Vein versus polytetrafluoroethylene in above-knee femoropopliteal bypass grafting: Five-year results of a randomized controlled trial

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Objective: **Controversy still exists whether polytetrafluoroethylene is equivalent to vein as bypass graft material for the above-knee femoropopliteal bypass. Therefore, a prospective randomized trial was performed to compare vein with polytetrafluoroethylene for femoropopliteal bypasses with the distal anastomosis above the knee.**
Methods: **Between January 1993 and December 1996, 151 above-knee femoropopliteal bypasses were performed. The indications for operation were severe claudication in 120 cases, rest pain in 20 cases, and ulceration in 11 cases. After randomization, 75 reversed saphenous venous bypasses and 76 polytetrafluoroethylene bypasses were performed.**
Results: **No perioperative mortality was seen, and 5% of the patients had minor infections of the wound, not resulting in loss of the bypass, the limb, or life. After 5 years, 38% of the patients had died and 7% were lost to follow-up. Only once was the saphenous vein necessary for coronary artery bypass grafting. Primary patency rates after 5 years were 75.6% for venous bypass grafts and 51.9% for polytetrafluoroethylene grafts ($P = .035$). Secondary patency rates were 79.7% for vein and 57.2% for polytetrafluoroethylene bypasses ($P = .036$). In the venous group, 14 bypasses failed, leading to five new bypasses. In the polytetrafluoroethylene group, 29 bypasses failed, leading to 16 reinterventions. For these 16 new bypasses, in four cases, the ipsilateral preserved saphenous vein was used. In both groups, one above-knee amputation and one below-knee amputation had to be performed.**
Conclusion: **We conclude after 5 years of follow-up of this randomized controlled trial that a bypass with saphenous vein has better patency rates at all intervals and needs fewer reoperations. Saphenous vein should be the graft material of choice for above-knee femoropopliteal bypasses and should not be preserved for reinterventions. Polytetrafluoroethylene is an acceptable alternative if the saphenous vein is not available. (J Vasc Surg 2003;37:149-55.)**

That autologous saphenous vein is the material of choice for a femoropoplitial bypass below the knee is generally accepted.[1-5] For the femoropopliteal bypass with the distal anastomosis above the knee, controversy still exists whether prosthetic materials like polytetrafluoroethylene, Dacron, and human umbilical vein are equivalent to autologous saphenous vein. Studies supporting other materials than vein for bypass either are not randomized[6,7] or do not compare prosthetic material with vein.[8] The only randomized controlled trial with a long-term follow-up that was performed before this study was started compared autologous saphenous vein and polytetrafluoroethylene for the above-knee femoropopliteal bypass graft and found no statistical difference between autologous vein and polytetrafluoroethylene after 4 years.[5]

In 1993, this randomized controlled trial was started in our institution to answer the following questions: 1, Is there a difference in cumulative patency rates between saphenous vein and polytetrafluoroethylene bypass grafts? 2, What are the consequences of bypass failure? and 3, If polytetrafluoroethylene is used, is the autologous vein still available and useful for more distal procedures or for coronary artery bypass grafting?

The conclusions, reported after 2 years of follow-up, were that there was no statistical significant difference in primary and secondary patency rates between vein and polytetrafluoroethylene. In the supragenicular position, polytetrafluoroethylene could be an acceptable alternative for femoropopliteal bypass grafting in above-knee procedures, especially in patients with a short life expectancy. There was minimal use of preserved veins for other bypass procedures. However, the follow-up period was only 2 years.[9]

Since the start of this study, two randomized trials comparing vein with polytetrafluoroethylene were published. AbuRahma, Robinson, and Holt[10] found no difference in primary patency rates after 6 years. However, Johnson and Lee[11] reported significant better primary patency rates for vein than for polytetrafluoroethylene after 5 years. This study reports the results of our prospective randomized trial with a 5-year follow-up period.

PATIENTS AND METHODS

Patients who underwent a femoropopliteal bypass operation with the distal anastomosis to the popliteal artery above the knee between January 1993 and December 1996

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Published online Nov 15, 2002.

0741-5214/2002/$30.00 + 0
doi:10.1067/mva.2002.86

were eligible for this study. Included were all patients with disabling claudication, rest pain, or tissue-loss who underwent arterial reconstruction. Excluded were patients with an earlier arterial bypass graft procedure in the same leg or with the greater saphenous vein removed earlier.

