Endovascular Femoropopliteal Bypass Combined with Remote Endarterectomy in SFA Occlusive Disease: Initial Experience


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Objectives: to evaluate the feasibility of endovascular femoropopliteal bypass in combination with remote endarterectomy of the superficial femoral artery (SFA).

Design: prospective, open study.

Materials: thirteen patients with chronic lower-leg ischaemia due to femoropopliteal occlusive disease underwent 14 SFA remote endarterectomy procedures followed by endovascular ePTFE femoropopliteal bypass. Primary endografting was performed in seven cases. The indication for endograft insertion was vessel-wall perforation during endarterectomy in the remaining seven cases.

Methods: pre- and postoperative clinic and haemodynamic data were collected and compared. Technical problems and procedure-related complications were noted.

Results: initial technical success was achieved in all 14 limbs. However, four early reocclusions occurred after 1, 4, 6 and 10 weeks postoperatively. Two late reocclusions were detected after 16 and 22 months without any preceding symptoms or haemodynamic changes. Primary and secondary patency rates were 61% and 70% at two years, probably due to graft-related factors, such as lack of radial force, graft folding or kinking, and possibly altered mechanical or thrombogenetic properties after dilatation of the ePTFE graft.

Conclusions: endovascular femoropopliteal endo-bypass after SFA remote endarterectomy is a feasible procedure. Further technical improvements are necessary to avoid procedure- and graft-related early failures.

Key Words: Remote Endarterectomy; Femoropopliteal; Endovascular Graft; ePTFE.

Introduction

Endovascular procedures have continued on their evolutionary path towards achieving optimum revascularisation with minimal invasiveness. Standard balloon angioplasty (PTA) has, by and large, performed well in the treatment of focal superficial femoral artery (SFA) occlusive disease, but the results are rather disappointing when treating long SFA occlusions. The addition of endovascular stents in the SFA has not led to better long-term patency results in several randomised trials. Semi-closed endarterectomy is another option aside from conventional bypass with comparable long-term patency rates of 67–71% at five years. The advent of ring-strip cutter device has made it possible to perform a remote endarterectomy of the entire SFA through a single groin incision. The initial clinical results of this less-invasive technique were encouraging, but a high incidence of recurrent stenosis due to intimal hyperplasia have been reported.

Recent developments in the treatment of SFA occlusive disease have focused on the combination of recanalisation and endoluminal grafting. The potential advantage of endovascular lining with a transluminally placed endoluminal graft (TPEG) is to reduce restenosis and subsequent SFA reocclusion. Therefore, SFA remote endarterectomy followed by endoluminal bypass has been suggested. Complete removal of the atherosclerotic intimal core could facilitate endograft insertion and reduce external compression from the vessel wall. Vessel lumen reduction due to the myoproliferative response may be less exuberant as the endarterectomised segment is covered with an endograft, so as to inhibit direct contact of the vessel wall with the blood flow. Moreover, this technique would eliminate the conventional end-to-side anastomosis that is a notorious site for intimal

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hyperplasia and graft thrombosis due to inherent flow disturbances.17

The purpose of this study was to evaluate the feasibility of endoluminal grafting. We describe our early experience with SFA remote endarterectomy followed by the insertion of a self-made endovascular femoropopliteal bypass.

Materials and Methods

Between February 1995 and January 1998, fourteen limbs in 13 patients underwent endoluminal graft implantation combined with remote endarterectomy. The reason for endograft placement was extravasation during remote endarterectomy procedures in seven cases. In seven cases primary endograft placement was planned. This study was approved by our Institutional Review Board and informed consent was obtained from all patients. Demographic data and risk factors for atherosclerosis were collected from the patients’ medical records. Preoperative assessment included measurement of Doppler ankle-brachial blood pressure index (ABPI), treadmill tests and arteriography for the evaluation of chronic lower-extremity ischemia and the femoropopliteal lesions (stenosis/occlusions). Aortoiliac inflow vessels were evaluated either by angiography and/or duplex scanning. The indications for operation were assessed using the ‘Suggested standards for reports dealing with lower extremity ischemia’ by Rutherford et al.18 All patients had long segmental SFA occlusion not suitable for PTA with a patent supragenicular popliteal artery and at least one crural run-off vessel (Fig. 1). Patients who had undergone previous femoropopliteal interventions were not excluded from this study.

