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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.