Heparin-bonded Dacron or polytetrafluoroethylene for femoropopliteal bypass grafting: A multicenter trial

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Background: **Dacron (polyester fiber) was largely abandoned for femoropopliteal bypass grafts 30 years ago because saphenous vein achieved better patencies. However, in patients taking aspirin, patency in above-knee femoropopliteal bypass grafts has recently been shown to be equivalent to that with saphenous vein. We compared heparin-bonded Dacron (HBD) and polytetrafluoroethylene (PTFE) in a randomized multicenter trial including below-knee popliteal or tibioperoneal trunk bypass graft where the long saphenous vein was absent or inadequate.**
Methods: **Over 28 months, 209 patients undergoing femoropopliteal bypass grafts (180 above-knee, 29 below-knee) were randomized to HBD (n = 106) or PTFE (n = 103). Each patient was given aspirin (300 mg/d) before surgery, and this continued unless the patient had intolerance to the aspirin.**
Results: **The mean follow-up was 42 months (range, 28-55). Fifteen (7.1%) patients died with patent grafts, and three (1.4%) infected grafts were removed. Patency (measured with Kaplan-Meier survival analysis) at 1, 2, and 3 years for HBD was 70%, 63%, and 55% compared with 56%, 46%, and 42%, respectively, for PTFE (*P* = .044). A total of 67 secondary interventions were performed on 48 thrombosed grafts; long-term patency was achieved in only three. Risk factors for arterial disease did not significantly influence patency. Amputations have been performed in 23 patients, six after HBD and 17 after PTFE bypass grafts (*P* = .015).**
Conclusions: **HBD achieved better patency than PTFE, which carried a high risk of subsequent amputation. (J Vasc Surg 2001;33:533-9.)**

Vascular surgery is a rapidly developing speciality into which new vascular grafts were introduced by individual surgeons who reported excellent results, often by virtue of unusual technical ability or careful case selection. These retrospective personal series were usually presented in a way that makes graft performance appear better.

Saphenous vein remains the graft of choice for small artery bypass graft distal to the knee. When this is not available, the leading alternatives are Dacron (polyester fiber), polytetrafluoroethylene (PTFE), and human umbilical vein (HUV), which were initially introduced on the basis of the results obtained by individual surgeons.[1-3] Dacron was widely abandoned for femoropopliteal bypass grafts before the introduction of carefully controlled clinical trials, and the choice of alternatives to saphenous vein was then between PTFE and HUV. In randomized clinical trials, HUV tended to achieve marginally better patency, up to 5 years, compared with PTFE.[4-8] However, these results have not greatly altered clinical practice, presumably because surgeons do not think that this small improvement in patency justifies the expense and technical difficulty of using HUV. Perhaps the most important observation in the UK randomized femoropopliteal trial was that in more than 800 femoropopliteal grafts, the patency in above-knee (AK) femoropopliteal bypass grafts was marginally better with prosthetic material rather than saphenous vein, with a cumulative patency at 3 years of 65% for prosthetic materials and 62% for vein.[6] There have been two prospective randomized trials comparing PTFE with saphenous vein and a number of nonrandomized studies in which investigators also reported comparable patencies for AK prosthetic bypass grafts in patients taking aspirin.[5,9-16]

As a substantial proportion of femoropopliteal reconstructions fail, any improvement in graft materials has important clinical implications. With cumulative graft failures of 30% within 2 years, femoropopliteal bypass graft is the ideal "test bed" for new vascular materials. In both saphenous vein and prosthetic bypass grafts most graft failures occur in the first few months. For prosthetic grafts, this failure rate is 53 per 1000 patient-months in the first 3 months, falling to 21 per 1000 at 6 to 12 months, and around 10 per 1000 in subsequent years.[6] Because there had been no adequate randomized trials involving Dacron, we compared collagen-coated heparin-bonded Dacron (HBD) with PTFE. The main outcome measure was primary patency with a minimum follow-up of 2 years. Our philosophy was that participating surgeons were free to choose saphenous vein whenever this was available but that prosthetic bypass graft for the AK popliteal bypass graft could be performed in preference to saphenous vein.

