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A Paper for Debate: Vein versus PTFE for Critical Limb Ischaemia – an Unfair Comparison?

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Introduction: *There is a widely held view that vein grafts for infrainguinal arterial reconstruction perform much better than prosthetic conduits, the best of which seems to be PTFE. Many randomised studies have been conducted which confirm this opinion, but is the difference as large as it is thought to be? One interesting feature of published trials is that the results for obligatory PTFE (when no vein is available) were much worse than the results for randomised PTFE grafts. The only way to explain this is that these groups of patients were not similar, and there are probably other factors which contribute to the difference in results when vein and PTFE grafts are compared.*
Materials and Method: *A consecutive series of 109 femoro-infrapopliteal grafts undertaken for critical limb ischaemia was analysed to see the difference between vein and PTFE with vein cuff grafts.*
Results: *Vein grafts were superior to PTFE grafts when the whole cohort was included ($p = 0.0038$); however, there was no significant difference when the patients were stratified for inflow and runoff status.*
Conclusions: *The difference between vein and PTFE has probably been exaggerated in the past, due to differences in risk factors and in the extent of arterial disease between the two groups of patients. The advantage of vein becomes more significant with time.*

Key Words: Femoro-infrapopliteal bypass; Distal bypass; Femorocrural bypass; Limb salvage; Patency rates; Runoff; Vein grafts; PTFE grafts; Critical limb ischaemia.

Introduction

Critical limb ischaemia (CLI) is often the result of multilevel arterial occlusion, which requires the insertion of a long graft from the femoral artery to the crural or pedal vessels in order to save the foot. Autologous saphenous vein provides the best available conduit for infrapopliteal reconstruction[1,2]; however, in a large proportion of patients these veins may be unavailable or inadequate.[2] This problem has encouraged the development of several types of synthetic grafts, of which polytetrafluoroethylene (PTFE) is the most widely used, with acceptable mid-term patency rates.[2–6]

Michaels,[7] in his excellent review article, performed a meta-analysis of approximately 40 publications of femoropopliteal grafts in order to establish whether vein or prosthetic material was superior. He showed that the differences in occlusion rate between vein and prosthetic grafts in the first year were related to the length of the graft, being smallest for above-knee grafts and greatest for distal grafts. He concluded that saphenous vein was the first choice for all infrainguinal bypass surgery. However, he suggested that the advantages of vein were overestimated.

In a well designed multicentre prospective randomised trial, Veith *et al.*[2] reported a primary patency rate of 29% at 3 years (12% at 4 years) for femorocrural PTFE grafts, which was low compared with the 50% primary patency rate observed for vein grafts at 3 years. There was also a further group of patients, who were unsuitable for randomisation, who had obligatory PTFE grafts. There were some interesting observations in this study which deserve further consideration. Firstly, the results for obligatory PTFE femorocrural grafts were considerably worse than those for randomised PTFE grafts. Primary patency at 3 years for randomised grafts was 29% at 3 years, compared with 18% for obligatory grafts. Secondly, this was also true for obligatory infragenicular (crural and popliteal) PTFE grafts, which showed patency rates of 47% for randomised compared with 29% for obligatory grafts at 4 years. Thirdly, there was no significant difference between randomised vein and PTFE grafts to the popliteal artery ($p > 0.25$). Furthermore, there was no significant difference in limb

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salvage between randomised vein and PTFE grafts (61% vs. 57% at 4 years).

Despite the initial enthusiasm based on good results for PTFE grafts to proximal outflow sites such as the above-knee (AK) or below-knee (BK) popliteal arteries,[2,6] the discouraging results of PTFE when used for femorotibial grafts[5,8–11] has compelled many surgeons to use vein in all cases of infrapopliteal reconstruction.[13] Some authors have recommended the use of other vein sources, such as short saphenous, arm or deep veins,[13] in order to avoid prosthetic material, while others suggest that primary amputation should be performed when autologous vein is unavailable.[9,14,15] However, patency rates for veins other than long saphenous vein (LSV) are initially good, but are inferior to those of LSV in the long-term.[16] The patency at 3–5 years for non-LSV vein grafts is similar to the best results reported for PTFE with vein cuff or patch[17,18] or composite grafts.[19] Abbot[16] reports a 3-year patency of 40% for alternate vein grafts, compared to 60% for LSV grafts. Taylor *et al.*[20] report 5-year secondary patency for PTFE grafts with vein patch, which varies from 77% (for AK grafts) to 54% for infrapopliteal grafts.

