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## REVIEW

## Saphenous Vein Versus PTFE for Above-Knee Femoropopliteal Bypass. A Review of the Literature

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*The autogenous saphenous vein is considered the best bypass graft material for arterial bypasses below the inguinal ligament. However, a synthetic graft or prosthesis is considered an acceptable alternative, especially when the distal anastomosis is situated above the knee. Some studies even suggest that patency rates for vein and synthetic grafts are comparable, whereas others indicate that a vein graft is superior to a prosthetic graft, even above the knee.*

*To test the hypothesis that both vein grafts and synthetic prostheses are equally beneficial in the above-knee position, we performed a systematic review of available studies comparing the patency of saphenous vein and polytetrafluoroethylene (PTFE) as bypass material. English and German medical literature from 1966 to 2002 was searched using Medline, and 25 articles meeting our inclusion and exclusion criteria were selected.*

*The patency of venous bypasses was superior to that of PTFE bypasses at all time intervals studied. After 2 years, the primary patency rate of venous bypasses was 81% as compared to 67% for PTFE bypasses, and after 5 years it was 69 and 49%, respectively. After 5 years, the secondary patency of PTFE bypasses reached 60%. When only randomized trials were considered, venous bypasses were again superior to PTFE bypasses at all intervals studied. After 2 years, the primary patency rate of venous and PTFE bypasses was 80 and 69%, respectively, and after 5 years it was 74 and 39%, respectively. Since both randomized and retrospective studies comparing venous with PTFE bypasses showed that vein grafts were 'better' than PTFE prostheses, the null hypothesis that there is no difference between the two types of graft material was rejected ( $p = 0.008$ ).*

*We conclude from this systematic review that if a saphenous vein is available, a venous bypass should be chosen at all times, even if patients have an anticipated short life expectancy (< 2 years). If the saphenous vein is absent or not suitable for bypass grafting, PTFE is a good alternative as bypass material.*

**Key Words:** Review; Vascular; Vascular patency; Saphenous vein; Polytetrafluoroethylene; Blood vessel prosthesis.

### Introduction

Since Kunlin performed the first bypass with an autologous saphenous vein in 1949, bypass grafting has proved to be an effective form of treatment for peripheral arterial occlusive disease.<sup>1</sup> Many studies have sought to determine the best material and technique for revascularization of the lower extremities in obstructive arterial disease. The saphenous vein is considered to be the gold standard for bypasses with a distal anastomosis below the knee.<sup>2</sup> For the femoropopliteal bypass, with the distal anastomosis above the knee (AK), there is still controversy as to

whether prosthetic materials like polytetrafluoroethylene (PTFE), Dacron and the human umbilical vein are equivalent to the autologous saphenous vein.<sup>3</sup> However, prosthetic bypass material may be needed if the saphenous vein is absent or not suitable for bypass grafting. Many authors have reported that the patency of PTFE is similar to that of the autologous vein, and thus synthetic prostheses are considered to be acceptable alternatives.<sup>4,5</sup>

The best evidence that one treatment is superior to another comes from randomized controlled trials (RCT). However, very few studies of vein versus PTFE grafts have been performed, and all had insufficient power to either prove or reject the hypothesis that vein is superior to PTFE. Several non-controlled studies have been performed but most

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of them were historical patient series with a non-controlled and non-randomized design. Moreover, different definitions of endpoints and outcomes of the bypass grafts were used. Since there are several reports on bypass operations above the knee, we performed a systematic review of the available studies reported in the literature to test the hypothesis of the equivalence of vein grafts and synthetic prostheses as infrainguinal bypasses for arterial disease in the above-knee position.

## Methods

English and German medical literature from 1966–2002 was searched using MEDLINE, with the following keywords: vascular, vascular patency, vascular disease, arterial occlusive disease, intermittent claudication, popliteal artery, blood vessel prosthesis, saphenous vein, and PTFE. All abstracts of the retrieved articles were reviewed.