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Table I. Inclusion and exclusion criteria

Inclusion criteria
Scheduled to undergo elective femoropopliteal reconstruction for occlusive arterial disease of the superficial femoral or popliteal artery with ipsilateral disabling intermittent claudication, rest pain, ischemic ulceration of the distal limb, or gangrene with an ankle/brachial pressure ratio < 0.8 at rest.
Fully informed consent given in writing.
Exclusion criteria
Emergency surgery for trauma, acute thrombosis, embolism, or popliteal artery thrombosis.
Symptoms not sufficiently severe to disrupt lifestyle or ankle/brachial pressure ratio > 0.8 at rest (unless aneurysm).
The diagnosis or treatment for malignancy within 12 months including all cases with residual malignancy being followed up or observed.
Hospital inpatient treatment for cardiac failure in the previous 6 months.
Where adequate follow-up would be impossible to arrange because the patient lived or was moving to an area where indepen dent follow-up could not be arranged.

Table II. Objective criteria for assessment of patency

Palpable pulsation of the graft with a *definite* distal pulse. In all other cases an objective investigation applied:
Duplex Doppler imaging
Angiography or digital subtraction angiography
Isotope angiography
Exploration of the graft where clinically indicated

We had two main objectives: (1) to compare patency achieved by HBD (InterVascular, La Ciotat, France) with PTFE (Atrium, Hudson, NH; WL Gore, Livingston, Scotland, or Impra Ltd, Crawley, West Sussex, UK) grafts in femoropopliteal bypass grafts and (2) to establish a complete database on patients undergoing prosthetic femoropopliteal bypass grafting for multivariate analysis of the factors leading to graft occlusion.

PATIENTS AND METHODS

Ethical approval was confirmed by the local Research Ethics Committees. All of the patients involved gave informed consent. A trial coordinator was hired to prevent protocol violations, to encourage complete participation, and to independently evaluate graft patency using objective criteria.

Patients. All patients undergoing elective AK reconstruction and those undergoing below-knee (BK) reconstructions where saphenous vein was not available were considered for entry with the use of the criteria listed in Table I. Sixteen participating surgeons at hospitals in the North West region of England submitted 352 patients for possible recruitment to this trial.

For the purpose of this trial, femoropopliteal bypass graft was defined as the insertion of a bypass graft with the proximal anastomosis to the common, profunda, or superficial femoral artery above the adductor canal and distal anastomosis to the popliteal artery above or below the knee or to the tibioperoneal trunk. Reconstructions with the proximal anastomosis above the inguinal ligament or from the contralateral femoral artery or with distal anastomoses to individual calf arteries were not included. Also, all eligible patients for whom distal anastomosis was planned to be above the knee joint could be randomized for the primary insertion of either HBD or PTFE, even where the saphenous vein was considered adequate for use. Where reconstruction was to be performed to the popliteal artery below the knee or the tibioperoneal trunk, then randomization was only appropriate when the ipsilateral saphenous vein was known to be absent or was found to be inadequate for reconstruction.

Preoperative assessment. Each patient underwent a detailed preoperative evaluation by the trial coordinator; medical history, details of previous surgery, symptoms of peripheral arterial disease (claudication, rest pain, ulceration, gangrene), smoking history, and drug therapy were all recorded. Peripheral pulses were coded as 2 (normal), 1 (weak), and 0 (absent), and ankle brachial pressure indices (ABPIs) were recorded with a handheld Doppler (Huntleigh Diagnostics, Cardiff, UK). Angiograms were examined, and the number of calf arteries patent to the ankle was recorded. Preoperative venous blood was sampled for glucose, fibrinogen, cholesterol, triglycerides, hemoglobin, and white cell and platelet counts. All patients were prescribed aspirin (300 mg/d), unless they could not tolerate aspirin.

Randomization. The trial coordinator was informed about any patient scheduled for femoropopliteal bypass grafting, for whatever reason and regardless of the availability of saphenous vein. Once consent had been obtained, the medical history taken, and preoperative investigations recorded, the coordinator would then deliver the randomization envelopes (one for AK, one for BK) to the vascular surgeon before surgery. Randomization, stratified for AK or BK and by the surgeon, was performed with a dedicated computer program held by the trial coordinator. Patients for whom a graft was to be implanted with a distal anastomosis in the popliteal artery above the knee were identified by the consecutive numbers AK1, AK2, AK3, etc. For surgeons planing to use a prosthetic graft regardless of the adequacy of the long saphenous vein, this sealed envelope was opened immediately before surgery. Patients for whom the distal anastomosis was planned to the BK popliteal artery or tibioperoneal trunk were identified by the consecutive numbers BK1, BK2, BK3, etc. The sealed envelope was