There are series which have shown good patency rates for femorotibial PTFE grafts, which are comparable to those for vein.[17,18,20] Recently established techniques using vein patches[12,17] or cuffs[18] for the distal anatomosis of femoro-below-knee popliteal and femorodistal PTFE grafts and the use of intense surveillance programmes have improved results.[21] The role of an adjuvant arteriovenous fistula is less clear.[22] Some vascular surgeons reject PTFE even for short grafts to the above-knee popliteal artery,[23] a site for which comparable results have been shown for both vein and prosthetic grafts.[2,3,5–7]

The problem of which conduit should be used for secondary revascularisation when the original infraguinal bypass has failed is pertinent. In a recent report,[13] secondary autogenous vein other than LSV when used for infraguinal bypass showed a 35% 5-year primary patency rate.

Even LSV grafts used for secondary procedures following early failure (within 3 months) of the original graft showed a discouraging primary patency rate of 27% at 5 years, compared to 25% for prosthetic grafts. These results are difficult to explain (poor quality of vein compromised runoff may be responsible), but confirm the differences observed by Veith *et al.*[2] There are several reasons why patients with aggressive atherosclerosis should have poor quality or absent LSV, including poor flow through diseased arteries, sedentary life style enforced by claudication or angina, and ischaemic heart disease for which coronary bypass saphenous vein grafts have been inserted. Since obligatory PTFE grafts are performed in high risk circumstances, usually as secondary procedures, it may not be fair to compare these with vein grafts, most of which are inserted as primary procedures. Furthermore, vein grafts are often undertaken for disabling claudication, an indication which is associated with a considerably better outcome compared with CLI.[11]

Differentiation of infrapopliteal PTFE grafts undertaken for CLI in primary and secondary revascularisation procedures may identify two different populations of patients. Schweiger *et al.*[24] reported primary patency rates of 42% at 4 years for primary femorotibial PTFE grafts, compared to 14% for secondary procedures. The incidence of risk factors was higher in the secondary group and they also had poor distal runoff. Christenson *et al.*[6] showed that secondary patency for infragenicular PTFE grafts undertaken for critical limb ischaemia varied from 55% at 6 years for limbs with two to three patent calf vessels to 25% for limbs in which a single or no calf vessel was patent. In most reports comparing vein to PTFE grafts, the proportion of secondary procedures is not stated, and if it is may vary from 7%[6] to 71%.[5] Therefore, the results should be cautiously interpreted and the negative view of PTFE grafts may thus be unfairly biased.

From the authors' experience with femorocrural arterial reconstruction undertaken for CLI, it could easily be deduced that PTFE (Impra, U.K.) grafts are not worthwhile, as they were associated with a dismal 23% secondary patency at 3 years, compared with 55% for vein grafts.[25] A vein cuff at the distal anastomotic site was used for all PTFE grafts. However, further analysis showed that 67% of PTFE grafts were undertaken as secondary procedures, compared to 35% of vein grafts. Furthermore, 62% of the PTFE grafts had poor outflow (judged by impaired pedal vessels and no calf vessel crossing the ankle) compared with 36% of vein grafts.

Based on the factors that were shown to affect the outcome, we developed a scoring system which could differentiate the patients into three groups: those with a poor, a moderate or an excellent inflow and runoff conditions (based on the number and quality of patent calf and pedal vessels and the number of vessels crossing the ankle).[26] Comparison of PTFE with vein grafts for each group (using the Log rank test), showed no statistical significance in secondary patency (Table 1, Figs 1–3). Vein and PTFE grafts seemed to perform equally well in good conditions ($p=0.7100$) and both did poorly when inflow and runoff were compromised

Table 1. Comparison of vein and PTFE grafts in the three groups of patients. Despite the fact that there was no significant difference in each individual group, overall vein grafts were shown to have a better statistically significant outcome.

