Endovascular Femoropopliteal Bypass: A Cadaveric Study*

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Objective: Patency rates of standard femoropopliteal bypass in infra-inguinal occlusive disease have yet to be matched by minimally invasive percutaneous procedures. We report a feasibility study of a less invasive endovascular femoropopliteal bypass technique.

Methods: (1) groin exposure of femoral artery, (2) guidewire passage and mechanical dilatation of superficial femoral artery (SFA), (3) expandable helical cutter endarterectomy of SFA, (4) transluminal placement of PTFE graft, (5) graft balloon dilatation to shape and set distal interface and (6) end-to-end anastomosis of proximal graft to femoral artery. Development and testing was undertaken in 48 limbs of 26 fresh human cadavers. Limbs with no demonstrable SFA disease were excluded. Seventeen limbs had mild, diffuse disease. Three limbs had a single, short, tight stenosis. Seventeen limbs had multiple, high grade stenotic lesions 12-40 cm long (mean 24 cm). Eleven limbs had occlusive lesions, 8-38 cm long (mean 24 cm).

Results: We successfully completed the procedure in 39 (81%) limbs. We failed to complete the procedure in nine limbs; four from failed guidewire passage, four from vessel avulsion, and one from graft deployment failure. Histology confirmed endarterectomy cleavage in the standard plane. Angiography and explants demonstrated a patent graft and popliteal artery, and smooth distal graft-arterial interface with no obvious defects in 24 (62%) cases. Defects included combinations of contrast extravasation/reflux, graft malpositioned/incorrectly sized, distal graft fold, and distal intimal flap.

Conclusion: Endovascular femoropopliteal bypass is feasible and warrants further studies for possible clinical application.

Key Words: Endarterectomy; Intraluminal; Femoropopliteal; Grafts; Cadaveric.

Introduction

The optimal treatment for patients suffering from intermittent claudication and superficial femoral artery occlusive disease has yet to be determined.¹ Failure of any intervention may result in an acute or chronic deterioration in the limb, destabilising the condition and resulting in an increased risk of limb loss. As a result many surgeons have a high threshold for intervening in this relatively benign condition.

At present, if intervention is undertaken, conventional femoro-popliteal bypass grafting offers the best medium and long-term benefits. Minimally invasive techniques, such as balloon angioplasty, laser-assisted angioplasty and atherectomy have so far, not been able to match femoro-popliteal bypass grafting 5 year patencies of up to 69% (PTFE), 75% (human umbilical vein) and 76% (reversed vein).²-⁴ Patency with balloon angioplasty has been reported in the range of 27–53% at only 2 years.⁵-⁶ Laser angioplasty patency is similar at approximately 48% at 3 years.⁷ Atherectomy results are even lower, with approximately 19% patent at 2 years.⁸ Superficial femoral artery endarterectomy, although equalling bypass patency rates in some hands, requires two substantial incisions and cannot be defined as minimally invasive. Five-year patencies for the technique range from 36–71%.⁹,¹⁰

If a less invasive reconstructive technique could be developed that gave patency rates comparable to, or better than, conventional femoro-popliteal bypass, there is a large cohort of potential patients that might benefit from intervention. In order to address this problem, we have evaluated and developed new devices (EndoVascular Instruments Inc.) enabling superficial femoral artery endarterectomy and transluminal femoro-popliteal grafting to be performed via a single small groin incision. This series of cadaveric
experiments has been completed to optimise methodology prior to evaluating the technique in a limited animal and clinical study.

**Materials and Methods**

This study was undertaken concurrently at the Department of Human Pathology, Addenbrooke's Hospital, Cambridge, U.K. and the Department of Surgery, UCLA Medical Center, Los Angeles, U.S.A. We were given permission to use 26 cadavers for these experiments. Potential subjects were screened with bilateral direct femoral angiography before inclusion. Any cadaver with no evidence of disease in both superficial femoral arteries was excluded prior to the study. All cadavers had been stored for a maximum of 5 days, at a temperature of 4 °C. Ages of the subjects ranged from 65-99 years with a mean of 82 years. Eighteen cadavers were female and eight were male. We used 48 limbs in the study, having excluded four limbs immediately: two from no disease, and two from lack of time.