The entire article was selected if it fulfilled the following selection criteria: (i) Follow-up of at least 2 years. (ii) Original study (series that contained duplicate material was excluded and those series with the best-documented material were included for analysis). (iii) Objective proof of patency of the bypass by duplex evaluation, arteriography, or Doppler ankle/arm pressure measurements, either alone or in combination; follow-up by simple palpation of the pulses of the bypass or the distal arteries was not considered sufficient.<sup>6</sup> (iv) Separate analysis of patency for the venous and prosthetic bypasses. (v) Distal anastomosis with the above-knee popliteal artery. Patency was defined and documented according to the requirements published by the Ad Hoc Committee on Reporting Standards. Primary patency was defined as uninterrupted patency with no procedure performed on the bypass graft. Secondary patency was the patency after restoring an occlusion or after a procedure to protect the bypass from occluding. Both reversed vein grafts and *in situ* vein grafts were considered as vein grafts.<sup>7,8</sup> Exclusion criteria were (i) the use of composite grafts that consisted of any combination of vein and prosthesis (including venous cuffs); (ii) the use of sequential grafts, grafts of arm veins; and (iii) articles reporting only on secondary interventions in femoropopliteal bypass grafts.<sup>9</sup> The following baseline characteristics were recorded: smoking, diabetes mellitus (type I and II), sex, and age. The indication for bypass surgery was either claudication or critical ischaemia (as defined by ulcers, ischaemic rest pain, limb-threatening ischaemia, or gangrene). Postoperative complications were

recorded. Postoperative mortality was defined as 30-day mortality, and the number of wound infections was recorded. During follow-up, all-cause mortality was documented as well as the amputation rate. Finally, prescriptions for postoperative anticoagulation therapy or antiplatelet therapy were noted.

Primary patency rates weighted for sample size were calculated for each interval and stratified by graft material. Weighted means were also calculated for the mean age, proportion of male patients, proportion of smokers, proportion of patients with diabetes, and proportion of patients with critical ischaemia.

Since we did not collect the primary data of all the studies, we could not perform a statistical comparison of the patency rates for vein and PTFE. We therefore used a non-parametric test, the sign test (which is simply the binomial test with  $p = 0.5$ ), as an appropriate alternative to test whether the results of the studies comparing vein with PTFE are consistent with the null hypothesis (i.e., no difference in patency rates between vein and PTFE).<sup>10</sup>

## Results

The Medline search retrieved 824 articles on infrainguinal bypasses. After the abstract was screened for the exclusion criteria, 713 articles were excluded. The main reasons for exclusion were distal anastomosis of the bypass to the infrainguinal or tibial arteries, the use of composite grafts, or the article did not report original research but was either a review or a comment. Thus 111 studies were selected for further review.

On the basis of the same inclusion and exclusion criteria, another 86 articles were excluded. Finally, 25 articles that fulfilled all the inclusion and exclusion criteria were used (Table 1). Only a minority of these articles presented data as recommended by the Ad Hoc Committee on Reporting Standards and included a complete life table. Most studies, in particular the non-randomized ones, presented a graphical analysis rather than numerical data. If life tables were not available, the patency rates at the various postoperative time intervals were determined from the graphs.

The 25 studies reported a total number of 3804 patients. There were 1284 patients with venous bypasses and 2520 with PTFE bypasses. Seven randomized and historical trials compared vein with PTFE and had a follow-up of at least 5 years; 1026 and 745 patients were included, respectively.<sup>11–17</sup> There were six RCT comparing vein with PTFE and human umbilical vein or Dacron. These trials included 429 patients with vein grafts and 643 with PTFE prostheses.<sup>11,15,17–20</sup> Four of

