Tibial bypass for limb salvage using polytetrafluoroethylene and a distal vein patch

Richard F. Neville, MD, Barbara Tempesta, NP, and Anton N. Sidawy, MD, *Washington, DC*

Objective: Tibial artery bypass for limb salvage may be required in patients without adequate autogenous vein. The interposition of venous tissue at the distal anastomosis has been advocated to improve the results of prosthetic grafts to tibial arteries. Having reported on technical feasibility and an early experience with polytetrafluoroethylene (PTFE) and a distal vein patch (DVP), we examine the results of this technique with 4-year follow-up.

Methods: From July 1993 to July 1999, 514 tibial bypass grafts were performed, with 80 bypass grafts in 79 patients with PTFE/DVP as the conduit. Patient demographics included 39 men and 40 women (mean age, 67 years); 42 had diabetes mellitus (53%), 16 had renal failure (20%), and 48 had Eagle criteria for increased cardiac risk (60%). Indications for revascularization were rest pain in 39 (49%) and tissue loss in 41 (51%). Lack of adequate vein resulted from previous failed lower extremity bypass graft (47 [59%]), previous coronary bypass graft (21 [26%]), unsuitable vein (8 [10%]), and absent vein due to ligation and stripping (4 [5%]). Follow-up ranged from 1 to 48 months. Results are reported as primary patency or limb salvage ± SE.

Results: Bypass grafts originated from the common femoral artery (40 [50%]), the superficial femoral artery (6 [8%]), and the external iliac artery (34 [43%]). Recipient arteries included anterior tibial (17 [21%]), posterior tibial (28 [35%]), and peroneal (35 [44%]). Four-year primary patency and limb salvage rates were 62.89% ± 10.6% and 79.21% ± 8.45%, respectively. There was a 24% mortality rate during the follow-up period. Acute failure occurred in 7 grafts with 5 immediate amputations and 2 revisions. A total of 17 grafts failed during the follow-up period, leading to 11 amputations.

Conclusion: The DVP technique allows PTFE bypass grafts to tibial arteries with acceptable long-term patency and limb salvage. (J Vasc Surg 2001;33:266-72.)

There is little question that saphenous vein is the conduit of choice for tibial bypass grafting. However, there seems to be an increasing number of patients in need of tibial bypass graft for limb salvage who do not have adequate saphenous vein available. Several alternative conduits have been proposed, including lesser saphenous vein, arm vein, composite veins, composite vein with polytetrafluoroethylene (PTFE), and PTFE with or without a distal arteriovenous fistula. Unfortunately, these alternative conduits have not resulted in equivalent results when used for distal bypass graft to tibial arteries.[1-4] This has led some to advocate primary amputation with no attempt at limb salvage in certain patient subgroups.[5] Conversely, several authors have reported on the use of venous tissue at the distal anastomosis in the form of cuffs, collars, and boots to improve the results of prosthetic grafts to tibial arteries.[6-8] These techniques have been proposed as an option for revascularization in patients without adequate saphenous vein in an attempt to obtain limb salvage.

Having tried several of the venous cuffs and collars, we found the procedures somewhat complex involving multiple intricate suture lines. In addition, there was difficulty in placement at the inframalleolar position because of space constraints. Therefore, we embarked on the use of PTFE grafts with a distal vein patch (DVP) to enhance the patency of tibial bypass grafts in limb-threatened patients without available autogenous vein. This series describes the long-term results of PTFE/DVP bypass grafts to tibial arteries for limb salvage.

From the Department of Surgery, Georgetown University Medical Center, and the Department of Surgery, Veterans Administration Medical Center.
Competition of interest: nil.
Presented at the American Association for Vascular Surgery and the Society for Vascular Surgery 2000 Joint Annual Meeting, Toronto, Ontario, Canada, Jun 10, 2000.
Reprint requests: Richard F. Neville, MD, Director, Vascular Surgery, Georgetown University Medical Center, 3800 Reservoir Road, 4 PHC, Washington, DC 20007 (e-mail: nevfamily@aol.com).
24/6/113131
doi:10.1067/mva.2001.113131

METHODS

A total of 514 tibial artery bypass grafts were performed for limb salvage from July 1993 to July 1999. Included in this patient cohort were 80 bypass grafts performed in 79 patients with PTFE/DVP as the graft conduit. The PTFE/DVP group represented 16% of the total tibial bypass graft experience during this time period. For the purposes of this report, the charts of the patients with a PTFE/DVP bypass graft were reviewed. Patient status was updated through direct contact with the patient or the family in each case.