All procedures were performed by a vascular surgeon in close collaboration with an interventional radiologist in the operating room equipped with a movable radiolucent surgical table combined with a digital angiographic system using a ceiling-suspended C-arm (OPC-9 and DSI, Philips Medical Systems, The Netherlands). The procedure started with SFA remote endarterectomy using a ring-strip cutter (Mollring Cutter™, Avatar Inc, Portola Valley, CA, U.S.A.) (Fig. 2). This technique has been described previously.19 After establishing complete recanalisation of the SFA, a guidewire was positioned in the lumen of the popliteal artery. The self-made endovascular bypass was composed of a thin-walled 3-mm ePTFE graft (Impra, Tempe, AZ, U.S.A.) with a small balloon-expandable Palmaz 204 stent (Johnson & Johnson Interventional Systems Co, Warren, NJ, U.S.A.). The stent was affixed to the distal portion of the graft with two sutures of 6-0 polypropylene (Ethicon, Somerville, NY, U.S.A.)

The stent-graft combination was then co-axially mounted on a 6- or 7-mm × 4 cm (5 Fr) balloon angioplasty catheter (Opta 6, Cordis, Miami, FLA, U.S.A.) and placed within a 30-cm (12 Fr) introduction sheath (Cook, Bloomington, IND, U.S.A.) which was inserted into the disobliterated SFA. After the endovascular bypass was properly positioned at the distal endpoint under fluoroscopic control, the stent was deployed to anchor the graft and the introduction sheath was removed gradually. The TPEG was then dilated up to 6 or 7 mm sequentially from distal to proximal. Completion angiography was performed before closure in all cases. The proximal end of the PTFE graft was finally cut and sutured as a patch plasty into the orifice of the SFA. All patients received intraoperative heparin during the procedure.

Duplicate scanning (HP Sonos 2000, Hewlett Packard Company, Imaging Systems Division, Andover, MA, U.S.A.) was performed as part of our surveillance programme within 1–6 weeks and at 3-monthly intervals during the first year. The severity of restenosis was determined according to previously validated criteria from our institution as published by Legemate et al.20 Local increase of peak systolic velocity (PSV) at the site of stenosis (PSV–max) was compared with the peak systolic velocity of a nearby normal arterial segment (PSV–normal). A PSV ratio (PSV–max/PSV–normal) >2.5 was considered a 50% diameter reduction (DR) or more. Clinical and haemodynamic status were evaluated by recurrent symptoms and ankle-brachial blood-pressure-index measurements at every follow-up visit. Patients were given oral anticoagulants one day prior to surgery and this was continued for a minimum of 6 months. Thereafter, this was changed for antiplatelet drugs.

Definitions, study endpoints and statistical methods

The primary end-point was any reocclusion, and radiological or surgical intervention prior to occlusion. Secondary end-points were recurrent haemodynamically significant stenosis detected by duplex scanning or angiography, limb salvage, or death. Immediate technical success and early and intermediate clinical and haemodynamic success were analysed according to the guidelines provided by the Society of Vascular Surgery and the International Society for Cardiovascular Surgery.18 Technical success was defined as any recanalisation of occlusive lesions or residual stenosis less than 20% (DR) for stenotic lesions on completion angiography. Clinical and haemodynamic
success was defined as an improvement of the clinical category by one level or the limb status by at least one point and rise of ABPI >0.10 after the procedure. Cumulative primary and secondary patency rates were calculated using the life-table method, according to the “Suggested standards for reports dealing with lower extremity ischemia”.\(^1\) Patency calculations were based on the number of procedures performed. Difference of mean ABPI pre- and post-procedurally was compared using the Student \(t\)-test. The limit of statistical significance was set at \(p=0.05\) (two-sided).

