Femorodistal PTFE Bypass Grafting for Severe Limb Ischaemia: Results of a Prospective Clinical Study Using a New Distal Anastomotic Technique

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Objectives: to analyse graft patency and limb salvage following femorodistal bypass with ePTFE using a new distal anastomotic technique.

Design: prospective non-randomised study.

Material and methods: one hundred and twenty-nine patients (M:F; 2.23:1; mean age 65.2 ± 10.0 years) underwent 135 operations for severe limb ischaemia. The new anastomosis, constructed entirely from ePTFE, was attached to the popliteal (21), anterior (46) and posterior (52) tibial, and peroneal (16) arteries. Cumulative primary (PPR) and secondary patency rates (SPR), limb salvage and survival were analysed using the Kaplan–Meier method.

Results: median follow-up was 45 (range 6 to 72) months. There was no perioperative mortality. PPR and SPR at 1, 2, 3, 4, and 5 years were 63.0%, 44.9%, 35.7%, 33.1% and 27.6% and 74.5%, 55.2%, 44.8%, 43.0%, and 37.6%, respectively. Cumulative limb salvage was 86.4%, 78.7%, and 73.2% at 1, 3, and 5 years, respectively.

Conclusions: this new anastomotic design was feasible and resulted in acceptable long-term results.

Key Words: Femorodistal bypass; Severe limb ischaemia; ePTFE grafts; Anastomotic technique; Patency rates; Limb salvage.

Introduction

Arterial bypass to restore flow to a patent distal artery has been established as the most appropriate treatment of lower extremity occlusive arterial disease. Although the greater saphenous vein represents the conduit of choice for infragenicular femorodistal bypass procedures, there remains a significant percentage of patients who lack autologous vein of adequate length or quality. In the absence of adequate autologous vein, expanded polytetrafluoroethylene (ePTFE) has been established as an alternative bypass graft material. The patency rates of heterologous grafts, however, are clearly inferior to autologous vein grafts. Several methods have been described to improve the patency of below-knee ePTFE arterial grafts including venous cuff techniques and arteriovenous fistula. Because of the importance of haemodynamics for the development of myointimal hyperplasia (MIH) a new type of distal end-to-side anastomosis was developed by Scholz in 1992. This, characterised by a bifurcated double bulb, is termed femorocrural patch prosthesis (FCPP). In vitro flow visualisation experiments using dye distribution techniques and colour-coded Doppler sonography and numerical simulation of the complex flow field have demonstrated improved haemodynamics within the FCPP compared to other types of end-to-side anastomosis. In particular, the flow phenomena associated with the development of MIH could be minimised or even were eliminated within the FCPP.

The purpose of the present study was to evaluate the feasibility, clinical and haemodynamic results associated with the use of the FCPP.

Materials and Methods

Patients

This was a single-centre, non-randomised prospective study and approved by the local ethics committee. After giving informed consent, all patients with critical
or severe ischaemia and who required infragenicular bypass surgery and in whom no greater or lesser saphenous vein was available, were eligible. Age, sex, and the co-morbidity and risk factors were recorded. Usable autologous vein was defined by duplex ultrasound and/or surgical explantation as a greater or lesser saphenous vein that had a diameter of greater than 3 mm after dilatation and one that permitted passage of a catheter through the entire lumen. Patients underwent preoperative non-invasive testing and digital subtraction angiography (DSA) prior to surgery whenever possible. DNA studies were used to assess the runoff status, including the number of patent crural vessels and the integrity of the primary plantar arch artery.

Primary patency was defined as continuous graft patency, uninterrupted by any intervention on the graft. Secondary patency was defined as patency up to the time of final graft closure and included the results of re-intervention for thrombosed or failing grafts. Limb salvage was defined as the preservation of a viable limb with a functional portion of the foot.

Patients were anticoagulated postoperatively and reviewed at 1 month and 3 months after revascularisation, and at 6-month intervals thereafter. Patency was confirmed by the presence of distal pulses, a persistent rise in ankle–brachial pressure index (>0.15), duplex ultrasonography or DSA. For occlusive inflow lesions or progression of distal atherosclerotic disease, adequate surgical intervention was performed including a proximal extension if required. Any acute thrombotic graft occlusion was managed by thrombectomy using the Fogarty manoeuvre.

**Surgical technique**

The 5 mm diameter, thin-walled and externally supported ePTFE grafts (Impra/C.R. Bard Inc., Tempe, AZ, U.S.A.) were positioned extra-anatomically with the newly designed distal end-to-side anastomosis being constructed entirely from ePTFE (beginning with patient no. 44, proximally tapered, 8/5 mm grafts were used). Bypasses originated from the external iliac, the common or the proximal superficial femoral artery.