Table 1. All included articles, meeting the in- and exclusion criteria

Author	Journal	Year	Material	Randomized
Aalders (21)	J Vasc Surg	1992	PTFE vs. HUV/Dacron	+
Abbot (7)	J Vasc Surg	1997	PTFE vs. HUV/Dacron	+
AbuRahma (14)	Surgery	1999	PTFE vs. Vein	+
Acherman (15)	Swiss Surg	1998	PTFE/Vein	-
Allen (23)	Ann Vasc Surg	1996	PTFE	-
Archie (24)	Ann Vasc Surg	1994	PTFE/Vein	-
Berlakovich (16)16	Arch Surg	1994	PTFE/Vein	-
Buchbinder (34)(*)	Ann Vasc Surg	1989	Vein	-
Burger (22)	J Vasc Surg	2000	PTFE vs. Vein	+
Davies (25)	Ann Vasc Surg	1991	PTFE	-
Evans (26)	Surgery	1981	PTFE	-
Gupta (27)	J Vasc Surg	1991	PTFE	-
Harris (28)	Aust N Z J Surg	1985	PTFE	-
John (17)	Ann R C Surg Eng	1993	PTFE/Vein	-
Johnson (18)(#)	J Vasc Surg	2000	PTFE vs. Vein	+
Kavanagh (29)	Ir J Med Sc	1998	PTFE	-
Kent (19)	Arch Surg	1988	PTFE/Vein	-
O'Donnell (35)	Surgery	1983	PTFE	-
Patterson (30)	Ann Vasc Surg	1990	PTFE	-
Plecha (31)	Cardiovasc Surg	1996	PTFE	-
Quinones-Baldrich (4)	J Vasc Surg	1992	PTFE	-
Rosenthal (5)	J Cardiovasc Surg	1990	PTFE	-
Stonebridge (32)	J Vasc Surg	1997	PTFE	-
Veith (20)	J Vasc Surg	1986	PTFE vs. Vein	+
Woratyla (33)	Am J Surg	1997	PTFE	-

these six prospectively randomized studies exclusively compared vein grafts (429 bypasses) with PTFE prostheses (475 bypasses).<sup>11,15,17,20</sup>

The patency of venous bypasses was better than for PTFE bypasses at all time intervals studied. After 2 years, the primary patency for the venous bypasses was 81% as compared to 67% for the PTFE bypasses. In both groups, bypass patency decreased gradually with time, but this decrease was less pronounced for vein grafts than for PTFE. After 5 years, the patency of the venous and PTFE bypasses was 69 and 49%, respectively. After the first year, the difference in patency between the two graft materials was 5%. This difference increased to about 14% after 2 years and to 20% after 5 years (Fig. 1).

Similar results were obtained when only randomized trials were considered. Again, vein grafts were

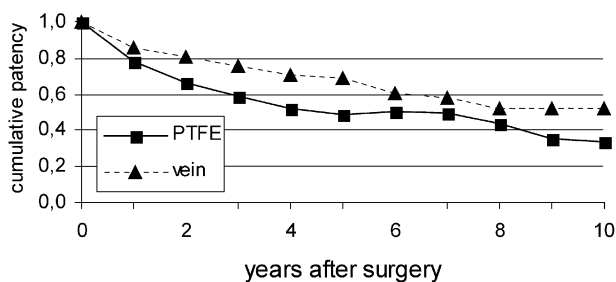


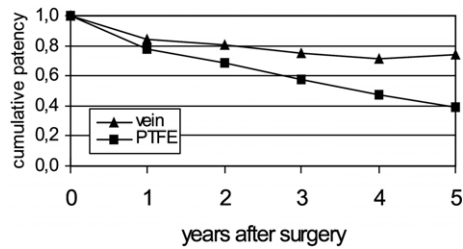
Fig. 1. Weighted mean primary patency rates for all included studies using vein grafts compared with those using PTFE grafts for above knee femoropopliteal bypass.

superior to PTFE at all time intervals. After 2 years the patency of venous and PTFE bypasses was 80 and 69%, respectively. After 5 years, it was 74 and 39%, respectively (Fig. 2).

Only three articles reported the secondary patency of venous bypasses.<sup>11,13,20</sup> The secondary patency for venous bypasses in these three articles was 77% after 2 years and 65% after 5 years. For PTFE bypasses it was 75 and 60%, respectively, and it was reported in more articles (Fig. 3).<sup>11,13,18-29</sup>

The baseline characteristics are listed in Table 2. There were more smokers in the venous bypass group and more diabetic patients in the PTFE bypass group. Critical ischaemia was present more often in the PTFE group. Sex and age were equally distributed between both the vein and the PTFE groups.

