NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease

Treating peripheral arterial disease using a laser and an inflatable balloon to unblock arteries

Blood vessels (arteries) in the legs can become blocked by the build-up of fatty deposits on the inner surface. This can cause leg pain when walking or at rest and, in advanced cases, foot ulcers and gangrene.

For this procedure, a laser attached to a flexible plastic tube (a catheter) is inserted into a blood vessel in the leg and moved to the site of the blockage to burn away the deposits. A balloon is then inserted and inflated to widen the artery at the site of the blockage. An expandable mesh tube (stent) may also be inserted to keep the artery open.

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 2011 and updated in July 2012.

Procedure name

- Percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease.

Specialty societies

- British Society of Interventional Radiology
- Vascular Society

Description

Indications and current treatment

Chronic atherosclerotic peripheral arterial disease causes narrowing or blockage of arteries distal to the aortic arch.

Symptoms of peripheral arterial disease include intermittent claudication (calf pain on exercise), ischaemic rest pain, ulceration and gangrene. The onset of critical limb ischaemia is associated with reduced life expectancy because of co-existing atheromatous disease in the coronary and intracerebral vessels.

Cardiovascular risk factor modification is fundamental to the management of peripheral arterial disease. Best medical therapy seeks to control cardiovascular risk factors and may relieve the onset of rest pain or tissue loss in some patients. However, for patients with severely reduced walking distance or critical limb ischaemia, revascularisation procedures such as balloon angioplasty, stenting or surgery (bypass grafts or endarterectomy) can be used.

There are a number of measures of severity for peripheral arterial disease. One classification is the Rutherford scale, which grades the clinical symptoms from 1) mild claudication to 6) major tissue loss. Additionally, the American Heart Association classifies limb status on a 4-point scale with the following categories: ‘asymptomatic’, ‘claudication’, ‘critical limb ischaemia’ and ‘acute limb ischaemia’. A third classification system is the Transatlantic Inter-Society Consensus (TASC) classification, which requires imaging assessment and defines 4 categories of increasing severity/complexity as follows.

- Grade A lesions:
  - Single stenosis less than or equal to 10 cm in length
  - Single occlusion less than or equal to 5 cm in length
- Grade B lesions:
  - Multiple lesions (stenoses or occlusions), each less than or equal to 5 cm
  - Single stenosis or occlusion less than or equal to 15 cm not involving the infrageniculate popliteal artery
  - Single or multiple lesions without continuous tibial vessels to improve inflow for a distal bypass
  - Heavily calcified occlusion less than or equal to 5 cm in length
  - Single popliteal stenosis
- Grade C lesions:
  - Multiple stenoses or occlusions totalling greater than 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 or over, involving the popliteal artery)
  - Chronic total occlusion of popliteal artery and proximal trifurcation vessels.

What the procedure involves

The aim of percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) is to achieve recanalisation when balloon angioplasty and/or stenting alone are considered not to be technically feasible or sufficiently safe.

Using local anaesthesia and standard endovascular technique and fluoroscopy, a guidewire and laser catheter are passed through the artery to the level of the stenosed or occluded segment. A laser device is advanced to the level of stenosis or occlusion – a guidewire may be used. The laser emits pulses of laser light to vaporise the blockage. This is carried out as an adjunct to recanalisation using balloon angioplasty. A stent may then be inserted to treat any stenosis and to prevent embolism and restenosis.

Several devices are available for this procedure.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease. Searches were conducted of the following databases, covering the period from their commencement to July 2012: 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 peripheral arterial disease
Intervention/test	Percutaneous laser atherectomy
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 1683 patients from 2 randomised controlled trials[1-2], 1 non randomised controlled study[3] and 6 case series[4-9].

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 laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease

Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; SFA, superficial femoral artery

Study details

Lammer J (1992)[1]

Randomised controlled trial

Austria

Recruitment period: 1989 onwards

Study population: patients with segmental femoropopliteal artery occlusions. Moderate to severe claudication = 72%, limb threatening ischaemia = 28%. Mean length of occlusion = 7.8 cm.

n = 116 (37 XeCl Excimer laser, 40 Nd:YAG laser, 39 balloon angioplasty alone)

Age: 65 years (mean)

Sex: 66% male

Patient selection criteria: patients with clinical symptoms for > 4 months, disease suitable for percutaneous treatment, refractory to conservative treatment, and occlusions of 1 to 20 cm. Patients with stenosis without occlusion were excluded.

Technique: local anaesthesia, percutaneous atherectomy with pulsed laser (XeCL Excimer laser, MAX 10, Technolas) plus balloon

Key efficacy findings

Number of patients analysed: **116 (37 pulsed laser, 40 continuous wave laser, 39 balloon angioplasty alone)**

Primary patency

Primary success was defined as 50% or less residual stenosis and antegrade flow (angiography), with restoration of popliteal pulse at 2-day follow-up.

Primary success	Rate
All patients	69.8% (81/116)
Pulsed laser and angioplasty	48.6% (18/37)*
Continuous wave laser and angioplasty	77.5% (31/40)
Angioplasty alone	82.1% (32/39)

* $p < 0.003$ for pulsed laser versus other two groups

No significant difference between continuous wave laser therapy and angioplasty alone.

Vascular success

Proportion of patients with improving ABI at 2-day follow-up.

Pulsed laser and angioplasty	40.5% (15/37)
Continuous wave laser and angioplasty	65.0% (26/40)
Angioplasty alone	66.7% (26/39)

Measurement of significance not reported.

Key safety findings

Complications:

Outcome	Pulsed laser and angioplasty	Continuous wave laser and angioplasty	Balloon alone
Embolus	0% (0/37)	5.0% (2/40)	7.7% (3/39)
Dissection	35.1% (13/37)	20.0% (8/40)	15.4%* (6/39)
Perforation	5.4% (2/37)	5.0% (2/40)	7.7% (3/39)
Spasm	0% (0/37)	0% (0/40)	2.6% (1/39)

* $p = 0.005$ (which comparison not reported)

No deaths reported within 30 days of treatment and no complications requiring emergency surgery.

Comments

Follow-up issues:

- Intention-to-treat analysis.
- 7 patients died and 6 others were lost to follow-up.

Study design issues:

- Randomisation method not reported. Patients stratified for length of occlusion, and number of patent crural arteries.
- No details reported regarding blinding of outcome assessment.
- Only patients who had successful initial recanalisation were included in analysis of long term patency.
- When primary recanalisation failed at 2-day follow-up a second treatment was chosen.
- Clinician experience with laser angioplasty not

<table>
<tr><td colspan="4">Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; SFA, superficial femoral artery</td></tr>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr><td>angioplasty, versus continuous wave (Nd:YAG, Surgical Laser Technologies) laser plus balloon angioplasty, versus guidewire balloon angioplasty.

Follow-up: 1 year (median)

Conflict of interest/source of funding: not reported</td><td>Long term follow-up
12-month patency (clinical assessment)<table><tr><td>Pulsed laser and angioplasty</td><td>34%</td></tr><tr><td>Continuous laser and angioplasty</td><td>70%</td></tr><tr><td>Angioplasty alone</td><td>71%</td></tr></table>Absolute figures and measurement of significance not reported.
12-month patency (angiography assessment)<table><tr><td>Pulsed laser and angioplasty</td><td>45%</td></tr><tr><td>Continuous laser and angioplasty</td><td>36%</td></tr><tr><td>Angioplasty alone</td><td>50%</td></tr></table>Absolute figures and measurement of significance not reported.</td><td></td><td>reported.

Study population issues:
• Patients selected as suitable for percutaneous treatment.

Other issues:
Laser devices used may not be the same as those currently available.</td></tr>
</table>

Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; SFA, superficial femoral artery			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Belli A-M (1991)[2] **Randomised controlled trial** UK Recruitment period: 1988-90 Study population: Patients with occlusive lesions in the iliac and femoropopliteal segment. **N = 81 patients (84 occlusions: 41 laser vs 43 conventional recanalisation)** Age: not reported Sex: not reported Patient selection criteria: patients suitable for percutaneous transluminal angioplasty by means of an ipsilateral femoral approach included. Patients in whom contralateral approach was necessary were excluded. Technique: PTA with continuous-wave argon laser (Cooper Lasersonics) or Nd:YAG generator. All cases treated with laser followed up with subsequent balloon dilatation versus conventional recanalisation (using guidewire and balloon dilatation). **Follow-up: not reported** Conflict of interest/source of funding: not reported.	Number of patients analysed**: 68 patients (34 laser vs 34 conventional recanalisation)** **Technical success** Defined as 'improvement in luminal diameter to < 50% residual stenosis as detected at angiography' was achieved in 82% (28/34) of patients treated by laser and 74% (25/34) of the patients treated by conventional recanalisation. In 6 patients the laser technique failed, 3 underwent successful balloon dilatation (reocclusion was reported in 1 patient within 24 hours). There was no significant difference between the two treatments with respect to length of occlusion ($p = 0.085$). **Clinical success** Clinical success, (defined as a 'relief of symptoms and improved peripheral pulses up to 2 weeks after the procedure') was achieved in 79% (27/34) of patients treated by laser recanalisation and 85% (29/34) of patients treated by conventional recanalisation. There was no difference in the primary success rate of either laser or conventional recanalisation regarding intermittent claudication or rest pain within or between the two treatments ($p = 0.41$)	Safety outcomes were not reported.	**Follow-up issues:** • 16% loss to follow-up (reasons unclear). **Study design issues:** • Randomisation performed by blindly picking a premarked card. **Study population issues:** • Baseline characteristics not reported.

Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; 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>Steinkamp HJ (2002)[3]

Non-randomised controlled study
Germany
Recruitment period: 1994−2000
Study population: patients with unilateral popliteal artery occlusions. Mean ABI = 0.35
n = 215 (127 laser and balloon angioplasty, 88 balloon angioplasty alone)
Age: 63 years (mean)
Sex: 57% male

Patient selection criteria: patients with unilateral popliteal occlusion and at least one patent crural artery. Patients with > 6 months' history of claudication.

Technique: percutaneous laser angioplasty with Excimer CVX300 or LAIS DYMER 200+ laser plus balloon angioplasty with step-by-step technique versus balloon angioplasty alone. Stents were placed as needed for suboptimal results.

Follow-up: 36 months (mean)</td>
<td>Number of patients analysed: 215 (127 laser, 88 balloon angioplasty alone)

Primary patency
Primary success was defined as < 30% residual stenosis on angiography, and clinical improvement of 2 or more grades (AHA limb status grade classification).
<table>
<tr><th></th><th>Laser and balloon angioplasty</th><th>Balloon angioplasty</th></tr>
<tr><td>Primary success</td><td>82.7% (105/127)</td><td>70.4 (62/88)</td></tr>
</table>
Measurement of significance not reported.
ABI – in successfully treated patients group, mean and standard deviation
<table>
<tr><th></th><th>Laser and balloon angioplasty</th><th>Balloon angioplasty</th><th>p</th></tr>
<tr><td>Baseline</td><td>0.34 ± 0.16</td><td>0.33 ± 0.18</td><td>–</td></tr>
<tr><td>Immediate follow-up</td><td>0.88 ± 0.17</td><td>0.86 ± 0.15</td><td>< 0.001</td></tr>
<tr><td>36 months follow-up</td><td>0.55 ± 0.16</td><td>0.52 ± 0.13</td><td>< 0.001</td></tr>
</table>
p values for each group versus baseline
At 36 months' follow-up 21.7% of patients in the laser group and 16.3% of patients in the balloon group maintained primary patency (absolute figures and measurement of significance not reported).</td>
<td>Complications:
<table>
<tr><th>Outcome</th><th>Laser and balloon angioplasty</th><th>Balloon</th></tr>
<tr><td>Vessel perforation (follow-up not reported)</td><td>3.1% (4/127)</td><td>Not reported</td></tr>
<tr><td>Major dissection</td><td>34.6% (44/127)*</td><td>50.0% (44/88)</td></tr>
<tr><td>Complete or partial embolic occlusion (of a proximal lower limb artery)</td><td>3.1% (4/127)+</td><td>5.7% (5/88)#</td></tr>
<tr><td>Pseudoaneurysm</td><td>2.4% (3/127)^</td><td>2.3% (2/88)</td></tr>
</table>
* (23 successfully treated by balloon dilatations, 21 with stents)
+ (3 symptomatic − treated by dilatation or local lysis)
# (4 symptomatic – treated by dilatation or local lysis)
^ (treated by ultrasound compression)</td>
<td>Follow-up issues:
• Outcomes assessed on an intention-to-treat principle.

Study design issues:
• Patient selection by patient preference.
• Study protocol allowed for up to 3 redo procedures in a 3-year period.
• ABI outcomes for groups not reported as a whole, only separately for patients treated successfully or not.

Study population issues:
• There were no significant differences between patient groups in terms of length of occlusions or patient demographics.

Other issues:
• Primary patency was defined as uninterrupted</td>
</tr>
</table>

<table>
<tr><td colspan="4">Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; SFA, superficial femoral artery</td></tr>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr><td>Conflict of interest/source of funding: not reported</td><td>Clinical signs (according to limb status grade)
Change from baseline limb status grade at immediate follow-up
<table><tr><th></th><th>Laser and balloon angioplasty</th><th>Balloon angioplasty</th></tr><tr><td>No change</td><td>19.7% (25/127)</td><td>30.7% (27/88)</td></tr><tr><td>+1 grade improvement</td><td>2.4% (3/127)</td><td>4.5% (4/88)</td></tr><tr><td>+2 grade improvement</td><td>51.2% (65/127)</td><td>42.0% (37/88)</td></tr><tr><td>+3 grade improvement</td><td>26.8% (34/127)</td><td>22.7% (20/88)</td></tr></table>Measurement of significance not reported.

Grade 0: no change in clinical category and < 0.10 change in ABI; grade 1+: > 0.10 increase in ABI but no categorical improvement or vice-versa; grade 2+ at least single category improvement, and ABI increase > 0.10 but not normal; grade 3: asymptomatic or markedly improved, ABI > 0.90.</td><td></td><td>patency after successful primary recanalisation without need for secondary intervention.</td></tr>
</table>

Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; SFA, superficial femoral artery

Study details	Key efficacy findings	Key safety findings	Comments
	Change from baseline in limb status grade at 36-month follow-up **Laser and balloon angioplasty** / **Balloon angioplasty** No change: 51.2% (65/127) / 50.0% (44/88) +1 grade improvement: 18.9% (24/127) / 20.4% (18/88) +2 grade improvement: 19.7% (25/127) / 18.2% (16/88) +3 grade improvement: 10.2% (13/127) / 11.4% (10/88) Measurement of significance not reported.		

Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; 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>Wissgott C (2004)[4]

Case series
Germany

Recruitment period: First assessment of SFA stenosis during 1994–99

Study population: patients with SFA occlusions. Range of occlusion length: 16–38 cm

n = 452 (452 SFA occlusions)

Age: mean 64 years

Sex: 58% male

Patient selection criteria included: Unilateral SFA occlusion, patent popliteal artery, patency of at least one crural artery, no aortic or pelvic artery stenoses,
claudication > 6 months, AHA claudication category 1–6.

Technique: Recanalisation performed using pulsed XeCL-Excimer laser (Spectranetics) and using fluoroscopic control. Mostly (n = 398) contralateral approach</td>
<td>Number of patients analysed: 452

Technical success
Technical success (defined as ‘required a residual stenosis < 50% according to angiography’) was achieved in 85.4% (386/452) of patients. Failure to recanalise in 14.6% (66/452) of patients.
Clinical improvement
(According to limb status in successfully treated patients [n = 386])
<table>
<tr><th>Grade</th><th>1 day post-intervention % (n)</th><th>Follow-up* % (n)</th></tr>
<tr><td>0 (no change)</td><td>1 (3)</td><td>25 (98)</td></tr>
<tr><td>+1 (minimally improved)</td><td>2(9)</td><td>22 (84)</td></tr>
<tr><td>+2 (moderately improved)</td><td>60 (234)</td><td>32 (123)</td></tr>
<tr><td>+3 (markedly improved)</td><td>37 (140)</td><td>21 (81)</td></tr>
</table>
Grade 0: no change in clinical category and < 0.10 change in ABI; grade 1+: > 0.10 increase in ABI but no categorical improvement or vice-versa; grade 2+ at least single category improvement, and ABI increase > 0.10 but not normal; grade 3: asymptomatic or markedly improved, ABI > 0.90.
*Mean 48 months</td>
<td>Complications
<table>
<tr><td>Perforation</td><td>3.9% (15/386)</td></tr>
<tr><td>Major dissections (after balloon dilatation)</td><td>36.8% (142/386) (‘at re-intervention’). 100 of these patients were managed by stenting and 42 by additional balloon dilatations.</td></tr>
<tr><td>Complete or partial embolic occlusion (peroneal trunk or of proximal lower limb arteries)</td><td>15 patients had angiographic post-procedural evidence of embolism – symptomatic (i.e. paraesthesia or pain) in 10 patients. Among the 15 patients with angiographic evidence of distal embolism, 4 were treated with angioplasty and 11 with local recombinant tissue plasminogen activator lysis.</td></tr>
<tr><td>Pseudoaneurysm (at puncture site)</td><td>12 patients (treated by ultrasound-guided compression).</td></tr>
</table>
Unless stated, the denominator of the reported events (whether 386 or 452) is not clear.</td>
<td>Study design issues:
• It is not entirely clear from paper whether balloon angioplasty was used after laser angioplasty as primary intervention, and if so, in how many patients.
• There are several uncertainties regarding the denominator of subgroups of patients described.
• Other issues: There is some apparent discrepancy in figures of patency given in abstract and in main paper (table 4). In case of conflicting information, table 4 of the paper was used.
• Percentages reported for clinical improvement according to limb status as reported in table 2 of the paper- although suspect there may be errors in reporting.</td>
</tr>
</table>

Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; SFA, superficial femoral artery

Study details	Key efficacy findings	Key safety findings	Comments
used (retrograde femoral puncture). Antegrade (n = 36) or transpopliteal (n = 18) approaches were used in cases of difficulties in crossing over the lesion. **Follow-up: mean 48 months** Conflict of interest/source of funding: not reported	**Vascular success** (In successfully treated patients; n = 386) **Time point** / **ABI (at rest)** Preintervention: 0.54 ± 0.24 Post interventional: 0.86 ± 0.18*+ 48 months: 0.62 ±0.20* *p < 0.001 compared with preinterventional value. +11 patients with early reocclusion in the first night after intervention. **Patency outcomes** At 48-month follow-up: • Primary patency (defined as 'uninterrupted patency with no procedure performed during the follow-up period') 26.0%. • Primary-assisted patency (lesions requiring PTA performed for restenosis) 40.9% including initial failures and 48.0% among patients in whom the procedure was technically successful. • Secondary patency (if a reocclusion was successfully retreated) 43.2% including technical failures and 54.2% when restricted to patients with successful primary recanalisation. 26% of patients were symptom-free during follow-up (numerator/denominator not reported, denominator could be assumed to relate to 386 patients with technical success). 74% of patients redeveloped claudication during follow-up, of whom 52.1% developed total occlusion, and 21.9% stenosis (ranging from 75% to 95%).		

Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; 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>Steinkamp HJ (2002)[5]

Case series
Germany
Recruitment period: 1994–9

Study population: patients with short (1–10 cm) SFA occlusions

n = 312 (312 occlusions)

Age: mean 63 years

Sex: 64% male

Patient selection criteria: Patients with history of claudication > 6 months with unilateral occlusion of the SFA, patency of the popliteal artery and least of one crural artery.

Technique: Under fluoroscopic guidance, pulsed laser-assisted recanalisation using XeCl Excimer laser (Spectranetics) system with step-by-step technique. Indications for stent implantation were recoil (restenosis > 50%), subintimal flap, obstructive calcified material with restenosis > 50% and total dilatation time of 9 min.
All patients received intravenous</td>
<td>Number of patients analysed: 312

Technical success
Technical success, defined as ‘a residual stenosis < 50% according to angiography’, was achieved in 91.7% (286/312).
Early reocclusion of the SFA reported in 10 patients (7 successfully retreated by recombinant tissue plasminogen activator lysis; 2 had conservative therapy; 1 bypass surgery).

Unsuccessful primary laser recanalisation in 8.3% (26/312) of patients (no emergency surgery or further intervention was necessary in patients with after the intervention).

Vascular success
In successfully treated patients (286/312):

<table>
<tr><th>Time point</th><th>ABI (at rest)</th></tr>
<tr><td>Preintervention</td><td>0.56 ± 0.18</td></tr>
<tr><td>Post interventional</td><td>0.88 ± 0.18*+</td></tr>
<tr><td>36 months</td><td>0.72 ±0.14*</td></tr>
</table>
*Significant change compared with preintervention ($p < 0.001$). +10 patients with early reocclusion in the first night after intervention.

Cumulative patency
At 36 months follow-up, primary clinical patency (defined as contrast limb status grading after successful primary recanalisation) was 49.2% (n = 122). Secondary patency (defined as patency of target vessel regardless of secondary interventions) was 86.3%</td>
<td>Complications
(Denominator not reported for all of the complications)

<table>
<tr><th>Outcome</th><th></th></tr>
<tr><td>Perforation of vessel wall (during intervention)</td><td>4.2% (13/312)</td></tr>
<tr><td>Major dissection*</td><td>39.2% (112/286)</td></tr>
<tr><td>Total or partial embolic occlusion^</td><td>n = 11</td></tr>
<tr><td>Pseudoaneurysms+</td><td>n = 10</td></tr>
<tr><td>Minor bleedingΔ</td><td>n = 20</td></tr>
<tr><td>Major bleeding~ (requiring blood transfusion)</td><td>n = 3</td></tr>
</table>
*Observed after balloon dilatation; 46.4% (52/112) successfully treated by one or several additional balloon dilatations; 53.6% (60/112) with stents
^6 symptomatic with progressive paraesthesia or local pain. 4 successfully treated by PTA and 7 by local recombinant tissue plasminogen activator lysis.
+ 8 of these occurred in patients who were treated with manual compression; all treated by ultrasound-guided compression
Δ15 treated with manual compression and 6 treated with suture device
~ All treated with manual compression</td>
<td>Follow-up issues:
• 14% (45/312) lost to follow-up.

Study design issues:
• ABI outcomes not reported as a whole, only separately for patients treated successfully or not.
• Repeat interventions were performed within 14 days.

Other issues:
• For the outcome ‘clinical improvement’, the percentage reported are as per table 2 in the paper but there are inconsistencies in the data.</td>
</tr>
</table>

<table>
<tr><td colspan="4">Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; SFA, superficial femoral artery</td></tr>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr><td>heparin therapy for 24 hours and low molecular-weight heparin subcutaneously for 2–4 weeks.

Follow-up: mean 36 months

Conflict of interest/source of funding: not reported.</td><td>(n = 205).

Clinical improvement
Defined according to limb status in successfully treated (n = 286) patients.

<table>
<tr><th>Grade</th><th>1-day post-intervention % (n)</th><th>follow-up % (n)</th></tr>
<tr><td>0 (no change)</td><td>1 (3)</td><td>25 (23)</td></tr>
<tr><td>+1 (minimally improved)</td><td>2 (7)</td><td>22(46)</td></tr>
<tr><td>+2 (moderately improved)</td><td>60 (200)</td><td>32(153)</td></tr>
<tr><td>+3 (markedly improved)</td><td>37 (76)</td><td>21 (64)</td></tr>
</table>

Grade 0: no shift in clinical category and < 0.10 change in ABI; grade 1+: > 0.10 increase in ABI but no categorical improvement or vice-versa; grade 2+ at least single category improvement, and ABI increase > 0.10 but not normalised; grade 3: asymptomatic or markedly improved, ABI > 0.90.</td><td></td><td></td></tr>
</table>

Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; SFA, superficial femoral artery

Study details

Lammer J (1991)[6]

Case series

Austria

Recruitment period: not reported

Study population: patients with femoropopliteal artery occlusions with severe claudication (n = 227), rest pain (n = 56) or gangrene (n = 55).

N = 338

Age: mean 68 years

Sex: 72% male

Patient selection criteria: Patients with femoropopliteal artery occlusions at least 2 cm long that have been present for at least 4 months. Patients with occlusions at iliac arteries and at the proximal origin of other SFA or with acute thrombotic or embolic occlusions, immobilised patients or unable to take long-term medication were excluded. Patients were excluded if the occlusion could be recanalised with guide wire and balloon angioplasty.

Key efficacy findings

Numbers of patients analysed: **338**

Procedure success

Laser recanalisation was initially successful in 85% of patients (288/338). In 15% (50/338) of patients laser angioplasty was unsuccessful and 6.2% (21/338) of patients had calcified plaques that could not be ablated.

Length of occlusion (cm)	Recanalisation rate % (n/N)	Clinical improvement* % (n/N)
< 3	90 (62/69)	88 (61/69)
3–7	89 (133/149)	87 (129/149)
> 7	78 (93/120)	75 (90/120)

*Clinical improvement defined as improvement of the Doppler index by at least 0.2.

Cumulative patency rate

Timepoint	Patency rate
6 months	80% (SD 2.5); n = 261
1 year	70% (SD 3.1); n = 176
2 years	62% (SD 4.0); n = 29
3 years	57% (SD 6.5); n = 11

Length of occlusion (cm)	Cumulative patency rate (3 years)
2–3	68%
3–7	48%
> 7	59%

Clinical success (follow-up at 3 years)

In 9% (32/338) of patients, restenoses of more than 50% within the recanalised segment observed (developed within first year mainly in the first 6 months). In 81% (26/32) of patients redilatation by second PTA was undertaken and the remaining 6 patients were

Key safety findings

Complications during or after the procedure

Complication	% (n/N)
Local warming (caused by thermal tissue ablation)	64 (215/338)
Painful heat sensation	11 (36/338)
Vessel wall injury*	9 (29/338)
Peripheral embolism	3 (9/338)
Local bleeding at puncture site	2 (6/338)
Emergency surgery (because of emboli, n = 3; bleeding at puncture site, n = 2)	1.5 (5/338)
Arteriovenous fistula	0.6 (2/338)
Vascular spasm	0.6 (2/338)
Pseudoaneurysm (required further surgery; no further details reported)	0.3 (1/338)

*29/36 patients who reported painful heat sensation subsequently developed a vessel wall injury (15 cases of dissection and 14 cases of perforation). After administration of protamine sulphate, perforation rethrombosed rapidly in all but 2 patients (who developed large haematomas at the perforation site).

In patients with reocclusion (n = 39):

Complication	% (n/N)
Rethrombosis (within first month)	72 (28/39)
Reoperations:	
Bypass surgery	56 (22/39)
Second laser recanalisation	13 (5/39)
Intra-arterial fibrinolysis (in patients in whom with rethrombosis occurred within 2 weeks)	10 (4/39)

Comments

Study design issues:

- Multicentre study
- Follow-up data analysed by means of life-table survival analysis.

Study population issues:

- Occlusions were in the superficial femoral artery in 73% (248/338) of patients, femoropopliteal artery in 16% (53/338) of patients and popliteal artery in 11% (37/338) of patients.

Other issues:

- There may be some overlap of patients with Lammer (1992)[1].

Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; SFA, superficial femoral artery

Study details	Key efficacy findings	Key safety findings	Comments
Technique: Percutaneous laser angioplasty with Nd-YAG laser (Surgical Laser Technologies) activated following unsuccessful guide-wire recanalisation. After successful laser recanalisation, 98% of patients underwent balloon dilatation to widen the artery to its original lumen. After recanalisation, IV infusion of heparin was continued for 2 days and most patients subsequently underwent long-term platelet inhibition therapy. **Follow-up: 3 years** Conflict of interest/source of funding: not reported	asymptomatic and PTA was not indicated. 12% (39/338) of patients developed a reocclusion within the recanalised segment.	Amputation 13 (5/39) Conservative therapy (no further details) 8 (3/39)	

Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; 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>Douek PC (1991)[7]

Case series
USA
Recruitment period: 1987–9
Study population: patients with occlusive peripheral vascular disease including claudication (n = 110), rest pain (n = 21) and gangrenous changes (n = 21).

N = 129 (140 occlusions)

Age: mean 65 years

Sex: 76% male

Patient selection criteria: Patients with chronic total occlusions. Criteria for exclusion were lack of peripheral runoff, unsatisfactory risk profile for general anaesthesia if urgent surgery was necessary and lesions crossed with standard guide-wire techniques.