All patients were evaluated preoperatively with contrast arteriography to plan the appropriate revascularization. An attempt was made to locate saphenous vein (ipsilateral or contralateral) through careful physical examination supplemented with duplex ultrasound evaluation. If the vein was of questionable quality, then it was evaluated under direct vision at operation. In each patient who received a PTFE/DVP bypass graft, the ipsilateral and the contralateral greater saphenous vein either was unavailable, having been used for previous revascularization procedures, or was unsuitable because of inadequate length or quality.

The bypass grafts were performed with patients under epidural anesthesia in most cases with selective use of Swan-

Fig 1. Intraoperative photograph showing PTFE/DVP distal anastomosis to a posterior tibial artery.

Fig 2. Completion arteriogram after PTFE/DVP bypass graft to a posterior tibial artery.

Ganz catheterization. The artery chosen as the inflow site was exposed in standard fashion. A retroperitoneal approach to the external iliac artery was used in several cases because of multiple previous groin procedures with subsequent scar formation. Distal exposure varied according to the tibial artery chosen for bypass graft. After proximal and distal arterial exposure, a 2- to 3-cm segment of vein was harvested from any available location. Vein for the patch included saphenous remnants, arm vein harvested with patients under local anesthesia, and, rarely, superficial femoral vein. This vein segment was gently irrigated with prepared vein solution and opened longitudinally. The vein solution was composed of buffered saline solution (Plasma-Lyte-A) (1000 mL, pH 7.4), heparin (5000 units), calcium chloride (10%, 100 mg), and papaverine (120 mg). Any valves were excised, and the vein segment was briefly stored in the vein solution. An externally reinforced, 6-mm, thin-walled PTFE graft was then tunneled between the proximal and distal arterial dissections. The tunnel was routed medially; however, when a bypass graft to the anterior tibial artery was planned, the tunnel was made laterally. In addition, if a distal peroneal artery was targeted via a lateral approach with segmental fibulectomy, a lateral tunnel was also used. Heparin was given, and an end-to-side proximal anastomosis was performed between the PTFE graft and the inflow artery with a standard continuous suturing technique. A 2- to 3-cm arteriotomy was then performed in the artery chosen for distal anastomosis. The venous segment was cut to the appropriate length and width in preparation for the patch. In most cases, the width was left unaltered to allow for a generous patch to permit bulging of the patch under arterial flow somewhat like a cuff. Rarely, the vein width was trimmed to allow for a better size match with a small tibial artery. The vein patch was sutured to the artery with 7-0 Prolene suture by means of standard parachute techniques. The PTFE/DVP anastomosis was then performed as previously described.[9] A longitudinal venotomy was then made in the proximal two thirds of the patch. The venotomy was positioned to begin the heel of the PTFE/vein anastomosis just beyond the artery/vein patch suture line. The PTFE graft was cut to the appropriate length in a sigmoidal fashion to allow the sides to flare in a "cobra-head" configuration. The PTFE graft was then sutured to the vein patch with 6-0 Prolene suture in a continuous fashion allowing a rim of venous tissue interposed between the PTFE graft and the arterial wall. More venous tissue was left interposed at the toe of the anastomosis than the heel (Fig 1). Completion arteriography was performed in each case (Fig 2).

Patients were transferred to the intensive care or step-down unit on the basis of their medical condition. A heparin infusion was started 4 to 6 hours postoperatively with Coumadin administered on the first postoperative day. Long-term anticoagulation with Coumadin was continued with an international normalized ratio of 2.0 as the goal. Patients were seen in the office 7 to 10 days after discharge from the hospital. The follow-up protocol included physical examination of the limb with pulse status, ankle pressures, and waveforms and graft duplex evaluation at 3 months, at 6 months, and then annually.

RESULTS

Eighty PTFE/DVP grafts were performed in 79 patients with follow-up ranging from 30 days to 4 years.