Table III. Reasons for not randomizing patients (n = 143)

Reason for nonrandomization	*No.*	*%*
Alternative operation	26	18
Problems with consent (refusal, not requested before surgery)	29	20
Consented but died before bypass graft	2	1.4
Emergency surgery	1	0.7
Protocol exclusion (violation, age, malignancy)	24	17
Exploration only or operation abandoned	8	5.6
Surgery canceled (symptoms improved)	24	17
Vein bypass graft	29	20

Table IV. Risk factors

Risk factor	*HBD (n = 106)*	*PTFE (n = 103)*	P *value*
Age (y) (range)	61.1 (32.9-83.3)	65.2 (35.3-86)	.429
Angina/myocardial infarction	29.2%	31.1%	.893
ABPI (% < mean 0.53)	49%	44.8%	.650
Cardiac failure	8.7%	9.6%	.867
Carotid disease	17%	19.4%	.782
Diabetes	17%	10.7%	.264
Sex			660
Male	68.9%	65%	
Female	31.1%	35%	
Hypertension	36.8%	35%	.894
Hyperlipidemia	13.2%	6.8%	.190
Patent calf arteries (> 2)	83.7%	79.7%	.072
Previous arterial surgery	49.1%	51.5%	.889
Smoking history			.299
Never	6.6%	6.8%	
Ex	59.4%	61.2%	
Current	34%	32%	
Indication for surgery			.494
Claudication	31.1%	35.9%	
Critical ischemia	68.9%	64.1%	

then opened in the operating theater only after the long saphenous vein had been found to be inadequate.

Follow-up. The trial coordinator followed up all patients at three monthly intervals for 1 year and six monthly intervals thereafter, either by attending outpatient clinics or visiting patients at home. At each visit, further detailed records were taken documenting changes in medical history, smoking habits, drug therapy, and current symptoms. Graft patency was independently assessed by means of objective criteria (Table II).

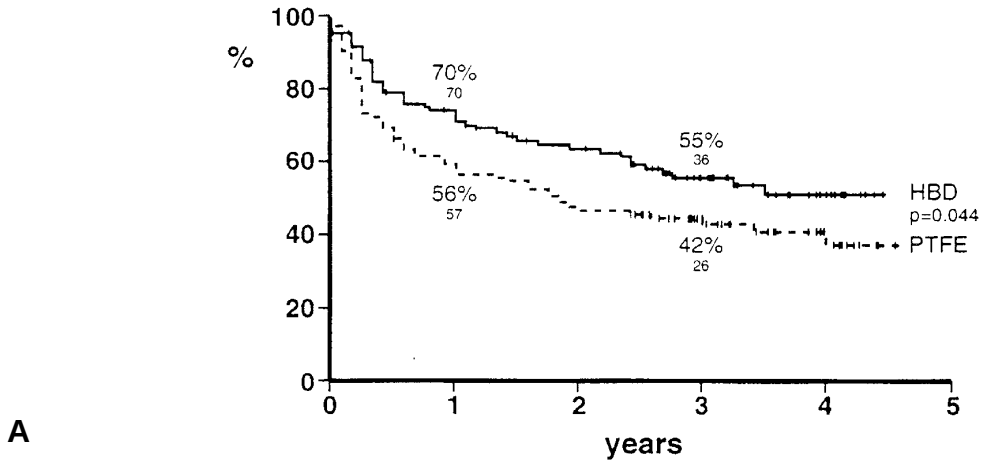
Sample size, trial end points, and statistical analysis. Sample size was based on the assumption that a one-third reduction (33%) in failure with either material would be clinically important. To achieve an 80% power to identify this difference at the conventional 5% significance, 126 patients would need to be recruited to each treatment group. The withdrawal of a number of patients has resulted in a power of 72% (based on our original assumptions and the number of patients finally recruited).

The principal outcome measure was primary patency, defined as the time to first graft occlusion. Secondary patency was defined as the time to final occlusion of the original graft despite secondary procedures. Secondary patency was not accepted if a substantial proportion of the original graft had to be replaced or bypassed.