The technique of performing the FCPP anastomosis is illustrated in Figs 1 and 2. About 6 cm length of ePTFE graft was removed and the external spiral stent denuded. This piece was then sutured end-to-side to the remaining graft to form a patch. Next, the patch was sutured under magnification with continuous Prolene (6/0 for popliteal, 7/0 for tibial or peroneal) to the recipient artery. The suture line was secured with a knot in the middle between the bulbs on each side (Fig. 2a), proceeding first on the superior edge of the arteriotomy towards the proximal apex and around it to the inferior edge (Fig. 2b). Thus the length of the arteriotomy could be exactly adapted to the size of the patch. Once the proximal segment of the FCPP anastomosis had been sutured into place, the distal part was created, again adapting the arteriotomy to the distal part of the patch (Fig. 2c) analogous to the proximal segment. Suturing was continued on the superior edge first and then around the distal apex to be completed on the inferior edge until the two separate sutures met, when they were tied together (Fig. 2d).

**Statistical analysis**

Statistical analysis of primary (PPR) and secondary patency rates (SPR) as well as limb salvage and patient survival rates over the time was performed using the product-limit method according to Kaplan–Meier with the S-PLUS 4.5 software package (Professional Rel. 2, MathSoft, Inc., Cambridge, MA, U.S.A.).

**Results**

Between June 1992 and July 1998, 129 patients undergoing 135 bypass procedures were studied. Six patients received a second graft, four because of definite graft occlusion and two because of graft infection. Median follow-up was 45 (range 6–72) months.

There were 89 men and 40 women with a mean age of $65.2 \pm 10.0$ years. At the time of operation, 44% of patients had diabetes, 72% had medically controlled
hypertension, 22.5% had had myocardial infarction, 64% had a history of smoking, and 9% had renal insufficiency on haemodialysis. Indications for operation were ulcer or gangrene in 70 cases (52%) and rest pain in 65 cases (48%).

In 95 limbs (70%) at least one previous infrainguinal bypass operation had failed. There were 19 grafts (14%) with a zero-vessel run-off and 38 grafts (28%) with a one-vessel run-off. Seventy-eight grafts (58%) had a two- or three-vessel run-off. The plantar arch was incomplete in 71 grafts (52%) and occluded in 24 grafts (18%). There was no perioperative mortality. The cumulative survival at 1, 3, and 5 years was 86.7%, 74.1%, and 68.9%, respectively (Fig. 3).

Twenty-seven grafts (20%) failed within 30 days. Thrombectomy was successful in 22 patients. Early occlusion was followed by limb loss in three patients. Another 20 grafts occluded within the first year, all of which were re-explored with restoration of patency. Thrombectomy was required during the postoperative course in altogether 58 grafts, sometimes repeatedly, between two and maximally eight times each. The duration of patency was thereby prolonged in 43 grafts, 11 of which remained permanently patent.

PPR and SPR at 1, 2, 3, 4, and 5 years were 63.0%,
Fig. 4. Cumulative primary (a) and secondary (b) patency rates according to Kaplan–Meier in 135 ePTFE bypass grafts with distal FCPP anastomosis. The dotted lines indicate the 95% confidence intervals. The numbers at each point give the number of grafts at risk and the number of censored events at the beginning of the interval.

44.9%, 35.7%, 33.1% and 27.6% and 74.5%, 55.2%, 44.8%, 43.0%, and 37.6%, respectively (Fig. 4a,b). Recipient arteries were below-knee popliteal (21), anterior (46) and posterior (52) tibial, and peroneal (16) (Fig. 5). There was no significant difference in PPR or SPR between the recipient arteries (log-rank test). The cumulative limb salvage was 86.4%, 78.7%, and 73.2% at 1, 3, and 5 years, respectively (Fig. 6).

Graft infection occurred in seven patients (5.2%) requiring explantation of the prosthetic graft in five cases after 1, 6, 9, 14, and 36 months. Re-grafting was later performed successfully in 2 patients. Major amputation was required after graft explantation in 3 patients.

Discussion

Autologous vein remains the conduit of choice for distal revascularisation. However, in up to 28% of patients, vein may be unavailable due to previous coronary artery bypass surgery, varicose-vein stripping, previous infrainguinal revascularisations, insufficient calibre, or as a result of previous episodes of thrombophlebitis. ePTFE-vein composite grafts have been shown to be a valuable alternative to all-autologous infragenicular reconstructions. In those patients in whom no saphenous vein is available, arm veins, spliced veins, superficial femoral vein, cryopreserved saphenous vein, and human umbilical vein have been used with varying degrees of success. However, when no venous conduit is available heterologous graft materials are required, of which ePTFE has been most commonly used. Long-term results of this prosthetic conduit when used entirely for infragenicular revascularisation procedures, however, are generally poor. There are only a few clinical studies...
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of ePTFE tibial grafts, most of them reporting PPR and SPR of 25% or less. Better results have been reported by Christenson et al.\textsuperscript{24} with 4- and 6-year cumulative patency rates of 47% and 43%, respectively, for below-knee and 49% for crural distal anastomosis. Parsons et al.\textsuperscript{5} reported 5-year PPR and SPR of 28% and 43%, respectively. In the present series there was a high early occlusion rate of 20%. However, the angiographic run-off status as a rough measure of outflow resistance characterised the patients in this series as mostly poor-risk candidates.\textsuperscript{7,24,25}

