NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices

Removing plaque from arteries in the legs using a small rotating blade

Debris that builds up in the large blood vessels of the leg leads to narrowing of the vessels and reduced blood flow, which can result in leg pain or the development of foot ulcers.

In this procedure, a special cutting device is used inside diseased blood vessels with the aim of removing the excess debris.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in June 2010.

Procedure name

- Percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices

Specialty societies

- The Vascular Society of Great Britain and Ireland
- British Society of Interventional Radiology
- British Society of Endovascular Therapy.

Description

Indications and current treatment

Femoropopliteal arterial lesions are common in patients with symptomatic peripheral arterial disease (PAD) of the lower limbs. The most usual symptom is intermittent claudication. If disease progresses to cause ischaemic rest pain, ulceration or gangrene, then amputation may be required.

The international classification of peripheral arterial disease in the lower limbs is the Inter-Society Consensus TASC II grading:

- Grade A lesions:
  - Single stenosis ≤ 10 cm in length
  - Single occlusion ≤ 5 cm in length
- Grade B lesions:
  - Multiple lesions (stenoses or occlusions), each ≤ 5 cm
  - Single stenosis or occlusion ≤ 15 cm not involving the infrageniculate popliteal artery
  - Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass
  - Heavily calcified occlusion ≤ 5 cm in length
  - Single popliteal stenosis
- Grade C lesions:
  - Multiple stenoses or occlusions totalling > 15 cm with or without heavy calcification
  - Recurrent stenoses or occlusions that need treatment after 2 endovascular interventions
- Grade D lesions:
  - Chronic total occlusions of the common femoral artery or superficial femoral artery (≥ 20 cm, involving the popliteal artery)
  - Chronic total occlusion of popliteal artery and proximal trifurcation vessels.

Cardiovascular risk factor modification is fundamental to management. Best medical therapy seeks to address these factors and will suffice in many cases. For patients with severely impaired walking distance or with critical limb ischaemia, revascularisation procedures such as balloon angioplasty, stenting or bypass grafting can be used.

What the procedure involves

The proposed advantage of percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices is to improve arterial flow by removing atheromatous plaque that is restricting blood flow.

The standard Seldinger technique is used to percutaneously access the femoral artery, with the patient usually under local anaesthesia. The atherectomy catheter is introduced over a fine guidewire. Catheters of various diameters are available to suit the arterial diameter at the site of the lesion. After appropriately positioning the device, a high-speed rotating cutting blade excises the plaque. Plaque debris are usually collected in a distal nosecone, and removed on device withdrawal. Alternatively, depending on the catheter design, the sheathed cutting blade may be advanced over the guidewire beyond the lesion and then exposed so that excision can be undertaken while the device is being withdrawn. Several passes of the catheter may be required. A distal embolic protection device is sometimes used, or an aspiration system activated within the tip of the catheter device. Adjunctive treatment may be undertaken with balloon angioplasty or stenting of the atherectomised segment before removal of the vascular sheath.

A number of different devices are available to perform this procedure.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to percutaneous atherectomy with plaque excision blade catheter for femoropopliteal arterial lesions. Searches were conducted of the following databases, covering the period from their commencement to 14 June 2010 and updated to 29 October 2010: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with femoropopliteal arterial lesions
Intervention/test	Percutaneous atherectomy with plaque excision devices
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on approximately 1242 patients from seven case series [1,2,3,4,5,6,7].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices

Abbreviations used: ABI, ankle-brachial index; CI, confidence interval; MI. myocardial infarction; TLR, target lesion revascularisation; SFA, superficial femoral artery

