NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of percutaneous laser coronary angioplasty

Treating blocked coronary arteries by using a laser with a minimally invasive technique

Blood vessels from the heart can become blocked by the build-up of deposits of fat on their inner surface. This can cause problems with the heart and circulation such as angina.

In this technique, a flexible plastic tube (a catheter), connected to a laser, is inserted though the leg and into the circulation. It is moved to the site of the blockage and the laser is then used to burn away the deposits. This procedure may be done on its own or with other techniques to help remove the deposits and/or keep the blood vessel 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 May 2010.

Procedure name

- Percutaneous laser coronary angioplasty

Specialty societies

- British Cardiovascular Intervention Society
- British Cardiovascular Society.

Description

Indications and current treatment

Coronary artery disease (CAD) refers to the narrowing and occlusion of the coronary arteries as a result of atherosclerosis. This can cause angina, myocardial infarction and heart failure.

Treatment options for patients with CAD with severe stenosis or occlusion include thrombolysis, percutaneous balloon angioplasty, stent placement, percutaneous cutting balloon or coronary artery bypass grafting.

Percutaneous laser coronary angioplasty has been used for CAD with severe stenosis or atherosclerotic occlusion, when standard techniques for recannalisation are unlikely to succeed or have failed.

What the procedure involves

Percutaneous laser coronary angioplasty aims to remove plaque from within coronary arteries. Its proposed advantage is that it can penetrate lesions that are not amenable to standard techniques such as balloon angioplasty or stenting alone.

This procedure involves introduction of a thin, flexible catheter with a laser emitting device at its tip into a coronary artery via femoral access. The catheter is advanced over a guidewire through the artery to the blockage in the coronary artery, under fluoroscopic guidance. The tip of the catheter system emits pulses of laser light to vaporise the plaque while being slowly advanced across the lesion.

Percutaneous laser coronary angioplasty has also been done using a laser guidewire system but that method is not now in regular use.

The procedure is often used with adjunctive balloon angioplasty and followed by angiography to document results.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to percutaneous laser coronary angioplasty. Searches were conducted of the following databases, covering the period from their commencement to 23 February 2010 and updated to 29 September 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 coronary artery disease or saphenous vein graft failure.
Intervention/test	Percutaneous laser coronary angioplasty.
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 28,000 patients from 2 meta-analyses[1,2], 2 randomised controlled trials[3,4], 2 non-randomised controlled studies[5,6], and 3 case series[7,8,9].

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 coronary angioplasty

Abbreviations used: CABG, coronary artery bypass graft; CI, confidence interval; DCA, directional atherectomy; MACE, major adverse cardiac events; MI, myocardial infarction; N/S; not significant; OR, odds ratio; ROTA, rotational atherectomy; SD, standard deviation; SVG, saphenous vein graft; TEC, transluminal extraction atherectomy; TIMI, thrombolysis in MI.

Study details	Key efficacy findings	Key safety findings	Comments
Bittl JA (2004)[1] **Meta-analysis** International Recruitment period: not reported Study population: **mixed**. Patients with native vessels, in-stent restenosis, SVG calcified vessels, **n = 9222 (500 laser angioplasty, 1344 cutting balloon, 1677 DCA, 862 ROTA, 4104 balloon angioplasty)** Age: not reported Sex: not reported Patient selection criteria: not reported Included studies: Appleman (1996), Vom Dahl (2002), Baim (1998), Izumi (2001), Topol (1993), Holmes (1995), Adelman (1993), Dill (2000), Mauri (2003), Reifert (1997), Mauri (2002), Stone (1997). Plus 4 unpublished studies Technique: laser angioplasty (technique used in primary studies is not reported) versus balloon angioplasty. **Follow-up: up to 1 year.** Conflict of interest/source of funding: not reported.	Number of patients analysed: **9222 (500 laser)** maximum (depending on outcome analysed) ***Restenosis*** Angiographically measured restenosis was significantly more common following laser angioplasty than balloon angioplasty; odds ratio 1.55 (95% confidence interval 1.09 to 2.20) (measurement of significance not reported) follow-up 3 months to 1 year. However, patients in the balloon angioplasty group were more often treated with concomitant stenting.	**Complications** ***Myocardial infarction*** 30-day MI rate was not significantly different following laser angioplasty compared to balloon angioplasty; OR 1.39 (95% CI 0.69 to 2.82). ***Major adverse cardiac events*** The rate of MACE (death, MI, or revascularisation) was significantly higher following laser angioplasty compared with balloon angioplasty; OR 1.32 (95% CI 1.01 to 1.73).	**Follow-up issues**: Revascularisation rates were not consistently reported in primary studies so this outcome was not analysed. Where patient follow-up was not reported event rates were calculated on an intention to treat basis. **Study design issues**: The meta-analysis groups together different ablative coronary interventions. Four active interventions were included in analysis: coronary balloon atherectomy, directional coronary atherectomy, percutaneous transluminal rotational angioplasty, and laser angioplasty. Comparator was balloon angioplasty in all studies. A limited literature search of 1 source was undertaken. No significant study heterogeneity identified. Pooling by Bayesian meta-analysis using a fixed-effects model. **Study population issues**: None **Other issues**: Data included from 4 studies unpublished at time of manuscript submission, Including the AMIGO, REDUCE, RESCUT, and SPORT trials.