Risk factors in the two treatment groups were tested with χ^2 analysis to check the effectiveness of randomiza-

Table V. Postoperative complications

Complication	*HBD*	*PTFE*	*Total*
Hematoma	2	5	7
Infection	13	6	19
Lymphedema	11	4	15
Cellulitis	1	2	3
Hemorrhage	2	1	3
Pyrexia (unknown origin)	1	2	3
Anemia	1	1	2
Cerebrovascular accident	1	—	1
Acute retention	1	—	1
Dehydration	1	—	1
Chest infection	1	2	3
Toe debridement	1	—	1
Painful calf	1	—	1
Pressure sore on heel	1	—	1
Deep venous thrombosis	1	—	1
Total	39	28	67



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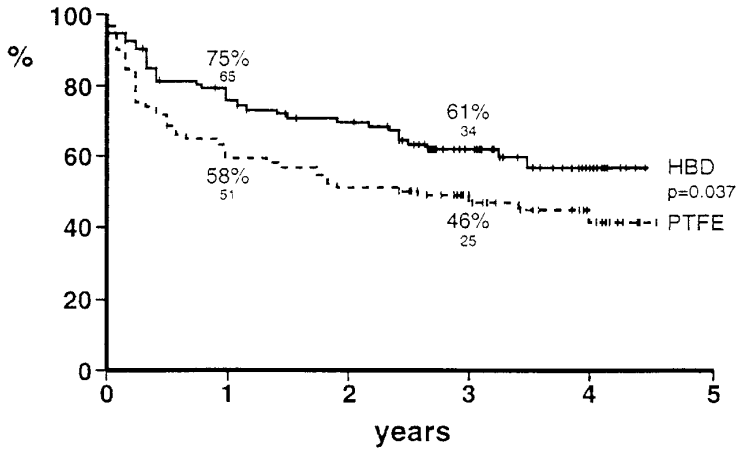

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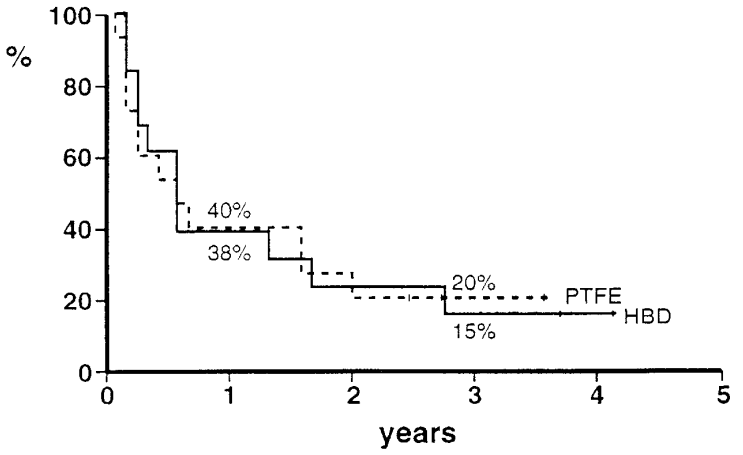

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Fig 1. Cumulative primary patency with life table is compared between HBD and PTFE. **A,** All 209 randomized grafts; **B,** 180 grafts to AK popliteal artery; and **C,** 29 grafts for BK popliteal artery. Larger percentage numbers refer to cumulative patency at 1 and 3 years with smaller numbers being number of patent grafts still being followed at these times. *HBD,* Heparin-bonded Dacron; *PTFE,* polytetrafluoroethylene.

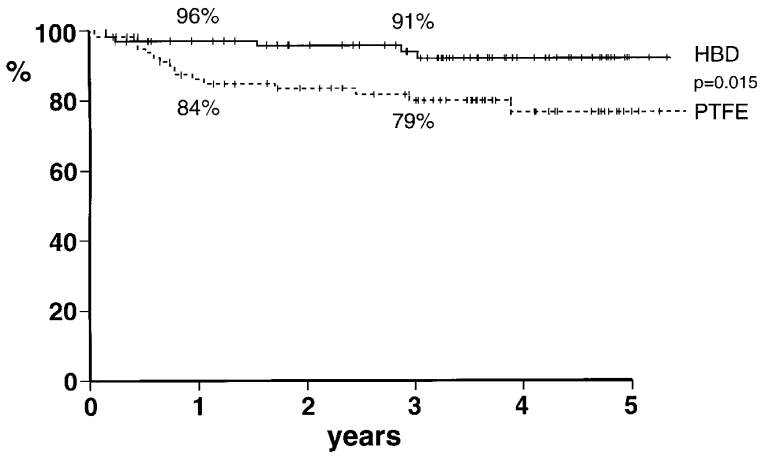

Fig 2. Limb survival by life table is plotted comparing patients after femoropopliteal bypass grafting with HBD and PTFE. Major limb amputation was significantly more frequent after PTFE bypass graft; 21% of patients had amputation by 3 years. *HBD,* Heparin-bonded Dacron; *PTFE,* polytetrafluoroethylene.