Study details	Key efficacy findings	Key safety findings	Comments
Ramaiah V (2006)[1] TALON registry **Case series** USA Recruitment period: 2003 to 2005 Study population: symptomatic lower extremity atherosclerotic lesions. 57% previous MI or coronary revascularisation, 62% previous peripheral arterial revascularisation. 27% occlusions, 13% restenosis. **n = 601 (1258 lesions)** Age: 70 years (mean) Sex: 59% ,male Patient selection criteria: no criteria used provided that plaque excision was planned as the primary endovascular therapy. Patients enrolled irrespective of comorbidity, disease severity, or lesion complexity. Technique: endovascular atherectomy with plaque excision blade catheter (SilverHawk). **Follow-up: not reported** Conflict of interest/source of funding: Some authors have interest in manufacturer.	Number of patients analysed: **601 (1258 lesions) for acute outcomes data.** **Revascularisation** TLR was defined as any revascularisation or amputation involving the treated lesion segment. TLR-free survival was achieved in 90% of patients at 6-month follow-up (n = 248) and 80% of patients at 12-month follow-up (n = 87) (absolute numbers not reported). Multivariate analysis identified a number of baseline factors to be predictors of TLR by 6-month follow-up. **Variable** / **Hazard ratio (95% CI)** / **p value** History of MI or coronary revascularisation: 5.49 (1.87 to 16.10) / 0.0008 ≥ 2 lesions treate□: 1.37 (1.11 to 1.70) / 0.0019 Increasing degree of ischaemia: 1.84 (1.28 to 2.65) / 0.0003 Lesions longer than 5 mm: 2.88 (1.18 to 7.01) / 0.012 **Device success** Defined as ≤ 50% final residual stenosis. Device success was achieved in 97.6% (1204/1234) lesions. Mean stenosis improved from 86% of diameter at baseline to 11% following percutaneous atherectomy (before adjunctive therapy) (n = 922). **Procedural success** Defined as ≤ 50% final residual stenosis with no death, MI, amputation, TLR, or major bleeding within 30-day follow-up. Procedural success was achieved in 94.6% (778/822) of lesions at 30 days follow-up. **Operative characteristics** 11% of lesions required balloon angioplasty before catheter insertion. Stand-alone percutaneous atherectomy was performed in 73.3% (922/1258) of lesions. The mean procedure time was 28 minutes.	Complications – periprocedural to 30 days **Outcome per lesion** / **Rate** Perforations: 0.8% (10/1258) Grade A/B dissection: 2.8% (35/1258) Grade C dissection: 0.8% (10/1258) Aneurysms: 0% (0/1258) Occlusion/thrombosis: ≤ 0.1% (1/1258) Embolism: ≤ 0.1% (1/1258) **Events during follow-up (length not reported) per patient** **Outcome per patient** / **Rate** Death: 4.0% (24/601) Above-knee amputation: 1.2% (7/601) Below-knee amputation: 1.5% (9/601) Below-ankle amputation: 1.2% (7/601) Pseudoaneurysm – emergency surgical intervention: 0.2% (1/601) Heart failure, MI, or coronary artery bypass graft: 1.5% (9/601) Renal failure: 0.7% (4/601) Stroke/transient ischaemic attack: 0.5% (3/601) All adverse events were unrelated to the percutaneous atherectomy procedure.	**Follow-up issues**: 19 participating centres. Consecutive patient enrolment. Adverse events were recorded at the time of the procedure and throughout the course of patients' participation in the registry. Mean or median follow-up not reported. **Study design issues**: Use of additional devices (balloon dilation or stent), adjunctive pharmacological therapy and duration of postoperative antiplatelet treatment were left to the discretion of the surgeon. Procedural success is a composite outcome which combines both efficacy and safety outcome. **Study population issues**: A non-selected patient cohort. **Other issues**: None.

Abbreviations used: ABI, ankle-brachial index; CI, confidence interval; MI. myocardial infarction; TLR, target lesion revascularisation; SFA, superficial femoral artery

Study details	Key efficacy findings	Key safety findings	Comments
McKinsey JF (2008)[2] **Case series** USA Recruitment period: 2004 to 2007 Study population: patients with claudication (37%) or critical limb ischaemia (63%). Lesions = SFAs (n = 199), popliteal (110), tibial (218), and multilevel (52). **n = 275 (579 lesions)** Age: 70 years (mean) Sex: 63% male Patient selection criteria: the decision to perform directional endovascular atherectomy vs other endovascular therapies or surgical bypass was at the preference of the surgeon. Technique: endovascular atherectomy with plaque excision blade catheter (SilverHawk). Stand-alone atherectomy attempted (primary atherectomy), with other therapy for residual stenosis (assisted atherectomy), or as a back-up to failed balloon angioplasty (adjunctive atherectomy). **Follow-up: 13 months (mean)** Conflict of interest/source of funding: not reported.	Number of patients analysed: **275 (579 lesions)** **Procedural success** Defined as ≤ 30% residual stenosis Primary patency for all lesions treated was achieved in 62.2% ± 2.5 of lesions at 12 months and 52.7% ± 2.8 of lesions at 18 months (absolute figures not reported). Secondary patency for all lesions treated was achieved in 80.3% ± 2.0 of lesions at 12 months and 75.0% ± 2.4 of lesions at 18 months (absolute figures not reported). There was no statistically significant difference in patency rates between femoral, popliteal or tibial lesions. Limb amputation was avoided in 93.1% of patients at 12-month follow-up and 92.4% of patients at 18-month follow-up (absolute figures not reported). No patients with claudication suffered limb loss. For all primary atherectomy procedures (without subsequent angioplasty) the primary and secondary patency rate was 53.5% ± 3.6 and 75.7% ± 3.0 respectively at 18-month follow-up (absolute figures not reported). For all assisted atherectomy procedures (with subsequent angioplasty) the primary (arterial duplex ratio <5.0 after 1st treatment) and secondary patency rate was 53.8% ± 4.7 and 75.0% ± 4.2 respectively at 18-month follow-up (absolute figures not reported). For all adjunctive atherectomy procedures (following failed angioplasty) the primary and secondary patency rate was 24.1% ± 18.9 and 90.9% ± 8.7 respectively at 18-month follow-up (absolute figures not reported). **Operative characteristics** The mean number of lesions treated per patient was 2.1 ± 1.4.	**Complications** **Outcome** / **Rate** **Periprocedural** Groin haematoma: 4.1% (n = 15) Pseudoaneurysm: 0.5% (n = 2) Acute renal insufficiency (dialysis in 2 patients): 0.5% (n = 3) Thrombosis: 0.3% Embolisation: 0.8% Death (none related to the procedure): 1.1% (n = 3) **30-day outcomes** Death (including 3 periprocedural): 1.8% (n = 5) Absolute figures not reported for all outcomes. Reintervention was required in 28.8% (n = 176) of patients treated due to recurrent symptoms. Of these 70.1% were repeat endovascular treatments, 10.8% surgical bypass grafting, and 7.6% major amputation. Reintervention was required at a mean follow-up of 6 months.	**Follow-up issues**. Prospective study with standardised follow-up protocol. **Study design issues**: 2 participating centres. Clinical and angiographic outcomes were reviewed by independent assessors. Primary patency assessed using arterial duplex evaluation with a cut off specified. Dominator used for analysis of complications is not clear and percentages appear to contradict the number of patients treated in the series based on the event rates stated. **Study population issues**: Included some patients who had residual stenosis following balloon angioplasty. **Other issues**: None.