Abbreviations used: CABG, coronary artery bypass graft; CI, confidence interval; DCA, directional atherectomy; MACE, major adverse cardiac events; MI, myocardial infarction; N/S; not significant; OR, odds ratio; ROTA, rotational atherectomy; SD, standard deviation; SVG, saphenous vein graft; TEC, transluminal extraction atherectomy; TIMI, thrombolysis in MI.

Study details	Key efficacy findings	Key safety findings	Comments
Radke PW (2003)[2] **Meta-analysis** International Recruitment period: not reported Study population: **in-stent restenosis**. Not otherwise described. **n = 3012 (474 laser angioplasty)** Age: not reported Sex: 72% male. Patient selection criteria: not reported Included studies: 28 studies included in meta-analysis, including 6 on laser angioplasty Mehran (1997), Mehran (2000), Koster (2000), Dahm (2000), Giri (2001), Dangas (2000). Technique: laser angioplasty technique used in primary studies is not reported. **Follow-up: not reported.** Conflict of interest/source of funding: supported by academic fellowship.	Number of patients analysed: **3012 (474 laser)** maximum (depending on outcome analysed)	**Complications** ***Major adverse cardiac events*** The overall mean rate of MACE (death, MI, or revascularisation) was 30.0% (95% CI 25.0 to 34.9). There was significant heterogeneity between study results (p = 0.0001). Overall, for all treatment modalities, post procedure stenosis (at immediate angiographic follow up) was the only positive predictor of MACE in multiple regression (p < 0.001). The overall mean rate of MACE by treatment modality was as follows Intervention — Probability of MACE Laser angioplasty — 34.8 % (95% CI 25.1 to 44.5) Balloon angioplasty — 28.9% (95% CI 20.1 to 35.1) Stent-in-stent — 31.4% (95% CI 20.5 to 42.3) Rotational atherectomy — 29.7% (95% CI 15.8 to 43.7) Directional atherectomy — 30.6% (95% CI 20.2 to 41.0) Intracoronary radiation — 28.9% (95% CI 23.6 to 34.2)	**Follow-up issues**: None. **Study design issues**: The meta-analysis groups together different ablative coronary interventions in analysis, balloon angioplasty, directional coronary atherectomy, stent-in-stent, rotational atherectomy, intercoronary radiation, and laser angioplasty. Random effects model used for pooling based on mean probability of a MACE occurring. A limited literature search of 1 source was undertaken. Relevant studies were cross-referenced. A priori inclusion criteria agreed and evaluated by 2 assessors. Primary study quality was assessed using a modified scale. Frequency of adjunctive balloon angioplasty used in the primary studies is not reported. **Study population issues**: Baseline clinical characteristics were not evenly distributed among the groups based on treatment modality. Not otherwise described. **Other issues**: Data included from a range of study designs not only RCTs. Overall pooling for MACE outcome was undertaken based on means of active study arm from primary studies and not on a comparative basis to a rates from a single / consistent control arm i.e. balloon angioplasty.

Abbreviations used: CABG, coronary artery bypass graft; CI, confidence interval; DCA, directional atherectomy; MACE, major adverse cardiac events; MI, myocardial infarction; N/S; not significant; OR, odds ratio; ROTA, rotational atherectomy; SD, standard deviation; SVG, saphenous vein graft; TEC, transluminal extraction atherectomy; TIMI, thrombolysis in MI.

Study details	Key efficacy findings	Key safety findings	Comments
Serruys PW (2000)[3] TOTAL trial **Randomised controlled study** European Recruitment period: 1995 to 1997 Study population: **native vessels**. Patients with total occlusions. Angina and/or ischaemia, with TIMI flow grade of 0 for > 4 weeks on angiography. Stable angina (73%), previous MI (56%). Mean time since occlusion onset 20 to 30 weeks. Mean occlusion length 17 mm. **n = 303** (144 laser angioplasty guidewire) Age: 59 years (mean) Sex: 82% male Patient selection criteria: poorly visualized arteries or evidence of thrombus in the target lesion were exclusion criteria. Technique: under fluoroscopic guidance, laser guidewire angioplasty with activation once resistance met vs mechanical guidewire angioplasty **Follow-up: 12 months (median)** Conflict of interest/source of funding: not reported.	Number of patients analysed: **303 (144 laser guidewire, 159 mechanical guidewire)** **Operative characteristics** (group mean ± SD) / Laser / Mechanical / p= Fluoroscopic time (min) / 42 ± 26 / 41± 26 / 0.84 Procedural time (min) / 172 ± 87 / 164 ± 102 / 0.25 Hospital stay (days) / 4.6 ± 3.7 / 4.0 ± 4.9 / 0.03 **Procedural success** Defined as ability to cross target lesion. Intention to treat analysis including crossover. % (absolute figures) / Laser / Mechanical / p= First attempt success / 52.8% (76/144) / 47.2% (75/159) / 0.33 Success after 3 attempts / 63.2% (91/144) / 66.0% (105/159) / 0.61 Per protocol analysis also showed no significant difference in treatment success. Follow-up angiography at 6-month follow-up (in patients who had successful angioplasty following guidewire crossing. % (absolute figures) / Laser (n = 66) / Mechanical (n = 81) / p= Restenosis / reocclusion / 45.5% (30/66) / 38.3% (31/81) / 0.38	**Complications** At 400 days follow up following angioplasty Outcome / Laser / Mechanical / p= Death / 2.1% (3/144) / 4.4% (7/159) / 0.26 MI / 9.0% (13/144) / 5.0% (8/159) / 0.17 Non-Q-wave MI / 8.3% (12/144) / 1.9% (3/159) / <0.01 CABG / 20.8% (30/144) / 14.5% (23/159) / 0.15 Repeat angioplasty / 23.6% (34/144) / 17.0% (27/159) / 0.15 No major event / 54.2% (78/144) / 66.7% (106/159) / 0.026 Angina / 63.2% (91/144) / 62.3% (99/159) / 0.87	**Follow-up issues**: Prospective clinical follow-up, and with angiography at 6 months. Some results reported based on success of angioplasty rather than per study group. **Study design issues**: Multicentre study, block randomisation. The choice of mechanical guidewire and adjunctive angioplasty was made at the discretion of the clinician. Study design allowed for crossover to the non-allocated guidewire type for an additional attempt cross the lesion. Angiographic assessment not blinded to assignment. **Study population issues**: No significant difference between study groups at baseline in terms of demographic or clinical characteristics. **Other issues**: It is not clear whether this excimer laser guidewire system is similar to other techniques used for laser angioplasty. TIMI grade is a scoring system to assess coronary blood flow using percutaneous coronary angioplasty, It is rated from levels 0 to 3 (low scores worst). TIMI 0 flow (no perfusion), TIMI 1 flow (penetration without perfusion) TIMI 2 flow (partial reperfusion) TIMI 3 flow (complete perfusion).