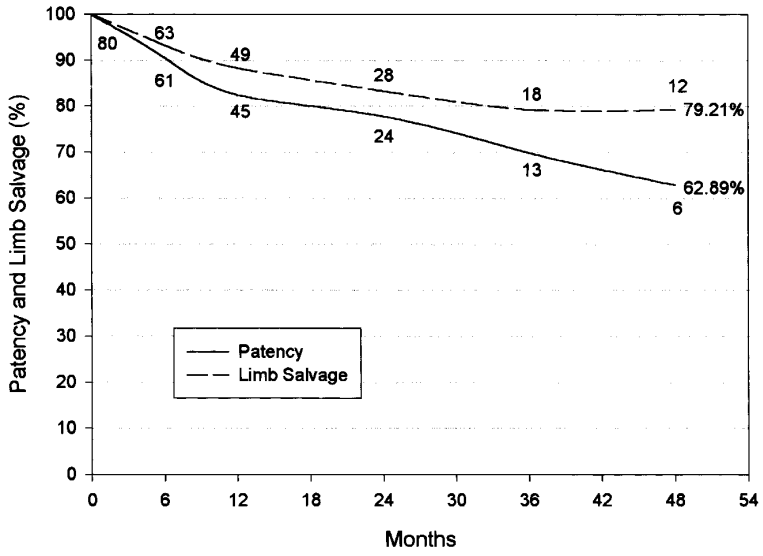

Fig 3. Primary patency and limb salvage rates. Numbers on graph represent grafts at risk at beginning of specific time interval.

Patient demographics included 39 men and 40 women (mean age, 67 years). Risk factor analysis revealed 42 (53%) patients with diabetes mellitus, 16 (20%) patients with renal failure, and 48 (60%) patients with increased perioperative risk cardiac risk as assessed with Eagle's criteria. Of the 16 patients with renal failure, 12 were undergoing dialysis with the remainder having a creatinine level greater than 2.5 mg/dL. The indication for revascularization was limb-threatening ischemia in all patients with rest pain in 39 (49%) limbs and gangrene or non-healing ulceration present in 41 (51%). Reasons for the lack of adequate saphenous vein included previous failed lower extremity bypass graft performed at another medical institution in 47 (59%) patients, previous coronary bypass graft in 21 (26%), unsuitable vein quality due to size or thrombosis in 8 (10%), and absence of vein due to varicose vein stripping in 4 (5%).

Bypass grafts originated from the common femoral artery in 40 (50%) cases, the external iliac artery in 34 (43%) cases, and the superficial femoral artery in 6 (8%) cases. Recipient arteries included the peroneal artery in 35 (44%) cases, the posterior tibial artery in 28 (35%) cases, and the anterior tibial artery in 17 (21%) cases. Two of the posterior tibial bypass grafts went in the inframalleolar plantar branches.

Graft patency and limb salvage rates were determined at follow-up intervals ranging from 6 to 48 months (Fig 3). Data were analyzed with the life-table method and reported as patency and limb salvage ± SE.[10] Primary graft patency was 90.6% ± 3.2% at 6 months and 82.44% ± 4.42%, 77.82% ± 5.46%, 69.88% ± 7.82%, and 62.89% ± 10.6% at 12-month intervals, to 48 months. Limb salvage was 93.3% ± 2.7% at 6 months, and 88.3% ± 3.8%, 83.3% ± 4.86%, 79.21% ± 6.77%, and 79.21% ± 8.45% at 12-month intervals to 48 months. Of note, limb salvage and secondary patency were equivalent at all time intervals. Therefore, secondary patency at 4 years' follow-up was 79.21% ± 8.45%. Beyond 48 months, six grafts remained at risk. Three grafts failed, resulting in three amputations. Because only six grafts remained at risk, the failures and the amputations were not included in the life-table analysis, and the results were given at a maximum of 48-month follow-up. There was one perioperative death due to myocardial infarction (1.25%) with a 24% total mortality rate during the 48-month follow-up period.

Seven grafts failed in the immediate perioperative period, leading to five amputations. Four of the patients with failed grafts had an operative thrombectomy with no technical problem noted at the time of reoperation. Two of the thrombectomies were successful, and these grafts are patent at 12 and 24 months. Two thrombectomies were unsuccessful, resulting in amputation. Three patients went directly to amputation without an attempt to reestablish graft patency. A total of 17 grafts failed in the follow-up period of 48 months, leading to 11 amputations. Two of these failed grafts were opened by means of lytic therapy with no anatomic abnormality noted, and one remains patent 12 months later. Five failed grafts required a thrombectomy, and three required revision. These three grafts were revised with a short distal extension by the use of a new segment of PTFE and new vein patch to bypass progressive distal arterial disease. Two of these grafts remain patent at 6 and 12 months. Another failed graft was converted to an ilioprofunda bypass graft to a diseased but patent profunda femoris artery. This bypass graft remained functional for an additional 12 months. Distal anastomotic anatomy of the failed grafts included 10 peroneal bypass grafts, 9 anterior tibial bypass grafts (2 dorsalis pedis), and 5 posterior tibial bypass grafts. There were three graft infections. Two were noted at the time graft thrombosis

was diagnosed, resulting in graft excision and amputation. The remaining infection occurred in a known thrombosed graft, leading to amputation.