Abbreviations used: ABI, ankle-brachial index; CI, confidence interval; MI. myocardial infarction; TLR, target lesion revascularisation; SFA, superficial femoral artery

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Zeller T (2009)[7] PATHWAY

Case series
Germany
Recruitment period: 2006 to 2007
Study population: patients with lower limb ischeamia.
645 femoral arteries, 28% popliteal arteries, 9% tibial arteries.
n = 172 (210 lesions)
Age: 72years (mean)
Sex: 49% male

Patient selection criteria: patients with diagnosed peripheral vascular disease >70% stenosis or occlusion of de novo lesions or restenosis, Vessel diameter or 3 to 5 mm. No instent restenosis.
Technique: Endovascular atherectomy with plaque excision blade catheter (Pathway) with aspiration tip for potentially embolic material.

Follow-up: 12 months (median)

Conflict of interest/source of funding: supported by manufacturer</td>
<td>Number of patients analysed: n = 172 at 1 month, 171 at 3 months, 170 at 6 months, 163 at 12 months.

Composite endpoint
Defined as freedom from major adverse event (including revascularisation, death, MI of amputation at 30 days follow-up)
98.8% (170/172) of patients met the composite endpoint, 2 patients required amputation.
Patency
Success defined as mean reduction in stenosis with or without adjunctive therapy.
Group mean (standard deviation) stenosis
<table><tr><th>Follow-up</th><th>Stenosis %</th></tr><tr><td>Baseline</td><td>79.4 ± 17.7</td></tr><tr><td>Following atherecctomy</td><td>35.0 ± 16.1</td></tr><tr><td>Following adjunctive treatment</td><td>21.4 ± 10.5</td></tr></table>P < 0.0001 (not clear for which comparison)

TLR or restenosis occurred in 15.7% of lesions at 6 months follow-up and 27.1% at 12 months follow-up (absolute numbers not reported)

Procedural success
99.0% (208/210) of lesions were successfully crossed and debulked. 32.9% (69/210) of procedures were stand-alone percutaneous atherectomy.

Ankle-brachial index
Group mean (standard deviation) ABI
<table><tr><th>Follow-up</th><th>ABI</th><th>p =</th></tr><tr><td>Baseline (n = 159)</td><td>0.59 ± 0.21</td><td>N/A</td></tr><tr><td>30 days (n = 149)</td><td>0.31 ± 0.26</td><td><0.0001</td></tr><tr><td>12 months (n = 104)</td><td>0.82 ± 0.29</td><td><0.0001</td></tr></table></td>
<td>Complications

<table><tr><th>Outcome</th><th>Rate per patient</th></tr><tr><td>Abrupt closure</td><td>1%</td></tr><tr><td>Dissections</td><td>9%</td></tr><tr><td>Minor embolisations</td><td>10%</td></tr><tr><td>Perforations</td><td>2%</td></tr></table>(absolute numbers not reported)
All events managed successfully during the index procedure.</td>
<td>Follow-up issues:
Prospective study with scheduled follow-up.
Study design issues:
Multicentre study at 9 sites.
Independent assessment of outcomes.
Study population issues:
46% of patients had diabetes mellitus.