Abbreviations used: CABG, coronary artery bypass graft; CI, confidence interval; DCA, directional atherectomy; MACE, major adverse cardiac events; MI, myocardial infarction; N/S; not significant; OR, odds ratio; ROTA, rotational atherectomy; SD, standard deviation; SVG, saphenous vein graft; TEC, transluminal extraction atherectomy; TIMI, thrombolysis in MI.

Study details

Haase J (1999)[4]

Randomised controlled study

Germany

Recruitment period: 1995 to 1996

Study population: **in-stent restenosis**. Patients with angina or objective evidence of ischaemia.

n = 96 (47 laser angioplasty)

Age: 64 years (mean)

Sex: 84% male

Patient selection criteria: patients without lesions outside of the stented segment, or evidence of stent thrombosis.

Technique: laser angioplasty with spectranetics laser using a single pass technique followed by adjunctive balloon angioplasty vs balloon angioplasty alone.

Follow-up: 163 days (median)

Conflict of interest/source of funding: not reported.

Key efficacy findings

Number of patients analysed: **96 (47 laser angioplasty plus balloon angioplasty, 49 balloon angioplasty alone)**

Procedural success

Post procedural angiographic success defined as final stenosis <50%

	Laser	Balloon
Angiographic success	97.9% (46/47)	98.0% (48/49)

Angiographic follow-up at 163 days was available in 72.9% (70/96) of patients

(group mean ± SD)	Laser n = 35	Balloon n = 35	p=
Minimal lumen diameter (mm)	1.32 ± 0.60	1.45 ± 0.75	N/S
Stenosis (%)	51.3 ± 20.7	45.9 ± 23.1	N/S
Restenosis rate (% patients with >50% restenosis)	52	47	N/S

Absolute figures not reported.

Key safety findings

Complications

Outcome	Laser	Balloon	p=
Perioperative			N/S
Acute occlusion within 48 hours	2.1% (1/47)	2.0% (1/49)	N/S
Repeat balloon angioplasty	2.1% (1/47)	0% (0/49)	N/S
CABG	2.1% (1/47)	0% (0/49)	N/S
Q-wave MI	0% (0/47)	0% (0/49)	N/S
Non-Q-wave MI	2.1% (1/47)	0% (0/49)	N/S
Bleeding	0% (0/47)	4.1% (2/49)	N/S
Death	0% (0/47)	2.0% (1/49)	N/S
Events during follow up			
Repeat balloon angioplasty	19.1% (9/47)	24.5% (12/49)	N/S
CABG	6.4% (3/47)	4.1% (2/49)	N/S
Death	0% (0/47)	2.0% (1/49)	N/S

Length of follow-up at which these events occurred is not reported.

Comments

Follow-up issues: 27% loss to angiographic follow-up.

Study design issues:

Adjunctive balloon angioplasty undertaken in all patients in the laser angioplasty group.

Method randomisation not reported.

Study population issues: No statistically significant differences between the groups at baseline in terms of history of MI, diabetes or unstable angina.

Other issues:

Not clear why study was not included in meta-analysis by Radke (2003).

Abbreviations used: CABG, coronary artery bypass graft; CI, confidence interval; DCA, directional atherectomy; MACE, major adverse cardiac events; MI, myocardial infarction; N/S; not significant; OR, odds ratio; ROTA, rotational atherectomy; SD, standard deviation; SVG, saphenous vein graft; TEC, transluminal extraction atherectomy; TIMI, thrombolysis in MI.