	Total	Number of events	Number censored	Percent censored	Secondary patency	Significance
Poor status						
All	35	27	8	22.86		$p=0.6850$
PTFE	23	17	6	26.09	0%	
Vein	12	10	2	16.67	0%	
Moderate status						
All	46	18	28	60.87		$p=0.4253$
PTFE	21	10	11	52.38	30%	
Vein	25	8	17	68.00	61%	
Good status						
All	28	4	24	85.71		$p=0.7100$
PTFE	5	1	4	80.00	75%	
Vein	23	3	20	86.96	83%	
Overall	109	49	60	55.05	45%	$p=0.0038$

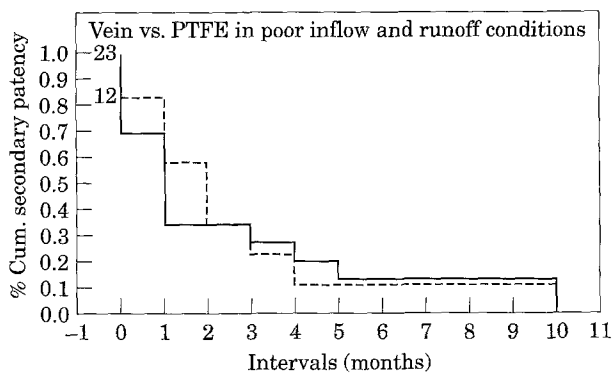

Fig. 1. Comparison of vein and PTFE femorocrural grafts in limbs with compromised inflow and outflow conditions. All of them failed in 9 months, irrespective of the type of conduit.
(---) Vein: SP = 0%, SE = 10.08. (—) PTFE: SP = 0%, SE = 8.83.

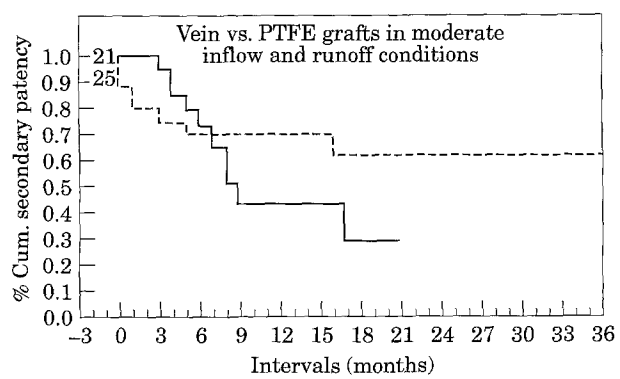

Fig. 2. Comparison in the intermediate group of patients. Despite the trend for vein grafts to perform better, no statistical significance was shown.
(---) Vein: SP = 61%, SE = 9.43. (—) PTFE: SP = 30%, SE = 9.72.

($p=0.6850$). There was a trend for vein grafts to perform better in the intermediate group, but this was not shown to be statistically significant ($p=0.4253$). In contrast, when vein and PTFE grafts were compared as independent variables, the overall difference was significant ($p=0.0038$), with PTFE grafts performing

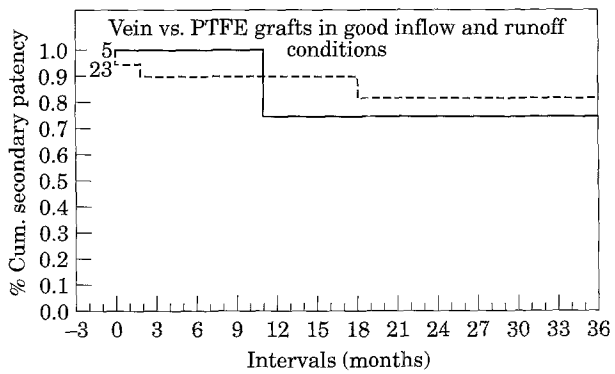

Fig. 3. Secondary patency of vein and PTFE grafts in limbs with good inflow and excellent runoff.
(---) Vein: SP = 82%, SE = 9.6. (—) PTFE: SP = 75%, SE = 21.65.

less well. However, the numbers in some groups were small and the length of the study relatively short, although the standard error was almost always below 10 (8.17 for vein and 8.11 for PTFE).

