



Transfemoral Treatment for Iliac Occlusive Disease with Endoluminal Stent-grafts

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Objectives: Percutaneous treatment of iliac artery occlusive disease has replaced open vascular reconstruction for several indications. A balloon angioplasty with or without stent is not an option in the presence of infrainguinal extension of the disease. The authors describe a technique that allows the construction of an aorto- or iliofemoral graft through a single groin incision, using a 4 mm PTFE graft, anchoring it proximally with a Palmaz stent and dilating both to the desired diameter.

Design: Retrospective non-randomised study.

Materials and Methods: Nineteen procedures were performed in 16 patients mainly because of ischaemic rest pain, often with trophic skin changes or minor gangrene. Three patients had a bilateral procedure. Twelve patients had one or more associated procedures: 10 distal bypasses, one thrombectomy, one reimplantation of a distal bypass on the iliofemoral graft, one contralateral profundaplasty and two stents of the contralateral common iliac artery.

Results: Two patients died, one of small bowel ischaemia and the other of a myocardial infarction. During the mean follow-up of 8.8 months, two graft thromboses occurred. In another patient bilateral stenting of a residual stenosis was necessary.

Conclusions: Our experience shows that the reported technique is feasible. Whether the procedure is truly "less invasive" and the long-term results acceptable remains to be shown.

Key Words: Vascular surgery; Occlusive disease; Stented graft; Palmaz stent; PTFE.

Introduction

In recent years aorto-bifemoral (ABF) and iliofemoral (IF) grafting have been replaced by percutaneous transluminal angioplasty (PTA) for short, non-complicated lesions and by stenting for restenoses, eccentric plaque, recoil, long segment disease, dissection and occlusions. However, both proximal and distal extension of the atherosclerotic disease can limit the application of these percutaneous techniques. In the former situation an ABF might still be the procedure of choice. If distal extension is the only limiting factor, stented PTFE grafts that are introduced transfemorally can avoid an abdominal approach.¹ We report our experience with the use of a 4 mm PTFE graft in combination with a balloon expandable stent.

Materials and Methods

From February 1995 to February 1996 there were 21 attempts to perform a transfemoral iliofemoral bypass.

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In two cases the iliac artery could not be recanalised and a standard femorofemoral cross-over bypass was performed. The remaining 19 procedures were performed in 16 patients (11 male, five female), with a mean age of 71 years (range 47–88). Five patients were current smokers, 11 had atherosclerotic heart disease, 12 were on antihypertensive drug therapy, and one patient had diabetes mellitus. Three patients had a serum creatinine of more than 1.5 mg/dl. The indications for surgery were incapacitating claudication ($n=5$), ischaemic rest pain ($n=7$) and rest pain with trophic skin changes or gangrene ($n=7$). The extension of the atherosclerotic lesions are described in Table 1.

Surgical technique

Following preparation of the patient for a possible open iliofemoral graft and other associated vascular reconstructions, the femoral bifurcation was exposed. The common femoral artery was punctured with an 18 G angiographic needle. Using portable C-arm

Table 1. Description of lesions.

	Normal	Stenosed	Occluded
Common iliac artery	12	5	2
External iliac artery	—	11	8
Common femoral artery	7	5	7
Superficial femoral artery	5	4	10

fluoroscopic imaging, the diseased segment was pre-dilated with a 10 mm PTA balloon after being recanalised with a hydrophilic guide wire (Terumo, Tokyo, Japan) and a 14F sheath was introduced. For an occluded external iliac artery, contralateral puncture and antegrade recanalisation might be expected to prevent an internal iliac artery occlusion due to upward dissection, and this was done in two patients. A 4 mm PTFE graft (Impra) was sutured to a Palmaz balloon expandable stent (P394 Johnson and Johnson, U.S.A.) with four stitches 5/0 polypropylene (Ethicon, Edinburgh, U.K.), leaving one-third of the stent outside the graft. This stented graft was mounted on a PTA balloon and introduced through the sheath. Following positioning of the proximal end, the stent and the entire graft were dilated with a 10 or 12 mm balloon. To avoid angulation of the graft, the common femoral artery was transected at the puncture site. Finally, the graft was sutured to the outflow tract, either the deep femoral artery or a distal bypass (Fig. 1). The anastomosis was made with 7/0 or 8/0 PTFE (Gore), to avoid large stitch-holes in a thin PTFE graft.