tion. The difference in patency between the two graft materials was compared with the Kaplan-Meier life-table method and analyzed statistically with the log-rank test. The influence of the various risk factors on patency was examined with multivariate analysis. The design and analysis of the trial fulfill the objectives for clinical trials suggested by statisticians in both the United Kingdom and the United States.[17,18]

RESULTS

Of the 352 patients referred to the trial coordinator by 16 surgeons from the North West region of England between October 1994 and January 1997, 209 were correctly randomized as 106 HBD and 103 PTFE (85 Impra, 7 Atrium and 11 WL Gore). Reasons for exclusion are given in Table III. Only prosthetic grafts inserted by surgeons who adhered to the randomization sequence were included in the analysis. Follow-up was for a minimum of 2 years and a mean of 42 months (range, 28-55 months).

Comparability of groups. Randomization achieved two comparable patient groups with risk factors equally distributed between patients randomized to HBD and PTFE (Table IV). Preoperative symptoms were grouped into claudication only (Fontaine II) or critical ischemia with either rest pain or ulcers/gangrene (Fontaine III and IV). Overall, 70 (33.5%) patients underwent surgery for claudication (HBD 33, PTFE 37), and 139 (66.5%) had symptoms of critical ischemia. The overall mean ABPI was 0.53 (range, 0-1.12) with that for critical ischemia only a little lower at 0.51 because of inclusion of patients with calcified arteries and falsely high ratios. Operations were performed on 98 (47%) right and 111 (53%) left legs. The common femoral artery was used for the proximal anastomosis in 199 (95.2%) of cases. Arteries used for the distal anastomosis were AK popliteal (176 [84%]), BK popliteal (25 [12%]), and tibioperoneal trunk (3 [1.4%]) with 5 uncertain (2.4%). A vein patch (4) or Miller cuff (6) was used at the distal anastomosis in 10 patients (2 AK, 8 BK).

Morbidity and mortality. There was no significant difference in the frequency of postoperative complications occurring in 39 patients with HBD and 28 PTFE (P = .18) (Table V). Wound morbidity (infection or edge necrosis) accounted for 19 of these events (HBD 13, PTFE 6). Two patients died within 30 days (operative mortality rate, 1%), and an additional 38 (18%) patients died during follow-up, with 15 patent grafts (HBD 11, PTFE 4). The mean cumulative survival with life table was 93%, 88%, and 84% at 1, 2, and 3 years, respectively, and was not influenced by the type of bypass graft.

Graft patency. Overall cumulative patency was 63%, 54%, and 48% at 1, 2, and 3 years, respectively. Patency for AK bypass graft was markedly better at 54% by 3 years compared with only 16% for BK bypass graft. A total of 106 grafts occluded (HBD 46, PTFE 60) with 75 (71%) occluding within the first 12 months; 68 occlusions were confirmed with arteriography, 27 with duplex Doppler imaging, and 5 with surgical exploration. Only six occlusions were not confirmed by objective testing (1 death, 2 emergency admissions, and 3 patients unwilling to be investigated). Patency in the 85 Impra grafts at 41% was not different than that in the 28 Atrium or Gore grafts (P = .95). Primary patency with life table for HBD was 70%, 63%, and 55% at 1, 2, and 3 years compared with 56%, 46%, and 42%, respectively, for PTFE (P = .044; Fig 1). The difference between patency rates for HBD and PTFE was confined to the AK grafts where the 3-year cumulative patency was 61% for HBD and 46% for PTFE (P = .037; Fig 1, *B*). The results for BK grafts were uniformly poor with no difference between the materials (Fig 1, *C*). When patients who had any procedure other than a common femoral artery to above the knee or below the knee popliteal artery with a prosthetic graft without a vein patch or cuff were excluded

(n = 8), the difference between patency rates for HBD and PTFE become even more significant ($P = .029$).