Disease severity was scored by pre-selection angiogram in the following categories: mild, diffuse (irregularity and some narrowing of lumen); single, high grade, discrete stenosis (greater than 75% lumen diameter); multiple, high grade, stenoses / diffuse disease (multiple lesions of equal to or greater than 50% lumen diameter), and arterial occlusion. The disease severity and lesion length for the cohort studied is shown in Table 1. Real-time fluoroscopic imaging was used for all experiments.

The technique for the procedure underwent a number of development modifications, and a final protocol defined as follows: (1) Exposure of the femoral arteries in the groin, gaining control of inflow and outflow vessels; (2) Femoral arteriotomy and insertion of 5fr sheath, or 16 gauge AngioCath™ and passage of 0.035 guide wire to cross lesion(s) to below the knee (Figs 1 (a) and (b)); (3) Select desired location of distal interface and note it with marker; (4) Introduction and passage of rotating Dynamic Dilator™ (EndoVascular Instruments Inc. (EVI)); graduated sizes from 3–5 mm, across lesion(s) to marker (Fig. 2a); (5) 5 cm incremental passes of collapsed Helical Endarterectomy Catheter™ (EVI); catheter expanded and withdrawn to engage atheroma, retrograde endarterectomy of SFA, in segments, to end point (Fig. 2b); (6) 6 mm balloon dilatation of end point; (7) Passage of peel-away sheath to end point (Fig. 3a); (8) Insertion of pre-loaded thin walled PTFE Goretexitm (WL Gore & Associates Ltd.) graft in peel-away sheath into previously positioned sheath to end point (Fig. 3b). Note: Thin-walled Goretex™ (WL Gore & Associates Ltd.) was chosen as preferred graft material, following experiments with other PTFE prostheses which failed to pass easily through the sheath, and exhibited marked distal folding; (9) Sheaths removed, maintaining graft placement with Graft Inserter™ (EVI) (Fig. 4a); (10) Remove Graft

![Fig. 1 (a)](image1.png) (a) Arteriotomy site Adductor canal Superficial femoral Deep femoral

![Fig. 1 (b)](image2.png) (b) Guide wire

**Table 1. Grades, frequency and extent of disease in limbs used in study**

<table>
<thead>
<tr>
<th>Lesion length</th>
<th>Number</th>
<th>Range (cm)</th>
<th>Mean (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal disease</td>
<td>17</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Single stenosis</td>
<td>3</td>
<td>1-1</td>
<td>1</td>
</tr>
<tr>
<td>Multiple stenoses</td>
<td>17</td>
<td>12-40</td>
<td>24</td>
</tr>
<tr>
<td>Occlusions</td>
<td>11</td>
<td>8-38</td>
<td>24</td>
</tr>
</tbody>
</table>

Eur J Vasc Endovasc Surg Vol 10, July 1995
Cadaveric Study of Endovascular F-P Grafting

Fig. 2 (a) Mechanical dilatation of the diseased superficial femoral artery using the Dynamic Dilator™. (b) Semi-closed endarterectomy using the Endarterectomy Catheter™ to engage atheroma.

Fig. 3 (a) Placement of a peel-away introducer sheath. (b) Placement of the graft through the introducer sheath and into the femoro-popliteal position by use of the Graft Inserter™. The Graft Inserter™ pinches the graft near the distal end and lays over the folded graft.

Fig. 4 (a) Removal of the peel-away sheath while holding the PTFE graft in place with the Graft Inserter™. (b) Balloon dilatation of the graft.
Inserter\textsuperscript{TM} (EVI); (11) Graft expanded, but not over distended, by incremental 6 mm balloon dilatations (Fig 4b); (12) Balloon dilatation of distal interface; (13) End to end anastomosis of proximal graft to femoral artery — not routinely completed in cadaveric study (Fig. 5); (14) Completion angiogram; (15) Casting of distal interface with dental moulding compound and explantation of specimen; (16) Formal histology of endarterectomy and explant specimens. The acceptable tolerances for distal graft/vessel interface control are shown in Fig. 6.

Fig. 5. Completion of the standard end-to-end anastomosis of the proximal graft to the common femoral artery.