Other issues:
None.</td>
</tr>
</table>

Abbreviations used: ABI, ankle-brachial index; CI, confidence interval; MI. myocardial infarction; TLR, target lesion revascularisation; SFA, superficial femoral artery

Study details	Key efficacy findings	Key safety findings	Comments
Zeller T (2006)[3] **Case series** Germany Recruitment period: 2002 to 2004 Study population: patients with femoropopliteal lesions, with chronic peripheral occlusive disease. 34% de novo lesions, 33% native vessel restenosis, 33% in-stent restenosis. 8.5% of the lesions were total occlusions. **n = 84 (131 lesions)** Age: 66 years (mean) Sex: 64% male Patient selection criteria: patients with stable chronic peripheral disease, vessel diameter 3 to 7 mm, stenosis > 70%, and no complete intraluminal calcification on ultrasound, acute occlusions, or thrombus. Technique: local anaesthetic in some patients. Endovascular atherectomy with plaque excision blade catheter (SilverHawk). Stand-alone atherectomy attempted. Additional balloon angioplasty at the discretion of the surgeon, stenting discouraged. **Follow-up: 18 months (median)**	Number of patients analysed: **n = 84 (131 lesions), n = 81 at 18-month follow-up.** **Procedural success** Technical success defined as ≤ 50%. Residual stenosis was achieved in 96.2% (126/131) of lesions following excision blade catheter atherectomy alone. Procedural success defined as ≤ 30% residual stenosis was achieved in 76.3% (100/131) of lesions following excision blade catheter atherectomy alone. The mean percentage of stenosis was reduced from 87% ± 10 at baseline to 27% ± 17 following atherectomy with plaque excision catheter (measurement of significance not reported). This fell further after balloon dilation or stent insertion to 12% ± 10. **Patency** Primary patency defined as freedom from restenosis on duplex ultrasound > 50% after atherectomy **Follow-up** / **De novo lesions** / **Restenosis native vessel** / **In-stent restenosis** / **p values** 12 months / 84% / 54% / 54% / 0.002 18 months / 73% / 42% / 49% / 0.008 (absolute figures not reported) Target vessel revascularisation **Follow-up** / **De novo lesions** / **Restenosis native vessel** / **In-stent restenosis** / **p values** 12 months / 16% / 44% / 47% / 0.003 18 months / 22% / 54% / 49% / 0.003 (absolute figures not reported) Event-free survival at 540 days was significantly greater in de novo lesions than native vessel restenosis, or in-stent restenosis (p = 0.005) (absolute figures not reported).	**Complications** There were 5 peripheral emboli of atherectomy wall material in the first 8 procedures. These were treated by aspiration catheter. **Outcome** / **Rate per lesion** Type C dissection following additional balloon dilation (treated with stent) / ≤ 1% (1/131) Temporary trapping of blade tip in catheter housing / 7.6% (10/131) Vessel wall perforation / 0% (0/131)	**Follow-up issues**: Prospective study with clinical and pressure-measuring protocol. Case accrual method not reported. 3 patients died during follow-up due to prostate cancer or MI. **Study design issues**: Single-site study. Patients received adjunctive balloon angioplasty or stenting where necessary. Not all outcomes reported for study population as a whole, only per group. **Study population issues**: A mixed patient cohort with a range of lesion locations. **Other issues**: None.

Abbreviations used: ABI, ankle-brachial index; CI, confidence interval; MI. myocardial infarction; TLR, target lesion revascularisation; SFA, superficial femoral artery

Study details	Key efficacy findings	Key safety findings	Comments
Zeller T (2006) Cont. Conflict of interest/source of funding: not reported.	There was no significant difference in rate of bypass graft surgery between the 3 groups (p = 0.722) **Ankle-brachial index** All three groups demonstrated significant improvement in ankle-brachial score compared with baseline at both timepoints		

Follow-up	De novo lesions	Restenosis native vessel	In-stent restenosis
Baseline	0.60 ± 0.19	0.52 ± 0.22	0.58 ± 0.38
12 months	0.80 ± 0.20	0.70 ± 0.35	0.80 ± 0.29
18 months	0.77 ± 0.27	0.74 ± 0.23	0.79 ± 0.35
p values	< 0.001	< 0.001	< 0.001

Abbreviations used: ABI, ankle-brachial index; CI, confidence interval; MI. myocardial infarction; TLR, target lesion revascularisation; SFA, superficial femoral artery