Of the 106 occlusions, 29 (27%) patients were treated conservatively, 20 (19%) had their randomized graft replaced and were therefore withdrawn from further study, 9 (9%) required immediate amputation, and 48 (45%) patients were offered a secondary procedure to conserve the study graft. Long-term patency was established in only three of these patients despite 67 procedures. These three were among the 12 offered surgical thrombectomy, with none of the 22 treated by lysis with or without angioplasty remaining patent up until the time of this analysis. Secondary patency rates for HBD were 74%, 64%, and 56% compared with 60%, 49%, and 45% for PTFE at 1, 2, and 3 years, respectively ($P = .052$). Compliance with anticoagulation at 12 months was good with only seven patients who did not take either aspirin or an oral anticoagulant.

Influence of risk factors. The influence of various arterial disease risk factors on patency (ABPI, cardiac failure, diabetes, sex, hypertension, hyperlipidemia, indication for surgery, luminal graft diameter, myocardial infarction or angina, number of calf arteries patent to the ankle, previous arterial surgery, smoking history, and symptomatic carotid disease) was subjected to χ^2 analysis or *t* test as appropriate. We could not find any significant influence of these risk factors on subsequent graft patency.

Amputation. Amputation was performed on 23 (11%) patients, six after HBD bypass grafts (5 AK, 1 BK) and 17 after bypass grafts with PTFE (12 AK, 5 BK) ($P = .015$, Fisher exact test) (Fig 2). The risk of amputation was thought to be low for patients undergoing femoropopliteal bypass grafting for intermittent claudication. However, of the 70 patients who underwent bypass grafting for claudication, eight subsequently underwent amputation despite attempts to reestablish patency after graft thrombosis. Seven of these eight patients had undergone bypass grafting with PTFE, which means that 18% of the 37 patients undergoing PTFE femoropopliteal bypass grafts for intermittent claudication underwent subsequent amputation despite a mean follow-up interval of only 4 years. Of the 23 amputations, 16 were above the knee (HBD 5, PTFE 11) and seven below the knee (HBD 1, PTFE 6).

DISCUSSION

Rather surprisingly, our results demonstrate significantly better patencies with HBD femoropopliteal bypass grafts than with PTFE. Since its inception in 1976, PTFE has become the most popular prosthetic graft for infrainguinal surgery. However, in retrospective reviews and previous studies comparing Dacron with PTFE, researchers report equivalent or sometimes better performances from Dacron.[19-23] Our poor results for PTFE were comparable to those previously reported in the Medical Research Council–funded study comparing HUV and PTFE where primary patency for PTFE (n = 104) was reported as 61%, 56%, and 48% at 1, 2, and 3 years, respectively.[6]

Amputation rates in this study were no worse than those previously published for PTFE because the Medical Research Council study reported amputation in 23 (22%) of PTFE grafts.[6] The high amputation rate in patients after PTFE bypass grafts in our current study included seven patients in whom the original indication for surgery was for claudication only. Because the risk of amputation is low for intermittent claudication that is treated conservatively, these results suggest that the risk of amputation may be increased by femoropopliteal bypass grafts with PTFE.

This study was conceived before the widespread adoption of vein graft surveillance programs, which detect stenoses in 25% to 30% of grafts.[24,25] The adoption of such surveillance programs may improve the patency in saphenous vein bypass graft so that the vein may again be the preferred option, even for AK bypass grafts. However, the initial enthusiasm for vein surveillance has been dampened by recent clinical trials in which little benefit has been found after the introduction of surveillance, and it is doubtful that there will be any major impact on the long-term patency of AK vein bypass graft.[24,26] Where the surgeon adopts a strategy of using prosthetic grafts for bypass grafts above the knee or where the vein is absent or inadequate for BK femoropopliteal bypass graft, our results demonstrate that HBD achieves better patency than PTFE.

Because our grafts were predominantly 6 mm, we were unable to analyze the influence of graft diameter on patency. However, where the operating surgeon had a choice, larger diameter grafts would be more likely to be implanted for larger patients with bigger arteries. This bias may explain the improved patency reported by the AK femoropopliteal study group led by Abbott et al.[22]

The high amputation rate after PTFE bypass grafting is comparable to that in a previous major study and suggests that this material may have unique features that increases the risk of subsequent amputation. We can only speculate that thrombosis of PTFE grafts may involve distal embolization.

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