One should not extrapolate from this observation and deduce that there is no difference between vein and PTFE grafts, as clearly there is. However, the difference is not as dramatic as previously believed. One reason may be the usage of poor quality veins, as it has been shown that veins with a diameter less than 3.5 mm and impaired compliance are more likely to occlude or develop stenoses[27]; however, the main reason is probably the poor stratification of patient risk factors, and the extent of arterial disease in studies which compare vein with PTFE. The longer the study, the more the advantage of venous conduits becomes evident.[2] This has been shown in many reports of both randomised and non-randomised series. Patency rates remain similar for the first 12–24 months and diverge thereafter, reaching statistical significance at 2–3 years, which becomes more important after 6 years.[2–4,8,28] The difference is less significant when grafts to more proximal outflow sites are compared.[2,5–7] This could

be attributed to the fact that PTFE patency may be more dependent on outflow resistance and less tolerant to low flow states, which is probably the reason why some may occlude without the presence of a stenotic lesion.[29]

Patients presenting with CLI usually have a lower survival rate compared with claudicants, and therefore the use of PTFE grafts for treating CLI when no vein is available is probably justified, particularly when used with vein cuffs or patches.[17,18,20] A case can also be made for use of prosthetic material for more proximal grafts in poor risk patients with less than 2–3 years' life expectancy. There may be other possible reasons for using prostheses in preference to vein. The value of preserving the vein for later surgery requires careful mathematical evaluation, which was done by Michaels in 1989.[7] Shorter operating time, fewer complications or shorter hospital stay may be other advantages, particularly for above-knee femoropopliteal grafts. This policy is supported by similar limb salvage rates in patients with infraguinal or infrapopliteal grafts that have been observed with both types of conduits.[2,5,18,19,24]

References

1 European Working Group on Critical Limb Ischaemia. Second European Concensus Document on critical limb ischaemia. *Eur J Vasc Surg* 1992; (6 Suppl. A): 1–32.

2 Veith FJ, Gupta SK, Ascer E *et al.* Six year prospective multicentre randomised comparison of autologous saphenous vein and expanded PTFE grafts in infrainguinal arterial reconstruction. *J Vasc Surg* 1986; **3**: 104–114.

3 Londrey GL, Ramsey DE, Hodgson KJ, Barkmeier LD, Sumner DS. Infrapopliteal bypass for severe ischaemia: comparison of autogenous vein, composite and prosthetic grafts. *J Vasc Surg* 1991; **13**: 631–636.

4 Feinberg RL, Winter RP, Wheeler JR *et al.* The use of composite grafts in femorocrural bypasses performed for limb salvage: a review of 108 consecutive cases and comparison with 57 in situ saphenous grafts. *J Vasc Surg* 1990; **12**: 257–263.

5 Flinn WR, Rohrer MJ, Yao JST, McCarthy WJ III, Fahey VA, Bergan JJ. Improved longterm patency of infragenicular PTFE grafts. *J Vasc Surg* 1988; **7**: 685–690.

6 Christenson JT, Bromme A, Norgren L, Eklof B. Revascularisation of popliteal and below knee arteries with PTFE. *Surgery* 1985; **97**: 141–149.

7 Michaels JA. Choice of material for above-knee femoropopliteal bypass graft. *Br J Surg* 1989; **76**: 7–14.

8 Whittemore AD, Kent KC, Donaldson MC, Couch NP, Mannick JA. What is the proper role of of PTFE grafts in infrainguinal reconstruction. *J Vasc Surg* 1989; **10**: 299–305.

9 Hobson RW II, Lynch TG, Jamil Z *et al.* Results of revascularisation and amputation in severe lower extremity ischaemia: a five year clinical experience. *J Vasc Surg* 1985; **2**: 174–185.

10 Brewster DC, LaSalle AJ, Robinson JG, Strayhorn EC, Darling RC. Femoropopliteal grat failures. *Arch Surg* 1983; **118**: 1043–1047.