Study details	Key efficacy findings	Key safety findings	Comments
Keeling W B (2007)[4] **Case series** USA Recruitment period: 2004 to 2006 Study population: patients with femoropopliteal arterial lesions. Lesions = common femoral artery (n = 1), SFA (52), popliteal artery (29), tibial artery (17). ABI 0.53. A third of patients had claudication. **n = 60 (66 limbs)** Age: not reported Sex: 62% male Patient selection criteria: patients with peripheral arterial occlusive disease. Technique: endovascular atherectomy with plaque excision blade catheter (SilverHawk). Adjunctive balloon angioplasty or stenting as required. **Follow-up: 5 months (mean)** Conflict of interest/source of funding: 1 author received funds from manufacturer.	Number of patients analysed: **n = 60 (70 lesions)** **Procedural success** A successful procedure (< 30% residual stenosis) was achieved in 87.1% (61/70) of patients. Amputation was required in 6.7% (4/60) of patients (3 below knee, 1 above knee). 2 of these patients had patent atherectomy sites but ongoing ischaemia. **Patency** Reocclusion or restenosis occurred in 17.1% (12/70) of lesions treated at a mean follow-up of 2.8 months. Primary patency was achieved in 61.7% of patients of patients at 1-year follow-up. **Ankle-brachial index** There was a mean increase in ABI of 0.27 ± 0.04 points following plaque excision. **Operative characteristics** The mean (standard error) length of plaque excision was 8.9 ± 0.8 cm. The mean time for plaque excision was 40 minutes (range 15 to 90 minutes) with reintroduction a mean of 4 times, with 4 to 6 passes of the lesion for each introduction. Mean length of stay was 5.7 ± 1.0 days.	**Complications** **Outcome** / **Rate per procedure** Distal embolisation leading to failure of procedure (treated with suction embolectomy or tissue plasminogen activator) — 7.1% (5/70) Repeat atherectomy — 5.7% (4/70) **Outcome** / **Rate per patient** Mortality to 30 days — 0% (0/60) Perforated common iliac artery (repaired with covered stent) — 1.7% (1/60) Myocardial infarction — 1.7% (1/60) Groin haematoma (operative intervention) — 1.7% (1/60) Perforation of treated vessel — 0% (0/60) Open revascularisation for persistent tissue ischaemia at < 1 month — 5.0% (3/60)	**Follow-up issues**: Prospective follow-up. 77% (46/60) patients underwent duplex ultrasound surveillance. **Study design issues**: All procedures undertaken by one surgeon. **Study population issues**: Patients in whom the lesion could not be crossed, or the plaque excision catheter could not be passed were excluded from analysis. 61% (70/115) of all patients screened were included in the study. **Other issues**: 70 lesions treated including 4 repeat treatments. Overall follow-up period not reported

Abbreviations used: ABI, ankle-brachial index; CI, confidence interval; MI. myocardial infarction; TLR, target lesion revascularisation; SFA, superficial femoral artery

Study details	Key efficacy findings	Key safety findings	Comments
Grubnic S (1996)[5] **Case series** UK Recruitment period: 1993 to 1994. Study population: patients with lower-limb atherosclerotic disease. 46% intermittent claudication, 24% rest pain, 24% tissue loss with ischaemic ulceration, 6% acute limb ischaemia. Procedure numbers = de novo lesions (n = 32), recurrent disease (n = 7). 51% occlusions, 49% stenoses. **n = 34 (35 limbs)** Age: 72 years Sex: 68% male Patient selection criteria: patients with peripheral arterial occlusive disease. Technique: Endovascular atherectomy with plaque excision blade catheter (Pullback). Adjunctive balloon angioplasty if lumen felt to be unsatisfactory. **Follow-up: 12 months (median)** Conflict of interest/source of funding: not reported.	Number of patients analysed: **n = 34 (37 lesions)** **Procedural success** Technical success was defined as improvement in lumen diameter of > 20% and residual stenosis of < 50%. It was achieved in 97.4% (38/39) of procedures. Mean stenosis improved from 89.4% at baseline to 12.1% at the end of the procedure (with balloon angioplasty where necessary) (measurement of significance not reported). **Patency** Patency was achieved in 55% of lesions at 6-months, and 45% at 12-month follow-up. **Clinical success.** Clinical success was defined as improvement by one or more grade (that is, from ulceration to rest pain, or from severe to mild claudication). It was achieved in 75% (27/36) of procedures at 1 month, 74% (25/34) at 6 months, and 55% (12/22) at 12 months. **Ankle-brachial index** Mean ABI improved 0.48 at baseline to 0.67 following the procedure (measurement of significance not reported). At 12-month follow-up, mean ABI was 0.83. **Operative characteristics** Pretreatment with thrombolysis prior to treatment was required for 4 lesions. In 3 patients, the initial procedure was balloon angioplasty. A mean of 5.8 passes with the plaque excision catheter were made per procedure. Mean procedural time was 27 minutes.	**Complications** **Outcome** / **Rate per procedure** Peripheral embolisation — 7.8% (n = 3) Graft thrombus (requiring surgery) — 2.6% (n = 1) Puncture site pseudoaneurysm (requiring surgery) — 2.6% (n = 1) Arterial spasm — 2.6% (n = 1) 5.9% (2/34) patients required above knee amputation at 1-month follow–up.	**Follow-up issues**: Prospective follow-up by clinical assessment or telephone. **Study design issues**: 69.2% of patients required additional balloon dilation after atherectomy to achieve a satisfactory lumen diameter. The denominator used for calculation of safety outcomes is not reported. **Study population issues**: None. **Other issues**: 39 procedures performed in 37 lesions.