DISCUSSION

Autogenous saphenous vein is the conduit of choice for tibial revascularization. Despite the use of duplex ultrasound techniques to improve the ability to locate acceptable saphenous vein, there is a seemingly growing subset of patients in whom the choice of conduit remains problematic because of a lack of suitable saphenous vein. This group has been estimated at almost 30% of those needing distal reconstruction with an increase to near 50% for those undergoing a repeat or secondary procedure.[11]

PTFE bypass grafts with direct anastomosis to the distal arteries have been used with generally poor results. Clinical series report 1-year patency rates between 20% and 50% with 3-year patency rates from 12% to 40%.[1,12,13] These bypass grafts are technically demanding, requiring an anastomosis between a small, diseased tibial artery and a fairly noncompliant prosthetic material. The major cause of these graft failures involving PTFE bypass grafts to infrainguinal arteries appears to be myointimal hyperplasia at the outflow anastomosis. Smooth muscle cell migration and proliferation result in hyperplasia distal to the toe and at the heel of the anastomosis causing a reduction in lumen area and subsequent graft failure.[14] Thrombogenicity may also play a role at the interface between the high resistance outflow artery and larger prosthetic graft.[15]

There have been many attempts to improve the results of PTFE bypass grafts to infrapopliteal arteries through the interposition of venous tissue between the PTFE and recipient artery. Although Siegman[16] first advocated the use of a venous cuff in 1979 to facilitate the technical performance of anastomoses to calcified arteries, Miller et al[6] first described a vein cuff in an attempt to improve the patency of PTFE bypass grafst to distal arteries. Miller et al reported a benefit for the vein cuff for PTFE bypass grafts to the below-knee popliteal artery (57% patency vs 29% patency at 36 months) without an advantage at the above-knee position.[6] No tibial artery bypass grafts were reported in this series. Taylor et al[8] reported a technique with a vein patch at the distal portion of the anastomosis with patency rates of 74% and 58% at 12 and 36 months, respectively. Stonebridge et al[17] have reported a prospective, randomized trial for PTFE grafts with a vein cuff. They did report a benefit for the vein cuff technique in tibial bypass grafts (52% vs 29% at 24 months); however, the report randomized 246 popliteal bypass grafts and only 15 tibial grafts. Hobson et al recently reported a benefit for tibial bypass graft with the Miller cuff. In 30 grafts they noted 54% patency for the cuffed grafts versus 12% patency for the noncuffed grafts at 24 months.[18] Several authors have reported on the use of arteriovenous fistulas to improve PTFE patency to infrainguinal arteries. Dardik et al[19] use human umbilical vein graft with a concomitant anastomotic arteriovenous fistula, reporting 61% patency at 36 months. Ascer et al[20] have also reported on an arteriovenous fistula technique using the corresponding tibial vein with a PTFE bypass graft to the vein as a type of vein cuff. This technique has resulted in 62% patency at 36 months. The Albany group has recently reported a retrospective series comparing PTFE grafts with the Tyrrell/Wolfe vein boot technique with grafts performed with an arteriovenous fistula distal to the actual anastomosis.[21] This St Mary's boot technique has been advocated as taking advantage of the best features of the prior techniques with promising early clinical results. The Albany series involved predominantly tibial bypass grafts, but did include a number of popliteal grafts. They noted similar graft patency between the two techniques at 12 and 36 months (96% vs 86% and 38% vs 48%, respectively). These authors indicated that they prefer the St Mary's boot technique because of technical ease and advantages in terms of graft salvage and secondary patency.