Caution should be used in interpreting the results of the present study for several reasons. The rather high percentage of secondary procedures in the present series reflects a non-selected poor prognosis patient population.\textsuperscript{7} In particular, occlusion of the pedal arch artery and all three crural arteries was not a contraindication to grafting with distal FCPP anastomosis. In this study, we did not attempt to diminish outflow resistance by creating an arteriovenous fistula. In a recent study, Hamsho et al. have shown that an adjuvant arteriovenous fistula confers no additional significant clinical advantage over interposition vein cuff alone.\textsuperscript{26}

MIH at the distal anastomosis remains a major cause of failure in ePTFE bypass grafts to the below-knee and crural level.\textsuperscript{25,27-29}

A vein cuff was originally suggested as a method of anastomosing mismatched Dacron grafts to smaller arteries.\textsuperscript{30} The modification of a vein cuff reported by Taylor et al.\textsuperscript{11} was shown to achieve high success rates with a 5-year PPR of 54% in a series of 83 tibioperoneal ePTFE bypass grafts. In a multicentre randomised prospective study, using a distal anastomosis interposition vein cuff as described by Miller et al.,\textsuperscript{10} there was a statistically significant advantage when PTFE bypass grafts were anastomosed to the popliteal artery below the knee.\textsuperscript{31} Favourable results for vein cuffs in femorodistal ePTFE grafts were also demonstrated in retrospective studies.\textsuperscript{32}

The vein cuff is believed to eliminate or at least diminish the compliance mismatch between a rigid graft and a small-calibre, more compliant recipient artery. However, the scientific evidence to support this hypothesis is lacking. Sottiurai et al.\textsuperscript{33} concluded from experimental work that improvement of compliance mismatch with distal vein patch angioplasty did not prevent MIH formation within the anastomotic site but seemed to reduce the extent of MIH in the more rigid and less compliant PTFE graft. However, while ingrowth of endothelial cells on to the flow surface of PTFE grafts occurs in dogs, it occurs in human beings to a much lesser degree. In the absence of living endothelial and smooth muscle cells MIH cannot develop. On the other hand, haemodynamics within the anastomotic site have been shown to determine the development and location of MIH, which, in turn, are related to its geometric configuration.

This is the first prospective clinical investigation of the FCPP. The elimination of the stagnation point at the floor opposite to the graft entrance may be an important feature of the FCPP anastomosis, as flow stagnation coincides with a high-pressure zone within the anastomotic site, and the development of MIH. The FCPP anastomosis strongly resembles two end-to-end anastomoses each with the proximal and distal recipient artery, thus possibly avoiding the basic haemodynamic disadvantages of end-to-side anastomoses.

Da Silva et al.\textsuperscript{34} showed that stable vortices within vein cuffs inhibit anastomotic MIH. Based on these observations, another new ePTFE graft design to inhibit MIH in small-vessel anastomoses was proposed.\textsuperscript{35} This development resulted in the Distaflo bypass graft now available, in which the distal end has the shape of a Miller cuff (Distaflo, Implyra/C.R.Bard Inc., Tempe, AZ, U.S.A.). Compared with the FCPP, the design of this graft represents a different way of dealing with MIH at the distal end-to-side anastomosis of ePTFE grafts. The Distaflo design differs from our new anastomosis, because detailed analyses of the complex flow field demonstrated only minimal vortex formation in the heel and virtually none in the toe region of the FCPP anastomosis. However, both the FCPP anastomotic design and the Distaflo prosthesis with its pre-shaped distal anastomosis represent alternative solutions of anastomotic engineering to overcome MIH. Although there are differences between the shapes and the flow structures generated, both grafts aim to minimise anastomotic MIH by eliminating areas of low shear stress.
In conclusion, our results indicate that ePTFE grafting can be a worthwhile option and is preferable to amputation in patients who lack a usable autogenous vein for infragenicular reconstruction. The new anastomotic design was feasible and resulted in acceptable long-term patency rates of femorodistal ePTFE bypass grafts. Although the new anastomotic design is not necessarily confined to the use of ePTFE, it represents another adjunct to possibly improve patency of femoroinfragenicular bypass allografts. However, a randomised, prospective trial will be necessary to confirm its value. At present, a comparison of the FCP with the Distaflo design and with a vein-cuffed anastomosis of the Taylor or Miller type would appear most reasonable.

Acknowledgement
We wish to express our gratitude to Mr. G. Kalb, Institute for Medical Biometrics, Humboldt University Medical School (Charité), for his assistance in performing the statistical analyses.

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