Abbreviations used: ABI, ankle-brachial index; CI, confidence interval; MI. myocardial infarction; TLR, target lesion revascularisation; SFA, superficial femoral artery

Study details	Key efficacy findings	Key safety findings	Comments
Yancey AE (2006)[6] **Case series** USA Recruitment period: 2004 to 2005 Study population: patients with TASC grade C lesions and critical limb ischaemia. 24% rest pain, 76% tissue loss. **n = 16 (17 limbs)** Age: 73 years mean. Sex: 94% male. Patient selection criteria: not reported. Technique: percutaneous or open femoral access. Endovascular atherectomy with plaque excision blade catheter (SilverHawk). Adjunctive procedures performed at the discretion of the surgeon. **Follow-up: 6 months (mean)** Conflict of interest/source of funding: none.	Number of patients analysed: **n = 16 (17 lesions for patency and ABI analysis, 18 for analysis of technical success)** **Procedural success** Technical success was defined as < 30% residual stenosis. 88% (16/18) of procedures were defined as a technical success. **Patency** Stenosis-free primary patency was estimated to be 22% at 12 months on Kaplan–Meier analysis. **Clinical success** **Outcome at 1-month follow-up** — **Rate** Improved symptoms — 70.6% (12/17) Stable or healing wounds — 11.8% (2/17) Below knee amputation — 17.6% (3/17) 41.2% (7/17) patents remained symptom-free at 6-month follow-up, although 2 of these patients have documented restenosis. **Ankle-brachial index** ABI improved significantly from 0.39 ± 0.08 at baseline to 0.75 ± 0.08 in the postoperative period (p = 0.02). However at 6-month follow-up it had regressed to 0.48 ± 0.07.	**Complications** 18 procedures were analysed, including 1 repeat procedure. **Outcome** — **Rate per procedure** Atheroembolism (treated with atherectomy, not otherwise described, of the embolised plaque) — 5.6% (1/18) Overall (early and late), amputation was required in 29.4% (5/17) of limbs.	**Follow-up issues**: Retrospective chart review Case-accrual method not reported. **Study design issues**: Single-centre study. All patients with inflow disease underwent concurrent inflow procedures (5). **Study population issues**: Highly selected patient cohort with severe diffuse stenosis and critical limb ischaemia. **Other issues**: Patients with TASC grade A or B lesions were treated non-operatively at the participating institution. Grade D lesions treated with bypass surgery. An embolic protection device was not used.

Studies report several outcomes that can be interpreted as either efficacy or safety outcomes. Where composite outcomes of patency without adverse event were described, these have been included in the efficacy section below.

Efficacy

Clinical outcomes

A case series of 34 patients reported that improvement in clinical peripheral arterial disease of 1 or more grades was achieved in 75% (27/36) of procedures at 1-month follow-up and 55% (12/22) of procedures at 12-month follow-up[5].

A case series of 275 patients reported that limb amputation was avoided in 93% of patients at 12-month follow-up and 92% of patients at 18-month follow-up (absolute figures not reported)[2]. A case series of 60 patients reported that amputation was required in 7% (4/60) of patients at a mean follow-up of 5 months. Of these patients, 2 had a patent atherectomy site but ongoing ischaemia.

A case series of 601 patients reported that target lesion revascularisation-free survival was achieved in 90% of patients at 6-month follow-up (n = 248), and in 80% of patients at 12-month follow-up (n = 87) (absolute figures not reported)[1]. History of myocardial infarction or coronary revascularisation, 2 or more lesions treated, increasing degree of ischaemia, and lesions larger than 50 mm were found to be risk factors for revascularisation.

A case series of 60 patients reported that amputation was required in 7% (4/60) of patients at a mean follow-up of 5 months. Of these patients, 2 had a patent atherectomy site but ongoing ischaemia[4].

