hypothesis there was a 20% difference in primary patency between both grafts at the end of 5-year follow-up, it was calculated by a two-sided power analysis that the study needed at least 110 grafts in each group to obtain sufficient statistical power ($\alpha = 0.05$ and power = 85%).

Cumulative patency rates were calculated with life-table analysis by the Kaplan–Meier method and compared with the log-rank test. Differences between the two groups for categorical data were analysed by means of Pearson's chi-square test and for continuous variables by Student's *t*-test.

A *p*-value of <0.05 was considered significant. All analyses were done on an intention-to-treat basis and performed with SPSS, V.15.01.

Results

A total of 228 limbs (219 patients) were randomly allocated for reconstruction with either Dacron ($n = 114$) or ePTFE ($n = 114$) between July 1992 and August 1996 in five hospitals in the Netherlands (Medisch Spectrum Twente, Enschede, $n = 60/60$, Twenteborg Hospital, Almelo, $n = 18/19$; Slingeland Hospital, Doetinchem, $n = 17/15$ General Hospital Midden-Twente, Hengelo $n = 18/20$, Koningin Beatrix Hospital, Winterswijk $n = 1/0$).

The group consisted of 147 (64%) male and 81 (36%) female limbs. Preoperative risk factors were diabetes

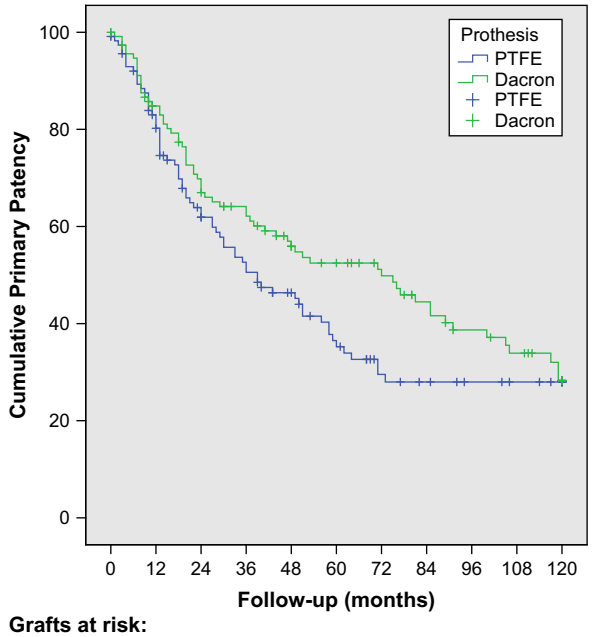

Figure 2 Kaplan–Meier analysis of primary patency rates for PTFE and Dacron.

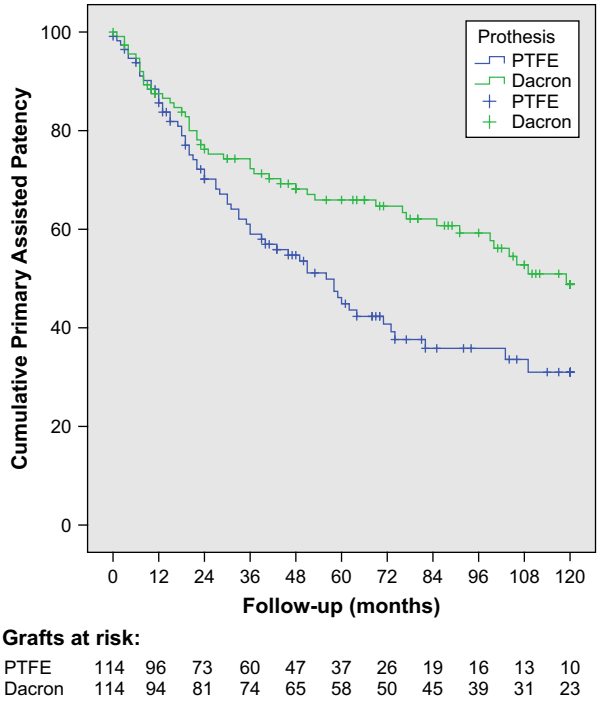

Figure 3 Kaplan–Meier analysis of primary assisted patency rates for PTFE and Dacron.