History was obtained from every patient and included previous operations and risk factors for arterial occlusive disease (diabetes, smoking, cerebrovascular accidents, and cardiac history). In every patient, a hemodynamic profile was obtained, comprising the ankle blood pressures and a velocity profile of the common femoral, popliteal, and distal arteries at the level of the ankle. Also, an arteriogram was obtained with the translumbar route or transfemoral with the Seldinger technique. The popliteal and tibial arteries were scored in terms of open or occluded to grade the runoff.[12] The Institutional Review Board of the Red Cross Hospital, The Hague, approved the study protocol. Patient consent was obtained in all cases.

Before the operation, all patients received 1 g of cefamandole intravenously. Patients underwent operation with general or regional anesthesia. The operating surgeon inspected the popliteal artery and the saphenous vein. Above-knee grafting was performed when the above-knee popliteal artery was patent and suitable for anastomosis during the operation. When the quality of the greater saphenous vein was suitable for bypass grafting (ie, with a diameter of more than 4 mm proximally and 3 mm distally), randomization took place with closed envelope allocation. Either the reversed vein or a stretched thin-walled 6-mm polytetrafluoroethylene (W. L. Gore, Flagstaff, Ariz) prosthesis was used. Before clamping, heparin was given intravenously in a dose of 5000 international units. All anastomoses were made end-to-side with continuous 6-0 prolene sutures, proximal to the common femoral artery and distal to the popliteal artery.

Oral coumarin (Sintrom, Ciba-Geigy) was started the day before the operation and was continued for 6 months, with aim for an international normalized ratio between 2 and 4. After 6 months, 38 mg acetylsalicylic acid was given daily.

Follow-up visits were carried out at discharge and thereafter at 6 weeks, 3 months, 6 months, and 1 year and every following year. Examination comprised a history, a physical examination, and a hemodynamic profile. Graft occlusion was determined with a drop in distal blood pressure of more than 20% compared with a previous visit and a velocity profile consistent with collateral flow in the distal popliteal artery. If a polytetrafluoroethylene bypass occluded and the occlusion was detected within 7 days, a thrombectomy was performed. In all other cases, a policy of "wait and see" was followed if the patient had mild claudication develop. In cases of rest pain or necrosis, a redo bypass procedure was performed.

The primary endpoint of the study was the patency of the bypass at the end of the fifth year. Patients could be included in the study twice for primary operation on either the left or the right limb. Analysis of the primary endpoint was performed per limb.

Primary patency was considered to be uninterrupted patency with no procedures performed on the bypass or the adjacent native vessel. Secondary patency was the patency after restoration of an occlusion or after a procedure to protect the bypass from occluding. Most of the original bypass and at least one of the anastomosis must have been retained in continuity.[12]

Cumulative patency rates were calculated with life-table analysis and compared with the log-rank test. Student *t* test was used to compare the patient characteristics. Differences in reinterventions were calculated with the χ^2 test.

RESULTS

Randomization took place in 151 bypass graft operations in 136 patients between January 1993 and December 1996. The risk factors and angiographic results were equally divided between those who received a venous bypass graft and those who received a polytetrafluoroethylene bypass graft, except for diabetes mellitus, which was significant lower in the venous group (Table I).

Reversed vein was used in 75 bypass grafts, and 6-mm stretched polytetrafluoroethylene prostheses were used 76 times. Bilateral reconstruction was done in 15 patients. Five patients received polytetrafluoroethylene bypass grafts in both limbs, two with only venous bypass grafts, and eight patients received polytetrafluoroethylene in one limb and vein in the other.

The operating time from skin incision until skin closure was significantly longer in venous bypasses (mean, 105 minutes) than in polytetrafluoroethylene grafts (mean, 73 minutes; $P = .002$). A superficial wound infection was seen in seven cases (three times with a polytetrafluoroethylene and four times with a venous bypass). None of these infections resulted in reoperation or loss of the bypass. None of the patients died in the hospital or within 30 days after the operation.

After 5 years, 57 patients had died (38%); 42 with an open and 15 with an occluded bypass. Eleven patients were lost to follow-up (7%).

Primary patency rates after 5 years were 75.6% for venous bypass grafts and 51.9% for polytetrafluoroethylene grafts ($P = .035$; Tables II and III; Fig 1). Secondary patency rates were 79.7% for vein and 57.2% for polytetrafluoroethylene ($P = .036$; Tables IV and V; Fig 2).