11 Conte MSD, Belkin M, Donaldson MC, Baum P, Mannick JA, Whittemore AD. Femorotibial bypass for claudication: do results justify an aggressive approach? *J Vasc Surg* 1995; **21**: 873–881.

12 Sayers RD, Thompson MM, London NJM *et al.* Selection of patients with critical limb ischaemia for femorodistal vein bypass. *Eur J Vasc Surg* 1993; **7**: 291–297.

13 Belkin M, Conte MS, Donaldson MC, Mannick JA, Whittemore AD. Preferred strategies for secondary infrainguinal bypass: lessons learned from 300 consecutive operations. *J Vasc Surg* 1995; **21**: 282–295.

14 Bell PRF. Are distal vascular procedures worthwhile? *Br J Surg* 1985; **72**: 335.

15 Jacobs MJHM, Ubbink DT, Hoedt R, Biasi GM. Current reflections of the vascular surgeon on the assessment and treatment of critical limb ischaemia. *Eur J Vasc Endovasc Surg* 1995; **9**: 473–478.

16 Abbott WM, Vignati JJ. Prosthetic grafts; when are they a reasonable alternative? *Semin Vasc Surg* 1995; **8**: 236–245.

17 Loh A, Chester JF, Taylor RS. PTFE bypass grafting to isolated segment in critical limb ischaemia. *Eur J Vasc Surg* 1993; **7**: 26–30.

18 Cheshire NJW, Wolfe JHN, Noone MA, Davies L, Drummond M. The economics of femorocrural reconstruction for critical leg ischaemia with and without autologous vein. *J Vasc Surg* 1992; **15**: 167–175.

19 Chang JB, Stein TA. The long-term value of composite grafts for limb salvage. *J Vasc Surg* 1995; **22**: 25–31.

20 Taylor RS, Loh A, McFarland RJ, Cox M, Chester JF. Improved technique for PTFE bypass grafting: longterm results using anastomotic vein patches. *Br J Surg* 1992; **79**: 348–354.

21 Bell PRF. Femorodistal grafts – can the results be improved? *Eur J Vasc Surg* 1991; **5**: 607–609.

22 Harris PL, Bakran A, Enabi L, Nott DM. ePTFE grafts for femorocrural bypass – improved results with combined adjuvant venous cuff and arteriovenous fistula. *Eur J Vasc Surg* 1993; **7**: 528–533.

23 Wilson YG, Wyatt MG, Currie IC, Baird RN, Lamont PM. Preferential use of vein for above knee femoropopliteal grafts. *Eur J Vasc Endovasc Surg* 1995; **10**: 220–225.

24 Schweiger H, Klein P, Lang W. Tibial bypass grafting for limb salvage with ringed PTFE prostheses. Results of primary and secondary procedures. *J Vasc Surg* 1993; **18**: 867–874.

25 Panayiotopoulos YP, Tyrrell MR, Owen SE, Reidy JF, Taylor PR. Outcome and cost analysis after femorocrural and femropedal grafting for critical limb ischaemia. *Br J Surg* 1997; **B4**: 207–212.

26 Panayiotopoulos YP, Edmondson RA, Reidy JF, Taylor PR. A scoring system to predict the outcome of long femorodistal arterial bypass grafts to single calf or crural vessels. *J Vasc Surg* 1996, in press.

27 Davies AH, McGee TR, Sheffield E, Baird RN, Horrocks M. The aetiology of vein graft stenosis. *Eur J Vasc Surg* 1994; **8**: 389–394.

28 Feinberg RL, Winter RP, Wheeler JR *et al.* The use of composite grafts in femorocrural bypasses performed for limb salvage: a review of 108 consecutive cases and comparison with 57 in situ saphenous grafts. *J Vasc Surg* 1990; **12**: 257–263.

29 Ouriel K, Shortell CK, Green RM, DeWeese JA. Differential mechanisms of failure of autogenous and non-autogenous bypass conduits; an assessment following successful graft thrombolysis. *Cardiovasc Surg* 1995; **3**: 469–473.

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