The addition of a Miller cuff, Taylor patch, or St Mary's boot to PTFE bypass grafts has led to a seeming improvement in patency versus PTFE alone; however, these adjunctive techniques have some theoretical and practical disadvantages. Miller[6] reported several early graft thromboses possibly related to increased turbulence caused by excessive bulging of the venous tissue at the distal anastomosis. The Taylor patch involves the direct suturing of PTFE to the artery at the heel of the anastomosis where hyperplasia is known to develop and requires the dissection of a long segment of tibial artery to accommodate the anastomosis. Our technique involved a standard patch angioplasty already familiar to vascular surgeons, with subsequent implantation of a PTFE graft into the vein patch. The length of vein segment required for this technique is minimized (2-4 cm). The vein is minimally trimmed to allow a pseudocuff to form without excessive bulging. The PTFE graft must be anastomosed to the proximal two thirds of the vein patch. This leaves a rim of venous tissue at the heel of the anastomosis and allows a vein pseudocuff to develop at the distal portion of the anastomosis. Ideally, the distal portion of the vein patch expands in a cuff-like configuration under arterial flow without ballooning into a protuberant bulge. Completion arteriography is mandatory in these cases because even a minor error can lead to graft failure.

The advantages bestowed by venous tissue at the distal anastomosis derive from both biologic and mechanical factors. A biologic "buffer zone" between the tibial artery and prosthetic graft has appealing theoretical possibilities. Although the causes of myointimal hyperplasia have not been completely delineated, the addition of venous tissue to PTFE grafts at the distal anastomosis may lead to a favorable biologic situation and decrease the development of hyperplasia as has been demonstrated in an animal model.[22] Venous endothelium may also confer a beneficial effect through fibrinolytic and antiplatelet activity, although these effects remain unproved. The mechanical factors of shear stress and compliance mismatch have also been implicated in prosthetic graft failure. Theoretically, vein interposed between a stiff prosthetic graft and a more pliable artery

would minimize the expansibility mismatch created with pulsatile flow and thus decrease mechanical injury at the anastomosis. However, an animal study addressing these mechanical properties did not prove them important in the reduction of observed hyperplasia.[23] Anastomotic turbulence and outflow resistance have also been suggested as mechanisms of graft failure. Anastomotic geometry may be altered by the presence of vein at the distal anastomosis, thereby effecting turbulence and shear forces that play a role in the hyperplastic process.[15,24] Finally, it is possible that venous tissue simply enlarges the distal anastomosis so that the formation of hyperplasia must encroach on a wider lumen before becoming clinically significant. The venous tissue is also technically easier to suture to small, calcified tibial arteries as originally observed by Seigman.[16] The secondary suture line between the PTFE graft and vein also becomes more technically appealing.

The current series involves only tibial artery bypass graft for patients in a limb-threatening situation. The patient group was typically high risk with comorbidities of diabetes, renal failure, and coronary artery disease. Careful perioperative medical care and excellent anesthetic techniques are crucial for acceptable results. We noted a relatively high proportion of women and renal failure in this series, possibly given the tertiary nature of the referral patterns. Most patients (59%) were referred for evaluation after one or more previous attempts at bypass grafting had failed. This led to a relatively high number of grafts originating from the external iliac artery to avoid a scarred or hostile groin. This was possible because graft length was not an issue given the use of PTFE. We also noted that graft failures could be lysed or thrombectomized often without any underlying anatomic defect found as the cause of graft failure. This was also noted by the Albany group in their failed grafts. Therefore, we think that an attempt at lytic therapy or thrombectomy through a limited distal incision is warranted in the event of graft failure. Intraoperative arteriography can then be used to determine the need for anastomotic revision or extension with a new vein cuff. However, we do note that one graft in the series failed because of progression of proximal disease in the common and external iliac arteries.

In conclusion, we think that patients in danger of limb loss without adequate saphenous vein can be considered for tibial bypass graft with PTFE/DVP as the conduit. This series shows that acceptable long-term patency and limb salvage can be achieved in these challenging patients. As the population ages and policies toward limb salvage become more aggressive, vascular surgeons will require alternative conduits to autogenous saphenous vein in a certain subset of patients. Although this was not a randomized trial, these early results indicate that a PTFE graft with a DVP may prove an acceptable alternative in the absence of saphenous vein. In our practice PTFE/DVP is preferred to PTFE bypass graft alone or composite grafts constructed with PTFE and longer segments of saphenous vein. A multicenter prospective randomized trial may be of benefit to address the question of the best alternative for the patient without suitable autogenous saphenous vein for limb salvage. Until then, we will offer the patient without adequate vein PTFE bypass grafts to tibial arteries for limb salvage with the addition of a DVP.