A case series of 16 patients (17 limbs) with TASC grade C lesions reported that 71% (12/17) had improved symptoms at 1-month follow-up, and 41% (7/17) of limbs remained symptom-free at 6-month follow-up[6].

Patency

A case series of 275 patients reported that for all primary percutaneous atherectomy procedures with a plaque excision catheter (but without adjunctive balloon angioplasty) the primary patency rate was 54% at 18-month follow-up (absolute figures not reported)[2].

A case series of 84 patients reported that patency (< 50% stenosis) was achieved in 73% of de novo lesions treated, 42% if restenotic native vessels, and 49% of ‘in-stent’ restenosis at 18-month follow-up (p = 0.008 for difference between groups) (absolute figures not reported)[3].

Procedural success

A case series of 34 patients reported that mean arterial stenosis improved from 89.4% at baseline to 12.1% following the procedure (with adjunctive balloon angioplasty where necessary) (measurement of significance not reported)[5].

A case series of 601 patients reported that procedural success (≤ 50% residual stenosis with no death, myocardial infarction, amputation, revascularisation, or major bleeding) was achieved in 95% (778/822) of lesions at 30-day follow-up[1].

Safety

Perforation

The rate of arterial wall perforation during the procedure was 1% (10/1258) per procedure in a case series of 601 patients[1], 0% (0/60) of patients in a case series of 60 patients[4], and 0% (0/131) of procedures in a case series of 84 patients (clinical sequelae were not reported)[3]. Perforation occurred in 2% of patients in a case series of 172 patients (absolute numbers not reported; all were managed successfully during the index procedure[7]).

Embolisation

Periprocedural embolism occurred in 1 out of 1258 procedures in a case series of 601 patients (clinical sequelae were not reported)[1], and in 7% (5/70) of procedures in a case series of 60 patients (treated with suction embolectomy or tissue plasminogen activator)[4]. Atheroembolism (treated with atherectomy of the embolised plaque) was reported in 1 out of 18 procedures in a case series of 16 patients[6].

Lesion site occlusion/thrombus

A case series of 34 patients reported that graft thrombus (requiring surgery) occurred in 1 patient undergoing the procedure[5].

Aneurysm

A case series of 34 patients reported pseudoaneurysm formation requiring surgery in 1 patient following percutaneous atherectomy with excision blade catheter[5]. A case series of 601 patients reported that there were no aneurysms following the treatment of1258 lesions (length of follow-up not reported)[1].

Other

Reintervention was required in 29% of patients treated in a case series of 275 patients at 13-month follow-up (absolute figures not reported)[2]. A technical difficulty with the blade tip of the catheter was reported during 8% (10/131) of procedures in a case series of 84 patients[3].

Validity and generalisability of the studies

- Patient selection varied between studies. Some recruited treatment-naive patients and some included patients with residual stenosis following balloon angioplasty or other intervention. This might be expected to influence efficacy outcomes.
- Adjunctive balloon dilation or stent placement was used in some patients; the degree of adjunctive interventions used varied between studies.
- Follow-up is seldom beyond 12 months in the published literature; there is some evidence of reducing patency and clinical success over time.
- Some studies include a mixture of femoropopliteal and tibial lesions, outcomes for which are not reported separately.
- Outcomes are often reported per procedure or per lesion rather than per patient in case series where patients either had multiple lesions (often bilateral lesions) or received repeated atherectomy. This makes interpretation of outcomes (particularly safety outcomes) difficult.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

There is currently no NICE guidance related to this procedure.

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr H Holsdworth, Mr I Nyamekye, and Mr S MacSweeney (The Vascular Society of Great Britain and Ireland), Dr S Macdonald, and Dr R McWilliams (British Society of Interventional Radiology).

- Two of the Specialist Advisers categorised this procedure as a minor variation on an established procedure, and two that it is novel and of uncertain safety and efficacy.
- The main comparators to the procedure include percutaneous balloon angioplasty or stenting, bypass surgery, cutting balloon angioplasty, or cryoplasty.
- The Specialist Advisers considered the key efficacy outcomes to include adequate luminal channel and long-term patency, limb salvage, improvement in claudication, quality of life, ulcer healing, and length of artery treated.
- Adverse events noted include distal embolisation.
- Additional theoretical adverse event might include vessel wall perforation, vessel thrombosis/occlusion of artery, limb loss, aneurysm/pseudoaneurysm, puncture site bleeding/haematoma, and technical complications with the catheter.
- One adviser commented that little training is required for this procedure above standard percutaneous interventions.
- Full vascular surgical support network is required on-site for this procedure.
- Previous atherectomy devices did not make it into full clinical practice.
- The reocclusion/restenosis rate in the long term is uncertain.
- No comparative or randomised controlled trial data are available at present.
- If the procedure proves successful, there is a large number of patients who could potentially benefit.
- There is an ongoing multicentre case series being supported by the manufacturer of 1 device, which is looking to recruit up to 800 patients.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme was unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

- Non-English language studies were not included in the overview.
- The scope of the intervention being considered excludes plaque excision catheters requiring balloon pressure to stabilise or advance the catheter, which was a feature of some older devices.
- There were no subgroups in areas covered by the Disability Discrimination Act (2005) identified at scoping.
- There is an ongoing US and European case series aiming to recruit 800 patients (‘Definitive LE’) that began recruitment in 2009.