Technique: Fluorescence-guided, pulsed dye laser-assisted balloon angioplasty. Patients underwent treatment with continuous administration of heparin for 6–24 hours for systemic effect.</td>
<td>Number of patients analysed: 95

Procedural success
Procedural success (defined as ‘primary laser recanalisation of a total occlusion with documented contrast patency’) was achieved in 72% of lesions (101/140) following the laser procedure. Subsequent balloon angioplasty was unsuccessful in 6 lesions in which laser success was achieved.
Laser recanalisation failures were because of heavily calcified fibrotic obstructions or after perforations or dissections.

Vascular success
<table>
<tr><th>Time point (n)</th><th>ABI</th></tr>
<tr><td>Baseline (n = 129)</td><td>0.57 ± 0.17</td></tr>
<tr><td>Immediately after treatment (n = unclear)</td><td>0.86 ± 0.23*</td></tr>
<tr><td>2 months (n = 61)</td><td>0.90 ±0.20*</td></tr>
<tr><td>6 months (n = 55)</td><td>0.83± 0.23+</td></tr>
</table>
Reported in limbs with initial angiographic success.
*Significant change compared with baseline (p < 0.001).
+Not significant compared with 2-month follow-up.</td>
<td>Complications
<table>
<tr><th>Complication</th><th>% (n/N) lesions</th></tr>
<tr><td>Perforation</td><td>19 (27/140)</td></tr>
<tr><td>Dissection</td><td>14 (20/140)</td></tr>
<tr><td>Haematoma</td><td>6 (8/140)</td></tr>
<tr><td>Thrombosis</td><td>4 (6/140)</td></tr>
<tr><td>Distal embolisation</td><td>4 (5/140)</td></tr>
<tr><td>Arterial spasm</td><td>1 (2/140)</td></tr>
</table>
Multiple complications occurred in 12 lesions.

Needing secondary intervention (within 1 month of procedure; 12 lesions)
<table>
<tr><th>Complication</th><th></th></tr>
<tr><td>Peripheral emboli (immediately after the procedure)</td><td>3 patients; treated by surgical embolectomy or a femoro-popliteal bypass.</td></tr>
<tr><td>Groin haematomas</td><td>3 patients; required transfusion or surgical evacuation.</td></tr>
<tr><td>Persistent bleeding from a perforation site</td><td>1 patient; needed proximal embolisation of coils</td></tr>
</table></td>
<td>Follow-up issues:
• In patients with angiographic success (n = 95), 42% lost to follow-up at 6 months.

Study design issues:
• Details of patient recruitment not reported.

Study population issues:
• 85% of lesions were in SFA, 9% in iliac arteries, 5% in popliteal arteries, and 1% in common femoral artery.
Other issues:
• Critical evaluation of diagnostic fluorescence spectroscopy not performed for all lesions in all centres.
• Variability in laser energies used and guide-wire recanalisation methods.</td>
</tr>
</table>

<table>
<tr><td colspan="4">Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; SFA, superficial femoral artery</td></tr>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr><td>Follow-up: 6 months

Conflict of interest/source of funding: not reported.</td><td></td><td>
<table>
<tr><td>Thrombosis</td><td>5 patients; treated successfully with thrombolytic therapy and repeated angioplasty</td></tr>
<tr><td>Thrombus of SFA (because of an enlarging haematoma)</td><td>1 patient; treated by thrombectomy</td></tr>
</table>
Following angiographic success (95/140 lesions)
<table>
<tr><th>Complication</th><th></th></tr>
<tr><td>Hospitalisation</td><td>8 patients (for repeated balloon angioplasty, n = 2; bypass surgery n = 2; stent placement, n = 1).</td></tr>
<tr><td>Below the knee amputations (no further details reported)</td><td>3 patients</td></tr>
<tr><td>Mortality</td><td>5 patients (1 patient from complications of below-knee popliteal-to-peroneal bypass surgery; 1 from complications of diabetes and 2 from complications of femoropopliteal and aortobifemoral bypass surgery; 1 unrelated to the procedure)</td></tr>
</table>
</td><td></td></tr>
</table>

<table>
<tr><td colspan="4">Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; SFA, superficial femoral artery</td></tr>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr><td></td><td></td><td>Rate of complications (by lesion length)
<table>
<tr><th>Lesion length (cm)</th><th>Number of lesions</th><th>Complication rate (%)</th></tr>
<tr><td>< 3</td><td>9</td><td>11</td></tr>
<tr><td>3–10</td><td>83</td><td>39</td></tr>
<tr><td>> 10</td><td>48</td><td>53</td></tr>
</table>
Study reported ‘the differences in the complication rates are clinically significant (p = 0.005)’.</td><td></td></tr>
</table>

Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; 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>Stoner MC (2007)[8]
Case series
USA

Recruitment period: 2004–6

Study population: patients with critical limb ischaemia (65%) and lower limb claudication (35%).

N = 40 patients (47 lesions)
Age: mean 68 years
Sex: 48% male

Patient selection criteria: Patients undergoing laser-assisted lower extremity revascularisation identified in a prospectively maintained computerised database.

Technique: Atherectomy undertaken with Excimer laser (CliRpath, Spectranectics) using a step-by-step technique. Adjunctive angioplasty (75%) or stenting (13%) undertaken at the discretion of the operating surgeon.

Follow-up: mean 461 days
Conflict of interest/source of funding: none.</td>
<td>Number of patients analysed: 40

Technical success
Technical success (defined as ‘ability to cross the target lesion with a wire and achieve a residual stenosis < 50%’) was achieved in 88% (35/40) of patients.

Haemodynamic success
Haemodynamic success (defined as ‘an increase in ABI > 0.01 or 5 mm improvement in pulse volume recording tracing’) was achieved in 75% (30/40) of patients.

Change in ABI: mean > 0.26 (SE 0.03)

Primary patency (at 12 months)
43.8% for all patients and 55% for critical limb ischaemia patients.

Limb salvage
Limbs were salvaged in 73% (19/26) of patients with critical limb ischaemia (4 above knee and 3 below knee amputations). No limb loss in patients with severe claudication.</td>
<td>Complications (30 days)
Overall: 33% (13/40) patients

<table>
<tr><th>Complication</th><th>% (n/N)</th></tr>
<tr><td>Dissection (non-flow limiting)</td><td>12.5 (5/40)</td></tr>
<tr><td>Death (not related to the revascularisation procedure)</td><td>5 (2/40)</td></tr>
<tr><td>Vessel perforation</td><td>5 (2/40)</td></tr>
<tr><td>Arteriovenous fistula</td><td>2.5 (1/40)</td></tr>
<tr><td>Pseudoaneurysm</td><td>2.5 (1/40)</td></tr>
<tr><td>Haematoma or bleeding</td><td>2.5 (1/40)</td></tr>
<tr><td>Other</td><td>2.5 (1/40)</td></tr>
</table>

All complications managed conservatively and no emergency procedures were needed.</td>
<td>Study design issues:
• Retrospective review
• Single centre study.

Study population issues:
• Patients with dialysis dependence and renal insufficiency included.

Other issues:
• Primary patency was determined by Rutherford guidelines and routine physiologic examinations in patients without a palpable pulse.</td>
</tr>
</table>

Abbreviations used: ABI, Ankle Brachial Index; AHA, American Heart Association; PTA, percutaneous transluminal angioplasty; 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>Scheinert D (2001)[9]
Case series
Germany
Recruitment period: 1995–96
Study population: patients with superficial femoral artery occlusions
n = 318 (411 occlusions)
Age: 64 years (mean)
Sex: 65% male

Patient selection criteria: angiographically confirmed chronic femoral artery occlusion > 10 cm long, > 6 months claudication – without symptomatic deterioration.

Technique: under fluoroscopic control laser atherectomy with CVX 300 (Spectranetics) or LAIS DYMER 200+ (Advanced Interventional Systems) using an over the wire or step-by-step technique. Balloon dilatation was performed in all cases after successful laser passage and stents implanted in 7.3% of cases.

Follow-up: 12 months (median)
Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 318 (411 occlusions)

Technical success
Defined as restored patency of vessel with < 30% residual stenosis on angioplasty, success was achieved in 83.2% (342/411) of superficial femoral artery occlusions.
Mean ABI improved significantly from 0.62 ± 0.15 at baseline to 0.95 ± 0.15 (measurement of significance not reported).

Clinical outcomes
Assessed using the Rutherford chronic limb status grading, post-operatively.
<table>
<tr><th>Change in status over baseline</th><th>Proportion</th></tr>
<tr><td>2 or more grades (marked improvement)</td><td>77.7% (247/318)</td></tr>
<tr><td>1 grade (minor improvement)</td><td>8.2% (26/318)</td></tr>
<tr><td>0 grades (no improvement)</td><td>14.1% (45/318)</td></tr>
</table>
Long-term patency
During 1 year of follow-up, 257 vessels reoccluded or restenosed. At 12-month follow-up, cumulative primary patency (defined as uninterrupted patency with no procedures performed on the treated segment or at its margins) was 0.336. Secondary patency (with additional interventions during laser atherectomy, or additional percutaneous interventions) was 0.759 at 12 months.</td>
<td>Complications:
There were no deaths or major procedure-related complications (such as amputation or surgical intervention).
<table>
<tr><th>Outcome</th><th>Rate</th></tr>
<tr><td>Acute reocclusion</td><td>1.0% (4/411)</td></tr>
<tr><td>Perforation</td><td>2.2% (9/411)</td></tr>
<tr><td>Embolisation/distal thrombosis</td><td>3.9% (16/411)</td></tr>
<tr><td>Pseudoaneurysm (treated by ultrasound-guided compression)</td><td>3.6% (15/411)</td></tr>
<tr><td>Haematoma</td><td>2.9% (12/411)</td></tr>
</table>
</td>
<td>Follow-up issues:
• Retrospective study.
• Analysis based on intention-to-treat principle.