REFERENCES

1. Bergan JJ, Veith FJ, Bernhard VM, et al. Randomization of autogenous vein and polytetrafluoroethylene grafts in femorodistal reconstruction. Surgery 1982;92:921-30.
2. Veith FJ, Gupta SK, Ascer E, et al. Six year prospective multicenter randomized comparison of autologous saphenous vein and expanded polytetrafluoroethylene grafts in infrainguinal arterial reconstructions. J Vasc Surg 1986;3:104-14.
3. Calligaro KD, Syrek JR, Dougherty MJ, et al. Use of arm and lesser saphenous vein compared with prosthetic grafts for infrapopliteal bypass: are they worth the effort? J Vasc Surg 1997;26:919-27.
4. Holzenbien TJ, Pomposelli FB, Miller A, et al. Results of a policy either arm veins used as the first alternative to an unavailable ipsilateral greater saphenous vein for infrainguinal bypass. J Vasc Surg 1996;23:130-40.
5. Bell PR. Are distal vascular procedures worthwhile? Br J Surg 1985;72:335.
6. Miller JH, Foreman RK, Ferguson L, Faris A. Interposition vein cuff for anastomosis of prostheses to small artery. Aust N Z J Surg 1984;54:283-5.
7. Tyrrell MR, Wolfe JN. New prosthetic venous collar anastomotic technique: combining the best of other procedures. Br J Surg 1991;78:10167.
8. Taylor RS, Loh A, McFarland RJ, et al. Improved technique for polytetrafluoroethylene bypass grafting: long-term results using anastomotic vein patches. Br J Surg 1992;79:348-54.
9. Neville RF, Attinger C, Sidawy AN. Prosthetic bypass with a distal vein patch for limb salvage. Am J Surg 1997;174:173-6.
10. Rutherford RB, Baker JD, Ernst CM, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. J Vasc Surg 1997;26:517-38.
11. Brewster DC. Composite grafts. In: Rutherford RB, editor. Vascular surgery. Philadelphia: WB Saunders; 1989. p. 481-6.
12. Hobson RW, Lynch TG, Jamil Z, et al. Results of revascularization and amputation in severe lower extremity ischemia: a five-year clinical experience. J Vasc Surg 1985;2:174-85.
13. Whittemore AD, Craig KK, Donaldson MC, et al. What is the proper role of polytetrafluoroethylene grafts in infrainguinal reconstruction? J Vasc Surg 1989;10:299-305.
14. Bassiouny H, White S, Glagov S, et al. Anastomotic intimal hyperplasia: mechanical injury or flow induced. Surgery 1992;15:708-17.
15. Wolfe J, Tyrell M. Venous patches, collars, and boots improve the patency rates of polytetrafluoroethylene grafts. Advances in Vascular Surgery 1995;3:134-43.
16. Siegman FA. The use of the venous cuff for graft anastomosis. Surg Gynecol Obstet 1979;148:930.
17. Stonebridge P, Prescott R, Ruckley C. Randomized trial comparing infrainguinal polytetrafluoroethylene bypass grafting with and without interposition vein cuff at the distal anastomosis. J Vasc Surg 1997;26:543-50.
18. Kansal N, Pappas PJ, Gwertzman GA, et al. Patency and limb salvage for polytetrafluoroethylene bypasses with vein interposition cuffs. Ann Vasc Surg 1999;13:386-92.
19. Dardik H, Silvestri F, Alasio T, et al. Improved method to create the common ostium variant of the distal arteriovenous fistula for enhancing crural prosthetic graft patency. J Vasc Surg 1996;24:240-8.
20. Ascer E, Gennato M, Pollina R, et al. Complementary distal arteriovenous fistula and deep vein interposition: a five year experience with a technique to improve infrapopliteal prosthetic bypass patency. J Vasc Surg 1996;24:134-43.
21. Kreienberg PB, Darling C, Chang BB, et al. Adjunctive techniques to improve patency of distal prosthetic bypass grafts: polytetrafluoroethylene with remote arteriovenous fistulae versus vein cuffs. J Vasc Surg 2000;31:696-701.

22. Suggs WD, Enrique HF, DePalma RG. Vein cuff interposition prevents juxta-anastomotic hyperplasia. Ann Surg 1988;207:717-23.
23. Norberto JJ, Sidawy AN, Trad KS, et al. The protective effect of vein cuffed anastomoses is not mechanical in origin. J Vasc Surg 1995;21 558-66.
24. How TV, Rowe CS, Gilling-Smith GL, et al. Interposition vein cuff anastomosis alters wall shear stress distribution in the recipient artery. J Vasc Surg 2000;31:1008-17.

Submitted Jun 1, 2000; accepted Nov 28, 2000.