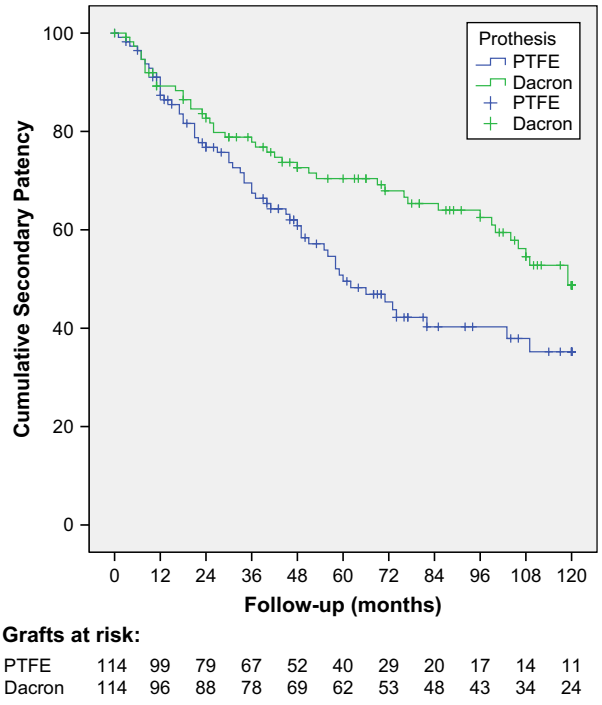

Figure 4 Kaplan–Meier analysis of secondary patency rates for PTFE and Dacron.

($n = 67$; 29.4%), hypertension ($n = 83$; 36.4%), cardiac disease ($n = 74$; 32.5%), cerebrovascular disease ($n = 27$; 11.8%) and smoking ($n = 110$; 48.2%). Baseline characteristics were equally divided between both groups, except for cerebrovascular disease, which was significantly lower in the Dacron group (Table 1).

Patients included in the trial were distributed between chronic limb ischaemia (CLI) grade I – 77% (category 1, 2 and 3, respectively, 3%, 37% and 37%), CLI grade II – 9% and CLI grade III – 14%, based on the Rutherford classification.

One hundred and twenty-two of the bypass grafts were performed under general anaesthesia (62 in the ePTFE group and 60 in the Dacron group). The remaining bypasses were performed with regional anaesthesia. All patients received heparin intra-operatively, and, in 224 limbs, the anastomoses of the bypass grafts were performed with prolene.

After 10 years only four (1.8%) patients were lost to follow-up. There was no in-hospital mortality, but two patients died in the first 30 days postoperatively, one in each group. The postoperative infection grade III was 0.9%.

After 2, 5 and 10 years, 28 (12.8%), 70 (32.0%) and 133 (60.7%), respectively, of the initial 219 patients had died; of whom, 22 (78.6%), 41 (58.6%) and 67 (50.4%) patients, respectively, had a primary patent bypass.

Patient allocation and follow-up is outlined in Fig. 1.

Occlusion of the bypass graft within 30 days postoperatively was seen in three limbs; of these, one (0.9%) was in the ePTFE group and two (1.8%) were in the Dacron group. Overall primary patency rates were 66.2%, 49.6% and 40.4% at 2, 5 and 10 years postoperatively.

The 2-year primary, primary assisted and secondary patency rates were 64%, 72% and 78% for ePTFE and 70% (log-rank test, $p = 0.38$), 77% (log-rank test, $p = 0.33$) and 84% (log-rank test, $p = 0.31$) for Dacron, respectively. The 5-year primary, primary assisted and secondary patency rates were 36%, 46% and 51% for ePTFE and 52% (log-rank test, $p = 0.04$), 66% (log-rank test, $p = 0.01$) and 70% (log-rank test, $p = 0.01$) for Dacron, respectively. The 10-year primary, primary assisted and secondary patency rates were 28%, 31% and 35% for ePTFE and 28% (log-rank test, $p = 0.12$), 49% (log-rank test, $p = 0.01$) and 49% (log-rank

Table 3 Patency results from existing RCT on femoro-popliteal bypass comparing PTFE versus Dacron

	Patients (no)	Above-knee *n* (%)	Follow-up time (years)	Primary patency		*p*-value	Secondary patency		*p*-value
				PTFE (%)	Dacron (%)		PTFE (%)	Dacron (%)	
Erasmi, 1996	103	103 (100)	1.5	–	–		79.6	87.1	NS
Green, 2000	240	240 (100)	5	43	45	NS	68	68	NS
Robinson, 1999	108	75 (69)	1	72	70	NS	74	78	NS
			2	52	56	NS	54	70	NS
			3	52	47	NS	54	53	NS
Devine, 2004[a]	209	179 (86)	1	66	76	NS	63	73	NS
			3	49	59	NS	48	55	NS
			5	41	50	NS	36	47	NS
Post, 2001	194	141 (73)	3	70	62	NS	75	81	NS
Robinson, 2003	129	76 (59)	0.5	71	50	NS	77	66	NS
			1	56	36	NS	60	49	NS
			2	47	36	$P = 0.00$	48	46	NS
Jensen, 2007	427	427 (100)	2	57	70	$P = 0.02$	65	76	$P = 0.04$
Van Det, 2008	228	228 (100)	2	64	70	NS	78	84	NS
			5	36	52	$P = 0.04$	51	70	$P = 0.01$
			10	28	28	NS	35	49	$P = 0.01$

[a] Com, compared heparin-bonded Dacron with PTFE.

test, $p = 0.01$) for Dacron, respectively (Table 2 and Figs. 2–4).