Results

The procedure was successfully completed in 39 limbs (81%). Four failures were guide wire related. Three of these were due to inability to cross the lesion satisfactorily with the guide wire — all in long occlusions starting at the origin of the superficial femoral artery. One experiment was aborted because of vessel perforation during guide wire positioning. In another case we were unable to pass the guide wire, but the procedure was completed satisfactorily by crossing the lesion with the Dynamic Guide Wire\textsuperscript{TM} and then passing the guide wire through it. One incomplete procedure was due to an early graft delivery system failure.

Vessel avulsion occurred in four limbs. Three of the cases had minimal disease and the oversized 15fr Endarterectomy Catheter\textsuperscript{TM} was used, these cases were late in the series when we were evaluating the larger catheter. As a result we conclude that use of the larger catheter is contraindicated in the SFA. Also, in the clinical situation the procedure would not be attempted in a minimally diseased vessel.

Fluoroscopy was performed routinely after endarterectomy, and before graft placement. It showed complete endarterectomy throughout the length of the traversed SFA in all cases with more than minimal disease.

Totally satisfactory radiological and explanted specimen appearances were obtained in 24 of the 39 completed procedures (62%). A satisfactory radiograph, with subsequent good specimen appearance, is shown in Fig. 7.

Abnormalities comprised combinations of: extravasation (proximal or distal), contrast reflux, graft inadequate length, distal graft fold, graft too small and a distal intimal flap. An example of an angiogram with a distal fold and contrast reflux is shown in Fig. 8. The details of these defects are described in Table 2.

Macroscopic observation of the endarterectomised specimens consistently revealed lengths of intact cores, corresponding in length to each Endarterectomy Catheter\textsuperscript{TM} pass; piecemeal retrieval of disease was not a problem, except in the occasional minimally diseased artery. Histological examination of the endarterectomised specimens confirmed the presence of intima, with atheroma through to media in all cases — the accepted endarterectomy plane. Explant sections all revealed an intact adventitia with some media — again the accepted endarterectomy plane.

The duration of the procedure was recorded in 28 cases. Mean operating time was 81 min, with a range of 35–150 min.
Discussion

The practice of endoluminal grafting via the femoral artery was first reported by Volodos' et al. in 1986. The method has been developed, particularly for aneurysmal disease, with most experience at aortic sites, and some reports in the femoro-popliteal segment. All of these techniques use stents to fix and/or expand the graft.

In all published cases of endovascular graft implantation for occlusive disease, the arterial wall remained complete, although dilated by standard balloon techniques. There is a natural tendency for elastic recoil to occur in this situation, leading to potential graft compression and thus reocclusion. Cragg and Drake have attempted to reduce this by occasionally deploying additional stents at the angioplasty sites, external to the graft, but this experience is limited. With our novel technique of endarterectomy the risk is theoretically eliminated, resulting in a possibility for improved patency over previously described methods for treating occlusive disease.

This study was designed to refine the techniques and equipment needed for endarterectomy and endoluminal, transaxial femoropopliteal bypass grafting, to a level of reproducibility acceptable for progression to a limited clinical series. It has been successful in this aim. Obviously no conclusions may be drawn as to patencies in the clinical situation.

A number of important developments have been made and lessons learned, which have now brought us to the point of being confident to undertake the procedure in animal and clinical situations. Graft sizing is crucial. As the study progressed we used tapered PTFE grafts more commonly, as we were able to trim these to a more accurate distal diameter compatible with the distal vessel interface. The result was a reduction in contrast and moulding compound reflux, and a reduction in the presence of a distal graft fold. It is however, debatable, how haemodynamically
Table 2. Range of defects recorded at experiment completion