In the venous bypass group, 14 bypasses failed. In nine patients, we did not perform a reintervention because the patient only had mild claudication. Five new bypass operations were performed: in three cases, a new polytetrafluoroethylene bypass was made above the knee; in one case, the venous bypass was extended with vein to below the knee; and in one case, a human umbilical vein (Dardik Biografts, Bio-Vascular, Inc, St Paul, Minn) was used for a femoroinfrapopliteal bypass. Failure of two of these redo bypasses led to two polytetrafluoroethylene femorotibial bypasses but finally an occlusion and an amputation (one above-knee and one below-knee). In this group, one coro-

Table I. Patient characteristics from included patients

	Total	*Vein*	*PTFE*	P *value*
Reconstructions	151	75	76	
Median age (y)	69	70	68	.10
Male gender	88	42	46	.28
Risk factors				
Smoking	105	48	57	.07
Diabetes mellitus	33	12	21	.04
Cardiac history	31	15	16	.44
Cerebrovascular accident	7	5	2	.12
Indication				.49
Claudication	120	62	58	
Rest pain	20	9	11	
Necrosis	11	4	7	
Open tibial arteries				.49
3	80	43	37	
2	47	21	26	
1	24	11	13	

PTFE, Polytetrafluoroethylene.

Table II. Life-table analysis of primary patency rate of autologous saphenous vein

Interval	*At risk*	*Occluded*	*Died*	*LFU*	*Cumulative patency rate*	*SEM*
0-6 wk	75	5	1	1	93.3%	2.9
6-12 wk	68	2	1	1	90.6%	3.4
12-26 wk	64	4	3	0	84.9%	4.2
26-52 wk	57	3	3	0	80.5%	4.7
1-2 y	51	3	2	2	77.3%	5.0
2-3 y	44	1	5	3	75.6%	5.2
3-4 y	35	0	7	0	75.6%	5.2
4-5 y	28	0	2	1	75.6%	5.2

LFU, Lost to follow-up; *SEM*, standard error of mean.

Table III. Life-table analysis of primary patency rate of polytetrafluoroethylene

Interval	*At risk*	*Occluded*	*Died*	*LFU*	*Cumulative patency rate*	*SEM*
0-6 wk	76	3	0	0	96.1%	2.2
6-12 wk	73	3	0	0	92.1%	3.1
12-26 wk	70	5	1	0	85.5%	4.0
26-52 wk	64	5	4	0	78.9%	4.7
1-2 y	55	6	2	0	68.8%	5.4
2-3 y	47	5	4	1	61.3%	5.8
3-4 y	37	2	5	0	57.9%	5.9
4-5 y	30	3	2	1	51.9%	6.2

LFU, Lost to follow-up; *SEM*, standard error of mean.

nary bypass operation was performed with the distal saphenous vein from the ipsilateral side as the graft material.

In the polytetrafluoroethylene group, 29 bypasses failed. Thirteen times, no reinterventions were planned because the patients only had mild claudication. Because of severe claudication or rest pain, three times a new bypass above the knee was performed, all with polytetrafluoroethylene. Twelve bypasses had to be performed below the knee: in eight cases, these were polytetrafluoroethylene bypasses; in one case, human umbilical vein; and in three cases, saphenous vein. One venous femorotibial bypass was constructed. There were significantly more reinterventions because of a failing polytetrafluoroethylene bypass graft compared with failing venous bypasses ($P = .011$). Because of failed reinterventions, three patients received a polytetrafluoroethylene femorotibial bypass. Two amputations had to be performed (one above-knee and one below-knee). In this group, two coronary bypass reconstructions were performed, but no bypass was constructed of saphenous vein.