References

1. Ramaiah V, Gammon R, Kiesz S et al. (2006) Midterm outcomes from the TALON Registry: treating peripherals with SilverHawk: outcomes collection. Journal of Endovascular Therapy 13: 592–602.

2. McKinsey JF, Goldstein L, Khan HU et al. (2008) Novel treatment of patients with lower extremity ischemia: use of percutaneous atherectomy in 579 lesions. Annals of Surgery 248: 519–28.

3. Zeller T, Rastan A, Sixt S et al. (17-10-2006) Long-term results after directional atherectomy of femoropopliteal lesions. Journal of the American College of Cardiology 48:1573–78.

4. Keeling WB, Shames ML, Stone PA et al. (2007) Plaque excision with the Silverhawk catheter: early results in patients with claudication or critical limb ischemia. Journal of Vascular Surgery 45: 25–31.

5. Grubnic S, Heenan SD, Buckenham TM et al. (1996) Evaluation of the pullback atherectomy catheter in the treatment of lower limb vascular disease. CardioVascular and Interventional Radiology 19: 152–9.

6. Yancey AE, Minion DJ, Rodriguez C et al. (2006) Peripheral atherectomy in TransAtlantic InterSociety Consensus type C femoropopliteal lesions for limb salvage. Journal of Vascular Surgery 44: 503–9.

7. Zeller T, Krankenberg H, Steinkamp H et al. (2009) One-year outcome of Percutaneous Rotational Atherectomy with Aspiration in Infraguinal peripheral arterial occlusive disease: the multicenter pathway PVD trial. Journal of Endovascular Therapy 16: 653–662.

Appendix A: Additional papers on percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Penugonda N, Duncan K, Schreiber T (2008) Popliteal artery pseudoaneurysm following FoxHollow atherectomy: a rare complication. Invasive Cardiology 20: 477–8.	n = 1 Follow-up = 2 years	Endovascular treatment of peripheral vascular disease has become increasingly common, therefore it is important to be aware of even the rare complications associated with this procedure. Pseudoaneurysm is one of the rare complications associated with FoxHollow device use.	Larger studies are included in table 2. Safety outcome is reported elsewhere in the evidence.

Appendix B: Related NICE guidance for percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices

There is currently no NICE guidance related to this procedure.

Appendix C: Literature search for percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	29/10/2010	October, 2010
Database of Abstracts of Reviews of Effects – DARE (CRD website)	29/10/2010	NA
HTA database (CRD website)	29/10/2010	NA
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	29/10/2010	October, 2010
MEDLINE (Ovid)	29/10/2010	1950 to October Week 3 2010
MEDLINE In-Process (Ovid)	29/10/2010	October 28, 2010
EMBASE (Ovid)	29/10/2010	1980 to 2010 Week 42
CINAHL (NLH Search 2.0 or EBSCOhost)	29/10/2010	NA
Zetoc	29/10/2010	NA

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	(angle* adj3 blade*).tw.
2	(cut* adj3 blade*).tw.
3	Atherectomy/
4	atherectom*.tw.
5	(plaque* adj3 excis*).tw.
6	(blade* adj3 cathet*).tw.
7	EV3.tw.
8	silverhawk.tw.
9	or/1-8
10	surgical procedures, minimally invasive/

11	percutan*.tw.
12	10 or 11
13	9 and 12
14	Femoral Artery/
15	(femor* adj3 arter*).tw.
16	Popliteal Artery/
17	(poplitea* adj3 arter*).tw.
18	or/14-17
19	(lesion* or obstruct* or stenosis* or restenosis* or (reduce* adj3 blood* adj3 flow*)).tw.
20	18 and 19
21	Intermittent Claudication/
22	(intermitt* adj3 claudicat*).tw.
23	Ischemia/
24	isch?emia*.tw.
25	Arterial Occlusive Diseases/
26	(arter* adj3 occlusi* adj3 diseas*).tw.
27	(vascular* adj3 recanalisat*).tw.
28	(atheromat* adj3 plaque*).tw.
29	Foot Ulcer/
30	(foot* adj3 ulcer*).tw.
31	20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
32	13 and 31