Study design issues:
• Comprehensive assessment of patency at follow-up.
• Primary patency was defined as patency with no other procedures.

Study population issues:
• Highly selected patient cohort.

Other issues:
• Different patient population from Steinkamp (2002)[3] above, because different arterial lesions being treated.
• Definition of assisted and secondary patency not clear.</td>
</tr>
</table>

Efficacy

Patency

A randomised controlled trial of 116 patients reported that angiographically assessed patency was achieved in 45% of patients treated by pulsed laser atherectomy catheter plus balloon angioplasty, 36% of patients treated by continuous-wave laser atherectomy catheter plus balloon angioplasty, and 50% of patients treated by balloon angioplasty alone at 1-year follow-up (measurement of significance not reported)[1].

A case series of 452 patients in patients treated by laser atherectomy reported a primary patency rate of 26% (defined as uninterrupted patency with no procedure performed during the follow-up period). The primary-assisted patency (defined as lesions needing percutaneous transluminal angioplasty for restenosis) rate was 41% and the secondary patency (if reocclusion was successfully retreated) rate was 43% of all patients in whom recanalisation was attempted at 48-month follow-up[4].

A case series of 318 patients (411 lesions) treated by laser atherectomy plus balloon angioplasty reported that primary patency (defined as uninterrupted patency with no procedures performed on the treated segment or at its margins) in patients was achieved in 34% of patients at 1-year follow-up[9].

Clinical success

A randomised controlled trial of 81 patients with 84 occlusions (41 occlusions were treated by laser and 43 were treated by balloon dilatation), reported clinical success (defined as a ‘relief of symptoms and improved peripheral pulses up to 2 weeks after the procedure’) in 79% (27/34) of patients treated by laser recanalisation and 85% (29/34) of patients treated by conventional recanalisation[2].

Limb salvage

A case series of 40 patients (47 lesions) treated by laser atherectomy with or without balloon angioplasty or stenting reported that limb salvage was achieved in 73% (19/26) of patients with critical limb ischaemia at mean 461-day follow-up[8].

Clinical signs

A non-randomised controlled study of 215 patients reported that there was an improvement in American Heart Association limb status grade of 1 grade in 19% (24/127) of patients, 2 grades in 20% (25/127) of patients, and 3 grades in 10% (13/127) of patients treated by laser atherectomy plus balloon angioplasty at 36-month follow-up. The respective percentages in patients treated by balloon angioplasty alone were 20% (18/88), 18% (16/88), and 11% (10/88) (significance not reported)[3].

The non-randomised controlled study of 215 patients reported significantly improved mean ankle brachial index 'at rest' for the 167 patients in whom technical success had been achieved (105 patients treated by laser atherectomy plus balloon angioplasty and 62 patients treated by balloon angioplasty alone in whom technical success was achieved). Pressure indices improved significantly from baseline to 36-month follow-up in both the laser atherectomy plus balloon angioplasty group (0.34 ± 0.16 to 0.55 ± 0.16) ($p < 0.001$) and the balloon angioplasty alone group (0.33 ± 0.18 to 0.52 ± 0.13) ($p < 0.001$) (measurement of significance not reported)[3].

The case series of 452 patients initially treated by laser atherectomy reported that 53% (204/386) of patients had 'moderate' or 'marked' improvement at 48-month follow-up (defined as at least single clinical category improvement and ABI increase > 0.10, but not normal)[4].

Safety

It is difficult to assess which safety outcomes for this procedure relate specifically to laser atherectomy rather than to adjunctive treatments such as balloon angioplasty.

Mortality (30 days)

A case series of 40 patients who had laser atherectomy (with or without balloon angioplasty or stenting) reported that 5% (2/40) of patients died within 30 days of the procedure but stated that neither death was related to the revascularisation procedure (no further details reported).

Dissection/perforation

Dissection of the arterial wall occurred in 35% (13/37) of patients following atherectomy with pulsed laser plus balloon angioplasty, 20% (8/40) of patients following atherectomy with a continuous-wave laser plus balloon angioplasty, and 15% (6/39) of patients treated by balloon angioplasty alone in the randomised controlled trial of 116 patients ($p = 0.005$) [1].

Vessel perforation occurred in 3% (4/127) of patients treated by laser atherectomy plus balloon angioplasty in the non-randomised controlled study of 215 patients at 36-month follow-up (no further details given); the rate in patients treated by balloon angioplasty alone was not reported[3].

A perforation of the vessel wall was reported in 4% (15/386) of patients in the case series of 452 patients treated by laser atherectomy[4].

Vessel wall injury (15 cases of dissection; 14 of perforation) was reported in 9% (29/338) of patients in a case series of 338 patients treated by laser atherectomy as an adjunct to balloon angioplasty (in 98% of patients) or laser atherectomy alone (complications occurred 'during or after the procedure')[6].

Embolisation

Complete or partial embolic occlusion of the proximal lower limb artery was reported in 3% (4/127) of patients treated by laser atherectomy plus balloon angioplasty (3 were symptomatic and were treated by dilatation or local lysis) and in 6% (5/88) of patients treated by balloon angioplasty alone (4 were symptomatic and were treated by dilatation or local lysis) in the non-randomised controlled study of 215 patients at mean 36-month follow-up[3].

Complete or partial embolic occlusion of the peroneal trunk or of proximal lower limb arteries was reported in 15 patients (shown on angiograph; denominator unclear, but may relate to 386 patients in whom the procedure was technically successful) in the case series of 452 patients. Among those 15 patients, 10 had symptoms (treated with angioplasty or local lysis)[4].

Embolisation or distal thrombosis occurred in 4% (16/411) of vessels treated in the case series of 318 patients (411 lesions) at 12-month follow-up. None needed amputation or surgical intervention[9].

Arteriovenous fistula

Arteriovenous fistula was reported in less than 1% (2/338) of patients in the case series of 338 patients ('during or after the procedure')[6] and in 3% (1/40) of patients in the case series of 40 patients at 30-day follow-up.

Pseudoaneurysms

Pseudoaneurysms at the puncture site were reported in 10 patients in a case series of 312 patients treated by laser atherectomy with stenting (if indicated) (these were treated using ultrasound-guided compression)[5].
Pseudonaeurysms were reported in 3% (1/40) of patients in the case series of 40 patients at 30-day follow-up (treated 'conservatively'; no further details reported)[8].

Local warming

Warming of tissues at the treatment site, thought to be due to direct thermal effect of the laser treatment ('during or after' the procedure) was reported in 64% (215/338) of patients in the case series of 338 patients[6].

Validity and generalisability of the studies

- Definitions used for angiographic patency vary between studies, making comparison difficult.
- Many studies are more than 10 years old and laser atherectomy catheters may have evolved over this period. Different types of lasers were used, some of which may be more effective than others. Very few comparative data are available against other endovascular interventions.

- The degree of concomitant treatment with the laser atherectomy procedure (such as stenting or balloon angioplasty) varies between studies, making evaluation of laser atherectomy as a standalone procedure difficult.
- The patient populations treated vary within and between studies, from claudication with stenosis but no occlusions, to critical limb ischaemia. The trade-off between efficacy and safety may be different in these different groups. Different scales have been used between studies for assessment of limb status, and this makes comparison between studies 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

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices. NICE interventional procedures guidance 380 (2011). Available from www.nice.org.uk/guidance/IPG380

Clinical guidelines

- Lower limb peripheral arterial disease: diagnosis and management. NICE clinical guideline 147 (2012). Available from www.nice.org.uk/guidance/CG147

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.

Specialist advice was received from John Brennan (Vascular Society), Jocelyn Brookes (British Society of Interventional Radiology), Teik Choon (British Society of Interventional Radiology), Sumaira Macdonald (British Society of Interventional Radiology), Mark McCarthy (Vascular Society), Sophie Renton (Vascular Society) and Mark Thornton (British Society of Interventional Radiology).

- One Specialist Adviser carries out this procedure regularly.
- Three Specialist Advisers regard the procedure as definitely novel and of uncertain safety and efficacy. One Specialist Adviser stated that laser atherectomy is relatively novel in that there is less evidence for the peripheral arteries, however, the safety and efficacy are likely to be comparable with percutaneous atherectomy devices in peripheral arterial

disease. Two Specialist Advisers regarded percutaneous laser atherectomy as a minor variation on an existing procedure and another Specialist Adviser stated that this procedure is established practice.

- The Specialist Advisers considered the main comparator interventions to be percutaneous balloon angioplasty with or without stenting, angioplasty with stenting, or percutaneous atherectomy with rotational atherectomy devices.
- The Specialist Advisers listed adverse events reported in the literature as amputation, dissection, perforation, acute thrombosis, distal embolisation, compartment syndrome, pseudoaneurysm formation and access site complications.
- The Specialist Advisers considered theoretical adverse events as thermal injury, laser related complications and arteriovenous fistula.
- The Specialist Advisers listed key efficacy outcomes as arterial diameter and increase in blood flow, tissue healing, symptom relief and improvement in quality of life, requirement for adjunctive angioplasty and/or stenting, re-intervention rate, and amputation-free survival.
- Most of the Specialist Advisers regarded training in the use of the laser catheter as important.
- If found to be safe and efficacious, percutaneous laser atherectomy is likely to be offered in fewer than ten specialist centres.

Patient Commentators' opinions

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

Issues for consideration by IPAC

- A significant proportion of the evidence comes from old studies, in which the laser elements of the intervention appear to be assisting balloon angioplasty rather than being the primary management strategy.
- A wide range of arterial lesions have been treated. It is possible that the safety and efficacy of the procedure may differ between distal and proximal arterial sites or between narrower and wider arteries. The scope was non-specific in this regard.
- Non-English language studies were not included in the overview.