All but one procedure were performed under general anaesthesia. A unilateral bypass was performed in 13 patients, and three patients were operated on

both sides during the same anaesthesia. The proximal stent was placed in the external iliac artery in three cases, and in the common iliac in 14. One patient had an aorto-bifemoral graft constructed with both stents placed at the aortic bifurcation. Twelve patients had one or more associated procedures: 10 distal bypasses, one thrombectomy, one reimplantation of a distal bypass on the iliofemoral graft, one contralateral profundaplasty and two stents of the contralateral common iliac artery. On average, 4 units of blood were transfused (range 0–8 units) and the mean procedure duration was 5 h (range 2.6–7 h). When no associated procedure was done the procedure duration ranged from 2.6 to 3.7 h.

Follow-up and statistics

Patients were examined at the outpatient clinic at regular intervals (1 month, 3 months, 6 months and 1 year), at which time a duplex scan was performed.

The study design was retrospective. Primary and secondary patencies were calculated using the Kaplan-Meier method. The 95% confidence limits (CL) are given in brackets.

Results

Two patients died in the postoperative period (2/16). The causes of death were small bowel ischaemia of

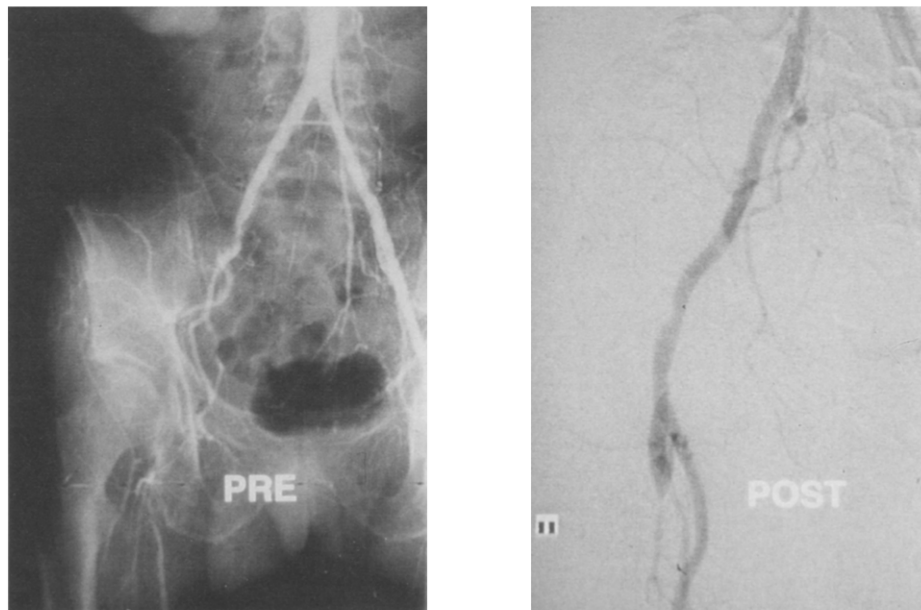


Fig. 1. Illustration of a typical case with extensive atherosclerotic disease, excluding percutaneous treatment as an option.

unknown aetiology, and myocardial infarction. Three patients had a general complication: a stroke, a bleeding episode of a gastric ulcer, and one episode of angina. In five out of 19 procedures a local complication occurred. One patient had an infection of the groin incision treated by i.v. antibiotics, wound debridement and a rectus femoris muscle flap. In one patient thrombosis of the contralateral femoral artery occurred following puncture at that side. A thrombectomy was successfully performed during the same anaesthesia. In the patient with the aorto-bifemoral graft the postoperative arteriogram showed a residual stenosis in the middle of each graft, probably caused by extrinsic compression or recoil. A few months later these were treated by percutaneous transluminal balloon angioplasty (PTA) and stenting. Of the nine patent internal iliac arteries at risk preoperatively, one occluded during the procedure. This occlusion remained asymptomatic.