DISCUSSION

Dr John H. N. Wolfe (London, United Kingdom). Thank you very much for sending me a very clear manuscript well before the meeting. Since, being British, I've been relegated to the oats that have gone through the horse by John Porter, you might like to take my comments with a pinch of salt.

I think that the thing we must first of all recognize is that these are excellent results. But we cannot be sure at this stage whether these excellent results are due to the skill of the surgeon or to a new technique. That is something that remains to be seen.

We also have to be aware that, like all series, there is a mixture of what I would call *subcritical ischemia* and *critical ischemia*. In the truly critically ischemic group, the patients with tissue loss, 95% of people lose their limbs at 6 months or a year without intervention. On the other hand, in those patients with rest pain alone (on a meta-analysis that has been done), 30% might keep their limb even without intervention. So that has to be taken into account when looking at results.

I believe that these vein interpositions help technically, and that is well supported by Mark Tyrrell's experimental work on the relationship between the vein interposition and direct PTFE anastomosis directly onto an artery, and also the Joint Vascular Research Group (JVRG) data on the randomized trial, which showed that it was the technical advantage of the collar that improved results. What I am less sure about is whether that advantage is maintained over a period of time and your follow-up is relatively short. My question to you is whether you are in a position to say that there is an advantage for this technique over PTFE alone and whether it does, in fact, do as well as autologous vein.

I do not personally believe that the choice of the interposition vein between the PTFE and the artery is of great consequence, providing it provides a short venous tunnel into the artery.

Another question I think that we have to answer is why you did not use arm vein. In my practice and, I think, in most tertiary referral practices, approximately 25% of grafts will be either spliced vein or arm vein. And in your series it appeared to be either long saphenous, as a full-length vein, or your new technique. Therefore, you clearly believe that this technique is as good as spliced vein.

And finally, 50% of your patients were diabetic. One of the advantages of diabetic patients is that the graft can often be started well down the leg, sometimes even as low as the popliteal fossa. Despite the fact that you have acquired a big diabetic population, your grafts were full length, with only 8% from the superficial femoral artery. Maybe, if you had been able to use shorter grafts, you would have been able to use vein, not PTFE.

Thank you.

Dr Richard F. Neville. Thank you very much, Mr Wolfe. As a recognized expert in this field, I appreciate your comments.

In terms of our limb salvage, I think this particular series does represent some certain degree of patient selection. If a tibial artery appeared to us horribly disadvantaged, at least early in the series, we sometimes did go right to primary amputation. Conversely, we do work very closely with a plastic surgeon whose major interest is limb salvage and has a very elegant series of flaps and various soft tissue procedures that I think have saved limbs that otherwise would not have been saved.

In terms of our long-term follow-up, I would not begin to say that this procedure is anywhere near as good as the autologous saphenous vein, and that's not what we're saying. I do believe in my heart of hearts that it's better than PTFE alone. I can't prove that to you, but in our experience it's better than purely a PTFE graft to the tibial artery.

We did use arm vein, actually a number of times, in our tibial artery series, for which I reported the numbers. We got away from the arm vein for a couple reasons. One was we can do the vein patch procedure all under epidural anesthesia, which in our anesthesiologist's opinion is better than general anesthesia for some of the people we were working on, although I know that's also debatable. We also did, on occasion, have trouble getting enough length with an arm vein, when we thought we had to go from the external iliac artery down to a distal tibial artery. So the combination of a length problem with trying to do these under epidural anesthesia, since that is the strong preference of our anesthesia team, led us to this particular technique.

Finally, in terms of your diabetic question, that's a very good question. We did not have as many SFAs and popliteal bypasses as you might have imagined. Although I think in those shorter bypasses we often could find enough autologous vein, whether it be arm vein or splicing together a couple of segments of saphenous vein, we would use vein if we were going with a shorter bypass.

Dr Frank J. Veith (Bronx, NY). I enjoyed this paper, since I was the first one in 1978 to advocate tibial bypasses with PTFE. It's nice to know that there still appears to be a role for them.