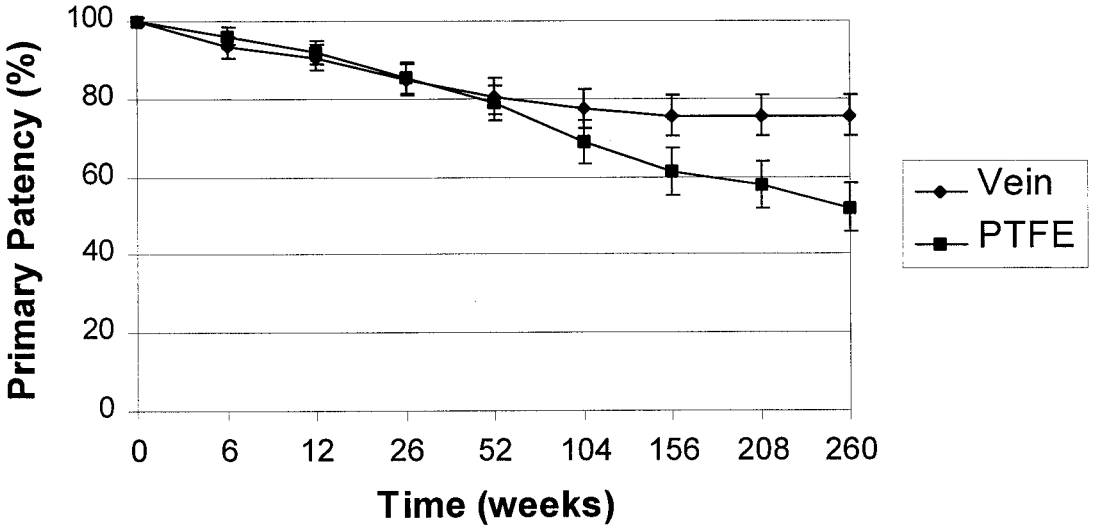

Fig 1. Primary patency rates over time comparing vein with polytetrafluoroethylene in above-knee femoropopliteal bypass. *Error bars* are standard error of mean.

Table IV. Life-table analysis of secondary patency rate of autologous saphenous vein

Interval	*At risk*	*Occluded*	*Died*	*LFU*	*Cumulative patency rate*	*SEM*
0-6 wk	75	4	1	1	94.7%	2.6
6-12 wk	69	1	1	1	93.3%	2.9
12-26 wk	66	3	3	0	89.1%	3.7
26-52 wk	60	2	3	0	85.5%	4.1
1-2 y	55	3	2	2	81.4%	4.7
2-3 y	48	1	5	4	79.7%	4.9
3-4 y	38	0	7	0	79.7%	4.9
4-5 y	31	0	2	0	79.7%	4.9

LFU, Lost to follow-up; *SEM*, standard error of mean.

Table V. Life-table analysis of secondary patency rate of polytetrafluoroethylene

Interval	*At risk*	*Occluded*	*Died*	*LFU*	*Cumulative patency rate*	*SEM*
0-6 wk	76	2	0	0	97.4%	1.8
6-12 wk	74	3	0	0	93.4%	2.8
12-26 wk	71	4	1	0	88.2%	3.7
26-52 wk	66	2	4	0	85.5%	4.0
1-2 y	60	6	2	0	76.9%	4.9
2-3 y	52	5	3	2	69.5%	5.4
3-4 y	42	4	5	0	62.9%	5.8
4-5 y	33	3	3	1	57.2%	6.2

LFU, Lost to follow-up; *SEM*, standard error of mean.

Primary patency rates were related to the outflow. After 5 years, the patency rates were 63.3% in the group with three open crural arteries, 57.6% with two open arteries, and 70.4% with one open artery ($P = .50$; Table VI).

DISCUSSION

The question of the best material for above-knee bypass graft surgery, polytetrafluoroethylene or saphenous vein,