Study details	Key efficacy findings	Key safety findings	Comments
Ajluni SC (1994)[5] **Non-randomised controlled study** USA Recruitment period: 1988 to 1992 Study population: **mixed**. Native coronary arteries (left main 3%, left anterior descending 35%, left circumflex 25%, right 25%), or SVG (12%). Restenosis present in 14% of patients at baseline. **n = 8932 procedures** (242 laser angioplasty, 7905 balloon angioplasty, 420 transluminal atherectomy, 116 mechanical rotational atherectomy, 249 directional atherectomy) Age: not reported Sex: not reported Patient selection criteria: not reported Technique: laser angioplasty technique or other atherectomy techniques not reported. **Follow-up: not reported.** Conflict of interest/source of funding: not reported.	Number of patients analysed: **8932 lesions (242 laser angioplasty)** Efficacy outcomes were not reported.	**Complications** Overall coronary artery perforation occurred following 0.4% (35/8932) of procedures. Intervention — Rate of perforation Laser angioplasty — 2.1% (5/242) Balloon angioplasty — 0.1% (11/7905) Transluminal atherectomy — 1.3% (6/420) DCA — 0.4% (1/249) Mechanical ROTA — 0% (0/116) (length of follow-up and measurement of significance not reported) Type of perforation (patients may have had more than one type) — n = Free perforation — 10 Contained perforation — 17 Guidewire perforation without contrast extravasation — 3 Unclassified perforation — 1 Liner dissection with intramural dye staining but without contrast extravasation — 1 Delayed perforation and cardiac tamponade — 3 These 3 patients developed sudden haemodynamic collapse within 8 hours follow-up, 1 had undergone laser angioplasty. Across all the perforations, remedial treatment included repeat balloon inflations (n = 32), protamine medication (n = 7), other medical therapy (n = 1), and thoracic surgical intervention (n = 13).	**Follow-up issues**: The overall number of perforations does not tally with that for the 5 different techniques compared. Retrospective database review No details provided of loss to follow-up. **Study design issues**: Single centre study Patient selection criteria or factors that led to treatment allocation are not reported. **Study population issues**: Among the patients who suffered arterial perforation, the mean age of patients was 66 years, and 66% were male. Baseline characteristics not reported. No comparison between clinical or demographic characteristics undertaken. The proportion of patients with severe lesions was higher in patients who suffered perforation than in the general interventional population. **Other issues**: The event rate for arterial perforation following DCA recorded in the study report does not correspond to the absolute figures provided and has been recalculated by NICE on the basis of these. Sequelae to perforations are also reported but these are not specific to intervention type. This adverse event not reported in other studies.

Abbreviations used: CABG, coronary artery bypass graft; CI, confidence interval; DCA, directional atherectomy; MACE, major adverse cardiac events; MI, myocardial infarction; N/S; not significant; OR, odds ratio; ROTA, rotational atherectomy; SD, standard deviation; SVG, saphenous vein graft; TEC, transluminal extraction atherectomy; TIMI, thrombolysis in MI.

Study details	Key efficacy findings	Key safety findings	Comments
Hong MK (1997)[6] **Non-randomised controlled study** USA Recruitment period: not reported Study population: **mixed**. Patients having both planned and emergency procedures with either native vessels or SVGs. **n = 3733 procedures (854 laser angioplasty)** Age: 63 years Sex: 65% male Patient selection criteria: not reported Technique: laser angioplasty with either excimer laser or spectranetic laser vs directional atherectomy, stenting (either Palmaz-Schatz stenting, or gianturco-roubin stenting), transluminal extraction atherectomy, or rotational atherectomy **Follow-up: not reported.** Conflict of interest/source of funding: not reported.	Number of procedures analysed: **3733 (854 laser angioplasty one of two different devices)** Most procedures undertaken and recorded in the database were planned (82.8% of all lesions in native vessels and 96.9% in SVGs). **Procedural success** Planned procedures / Unplanned procedures / p= Native vessels: 90.4% / 76.7% / <0.001 SVGs: 87.9% / 73.9% / 0.08 Absolute figures not reported Device success (%) planned procedures DCA / Stent / Stent / TEC / ROTA / Laser / Laser Native vessels: 91.8 / 100.0 / 95.2 / 54.1 / 67.2 / 37.9 / 38.0 SVGs: 94.2 / 98.8 / N/A / 60.4 / N/A / 70.0 / 49.1 Absolute figures and significance not reported Angiographic lesion success (%) planned procedures DCA / Stent / Stent / TEC / ROTA / Laser / Laser Native vessels: 94.7 / 97.9 / 90.7 / 84.3 / 97.2 / 89.0 / 93.7 SVGs: 98.0 / 100.0 / N/A / 94.6 / N/A / 95.0 / 90.6 Absolute figures and significance not reported Procedural success (not described for each primary dtudy) (%) planned procedures DCA / Stent / Stent / TEC / ROTA / Laser / Laser Native vessels: 92.7 / 95.7 / 85.0 / 78.3 / 86.8 / 82.1 / 84.6 SVGs: 88.3 / 96.0 / N/A / 85.4 / N/A / 83.3 / 84.2 Absolute figures and significance not reported	**Complications** Combined major ischaemic complications Planned procedures / Unplanned procedures / p= Native vessels: 2.7% / 9.9% / <0.001 SVGs: 3.6% / 8.7% / N/S Absolute figures not reported Native vessels (planned procedures Total / Death / MI / CABG DCA: 2.0% / 0.3% / 0.4% / 1.3% Stent: 2.3% / 0.5% / 1.4% / 0.5% Stent: 4.4% / 2.2% / 0.0% / 2.2% TEC: 2.3% / 1.2% / 1.2% / 0.0% ROTA: 2.2% / 0.9% / 1.1% / 0.2% Laser: 3.1% / 0.7% / 0.5% / 1.9% Laser: 5.5% / 0.9% / 0.0% / 4.5% Absolute figures and significance not reported SVG (%) planned procedures Total / Death / MI / CABG DCA: 2.8% / 1.4% / 1.4% / 0.0% Stent: 2.2% / 2.2% / 0.0% / 0.0% TEC: 6.2% / 5.4% / 0.8% / 0.0% Laser: 1.6% / 1.6% / 0.0% / 0.0% Laser: 1.7% / 1.7% / 0.0% / 0.0% Absolute figures and significance not reported	**Follow-up issues**: Retrospective review of a prospectively completed database recording consecutive patients. Only patients with angiographic follow-up at the same location as at baseline were included in analysis (82.1%; 3340/4067) No details provided of loss to follow-up. **Study design issues**: Patient selection criteria or factors that led to treatment allocation are not reported. Outcomes are reported separately for patients with native arteries and those with SVGs. Only variables with an association to outcome of $p < 0.20$ in univariate analysis were included in multivariate analysis. **Study population issues**: There were significant differences in baseline clinical characteristics between patients with native vessels and those with SVG, and between those having a planned procedure and those having an unplanned procedure. **Other issues**: None