References

1. Lammer J, Pilger E, Decrinis M et al. (1992) Pulsed excimer laser versus continuous-wave Nd:YAG laser versus conventional angioplasty of peripheral arterial occlusions: prospective, controlled, randomised trial. Lancet 340: 1183−8.
2. Belli AM, Cumberland DC, Procter AE. et al (1991) Total peripheral artery occlusions: conventional versus laser thermal recanalization with a hybrid probe in percutaneous angioplasty--results of a randomized trial. Radiology Oct;181(1):57-60.
3. Steinkamp HJ, Rademaker J, Wissgott C et al. (2002) Percutaneous transluminal laser angioplasty versus balloon dilation for treatment of popliteal artery occlusions. Journal of Endovascular Therapy 9: 882–8.
4. Wissgott C, Scheinert D, Rademaker J et al (2004) Treatment of Long Superficial Femoral Artery Occlusions with Excimer Laser Angioplasty: Long-Term Results After 48 Months. Acta Radiologica.45:23-9.
5. Steinkamp HJ, Rademaker J, Wissgott C et al. (2002) Percutaneous transluminal laser angioplasty versus balloon dilation for treatment of popliteal artery occlusions. Journal of Endovascular Therapy 2002 Dec;9(6):882-8.
6. Lammer J, Pilger E, KarnelFet al. (1991) Laser angioplasty: results of a prospective, multicenter study at 3-year follow-up. Radiology Feb;178(2):335-7.
7. Douek PC, Leon MB, Geschwind H, et al. (1991) Occlusive peripheral vascular disease: a multicenter trial of fluorescence-guided, pulsed dye laser-assisted balloon angioplasty. Radiology Jul;180(1):127-33.
8. Stoner MC, deFreitas DJ, Phade SV et al (2007) Mid-term results with laser atherectomy in the treatment of infrainguinal occlusive disease. J VascSurg 46:289-95
9. Scheinert D, Laird JR Jr, Schroder M et al. (2001) Excimer laser-assisted recanalization of long, chronic superficial femoral artery occlusions. Journal of Endovascular Therapy 8: 156–66.

Appendix A: Additional papers on percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease

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
Balzer JO, Gastinger V, Thalhammer A et al. (2006) Percutaneous laser-assisted recanalization of long chronic iliac artery occlusions: primary and mid-term results. European Radiology 16: 381–90.	N = 43 Follow-up = 45 months	Technical success achieved in 95.3% of patients. Primary patency was 86.1% and secondary patency 95.4% at 48 months follow-up. Overall complications was 11.6%.	Larger studies included in table 2.
Bauer R, Pokorny E, Muckenhuber P,et al(1991) Is laser assisted angioplasty a real alternative to surgical treatment of occluded peripheral vessels? European Journal of Vascular Surgery Dec;5(6):637-40.	N = 250 Follow-up = 3 years	The primary success rate was 81.5% with a perforation rate of less than 2%. The patency rate after 96 weeks was 80%. Complications included embolisations (n = 10), dissections (n = 7), acute renal failure (n = 4) and heat perforation (n = 4).	Larger studies included in table 2.
Belli AM, Cumberland DC, Myler RK et al. (1990) Peripheral arterial occlusions: initial results from percutaneous angioplasty with a hybrid laser probe.Radiology 174 (2): 447−9.	N = 37 Follow-up = 6 months	Primary success in the iliac segments was 70% and in the femoropopliteal segments was 85% (overall, 81%). The only complication was an arterial wall perforation, which had no sequelae.	Larger studies included in table 2.
Belli AM, Cumberland DC, Procter AE et al (1991)Follow-up of conventional angioplasty versus laser thermal angioplasty for total femoropopliteal artery occlusions: results of a randomized trial. Journal of Vascular & Interventional Radiology Nov;2(4):485-8.	N = 68 Follow-up = 1 year	At 1-year follow-up, the cumulative success rate was 47% for patients treated with conventional angioplasty versus 39% for those treated with laser angioplasty. Statistical analysis showed no significant difference in clinical success between the two treatment groups	Larger studies included in table 2.
Berengoltz-Zlochin SN, Westerhof PW, Mali WP et al. (1992) Nd:YAG laser-assisted angioplasty in femoropopliteal artery occlusions: 'hot' versus 'cold' recanalization with transparent contact probe.	N = 50 Follow-up = 12 months	Cold and hot groups did not differ with regard to functional improvement and angiographic patency at 3 and 12 months.	Larger studies included in table 2.

Radiology 182 (2): 409–14.			
Berengoltz-Zlochin SN, Mali WP, Borst C et al.(1994) Subintimal versus intraluminal laser-assisted recanalization of occluded femoropopliteal arteries: one-year clinical and angiographic follow-up. Journal of Vascular &Interventional Radiology	n = 64 Follow-up = 1 year	Significant complications were distal embolisation in 3 patients, followed by death in 1 patient and puncture site bleeding in 2 patients. The 1-year clinical and angiographic results of assumed subintimal and intraluminal recanalisation are comparable.	Larger studies included in table 2.
Boccalandro F, Muench A, Sdringola S et al. (2004) Wireless laser-assisted angioplasty of the superficial femoral artery in patients with critical limb ischemia who have failed conventional percutaneous revascularization. Catheterization and Cardiovascular Interventions 63 (1): 7–12.	N = 25 Follow-up = 13 months	These results suggest that the use of laser ablation is safe and facilitates angioplasty and stenting in patients with critical limb ischaemia that failed conventional endovascular revascularisation. This technique might prevent limb loss in patients with critical limb ischaemia caused by femoropopliteal total occlusions, particularly in patients for whom surgical revascularisation is unsuitable.	Larger studies included in table 2.
Bosiers M, Hart JP, Deloose K (2006)Endovascular therapy as the primary approach for limb salvage in patients with critical limb ischemia: experience with 443 infrapopliteal procedures. Vascular14(2):63-9.	N = 443 Follow-up = 12 months	The primary patency and limb salvage rates of the entire population were 85.2% and 97.0% and 74.2% and 96.6% at 6 months and 1 year, respectively. Stratified for the treatment strategy (PTA alone in 79, PTA with stenting in 300 patients, and laser in 64), 1-year primary patency rates were 68.6%, 75.5%, and 75.4%, whereas the limb salvage rates were 96.7%, 98.6%, and 87.9% for each modality, respectively	Larger studies included in table 2.
Cull DL, Feinberg RL, Wheeler JR, et al. (1991) Experience with laser-assisted balloon angioplasty and a rotary angioplasty instrument: lessons learned. Journal of Vascular Surgery 14(3):332-9.	N = 93 Follow-up = 19 months	Technically successful recanalization was achieved in 67% of Kensey dynamic angioplasty instrument-assisted balloon angioplasty procedures and 82% of laser-assisted balloon angioplasty procedures.	Larger studies in table 2
Dave RM, Patlola R, Kollmeyer K, Bunch F, Weinstock BS, Dippel E, 2009et al. Excimer laser recanalization of femoropopliteal lesions and 1-year patency: results of the CELLO registry. Journal of Endovascular Therapy Dec;16(6):665-75.	N = 65 Follow-up = 12 months	Patency rates (% DS < 50%) were 59% and 54% at 6 and 12 months, in the laser-assisted recanalisation29 with optional balloon angioplasty (BA) or BA and stenting, respectively. There were no major adverse events.	Larger studies included in table 2.
Diethrich EB, Timbadia E, Bahadir I. (1989) Complications of laser-assisted angioplasty. Definition and classification of	N = 349 Follow-up = 15 months	The following complications were reported: hematoma formation, 100 cases (15.0%);	Larger studies included in table 2.

perforations. Texas Heart Institute Journal;16(3):171-6.		perforation/dissection, 38 cases (5.7%); acute thrombosis, 23 cases (3.5%); false aneurysm formation at the puncture site, 7 cases (1.1%); vascular spasm, 5 cases (0.8%); and embolism, 1 case (0.2%).	
Fisher CM, Fletcher JP, May Jet al. (1996) No additional benefit from laser in balloon angioplasty of the superficial femoral artery. European Journal of Vascular & Endovascular Surgery Apr;11(3):349-52.	N = 82 Follow-up = 350 days -	This study found no significant benefit was gained by the addition of laser to balloon angioplasty and that the long term success was modest for lesions considered to be suitable for angioplasty	Larger studies included in table 2.
Fletcher JP, Hazelton S, Wong KP(1992)et al. Laser angioplasty for superficial femoral and proximal popliteal artery occlusion. Journal of Cardiovascular Surgery ;33(1):75-8.	N = 93 Follow up = mean 18 months	Technical success was achieved in 78 patients (84%). The crude patency rate for successfully recanalised vessels was 48% during a mean follow-up period of 18 months. Subsequent femoropopliteal bypass or amputation was required in 20% of these patients. Factors predictive of reocclusion were a length of occluded segment greater than 8 cm (p = 0.05) and less than two patent vessels below the knee (p = 0.005)	Larger studies included in table 2.
Geschwind HJ, Boussignac G, Dubois-Rande J-L et al (1991)Laser angioplasty in peripheral arterial disease. Lasers in Medical Science;6(3):307-10.	N = 66 Follow-up = 18 months	The primary success rate was 82%, the complication rate was 15% without any clinical sequelae and the 18 month follow-up patency rate was 64%.	Larger studies included in table 2.
Geschwind HJ, Aptecar E, Boussignac G et al. (1991) Results and follow-up after percutaneous pulsed laser-assisted balloon angioplasty guided by spectroscopy. Circulation Mar;83(3):787-96.	N = 66 Follow-up = 18 months	The primary success rate was 82%. Complications included early reocclusions (n = 7) that could be recanalised and perforations without clinical sequelae (8) . At a mean 18-month follow-up, 64% of the laser-treated arteries remained patent.	Larger studies included in table 2.
Haase KK, Baumbach A, Hanke H,et al (1992). Success rate and incidence of restenosis following coronary excimer laser angioplasty: results of a single center experience. Journal of Interventional Cardiology;5(1):15-23.	N = 96 Follow-up = mean 163 days	Late adverse events included nine repeat PTCA with ELCA +/- PTCA (19%) versus 12 with PTCA (24%), three CABG with ELCA +/- PTCA (6%) versus two with PTCA (4%), and one death (2%) with PTCA (P = NS). Angiographic restenosis rate was 52% with ELCA +/- PTCA versus 47% with PTCA alone (P = NS). Our data suggest that excimer laser angioplasty with adjunctive balloon dilatation for the treatment of in-stent restenosis provides similar	Studies with longer length of follow-up included in table 2.