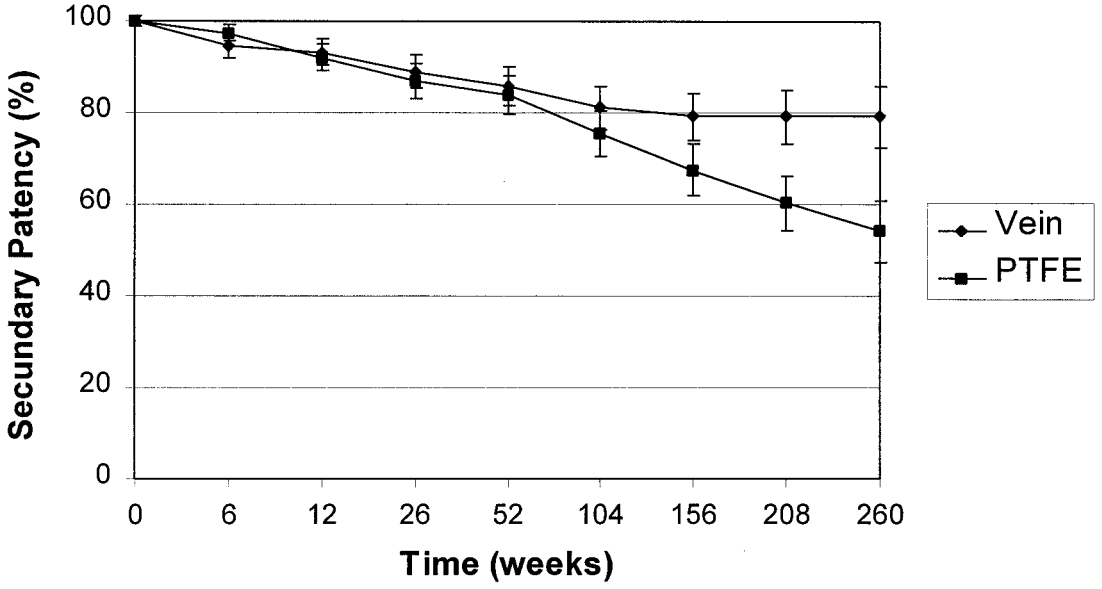

Fig 2. Secondary patency rates over time comparing vein with polytetrafluoroethylene in above-knee femoropopliteal bypass. *Error bars* are standard error of mean.

Table VI. Primary patency after 5 years compared with number of patent tibial arteries with preoperative arteriography ($P = .50$)

Interval	*Three open arteries*	*SEM*	*Two open arteries*	*SEM*	*One open artery*	*SEM*
0-6 wk	97.4	1.8	92.0	3.8	92.0	5.4
6-12 wk	94.7	2.6	90.0	4.2	84.0	7.3
12-26 wk	85.2	4.1	85.8	5.0	84.0	7.3
26-52 wk	78.2	4.8	81.5	5.6	79.8	8.1
1-2 y	73.9	5.2	69.9	6.8	75.1	8.9
2-3 y	69.2	5.5	64.9	7.2	70.4	9.5
3-4 y	67.4	5.6	61.5	7.6	70.4	9.5
4-5 y	63.3	6.0	57.6	8.0	70.4	9.5

SEM, Standard error of mean.

was once controversial. Our randomized controlled trial was one of the few that was started to answer this question. The problem with many of these randomized trials, including our own, was that patient recruitment proved to be difficult, resulting in deficient power for conclusion. Our conclusion after 2 years of follow-up was that polytetrafluoroethylene was a reasonable alternative but that long-term results should be awaited. Another problem is that follow-up is often deficient.[13,14] With respect to follow-up, we were successful in seeing all but seven of our patients in the outpatient clinic. After 5 years of follow-up, we found a significant difference in primary patency rates of 75.6% for vein and 51.9% for polytetrafluoroethylene ($P = .035$). The secondary patency rates were 79.7% and 57.2%, respectively ($P = .036$).

In Table VII, our results are compared with the three other published randomized trials.[5,10,11] The difference between the four studies is that in the series of Veith et al[5] and Johnson and Lee,[11] 87% and 72%, respectively, of the patients had severe ischemia (rest pain or necrosis). This differs from our series (24%) and the series of AbuRahma, Robinson, and Holt[10] (0). It can be expected that the outflow in patients with severe ischemia is poor compared with those with claudication. This might explain the less favorable long-term patency rates described by Veith et al[5] and Johnson and Lee[11] (38% and 39%, respectively).

Michaels[15] estimated that 160 grafts are required in the two randomized groups to have a 95% chance of showing significance ($P < .05$), assuming that there is a 20% difference in 5-year patency rates. Despite the fact that we did not include that many patients, we found a statistical difference in favor of venous graft material. Johnson and Lee[11] presented the only other trial with a statistically significant difference between vein and polytetrafluoroethylene. They

Table VII. Comparisons of primary patency rates of venous and polytetrafluoroethylene bypass grafts from randomized controlled trials

	Veith et al[5]		*AbuRhama et al*[10]		*Johnson and Lee*[11]		*This article*	
Years	*Vein*	*PTFE*	*Vein*	*PTFE*	*Vein*	*PTFE*	*Vein*	*PTFE*
1	82%	82%	88%	81%	84%	77%	81%	80%
2	79%	69%	78%	68%	81%	69%	77%	69%
3	70%	56%	76%	68%	77%	58%	76%	61%
4	61%	38%	76%	68%	75%	50%	76%	58%
5			76%	68%	74%	39%	76%	52%

PTFE, Polytetrafluoroethylene.

included 226 patients in the venous group and 265 in the polytetrafluoroethylene group. If we compare the patency rates for vein and polytetrafluoroethylene in all four randomized trials, we see at all intervals a better primary patency rate for vein.[5,9-11] It was shown in a critical review as well that if saphenous vein is available, a venous bypass should be chosen.[15] When the saphenous vein is absent or not suitable for bypass grafting, polytetrafluoroethylene is a good alternative for femoropopliteal bypass material above the knee.