Abbreviations used: CABG, coronary artery bypass graft; CI, confidence interval; DCA, directional atherectomy; MACE, major adverse cardiac events; MI, myocardial infarction; N/S; not significant; OR, odds ratio; ROTA, rotational atherectomy; SD, standard deviation; SVG, saphenous vein graft; TEC, transluminal extraction atherectomy; TIMI, thrombolysis in MI.

Study details	Key efficacy findings	Key safety findings	Comments
Topaz O (1998)[7] Holmium :YAG registry **Case series** USA Recruitment period: 1990 to 1995 Study population: **mixed** native vessels and SVGs. Patients with symptomatic coronary artery disease, or positive exercise test with >70% reduction in lumen diameter. Mean lesion length 13 mm. **n = 1862** Age: 61years Sex: 75% male Patient selection criteria: patients without unprotected left main coronary artery (not otherwise defined), severe angulation, coronary dissection, lesions in vessels smaller than catheter diameter, or lesions not traversable by guidewire. Technique: laser angioplasty with holmium:YAG laser. Adjuvant balloon angioplasty in 'the vast majority' of patients. **Follow-up: 6 months (median)** Conflict of interest/source of funding: supported by manufacturer.	Number of procedures analysed: **1862 (2038 lesions)** **Technical success** Laser success was defined as >20% decrease in stenosis following laser angioplasty. It was achieved in 87.3% (1620/1862) of patients treated. **Procedural success** Procedural success was defined as final reduction of stenosis to less than 50% following adjunctive balloon angioplasty without major complication (death, emergency CABG, or Q-wave MI). It was achieved in 93% of patients treated (absolute figures not reported). Multivariate analysis reported that bifurcation lesions (OR 0.5; 95% CI 0.2 to 1.0)(p = 0.05), and severe tortuosity of the target lesion (OR 0.4; 95% CI 0.2 to 0.9)(p = 0.02) were independent predictors of an unsuccessful outcome. Lesion location was not found to be a predictor of success. **Clinical outcomes** At 6-month follow-up, 71% of patients reported angina symptoms as improved, 13% reported unchanged symptoms and 16% had worse symptoms compared to baseline. Clinical restenosis occurred in 34% of patients **Angiographic assessment** Angiographic follow-up was available for 54% (797/1484) of eligible patients. Restenosis (stenosis >50%of diameter) was reported in 54.5% (434/797) of patients.	**Complications** Perioperative outcomes Complication — Rate Death — 0.8% (14/1862) Emergency CABG — 2.5% (46/1862) Q-wave MI — 1.2% (23/1862) Non-Q-wave MI — 3.4% (64/1862) Acute occlusion — 2.5% (47/1862) Spasm — 12.6% (234/1862) Thrombus — 2.5% (46/1862) Perforation — 2.2% (40/1862) Embolism — 1.4% (26/1862) Major dissection — 5.8% (109/1862) Minor dissection — 11.4% (213/1862) Loss of side branch — 1.3% (25/1862) Groin complication — 0.4% (8/1862) Multivariate analysis did not identify any predictor of a major adverse event. 6-month follow-up Complication — Rate Late cardiac death — 1.7% Recurrent angina — 19.7% Q-wave MI — 1.1% Non-Q-wave MI — 1.2% Repeat percutaneous intervention (balloon or other device) — 17.7% Absolute figures not reported	**Follow-up issues**: Registry coverage not reported. 93.5% (1905/2038) of lesions treated were included in analysis for technical and procedural success. 74% (1206/1625) of eligible patients were available for clinical follow-up. Not all patients underwent postoperative or 6-month follow-up angiographic assessment. Denominator number of patients used for analysis of 6-month follow-up is not clear. Percentages reported in study paper do not seem to be consistent with the 1206 patients quoted. **Study design issues**: 44 study centres, recording consecutive patients. Laser advancement procedure changes during the course of the treatment period. Independent quantitative angiographic follow-up assessment only undertaken in 105 patients. **Study population issues**: Majority of patients (69%) had unstable angina as indication for treatment. Other indications were stable angina (20%), acute MI (6%) or positive exercise test (5%). **Other issues**: Authors state that randomised trials are required to prove whether this procedure offers clinical advantages over stand-alone balloon angioplasty

Abbreviations used: CABG, coronary artery bypass graft; CI, confidence interval; DCA, directional atherectomy; MACE, major adverse cardiac events; MI, myocardial infarction; N/S; not significant; OR, odds ratio; ROTA, rotational atherectomy; SD, standard deviation; SVG, saphenous vein graft; TEC, transluminal extraction atherectomy; TIMI, thrombolysis in MI.