**Results**

Fourteen endografts were implanted in ten males and three females with a mean (± standard deviation (s.d.)) age of 68 (±9.4) years. Co-morbid risk factors for atherosclerosis included: smoking in 10/13 patients; hypertension in 8/13 patients; hypercholesterolaemia in 6/13 patients, and diabetes mellitus in 5/13 patients. Associated symptomatic coronary disease was present in 7/13 patients and cerebrovascular disease in 2/13 patients. Four patients had a medical history of (attempted) angioplasty in the ipsilateral SFA. Two patients had previously undergone a local endarterectomy of the common femoral artery and a profundaplasty. The indications for operation (SVS/ISCVS-NA criteria) were chronic lower-extremity ischaemia Category 1–3 in 6, Category 4 in 5, and Category 5 in 3 patients. The median length of the SFA occlusion was 18 (interquartile range 10–23) cm. The median length of the endarterectomised segment was 33 (interquartile range 30–36) cm.

Initial technical success was achieved in all 14 cases (Fig. 3). However, in one patient we had difficulty in positioning the guidewire in the popliteal artery. The guidewire eventually re-entered the true distal lumen after subintimal positioning, which was recognised after deployment of the distal stent. A second stent was deployed and SFA patency was restored and accepted, despite improper implantation of the TPEG. The mean (±s.d.) ABPI rose from 0.61 (±0.16) preoperatively to 0.98 (±0.05) postoperatively (\(p<0.001\)). One patient, who was diabetic and dialysis-dependent, had severe gangrene of his right foot. He underwent
Fig. 2. Fluoroscopic image of remote endarterectomy procedure: (a) conventional Vollmar ring stripper at level of distal SFA; (b) activated ring strip cutter transecting the intima core endoluminally; (c) angiography after removing occluded intima core from SFA. Notice distal endpoint (arrow) with intima edge before introduction of guidewire and endograft.

Table 1. Life-table analysis for primary patency rates of 14 SFA remote endarterectomy with endovascular femoropopliteal bypass.

<table>
<thead>
<tr>
<th>Interval (months)</th>
<th>No. at risk</th>
<th>Failed</th>
<th>Duration</th>
<th>Loss to follow-up</th>
<th>Death</th>
<th>Interval patency rate</th>
<th>Cumulative patency (%)</th>
<th>Standard error (%)</th>
</tr>
</thead>
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<tr>
<td>0–1</td>
<td>14</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0.85</td>
<td>100.00</td>
<td>0.00</td>
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<td>1–6</td>
<td>11</td>
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<td>0</td>
<td>0</td>
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<td>0.82</td>
<td>85.19</td>
<td>9.89</td>
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<td>12.79</td>
</tr>
<tr>
<td>12–18</td>
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<td>1</td>
<td>0</td>
<td>0</td>
<td>0.88</td>
<td>69.70</td>
<td>12.79</td>
</tr>
<tr>
<td>18–24</td>
<td>7</td>
<td>1</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0.86</td>
<td>61.50</td>
<td>14.42</td>
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successful revascularisation but shortly thereafter a below-knee amputation was required, despite a patent endograft. All other patients initially showed improvement of their clinical category by one level or the limb status by at least one point. No in-hospital mortality was noticed. One early procedure-related complication was observed: a deep groin infection necessitated surgical treatment. This patient recovered uneventfully. Distal embolisation was not encountered.

Four early reocclusions occurred after one week, four, six, and ten weeks. One patient with claudication had a graft occlusion at the six weeks follow-up and underwent thrombectomy. A second patient with rest

Table 2. Life-table analysis for secondary patency rates of 14 SFA remote endarterectomy with endovascular femoropopliteal bypass.