		acute results as plain balloon dilatation and may offer no advantage over PTCA alone with regard to intermediate-term outcomes	
Hundt C, Berger H, Schmand J, (1993) Therapy of peripheral arterial disease: Laser-assisted angioplasty combined with intravascular endoprosthetic stents. Vascular Surgery;27(2):81-8.	N = 56 Follow-up = mean 16 months	The initial success rate of PTLA was 83.9%. Reocclusions (4 immediate and 5 at follow-up) occurred only in patients with initially insufficient morphologic result after balloon dilatation. In 17 of such cases with residual stenosis after PTLA, stents were implanted. Stent implantation was completed in 88.2%. The overall cumulative success was 68.4%. No difference was observed in this study between the long-term patency rates of treated iliac and femoropopliteal vessels. The combination of laser recanalization and implantation of vascular stents is a promising method in the management of peripheral arterial occlusive disease. It can prevent reocclusions after PTLA and avoids bypass surgery	Larger studies included in table 2.
Huppert PE, Seboldt H, Duda SH et al (1991) Laser angioplasty of peripheral arterial occlusive disease. Thoracic & Cardiovascular Surgeon 39: Suppl-51.	N = 103 Follow-up = 12 months Dilatation performed subsequently if a >30% stenosis after the laser procedure.	The clinical success rate at 6 and 12 months after the treatment was better in occlusions with a length between 6 and 10 cm, however no improvement was seen in either shorter or longer occlusion. Clinical success rate was 68% at 1 year after excimer laser-assisted angioplasty.	Larger studies included in table 2.
Laird JR, Zeller T, Gray BH et al. (2006) Limb salvage following laser-assisted angioplasty for critical limb ischemia: results of the LACI multicenter31 trial. Journal of Endovascular Therapy: Official Journal of the International Society of Endovascular Specialists 13: 1–11.	N = 145 Follow up = 6 months	Procedural success was achieved in 85.2% (132/155) limbs. Avoidance of major amputation was achieved in 92.9% (118/127) of limbs.	Larger studies included in table 2.
Levy JM, Hessel SJ, Horsley WW(1989) Value of laser-assisted angioplasty in the community hospital. Radiology ;170(3:Pt 2):t-8.	N = 80 Follow up = 7 month	65% (11/17) laser-assisted angioplasty was successful (technical success – if symptoms abated within 24 hours). No significant complications were encountered. In 2 patients, the laser perforated the lumen of the superficial femoral artery without sequelae. No significant bleeding, haematoma or	Larger studies included in table 2.

		thrombosis was observed. No patient required immediate transfusion or surgery.	
Litvack F, Grundfest WS, Adler L et al. (1989) Percutaneous excimer-laser and excimer-laser-assisted angioplasty of the lower extremities: results of initial clinical trial. Radiology 172 (2): 331–5.	N = 30 Follow-up = 9 months	The data suggest that these procedures may be useful for the treatment of peripheral vascular disease in selected patients.	Larger studies included in table 2.
Marzelle J, Fichelle J-M, Cormier F et al. (1995) Outcome of infrainguinal endovascular revascularization procedures for limb-threatening ischemia. Annals of Vascular Surgery;9(SUPPL.):S24-S31.	N = 86 Follow-up = 10 months	Primary patency, secondary patency and limb salvage rates calculated according to the actuarial method were 65%, 75%, and 84%, respectively, at 6 months and 47%, 67%, and 81%, respectively, at 1 year. Limb salvage rates for the endoluminal techniques used in this study were satisfactory, especially in elderly patients with either segmental lesions or contraindications for distal bypass	Larger studies included in table 2.
McAlpin GM, Rama K, Berg RA. (1991) Thermal laser assisted balloon angioplasty in lower extremity occlusive disease. American Surgeon ;57(9):558-65.	N = 23 Follow-up = range 6 -12 months	Twenty-four (86%) procedures were technically successful; however, there were only 15 (54%) clinical successes during the follow-up period (0.5-12.5 months). Complications occurred following 10 (36%) procedures with 1 mortality (4%) unrelated to the procedure.	Larger studies included in table 2.
Odink HF, de Valois HC, Eikelboom BC (1991) Femoropopliteal arterial occlusions: laser-assisted versus conventional percutaneous transluminal angioplasty. Radiology 181 (1): 61–6.	N = 75 (legs) Follow-up = 1 day	This method appeared to be safe and allowed passage through occlusions longer than 10 cm.	Studies with longer follow-up included in table 2.
Odink HF, de Valois HC, Eikelboom BC. (1995) Femoropopliteal artery recanalization: factors affecting clinical outcome of conventional and laser-assisted balloon angioplasty. Cardiovascular and Interventional Radiology 18: 162–7.	N = 47 Follow up = 1 year	Clinical success was achieved in 59% of patients at 1 year, 53% at 2 years and 53% at 3 years. Occlusion length was not related to successful clinical outcome.	Larger studies included in table 2.
Okada M, Yoshida M, Tsuji Y. (1998) Clinical experience of endovascular laser intervention in cardiovascular disease. Journal of Clinical Laser Medicine & Surgery 16(5):249-54.	N = 113 Follow-up = 106 months	The initial success rate of laser angioplasty for the peripheral artery was 92% in the stenotic lesions and 73% in the occlusive lesions. However, cumulative patency rate was 85% in the stenotic lesions and 74% in the occlusive lesions in the long-term follow-up study of	Larger studies in table 2.

		106 months among the patients with clinical success	
Pilger E, Lammer J, Bertuch H, et al. (1991) Nd:YAG laser with sapphire tip combined with balloon angioplasty in peripheral arterial occlusions. Long-term results. Circulation ;83(1):141-7.	N = 167 Follow-up = mean 14 months	PTLA was unsuccessful in 35 patients, and in 15 of these, injury of the vessel wall occurred. In one patient, surgical drainage of a large hematoma became necessary. 15/103 complained of burning pain and ceased when laser was not activated. In 9% (15/167) , dissection (9/167) or perforation (6/167) of the vessel wall was detected.	Larger studies in table 2.
Richards DM, Hulton NR, McIntosh IH et al. (1994) The evolving role of laser-assisted angioplasty in a United Kingdom district general hospital. Annals of the Academy of Medicine, Singapore Jan;23(1):35-7.	N = 55 Follow up = mean 7 months	The overall success rate for LAA alone was 79%. The guide wire followed by laser-assisted angioplasty , if necessary, succeeded in 77%. The 'hot probe' resulted in four perforations; only one perforation was seen with the guide wire.	Larger studies in table 2.
Sanborn TA, Cumberland DC, Greenfield AJ et al.(1988) Percutaneous laser thermal angioplasty: Initial results and 1-year follow-up in 129 femoropopliteal lesions. Radiology;168(1):121-5	n = 119 Follow-up = 1 year	The 1-year cumulative clinical patency was 77% for the 99 lesions with an initial clinical success. In the 21 stenoses and 17 short occlusions, the cumulative clinical patency rates were 95% and 93%, respectively. In the longer occlusions (4–7 cm and greater than 7 cm), the clinical patency rates were 76% and 58%, respectively. Complications reported included perforation, dissection with probe, dissection with guide wire, thrombosis in first 72 hours and transient embolisation33 in 24 hours.	Larger studies in table 2.
Serino F, Cao Y, Renzi C et al. (2011) Laser atherectomy in the treatment of critical limb ischemia in diabetic patients. Italian Journal of Vascular and Endovascular Surgery;18(1):39-43.	N = 35 Follow-up = median 6 months	The patency rates (freedom from target lesion revascularization) were 94.7% at three months, 91.8% at six months, 85.0% at nine months, 85.0% at 12 months and 72.8% at 15 months. Limb salvage rate at 6 and 12 months were 100% and 94% (33 out of the 35 patients) respectively. Our study showed that the excimer laser assisted angioplasty is effective in limb salvage in CLI patients with diabetes, and that endoluminal driven atherectomy allows long-term success reducing the need of stents application in the lower limb arteries	Larger studies in table 2.