Study details	Key efficacy findings	Key safety findings	Comments
Margolis JR (1992)[8] ELCA registry **Case series** USA Recruitment period: not reported. Study population: **mixed** mostly native vessels but some SVGs. 30% of patients had previously undergone balloon angioplasty, and 26% CABG. 'Most' patients severely symptomatic. 10% of lesions were totally occluded. **n = 958** Age: 61years Sex: 78% male Patient selection criteria: protocol included patients with stenoses or occlusions that couldn't; be crossed by a guidewire. Technique: laser angioplasty with excimer laser **Follow-up: 6 months (median)** Conflict of interest/source of funding: not reported.	Number of procedures analysed: **958 (1136 lesions)** **Technical success** Defined as reduction in stenosis diameter of >20%with a channel diameter roughly 0.5 mm less than the size of the catheter used. 85.1% (967/1136) of lesions were successfully treated. **Procedural success** Defined as final luman diameter >50% following the procedure (with or without adjunctive balloon angioplasty). 93.2% (1059/1136) of lesions had a successful procedure. Lesion location did not appear to effect success rate, which was 100% in the left main artery, 89% in the left anterior descending artery, 92% in the left circumflex artery, 93% in the right coronary artery, and 95% in SVGs (measurement of significance not reported). The success rate was 94% for stenoses and 91% for occlusions. **Angiographic assessment** 55 patients underwent immediate postoperative angiographic assessment (number of lesions treated not stated). Mean stenosis improved from 83% at baseline to 49% following laser angioplasty and 38% after adjunctive balloon angioplasty (measurement of significance not reported). 88% (812/958) of patients underwent 6-month follow-up angiographic assessment. 51% of patients had restenosis (>50% of diameter). 3.3% of patients had new symptoms or a positive treadmill test at 6-month follow-up (absolute figures not reported). .	**Complications** Perioperative outcomes Complication — Rate Acute occlusion — 5.4% Spasm — 2.0% Thrombus — 1.9% Perforation (50% of patients required emergency surgery) — 1.1% Embolism — 0.8% Aneurysm — 0.5% Emergency CABG — 3.5% MI — 1.4% Death — 0.3% Absolute figures not reported 6-month follow-up Complication — Rate Acute occlusion — 5.4% Spasm — 2.0% Thrombus — 1.9% Perforation (50% of patients required emergency surgery) — 1.1% Embolism — 0.8% Repeat intervention (balloon, laser or atherectomy) — 15% CABG — 7% MI — 1.5% Death — 1.4% Absolute figures not reported	**Follow-up issues**: Registry coverage not reported. Not all patients underwent postoperative or 6-month follow-up angiographic assessment. Reasons for selection or comparison of patients without assessment not reported. **Study design issues**: 15 study centres. Patient accrual technique not reported. **Study population issues**: Baseline characteristics described as 'similar to that of a conventional balloon angioplasty cohort'. **Other issues**: None

Abbreviations used: CABG, coronary artery bypass graft; CI, confidence interval; DCA, directional atherectomy; MACE, major adverse cardiac events; MI, myocardial infarction; N/S; not significant; OR, odds ratio; ROTA, rotational atherectomy; SD, standard deviation; SVG, saphenous vein graft; TEC, transluminal extraction atherectomy; TIMI, thrombolysis in MI.