The only statistically significant risk factor difference between the two groups was the prevalence of diabetes, with significantly more patients in the polytetrafluoroethylene group ($P = .04$). Evans et al[16] and Prendiville et al[17] found that diabetes has a negative influence on the patency of the bypass, whereas others did not find that effect.[6,18] Because of the small numbers of patients with risk factors, no multivariate analysis could be performed. We realize that because of the small numbers in the subgroups of patients, a type II statistical error could exist.[13]

In 14 failing venous bypasses, five patients had critical ischemia and needed a reoperation. From these five reoperations, only two had to be performed below the knee. In the polytetrafluoroethylene group, 16 reoperations had to be performed for 29 failing bypass grafts. Thirteen bypasses had to be placed below the knee. Clearly, less reoperation had to be performed in the venous group ($P = .011$). The fact that in the polytetrafluoroethylene group during reoperation the distal anastomosis was more often below the knee might strengthen the idea that the polytetrafluoroethylene graft promotes progression of distal atherosclerosis.[5,7]

One of the arguments for use of polytetrafluoroethylene for the above-knee femoropopliteal bypass graft is preservation of the vein for a later distal procedure or a coronary bypass. In the group of 76 polytetrafluoroethylene bypasses, thus the group in which the vein was preserved, 29 graft failures occurred, with necessity for a venous bypass in only four cases. Two coronary bypasses were performed with the mammary artery in this patient group during the follow-up period. In other studies, these similar conclusions were made.[19,20] So, it seems unnecessary to save the vein because in case of a failing bypass graft the spared vein was not used often. Moreover, if the vein were used for the above-knee bypass, less reoperations had to be performed below the knee with need for the vein. When an infrapopliteal bypass or a coronary bypass is needed, the saphenous vein of the contralateral side is still available. To save the saphenous vein for coronary bypass grafts can be argued because of the advancement of cardiac revascularisation techniques, for example, percutaneous treatment or the use of the mammary artery.

Finally, four major amputations had to be performed: two lower leg and two upper leg amputations. In three of these cases, the indication for the femoropopliteal bypass was critical ischemia. These results are comparable with the results described by Johnson and Lee,[11] although they performed more bypasses in patients with critical ischemia. AbuRahma, Robinson, and Holt[10] had no amputations at all and performed bypasses in patients with claudication only. Veith et al[5] described limb salvage rates of 77% after 4 years but also had many patients with critical ischemia. No difference was seen between the venous and the polytetrafluoroethylene group. Although the use of polytetrafluoroethylene for above-knee bypass did not result in a significant increase in major limb amputation rates compared with use of vein conduits, the patency rates for polytetrafluoroethylene were distinctly inferior to those of vein and significantly more reinterventions were necessary to maintain equivalent limb salvages rates in this series consisting primarily of patients with claudication.

An advantage of polytetrafluoroethylene is the significantly shorter operation time. One can consider in patients with short life expectancy and high operative risk use of polytetrafluoroethylene as bypass graft material.[9]

Some authors showed that the runoff (number of patent tibial arteries) did influence the patency of bypass grafts.[17] We found no significant differences between good and poor runoff for either venous and polytetrafluoroethylene bypass grafts. This could be explained either by the small size of the group or by the relatively proximal site of the distal anastomosis.

Our conclusion after 2 years of follow-up was that polytetrafluoroethylene could be safely used for above-knee femoropopliteal bypass in patients with compromised conditions and in those with short life expectancy. The current results after 5 years of follow-up show that saphenous vein has better patency rates at all intervals and needs fewer reoperations and that saphenous vein should not be spared for reinterventions. We therefore now prefer the vein as

graft material in our institution for all patients needing an above-knee bypass procedure. Polytetrafluoroethylene is an acceptable alternative when the saphenous vein is not available.

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Submitted Apr 18, 2002; accepted Jul 8, 2002.