Shrikhande GV, Khan SZ, Hussain HG et al. (2011) Lesion types and device characteristics that predict distal embolization during percutaneous lower extremity interventions. Journal of Vascular Surgery 53: 347−52.	N = 1029 (55 laser atherectomy) Follow up = 2 years	Distal embolisation34was reported in 3.6% (2/55) patients treated by laser atherectomy.	Larger studies in table 2.
Spies JB, LeQuire MH, Brantley SD (1990) et al.. Comparison of balloon angioplasty and laser thermal angioplasty in the treatment of femoropopliteal atherosclerotic disease: initial results of a prospective randomized trial. Work in progress. Journal of vascular and interventional radiology : Journal of Vascular and Interventional Radiology1(1):39-42.	N = 25 Follow-up = 1 year	Of the 14 laser procedures, five were initial failures; three of these failures were subsequently treated successfully with the balloon technique. Three of 13 balloon procedures were failures; none were subsequently successful with use of the laser.	Larger studies included in table 2.
Sultan S, Tawfick W, Hynes (2011) Cool excimer laser-assisted angioplasty vs tibial balloon angioplasty in management of infragenicular tibial arterial occlusion in critical lower limb ischemia TASC D. Vascular Disease Management;8(11):E187-E197.	N = 56 Follow-up = 4 years	Four-year limb salvage rates (93% vs 89%, p=0.482) were improved with CELA. There was no 30-day mortality in either group and no significant difference in 30-day morbidity between treatment groups. Technical success (residual stenosis of 30%) was achieved in 80% (24/30 procedures) and 74% (26/35 procedures) for the laser and balloon angioplasty groups, respectively.	Larger studies included in table 2.
Thomas HM, Jr, Siragusa V, Bowers JA et al. (1989) Percutaneous laser-assisted balloon angioplasty of lower-extremity arterial disease in a free-standing laboratory: clinical experience with 100 cases. Texas Heart Institute Journal 16: 216–23.	N = 88 Follow-up = 17 weeks	Technical success was achieved in 75% of limbs (75/100). Serious complications included urgent surgery, fistula and thrombosis.	Larger studies included in table 2.
Tobis JM, Conroy R, Deutsch LS et al. (1991Laser-assisted versus mechanical recanalization of femoral arterial occlusions. American Journal of Cardiology Oct 15;68(10):1079-86.	N = 40 Follow-up = 12 months	The success rate for the laser probe was 75% (15/20), which was not significantly different from the standard method, 95%(19/20). Complications observed perforation of the arterial wall, arteriovenous fistula and haematoma.	Larger studies included in table 2.
Visona A, Liessi G, Bonanome A, , et al. (1992)Percutaneous excimer laser angioplasty of peripheral vessels: Primary success and follow-up results. Vascular Surgery;26(8):622-9.	N = 59 Follow-up = median 6 months	The success rate was higher for lesions < 10 cm in length. Early reocclusion was observed in 7 patients and was associated with poor runoff. The cumulative patency rate was 81% at one month, 67% at six months, and 51% at one year	Larger studies in table 2.
Visona A, Perissinotto C, Lusiani L, et al. (1998) Percutaneous	N = 78 Follow-up= 24	Early reocclusions occurred in 8% of patients. The	Larger studies in

excimer laser angioplasty of lower limb vessels: results of a prospective 24-month follow-up. Angiology ;49(2):91-8.	months	cumulative patency rate was 47% at the 12-month interval and 40% at the 24-month interval. Poor runoff and the length of the lesions negatively influenced the outcome. Excimer laser angioplasty is an effective procedure, indicated in selected patients showing < 10 cm occlusions and good runoff	table 2.
Visona A, Miserocchi L, Lusiani L, et al. (1993) Arterial mapping with color flow duplex imaging of the lower extremities after excimer-laser-assisted angioplasty.Angiology 44 (9): 687–93.	N = 61 Follow-up = 12 months	Colour flow duplex imaging provides an accurate non-invasive technique for following up patients after excimer laser angioplasty, allowing for asymptomatic reocclusions to be recognised and treated if necessary, and permitting symptoms not caused by reocclusions to be properly identified, thus avoiding unnecessary angiography.	Studies with longer follow up included in table 2. Few clinical outcomes reported.
Wollenek G, Laufer G, Grabenwoger F. (1988) Percutaneous transluminal excimer laser angioplasty in total peripheral artery occlusion in man.Lasers in Surgery and Medicine 8 (5): 464–8.	N = 1 Follow-up = 3 months	This percutaneous laser recanalisation35 of an occluded peripheral artery is one of the first to be done in people using excimer laser radiation, thus demonstrating that the technique is feasible and the system potentially useful.	Larger studies included in table 2.

Appendix B: Related NICE guidance for percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease

Guidance	Recommendations
Interventional procedures	**Percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices. NICE interventional procedures guidance 380 (2011)** 1.1 Current evidence on the efficacy of percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices is inadequate in quality. Evidence on safety is inadequate, specifically with regard to the risk of distal embolisation. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/guidance/IPG380/publicinfo). • Audit and review clinical outcomes of all patients having percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices (see section 3.1). 1.3 Further research into percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices should take the form of well-conducted trials, which should define patient selection, treatment protocols and location and types of arterial lesions treated, and report long-term patency outcomes. NICE may review this procedure on publication of further evidence.
Clinical Guidelines	**Lower limb peripheral arterial disease: diagnosis and management. NICE clinical guideline 147 (2012)** **1.5 Management of intermittent claudication** **Angioplasty and stenting** 1.5.3 Offer angioplasty for treating people with intermittent

claudication only when:

- advice on the benefits of modifying risk factors has been reinforced (see recommendation 1.2.1) **and**
- a supervised exercise programme has not led to a satisfactory improvement in symptoms **and**
- imaging has confirmed that angioplasty is suitable for the person.

1.5.4 Do not offer primary stent placement for treating people with intermittent claudication caused by aorto-iliac disease (except complete occlusion) or femoro-popliteal disease.

1.5.5 Consider primary stent placement for treating people with intermittent claudication caused by complete aorto-iliac occlusion (rather than stenosis).

1.5.6 Use bare metal stents when stenting is used for treating people with intermittent claudication.

Bypass surgery and graft types

1.5.7 Offer bypass surgery for treating people with severe lifestyle-limiting intermittent claudication only when:

- angioplasty has been unsuccessful or is unsuitable **and**
- imaging has confirmed that bypass surgery is appropriate for the person.

1.5.8 Use an autologous vein whenever possible for people with intermittent claudication having infra-inguinal bypass surgery.

1.6 Management of critical limb ischaemia

1.6.1 Ensure that all people with critical limb ischaemia are assessed by a vascular multidisciplinary team before treatment decisions are made.

	Revascularisation 1.6.2 Offer angioplasty or bypass surgery for treating people with critical limb ischaemia who require revascularisation, taking into account factors including: • comorbidities • pattern of disease • availability of a vein • patient preference. 1.6.3 Do not offer primary stent placement for treating people with critical limb ischaemia caused by aorto-iliac disease (except complete occlusion) or femoro-popliteal disease. 1.6.4 Consider primary stent placement for treating people with critical limb ischaemia caused by complete aorto-iliac occlusion (rather than stenosis). 1.6.5 Use bare metal stents when stenting is used for treating people with critical limb ischaemia. 1.6.6 Use an autologous vein whenever possible for people with critical limb ischaemia having infra-inguinal bypass surgery.

Appendix C: Literature search for percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease

Databases	Date searched	Version/files	No. retrieved
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	30/07/2012	July 2012	9
Database of Abstracts of Reviews of Effects – DARE (CRD website)	30/07/2012	N/A	0
HTA database (CRD website)	30/07/2012	N/A	0
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	30/07/2012	July 2012	0
MEDLINE (Ovid)	30/07/2012	1946 to July week 3 2012	4
MEDLINE In-Process (Ovid)	30/07/2012	July 27, 2012	0
EMBASE (Ovid)	30/07/2012	1974 to 2012, week 30	18
CINAHL (NLH Search 2.0 or EBSCOhost)	30/07/2012	N/A	7
JournalTOCS	30/07/2012	N/A	0

Trial sources searched

- Current Controlled Trials *meta*Register of Controlled Trials –*m*RCT
- Clinicaltrials.gov
- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database

Websites searched

- National Institute for Health and Clinical Excellence (NICE)
- Food and Drug Administration (FDA) - MAUDE database
- French Health Authority (FHA)
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- Conference search
- General internet search

MEDLINE search strategy

Strategy used:.

1 exp Peripheral Vascular Diseases/
2 Peripheral Arterial Disease/

3 PAD.tw.
4 pvd.tw.
5 PAOD.tw.
6 (Peripher* adj3 Vascul* disease*).tw.
7 (peripher* adj3 arter* disease*).tw.
8 Arterial Occlusive Diseases/
9 (Arter* adj3 occlus* disease*).tw.
10 Atherosclerosis/
11 Atheroscleros*.tw.
12 (Critical* adj3 limb ischem*).tw.
13 or/1-12
14 Atherectomy/
15 (laser* adj3 Atherect*).tw.
16 (laser adj3 assisted angioplast*).tw.
17 or/14-16
18 Clirpath.tw.
19 Cool Laser.tw.
20 or/18-19
21 13 and 17
22 20 or 21
23 exp laparoscopy/
24 exp laparoscopes/
25 surgical procedures, Minimally Invasive/
26 laparoscop*.tw.
27 endoscop*.tw.
28 percutan*.tw.
29 or/23-28
30 22 and 29
31 Animals/ not Humans/
32 30 not 31
33 exp Peripheral Vascular Diseases/
34 Peripheral Arterial Disease/
35 PAD.tw.
36 PVD.tw.
37 PAOD.tw.
38 (Peripher* adj3 Vascul* disease*).tw.
39 (Peripher* adj3 arter* disease*).tw.
40 Arterial Occlusive Diseases/
41 (Arter* adj3 occlus* disease*).tw.
42 Atherosclerosis/
43 Atheroscleros*.tw.
44 (Critical* adj3 limb ischem*).tw.
45 (critical adj3 limb ischaem*).tw.
46 or/33-45
47 Atherectomy/
48 (Laser* adj3 atherect*).tw.
49 (laser* adj3 assist* angioplast*).tw.
50 exp Angioplasty, Laser/
51 or/47-50
52 46 and 51
53 clirpath.tw.
54 Cool Laser.tw.
55 53 or 54
56 52 or 55
57 Animals/ not Humans/

58 56 not 57
59 58 not 32
60 limit 59 to ed=20120101-20120229