The mean hospitalisation of the survivors (14) was 15 days (range 3–57 days). Seven were discharged within 10 days of the procedure. Five patients were continued on coumadine derivatives, one patient had no medication, because of an active gastric ulcer, and the remainder continued with anti-platelet agents.

The mean follow-up of the 14 survivors was 8.8 months (range 2–13 months). For eight patients there was more than 12 months' follow-up. Two patients died during the third postoperative month: the first because of heart failure, and the second from sudden death of unknown cause. Survival was 88% (CL 71–104%) at 1 month and 75% (CL 54–96%) at 1 year. During the second month one graft occlusion occurred. The patient was in heart failure at the time and he subsequently died, as already mentioned. A second graft occluded at 11 months. A thrombectomy with associated distal bypass was performed. Except for the patient with a residual stenosis on both aortofemoral grafts, no other stenoses or occlusions occurred. So the primary patency of the 19 reconstructions was 100% at 1 month and 70% (CL 44–95%) at 1 year. The secondary patency was, respectively, 100% and 93% (CL 81–106%).

Discussion

PTA is generally accepted as the treatment of choice for a short iliac stenosis. Although the long-term result of stenting of complex lesions is awaited, the procedure is certainly less invasive compared to an open vascular reconstruction or bypass. Sometimes the atherosclerotic disease extends down to, or even beyond, the

level of the femoral bifurcation. In that case surgery is the only option besides a conservative approach. An anatomical reconstruction such as an aorti-bifemoral or iliofemoral graft is considered by most vascular surgeons as the treatment of choice, with excellent long-term results. However, the procedure is more invasive and is associated with a higher morbidity and longer hospital stay. Furthermore, suturing a graft to a sometimes very calcified aorta or iliac artery can be very difficult and hazardous. An extra-anatomical reconstruction, be it an axillofemoral or a femoro-femoral cross-over bypass, might be less invasive, but leads to inferior results in the long run.^{2–5}

In search of a procedure that is less invasive with good long-term results, a few vascular surgeons have explored the possibilities of limiting the surgical approach to a single groin incision.

Both iliofemoral and femoropopliteal bypasses through a single groin incision have been proven to be feasible in animal and human cadaver studies⁶ as well as in clinical circumstances^{1,7} using a 6 mm PTFE graft and a Palmaz stent for proximal anchoring. Although the preliminary results are comparable to the results in this report, we believe that a 6 mm graft in aortofemoral or iliofemoral position constitutes somewhat of a mismatch to the diameter of the native vessels. However, Bergeron has shown that PTFE grafts can be radially dilated to 400%, or five times the initial diameter, before rupture.⁸ Therefore, we have chosen to balloon dilate a small calibre PTFE graft to the desired diameter after introduction.

The retrograde iliofemoral endarterectomy facilitated by balloon angioplasty has been proposed as an alternative procedure.⁹ The fact that a prosthesis is no longer necessary would be a clear advantage if the procedure is feasible and the results acceptable. Both conditions seemed to be fulfilled in the report of Queral, with three failures on a total of 36 cases and primary patency rate of 80% at 3 and 5 years. However, many patients were not considered as candidates for this procedure. A tortuous, extremely calcified or occluded iliac artery was considered a contraindication.

The technique described in the present report is a feasible and valuable procedure, providing good arterial inflow with a good match between artery and graft diameter and avoiding a surgical approach to the iliac arteries. Whether this procedure is truly less invasive compared to the open technique can only be determined by a prospective, randomised trial. Although the initial results are encouraging, long-term graft behaviour and results have to be awaited.

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