Study details	Key efficacy findings	Key safety findings	Comments
Bittl JA (1994)[9] ELCA registry **Case series** USA Recruitment period: 1989 to 1993 Study population: **SVGs**. Mean graft age = 8 years. 52% of lesions were eccentric. 16% had restenosis. 86% had unstable angina and 21% diabetes mellitus. **n = 495** Age: 63 years Sex: 77% male Patient selection criteria: patients without filling defect in the target graft (not otherwise defined) or lesions in the angulated anastomotic site. Technique: laser angioplasty with excimer laser. 91% of patients had adjunctive balloon angioplasty. No patients received a stent. **Follow-up: 6 months (median)** Conflict of interest/source of funding: not reported.	Number of procedures analysed: **495 (545 lesions)** **Procedural success** Clinical success was defined as <50% stenosis in every targeted lesion and no major complication during hospitalisation. 91.2% (455/495) of patients demonstrated clinical success. Multivariate analysis demonstrated that lesions >10 mm were less likely to result in clinical success; OR 0.30 (95% CI 0.16 to 0.56) (p = 0.001). **Angiographic assessment** Mean stenosis improved from 88% at baseline to 45% following laser angioplasty and 20% after adjunctive balloon angioplasty or atherectomy (measurement of significance not reported). 44% (161/364) of patients underwent 6-month follow-up angiographic assessment. 55% of patients had restenosis (>50% stenosis).	**Complications** Complication — Rate Per lesion Dissection — 8.8% (48/545) Abrupt closure — 4.0% (22/545) Embolism — 3.3% (18/545) Perforation (minor contrast extravasion) — 1.3% (7/545) Perforation (with clinical complication) — 0.0% (0/545) Per patient Death during hospitalisation — 1.0% (5/495) CABG during hospitalisation — 0.6% (3/495) Q-wave MI — 2.4% (12/495) Non-Q-wave MI — 2.2% (11/495) Multivariate analysis demonstrated that lesions >10 mm were more likely to result in complications, OR 3.3 (95% CI 1.6 to 6.6) (p = 0.004). Conversely, ostial lesions OR 0.10 (95% CI 0.01 to 0.79) (p = 0.03) and lesions in grafts <3.0 mm diameter OR 0.31(95% CI 0.10 to 0.94) (p = 0.03) were less likely have complications.	**Follow-up issues**: Registry coverage not reported. Not clear why only 364 of 495 patients were eligible for 6-month follow-up assessment. Only 44% of patients returned for 6-month angioplasty. Authors state that asymptomatic patients are less likely to return. **Study design issues**: No independent outcome assessment. **Study population issues**: Some patients had previously been treated for restenosis at baseline, whereas some were being treated for restenosis for the first time. Details of SVG procedure not described. **Other issues**: possibly some of the same patients as reported in Margolis (1992).

Efficacy

Procedural success.

A non-randomised controlled study of 3733 procedures reported that angiographically assessed lesion success was achieved in 89% and 94% of native vessels treated with laser angioplasty using two different laser devices, and in 91% and 95% of saphenous vein grafts treated. In comparison, the angiographic lesion success rate for directional atherectomy was 95% for native vessels and 98% for saphenous vein grafts (measurement of significance not reported)[6]. A case series of 958 patients reported that coronary stenosis (assessed by the percentage of artery diameter blocked) decreased from 83% at baseline to 49% following laser angioplasty, and 38% following adjunctive balloon angioplasty[8]. A randomised controlled trial of 303 patients reported that there was no statistically significant difference in procedural success (defined as the ability to cross the target lesion) between patients treated with a laser guidewire (53% [76/144]) and those treated with a mechanical guidewire (47% [75/159]) ($p = 0.33$)[3].

Clinical outcome

A case series of 1862 patients reported that 71% of patients treated with laser angioplasty had an improvement in their angina symptoms, 13% had unchanged symptoms, and 16% had worse symptoms at 6-month follow-up[7]. Clinical restenosis was judged to have occurred in 34% of patients (absolute figures not reported).

Restenosis (angiographic assessment)

A meta-analysis of 9222 patients from 16 studies reported that angiographically measured restenosis was significantly more frequent following laser angioplasty than following balloon angioplasty (odds ratio [OR] 1.55; 95% confidence interval [CI] 1.09 to 2.20) at follow-up of between 3 months and 1 year (measurement of significance not reported)[1]. A randomised controlled trial of 96 patients reported that restenosis following laser angioplasty and adjunctive balloon angioplasty occurred in 52% of patients compared with 47% of patients who had balloon angioplasty alone (p = not significant) at 5-month follow-up[4] (absolute figures not reported).

The case series of 1862 patients reported restenosis (stenosis greater than 50% of the artery diameter) in 54% (434/797) of eligible patients undergoing angiographic assessment at 6-month follow-up[7]. A case series of 495 saphenous vein grafts treated by laser angioplasty reported restenosis in 55% of the 161 patients who had angiographic assessment at 6-month follow-up (absolute numbers not reported)[9].

Safety

Major adverse cardiac events

The meta-analysis of 9222 patients reported that the rate of major adverse cardiac events (death, myocardial infarction or revascularisation) was significantly higher following laser angioplasty compared with balloon angioplasty (OR 1.32; 95% CI 1.01 to 1.73) (measurement of significance not reported)[1]. However, there was no significant difference between the groups in the rate of myocardial infarction at 30-day follow-up (OR 1.39; 95% CI 0.69 to 2.82). A meta-analysis of 3012 patients being treated for in-stent restenosis reported that the pooled mean rate of major adverse cardiac events was 35% following laser angioplasty, 29% for balloon angioplasty and 31% for stent-in-stent treatment[2].

A randomised controlled trial of 303 patients reported that significantly fewer patients treated with a laser guidewire had no major adverse cardiac events (54% [78/144]) compared with patients treated with a mechanical guidewire (67% [106/159]) (p = 0.026) at 400-day follow-up[3]. A non-randomised controlled study of 3733 procedures reported total serious adverse event rates of 3% and 6% in native vessels treated with laser angioplasty using two different laser devices, 2% for directional atherectomy and 2% for rotational atherectomy (absolute figures not reported)[6].

Emergency coronary artery bypass grafting (CABG)

A randomised controlled trial of 96 patients reported that 1 out of 47 patients required emergency CABG following laser angioplasty, compared with 0 out of 49 patients treated by balloon angioplasty alone (p = not significant)[4].

Artery perforation

A non-randomised controlled study of 8932 procedures reported that the overall rate of coronary artery perforation was less than 1% (35/8932) for all techniques. For laser angioplasty the rate of artery perforation was 2% (5/242), for balloon angioplasty it was less than 1% (11/7905), and for mechanical rotational atherectomy it was 0% (0/116)[5].