Postoperative mortality was reported in 18 articles and was shown to be 2.2% overall. For patients with a venous bypass it was 1.1% (range 0-5)<sup>15-17,20,30,31</sup> and for patients with a PTFE bypass it was 2.5% (range 0-4.7).<sup>5,15-17,21-23,25-30,32-34</sup> Information on postoperative wound infection was available in 12 articles. In the venous bypass group the average postoperative wound infection rate was 5.3% (range 0-9.3),<sup>5,15,20,22,23,25,28-30,34</sup> and in the PTFE bypass group it was 4.6% (range 0-6.1).<sup>15,20,21,31</sup> Because of missing and/or inconsistent data, the amputation rate, the long-term mortality, and the effect of postoperative anticoagulation therapy could not be analysed reliably.

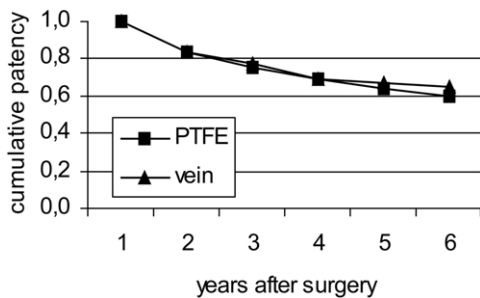


**Fig. 2.** Weighted mean primary patency rates for all randomized controlled trials comparing vein with PTFE grafts for above knee femoropopliteal bypass.

**Discussion**

For many years it has been debated as to whether PTFE and saphenous vein grafts have a similar patency for above-knee femoropopliteal bypasses. While authors agree that only a randomized controlled trial can definitely resolve this issue, to have adequate power (80) and significance (0.05) such a study would need to include about 300 bypasses in each arm. So far, such a randomized controlled trial has not yet been performed. Four smaller RCT comparing vein grafts and PTFE prostheses have been performed, but they were too small to draw firm conclusions.<sup>11,15,17,20</sup> For this reason, we performed this systematic review.

None of the studies showed PTFE to be superior or even equivalent to saphenous vein as graft material for above-knee femoropopliteal bypasses. The mean difference in 5-year patency was 20%, which is clinically relevant. Indeed, a significant difference in patency was already observed after 2 years (a mean difference of 14%). Since all seven randomized and non-randomized studies comparing saphenous vein grafts and PTFE demonstrated the superiority of saphenous vein grafts, the null hypothesis that there is no difference between the two types of graft material was rejected ( $p = 0.008$ ). When only RCT were considered, which provide level I evidence, saphenous vein grafts were clearly superior to PTFE. Secondary patency appeared to be similar for the two graft



**Fig. 3.** Weighted mean secondary patency rates for all included studies using vein grafts compared with those using PTFE grafts for above knee femoropopliteal bypass.

**Table 2. Demographic data of all included articles**

	Vein		PTFE	
Smoking	87.7%	N = 474	65.2%	N = 1771
Diabetes	26.5%	N = 914	37.1%	N = 2130
Male	67.2%	N = 1155	66.2%	N = 1729
Severe ischemia	55%	N = 974	61%	N = 2269
Average age	65.6 years	N = 1284	66.0 years	N = 2401

materials; however, only a few articles reported the secondary patency of venous bypasses.

Discussion about the patency of PTFE and venous bypasses is not new. Michaels also did not find evidence that prosthetic grafts, including PTFE, had a better patency than vein grafts in his review on materials for above-knee femoropopliteal bypass grafts in 1989. He concluded that there was an advantage in using vein for above-knee bypass grafting.<sup>35</sup> One of his most important conclusions was that he had statistical difficulties drawing conclusions from insufficient data. Twelve years later, this conclusion is still valid. However, the report of three randomized studies have been published, which make our conclusions stronger.<sup>11,15,20</sup>