<table>
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<tr>
<th>Interval (months)</th>
<th>No. at risk</th>
<th>Failed</th>
<th>Duration</th>
<th>Loss to follow-up</th>
<th>Death</th>
<th>Interval patency rate</th>
<th>Cumulative patency (%)</th>
<th>Standard error (%)</th>
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<tr>
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<td>100.00</td>
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<td>0</td>
<td>0.84</td>
<td>92.86</td>
<td>6.88</td>
</tr>
<tr>
<td>6–12</td>
<td>10</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>1.00</td>
<td>78.00</td>
<td>11.57</td>
</tr>
<tr>
<td>12–18</td>
<td>10</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.90</td>
<td>78.00</td>
<td>11.57</td>
</tr>
<tr>
<td>18–24</td>
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<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0.88</td>
<td>70.20</td>
<td>12.77</td>
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pain underwent thrombectomy one week following endografting until reocclusion was noted after four months, but she has not suffered from recurrent critical limb ischaemia. In a third case with gangrene and high outflow resistance, graft occlusion at four weeks necessitated a femorocrural bypass which ultimately could not prevent major amputation. The fourth early failure at ten weeks was the aforementioned patient with improper TPEG placement. He was initially treated for a non-healing foot ulcer. Ten weeks after the first operation, he was re-admitted to undergo a correction of his endograft. It appeared on the angiogram that some folding of the endograft had obstructed the lumen of the graft proximally. The endograft was “pulled up” surgically and sutured again into the common femoral artery. Intraoperative angiography showed no folding of the endograft. Four days later the endograft became occluded. Despite thrombectomy of the endograft, he later underwent a below-knee amputation.

After a median follow-up of 20.8 (interquartile range 13.2–29.3) months, two late endograft reocclusions occurred after 16 and 22 months postoperatively. The first patient had been treated for rest pain. Sixteen months later, he suffered a stroke and was admitted to the neurology department. Shortly thereafter, ischaemia of his left leg was noted due to occlusion of his SFA endograft. Ultimately, we decided to perform a below-knee amputation. The patient with an endograft that became occluded after 22 months was initially treated for disabling claudication. He was re-admitted with upper gastrointestinal bleeding and his anticoagulants were discontinued. Two weeks later he started to complain of progressive ischaemic leg pain due to occlusion, ultimately resulting in a femoropopliteal in situ vein graft. The one- and two-year
cumulative primary patency rate was 70% and 61% and the secondary patency rate 78% and 70% respectively. During follow-up, one restenosis has been detected with duplex surveillance after 19 months. The restenosis was located at the proximal part of the endograft without any clinical or haemodynamic effect. The endograft is still patent after 28 months without any interventions.

**Discussion**

Endoluminal grafting via the femoral approach was first reported by Volodos’ et al. in 1986. The method has been developed and refined extensively, particularly for the treatment of aneurysmal disease, most experience being gained at aortic sites. More recently, several studies have been published about endovascular grafting to treat femoropopliteal occlusive disease. An endovascular femoropopliteal bypass could offer the durability of a standard conventional bypass and the benefit of a less-invasive endovascular procedure.

Most experience of endovascular grafting has been gained without removing the atherosclerotic intima core prior to graft insertion. Recanalisation through atherectomy devices or the use of guidewires were combined with predilatation. This technique might lead to increased external endograft compression due to the natural tendency for elastic recoil of the arterial wall after dilatation. However, Spoelstra et al. reported a 98% technical success rate in 55 SFA endobypass procedures with predilatation only. He achieved a 73% primary and 86% secondary patency rate at 12 months. Stockx used the same technique and device in 25 patients, but could not duplicate Spoelstra’s favourable results. Despite a similar high initial technical success rate, more than 50% of the endobypasses occluded within six months. Marin et al., who reported the first TPEG for the treatment of femoropopliteal occlusive disease in 1994 in three patients without arterial debulking, has abandoned femoropopliteal endografting with predilatation only (personal communication). On the other hand, Bergeron and Morris, were, like us, proponents of arterial debulking prior to endografting to reduce elastic arterial recoil. With our novel technique of remote endarterectomy combined with femoropopliteal endobypass, the risk of graft compression is theoretically eliminated, theoretically resulting in improved long-term patency rates.