<table>
<thead>
<tr>
<th>Defect</th>
<th>Number</th>
<th>Position in series</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extravasation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proximal</td>
<td>8</td>
<td>4 early, 4 late</td>
<td>Insignificant in 6 cases - subsequent graft coverage</td>
</tr>
<tr>
<td>Distal</td>
<td>3</td>
<td>2 early, 1 late</td>
<td>Size mismatch</td>
</tr>
<tr>
<td>Contrast reflux</td>
<td>3</td>
<td>2 early, 1 late</td>
<td>Size mismatch</td>
</tr>
<tr>
<td>Graft inadequate length</td>
<td>3</td>
<td>All early</td>
<td>Deployment learning curve</td>
</tr>
<tr>
<td>Distal graft fold</td>
<td>4</td>
<td>3 early, 1 late</td>
<td>Size mismatch</td>
</tr>
<tr>
<td>Graft too small</td>
<td>2</td>
<td>Both early</td>
<td>Size mismatch</td>
</tr>
<tr>
<td>Distal intimal flap</td>
<td>1</td>
<td>Late</td>
<td>Significant</td>
</tr>
</tbody>
</table>

A total of 15 cases exhibited combinations of the above abnormalities.

Position in Series: ‘early’ indicates limb in first 20 cases, ‘late’ indicates limb in last 19 cases.

significant a small distal fold would be in the clinical situation.

Graft deployment techniques have undergone considerable modification. The pre-loading of the graft into a sheath and then positioning this via a second outer sheath, has been a significant advance in gaining good control of the distal interface.

Sophisticated fluoroscopic imaging is mandatory, both to avoid guidewire mishaps and to ensure that the distal interface placement tolerances are maintained. In the clinical situation we are including angioscopy in our experimental protocol, in order to directly assess the distal interface after endarterectomy, and on graft placement.

The 15fr Helical Endarterectomy Catheter™ is too large for the SFA and should not be used. The 10fr catheter worked well and the endarterectomy separation plane was consistently reproducible. The only vessel damage sustained with this catheter was when minimal disease was present — a contraindication to reconstruction anyway.

All previously published methods of semi-closed endarterectomy have involved pushing Cannon (or modifications thereof) ring cutters along the artery, necessitating a further incision and arteriotomy to obtain a clean, undissected end-point. Our unique method of retrograde endarterectomy, i.e. pulling back to engage the atheroma, results in a shelved, undissected distal interface.

It might be suggested that with such a clean endarterectomy, graft placement is unnecessary. We would suggest that using a graft conveys three potential benefits. Firstly, femoro-popliteal endarterectomy has comparable patency to conventional grafting only in the best hands, therefore having a smooth graft lining over the roughened vessel outer media may improve patency, by limiting restenosis risks to the proximal and distal interfaces. Secondly, any small distal flap at risk of dissection is covered by graft. Finally, any mural perforations along the endarterectomised segment are excluded from the circulation by the graft.

Another debatable issue is our decision not to stent the distal end of the graft. There is evidence that stents might encourage intimal growth at the site of placement. Currently available stents would also narrow further what is already a small diameter graft. When a graft with an intrinsic intramural stent becomes available, this may offer an advantage. However, it should be noted that there is a reported risk of stent collapse with placement adjacent to the knee — obviated by having a flexible distal interface. There is some clinical and experimental evidence that lack of a distal graft stent in endovascular aortic aneurysm exclusion may result in reflux around the graft, and thus continued expansion of the aneurysm. The aneurysmal abdominal aorta has a highly elastic wall, and we believe a similar failure is unlikely to occur when treating a less elastic vessel for occlusive disease. No final answer to the question of distal stenting is possible until we have undertaken clinical studies.

In conclusion, we feel this series of experiments has been sufficiently successful to justify animal and clinical studies of endarterectomy and endoluminal, transaxial femoropopliteal grafting.

The technique has the potential to convey significant benefits in terms of a less invasive method and reduced hospital stay for patients requiring intervention for femoropopliteal occlusive disease. Admission may be reduced to less than 24 h, with rapid remobilisation due to the limited dissection.

Acknowledgements

The majority of the work in this study was performed at Addenbrooke’s Hospital, Cambridge, U.K. We wish to thank all the authorities and members of staff involved in the project at that Institution for their understanding and enthusiasm in allowing us to complete the experiments. We would like to thank Jane Izatt, Chris Grundy and Sifas Lacy for technical assistance, Candace Vescera and Jill Atkin for administrative and technical assistance, and Tom Kelly, Tom Wiita and Rick Stout MD for their technical advice. The study was funded in part by the JOASH Foundation, Santa Monica, California and EndoVascular Instruments Inc., Portland, Oregon, U.S.A.

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