After 10 years, seven above-knee amputations had been performed: three (2.6%) in the ePTFE group and four (3.5%) in the Dacron group. Below-knee amputations had been performed 4 (3.5%) times in the group with ePTFE and 5 (4.4%) times in the Dacron group.

Discussion

This study showed that Dacron provided significantly improved long-term graft patency compared to ePTFE when used for suprageniculate femoro-popliteal bypass.

In the last decade, it has become clear that the patency rates for venous grafts are superior to that of ePTFE for femoro-popliteal bypass.[1,4,8,17–19]

In the last three decades, nearly exclusively based on personal preference and experience, opinion leaders have suggested that if autologous graft material was not available, PTFE was the preferred prosthetic material for femoro-distal bypass surgery.[19–28] However, until the present study, there has been no conclusive evidence on which to base the choice of prosthetic graft material for a suprageniculate femoro-popliteal bypass. Retrospective studies comparing PTFE with knitted Dacron at 5 years had produced varied results.[23,29] Several randomised controlled trials have been published comparing PTFE and Dacron, again with varied results (Table 3).[6,7,9–12]

One of the first published trials comparing PTFE and knitted Dacron polyester suprageniculate grafts randomised 244 patients. After 3 years, there was no statistically significant difference in primary or secondary patency rates between the two grafts.[6] In a further trial, the 5-year primary patency rates of PTFE and Dacron were similar; however, different graft diameters were used in this trial, making interpretation of results difficult.[9]

Post et al. compared PTFE with Dacron prosthesis in 203 patients. They included both supra- and infrageniculate femoro-popliteal bypasses, but primary patency rates of both groups were analysed separately. Patency rates for suprageniculate grafts were similar at 3 years.[10]

The trial of Robinson and co-workers also included both supra- and infrageniculate femoro-popliteal bypasses. They found no significant difference in primary and secondary patency rates at 1, 2 and 3 years. The patency rates reported in that study were considerably lower than found in the current trial.[7] The same Australian group compared fluoropolymer-coated Dacron to PTFE in 129 patients receiving both above- and below-knee reconstructions and used grafts of different sizes. A significant difference was reported in primary patency after 2 years in favour of PTFE (47%) over Dacron (36%), whereas the difference in secondary patency was not significant.[11]

Devine et al. reported that heparin-bonded Dacron grafts had improved patency compared to PTFE at the 3-year follow-up ($p = 0.04$). Again, this study included both supra- and infrageniculate bypasses. When they analysed the group of the above-knee bypasses separately, the 3-year primary patency results were 46% for PTFE and 61% for Dacron, which was significantly different ($p = 0.04$). The overall primary patency rates for the above-knee bypasses in that study were 71%, 54% and 45% at 1, 3 and 5 years, respectively. Their 5-year result resembles our overall patency of 40% at 5 years.[8,12] It is possible that this difference in patency achieved between heparin-bonded Dacron and PTFE may be due to the influence of heparin bonding.

In the most recent randomised controlled trial, Jensen et al. found better primary and secondary graft patency rates for Dacron as compared to PTFE. The primary and secondary patency rates were 70% and 76% for Dacron and 57% ($p = 0.02$) and 65% ($p = 0.04$) for PTFE at 2 years, respectively.[13]

Evidence from the present study has shown that for a suprageniculate femoro-popliteal bypass, Dacron has significant superior primary, primary assisted and secondary patency rates at 5 years of follow-up. After 10 years, the primary patency rates approach each other; however, the primary assisted and secondary patency rates still significantly favour the use of Dacron prosthesis.

Based on these results, we propose that Dacron should be preferentially used for prosthetic femoro-popliteal above-knee reconstructions. This graft choice is also supported by the fact that a Dacron graft is less expensive than a PTFE prosthesis.

Developments in graft technology continue and variations of ePTFE and Dacron grafts with different coatings have been introduced into the market. These new grafts have currently not been shown to be superior to older grafts in well-conducted randomised trials.

The results from our study would justify the preferential use of Dacron in patients with intermittent claudication or CLI selected to undergo femoro-popliteal bypass, where a suitable saphenous vein is absent and a distal above-knee anastomosis is possible.

Conflicts of Interest

For this study we received an unrestricted grant from W.L. Gore & Ass., Flagstaff, AZ, and from Meadox, Oakland, NJ (Boston Scientific).

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Appendix

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