This study was designed to evaluate the feasibility of this technique and to report on our initial clinical results. Obviously, no firm conclusions can be drawn from the small numbers of this study. Nevertheless, femoropopliteal endografting after remote endarterectomy seems to be a feasible procedure. All procedures were successfully completed, although one TPEG was not inserted properly. This technical problem resulted from malpositioning of the guidewire, which occurred only once. The passage of the guidewire may be difficult, even in experienced hands. A solution to this problem was recently suggested by Whiteley et al., using a retrograde approach via the popliteal artery.

The early recurrences are another matter for concern. Despite pre-implantation remote endarterectomy and completion angiogram to ensure technical adequacy of the procedure, three out of four early failures occurred within six weeks after endografting. Endovascular graft twisting, kinking and folding as described by Ahn et al., may have caused these early failures. White et al. had similar problems with graft narrowing and subsequent thrombosis in the unstented segments of stented grafts in a canine study. They concluded that completely supported (stented) grafts as endoluminal prosthesis should be further developed and used. Another mechanism that may have contributed to endograft compression or occlusion is back-bleeding from side-branches after endarterectomy of the SFA. However, we have no indications that this was the case in one of our failures.

Certainly, the self-made endografts can be improved and perhaps our unsupported endografts are not adequate. Several fully supported stent grafts like the Cragg Endopro System I (Mintec, La Ciotat, France), its successor the Passager (Boston Scientific, Meadow Medicals, Oakland, NJ, U.S.A.), and the Hemobahn (Gore, Putzbrunn, Germany) are now commercially available. Disadvantages of these covered stents are the scarce clinical data and the maximum stent length of 15 centimetres only. In the SFA region, several stent grafts would then be needed, which makes the procedure more costly. Fully supported TPEGs have been attempted by Cragg and Dake to reduce the risk of graft occlusion, but their experience is limited.

Another cause of early failure may have been altered mechanical or thrombogenetic properties of dilated ePTFE endografts. Marston et al. found that both 3- and 4-mm thin-walled ePTFE grafts could easily be dilated to five times their initial diameter before rupture occurred. PTFE node size was significantly smaller in dilated grafts, but there was no change in internodal distance after dilatation. Different healing mechanisms of high-porosity versus standard PTFE grafts...
have been reported as well, but the effects of these findings upon graft patency are still unknown. In one study, histopathologic analysis of endografts in femoral-artery occlusive disease revealed that endothelial cells on the luminal surface were found remote from the graft–artery anastomosis. However, the principal mechanism of endothelialisation of PTFE grafts is considered in-growth from the anastomoses, rather than transmural endothelialisation, even in high-porosity grafts. Whether cell-seeded endografts will be the next step in endovascular grafting needs to be awaited.

Previously, we noticed a 46% prevalence of recurrent stenoses after SFA remote endarterectomy without endografting. In this study, recurrent stenosis was detected in one endograft only. This endograft is still patent thus far. Reocclusions were not preceded by any recurrent stenoses. Although our experience is very limited, the low incidence of mid-graft stenosis supports the concept that ePTFE endografts may effectively reduce intimal hyperplasia. There are controversial results in the literature concerning the prevention of neointimal ingrowth along the entire stent graft. While some authors indeed noticed that the stent graft effectively limits formation of neointimal hyperplasia, others have observed restenoses along the entire length of the stent graft.

In conclusion, endovascular femoropopliteal endobypass in combination with SFA remote endarterectomy is a feasible procedure. Further technical improvements of this technique are necessary to avoid procedure- and graft-related early failures.

References

21 Volodos NL, Shekhanin VE, Karpowich IP, Tridan VI, "Acknowledgements

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