In my heart, I remain unconvinced that the patches, the boots, the cuffs make a difference. Four years ago Richard Parsons from our group presented our data at this meeting with cases very similar to yours, all followed for 4 or 5 years or until they died (J Vasc Surg 1996;23:347). The secondary patency rates at 3 and 5 years were 55% and 43%, respectively. And the limb salvage rates at 3 and 5 years were 71% and 66%, respectively. These are not quite as good as yours, but probably not statistically significantly different. So we still do the procedure without the cuffs and boots, but occasionally we do use a patch when we have a particularly small or calcified artery. It's a lot easier to do, and it makes the procedure technically better. However, I believe that until we have an even larger randomized study than the British study (which had abysmal results with the PTFE grafts without the cuffs or boots), I still remain unconvinced. I also remain unconvinced about the benefits of AV fistulas and all the other adjuncts that have been advocated because of our results summarized in the Parsons article. I enjoyed this paper and commend you for telling us about a technically easier adjunct that may help to improve the patency of infrapopliteal PTFE grafts. They remain a useful procedure in our limb salvage practice.

Dr Neville. Thank you very much, Dr Veith. And from the data this paper represents, I can't begin to convince you of our separate biases; but I do agree wholeheartedly that this technique, I think, in most people's hands, makes it technically easier to perform bypasses to these small calcified tibial arteries instead of sewing the PTFE directly to the artery.

Dr Michael F. Silane (New York, NY). We also are of the bias that these vein patches are a major advantage over the PTFE by themselves. We have been doing them for about 11 years now. And I think this is at least the third study to support this. There was, of course, the Taylor study, and then there was the study from New Jersey, and now this study. I think Dr Kemplinski was getting ready to do a randomized study between synthetic with vein patch and veins pieced together in a composite fashion. I think we're all still in a quandary. I don't think anybody questions that a good saphenous vein is our first choice. But the quandary is if we don't have a saphenous vein that reaches from the groin to the ankle, what's the second best choice? And I think it's time for a randomized study comparing PTFE and a patch, to composite veins, to

possibly synthetic to the tibial by itself. But I suspect the latter is going to be out of the ballpark very quickly. I think the vein patch or the composite veins are the second choice, but I don't know which is better and I think it's time to do that study.

Dr Neville. I agree wholeheartedly.

Dr Peter J. Pappas (Newark, NJ). Rich, I rise to congratulate you and your group and also to acknowledge your group's leadership in recommending the use of vein interposition cuffs. I'd like to point something out though in your study that I think is of major significance.

First of all, all of these were done to tibial vessels. Your 80 patients constitute the largest series, at least to my knowledge, of PTFE with vein cuffs to a tibial vessel. The thing that struck me, though, in your presentation was that all of your patients were on Coumadin. And to my knowledge, that's the first study using the vein interposition cuff in conjunction with Coumadin. I think this fact is reflective of your date. Most of the long-term studies have reported that at 2 years there seems to be a 60% patency, and thereafter, the patency seems to drop. In your study the patency seems to have been maintained. And I'm beginning to wonder if that's not a reflection of the anticoagulation in addition to the vein cuff. However, I was wondering if you noticed any difference with your bypasses that went to the peroneal? In our series we had the same experience where most of the graft failures were to the peroneal. And although we couldn't show a statistical difference between peroneal arteries versus any other arteries, there seemed to be a trend toward the peroneals failing more. I was wondering if you also noticed that in your series as well?

Dr Neville. Those are two great points, Peter. We are very aggressive with anticoagulation. Our nurse practitioner, who is listed as the second author, aggressively follows these people in terms of their Coumadin, managing their Coumadin, making sure the INR is around 2.0. She'll bring them in and counsel them on how to take their Coumadin. We are very aggressive, and she's great at keeping those Coumadin levels where they need to be. We also do use antiplatelet therapy as well.

In terms of the peroneal arteries, we looked at that. And of the grafts that failed, there were not a disproportionate number of peroneals. It was approximately equally distributed between posterior tibial, anterior tibial, and peroneal bypasses. There really didn't seem to be much difference at all.

And also back to the Coumadin, anecdotally, of the grafts that failed, we did notice a couple of patients who had their Coumadin stopped for dental procedures or another operative procedure, and the graft failed. There weren't enough to come up with any statistical evaluation, but we did anecdotally note that several of the failed grafts, when we brought them back to thrombectomize them, had no anatomic problem.

Dr Sateesh C. Babu (Valhalla, NY). I have a question about the placement of the graft. Is it subcutaneous? And your peroneal approach, is it lateral or medial?

Dr Neville. Very good questions. It's a subcutaneous approach. We do occasionally tunnel it anatomically, whichever way it lies the best, but usually subcutaneously. For the majority of our approaches, the proximal two thirds of the peroneal, we approach medially. The distal one third we approach laterally.