Mamody stated in his Cochrane review that it is tempting to conclude that autologous vein is better than PTFE, but his results did not firmly support this conclusion.<sup>36</sup> He suggested that a good randomized controlled trial with a standardization of definitions was required. In this article, we clearly show that PTFE bypasses are not equal to venous bypasses. We therefore think that it is no longer necessary to perform a randomized controlled trial, especially in view of the large number of patients that need to be recruited. After the inclusion period of this review one RCT comparing vein and PTFE was published in 2003 which found a statistically better patency rate for vein, which only strengthens our conclusion.<sup>37</sup>

Since our systematic review included all reports and not only RCT, there are differences in risk factors between the groups of patients who underwent reconstruction with a vein and those with PTFE. We also combined studies with various designs. Differences between studies were observed in inclusion criteria, follow-up methods, and the reporting of risk factors. Moreover, information on some characteristics, such as postoperative anticoagulant prescription could not be analysed, as this information was missing in most of the studies. Studies of PTFE grafts generally included a higher proportion of diabetic patients and patients with critical ischaemia; this might have caused a lower patency. However, both Aalders *et al.*<sup>18</sup> (16% diabetics; 16% severe ischaemia) and Rosenthal *et al.*<sup>27</sup> (26% diabetics; 0% critical ischaemia)

also reported a low 5-year patency (39 and 52%, respectively). None of the eight trials comparing vein grafts with PTFE showed diabetes mellitus to affect patency.<sup>11-17,20</sup> Three of these trials found no difference in patency between the two types of grafts in patients with claudication or critical ischaemia,<sup>12,13,15</sup> three did not report on differences,<sup>14,17,20</sup> and two only included patients with claudication.<sup>11,15</sup>

Because more smokers received saphenous vein grafts than PTFE grafts, the difference in patency might be caused by a lower survival of patients treated with vein grafts. However, both Johnson *et al.*<sup>15</sup> (98% smokers) and Patterson *et al.*<sup>25</sup> (85% smokers) showed similar 5-year patency rates (39 and 54%, respectively) to other PTFE studies. None of the eight trials comparing vein grafts with PTFE grafts reported smoking to affect patency.<sup>11,12-17,20</sup> Therefore, differences in the distribution of risk factors are unlikely to explain the better patency of vein grafts over PTFE grafts.

Postoperative mortality was lower for saphenous vein grafts than for PTFE grafts, but the difference was very small. It could not be explained by differences in baseline characteristics. This small difference would not constitute a clinically relevant argument to favour saphenous vein grafts.

Wound infections occurred more frequently in patients with a venous bypass, but again this difference was very small. It could be explained by the larger wounds required for excision of the vein and the longer operation time. However, the difference was not so large that PTFE should be preferred, especially when bearing in mind the superior patency of vein grafts.

It would not be expected to perceive a difference in long-term mortality because the two patient groups were of the same age. Strikingly, there was a difference in favour of vein grafts. Differences in demographic data could not explain this difference because age and sex were equally distributed among the two patient groups. There was, however, a difference in follow-up time, which was longer in the PTFE group. Patients who receive infrainguinal bypasses generally have widespread occlusive arterial disease, especially of the coronary and cerebrovascular arteries, so a longer follow-up for patients with PTFE grafts may cause the observed higher mortality among patients with PTFE grafts. Conclusions on the type of graft and the long-term amputation rate and postoperative anticoagulation therapy could not be drawn because of missing and/or inconsistent data.

## Conclusions

This systematic review shows that the saphenous vein is superior to PTFE at all time intervals studied, with a primary patency at 5 years of 69% compared with 49%, respectively. Since all seven randomized and non-randomized studies comparing vein with PTFE demonstrated vein grafts to be advantageous, the null hypothesis that there is no difference between the two types of graft material is rejected ( $p = 0.008$ ). More strikingly, if only the four RCT were considered, providing level I evidence, the difference in patency for venous and PTFE bypasses was even greater, 74 and 39%, respectively. After 2 years the difference in patency for venous and PTFE bypasses was 81 and 67%; in the randomized controlled trial it was 80 and 69%, respectively.

We have convincingly demonstrated that if the saphenous vein is available, a venous bypass should be chosen, even for patients with a short anticipated life expectancy (<2 years). When the saphenous vein is absent or not suitable for bypass grafting, PTFE is a good alternative for bypass material.

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