Other complications

Perioperative thrombus was reported in 2% (46/1862) of patients in a case series of 1862 patients[7], and 2% of patients in a case series of 958 patients (absolute figures not reported)[8].

Perioperative complete coronary artery closure was reported in 3% (47/1862) of patients in a case series of 1862 patients[7], 5% of patients in a case series of 958 patients (absolute figures not reported)[8] and 4% (22/545) of lesions treated for saphenous vein graft occlusion in a case series of 495 patients[9].

Validity and generalisability of the studies

- The devices used for this procedure may have evolved over time making comparison of earlier and later studies difficult. Much of the data available was published in the 1990s.
- There is some comparative data, both randomised and non-randomised, comparing results for percutaneous laser angioplasty with those for standard balloon angioplasty.
- Length of follow-up in the studies is poorly reported and often minimal (at immediate postprocedure assessment) and seldom longer than 1 year; this is a condition where restenosis might be expected.
- Some patients treated had recent myocardial infarction. Worse immediate outcomes might be expected in these patients.

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 laser revascularisation for refractory angina pectoris. NICE interventional procedures guidance 302 (2009). Available from www.nice.org.uk/guidance/IPG302

- Transmyocardial laser revascularisation for refractory angina pectoris. NICE interventional procedures guidance 301 (2009). Available from www.nice.org.uk/guidance/IPG301

Technology appraisals

- Guidance on the use of drugs for early thrombolysis in the treatment of acute myocardial infarction NICE technology appraisal 052 (2002). Available from www.nice.org.uk/guidance/TA052

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.

Dr S Doshi, Dr S Redwood (British Cardiovascular Intervention Society)

- Both the Specialist Advisers classified the procedure as established and no longer new.
- Laser-assisted angioplasty has been in use for nearly two decades as an optional, adjunctive device in coronary intervention but has not, so far, found an application where it is demonstrably superior to existing devices.
- One Specialist Adviser commented that with undilatable lesions, rotational atherectomy is preferred at their centre.
- The main comparator for this procedure depends on the indication for which it is used. For undilatable coronary lesions, the main comparator would be rotational atherectomy, for thrombus ablation the main comparator would be thrombus aspiration catheters, and for complex lesions the main comparator would be balloon angioplasty followed by stenting.
- The key efficacy outcomes for this procedure include procedural success, angiographic success, quality of life scores, target vessel revascularisation, and cardiac enzyme level post procedure.
- The procedure is undertaken in a standard catheter laboratory using conventional guidewires and delivery catheters. Minimal training is required.
- Theoretical adverse events following this procedure include death, coronary dissection, abrupt vessel closure, coronary perforation, thermal damage to the vessel and restenosis.
- Since new techniques were introduced including saline flush the risks relating to thermal wall damage is very small.
- The procedure is available in a few centres.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme sent 50 questionnaires to one trust for distribution to patients who had the procedure (or their carers). NICE received 13 completed questionnaires.

The Patient Commentators' views on the procedure were consistent with the published evidence and the opinions of the Specialist Advisers.

Issues for consideration by IPAC

- The overview contains evidence on percutaneous laser coronary angioplasty either alone, or in combination with balloon angioplasty.
- The published data available reflect a variety of indications for treatment, including lesions in native veins, recurrent stenosis or failure of saphenous vein grafts, and in-stent restenosis. Many of the studies include patients with a mixture of these indications.
- There is particular interest in the role of this procedure in treating diseased, narrowed and/or blocked coronary arteries or saphenous vein grafts where alternative treatment strategies have failed. It may enable balloon dilation where previously a catheter could not be passed across the lesion.
- No issues relating to equality in terms of patient subgroups covered in the Disability Discrimination Act were identified during scoping.

References

1 Bittl JA, Chew DP, Topol EJ et al. (2004) Meta-analysis of randomized trials of percutaneous transluminal coronary angioplasty versus atherectomy, cutting balloon atherotomy, or laser angioplasty. Journal of the American College of Cardiology 43: 936–43.

2 Radke PW, Kaiser A, Frost C et al. (2003) Outcome after treatment of coronary in-stent restenosis: Results from a systematic review using meta-analysis techniques. European Heart Journal 24: 266–73.

3 Serruys PW, Hamburger JN, Koolen JJ et al. (2000) Total occlusion trial with angioplasty by using laser guidewire: The Total trial. European Heart Journal 21: 1797–805.

4 Haase J, Storger H, Hofmann M et al. (1999) Excimer laser angioplasty with adjunctive balloon dilatation versus balloon dilatation alone for the treatment of in-stent restenosis: Results of a randomized single-center study. Journal of Interventional Cardiology 12: 513–7.

5 Ajluni SC, Glazier S, Blankenship L et al. (1994) Perforations after percutaneous coronary interventions: Clinical, angiographic, and therapeutic observations. Catheterization and Cardiovascular Diagnosis 32: 206–12.

6 Hong MK, Popma JJ, Baim DS et al. (1997) Frequency and predictors of major in-hospital ischemic complications after planned and unplanned new-device angioplasty from the New Approaches to Coronary Intervention (NACI) registry. American Journal of Cardiology 80: 40K–49K.

7 Topaz O, McIvor M, Stone GW et al. (1998) Acute results, complications, and effect of lesion characteristics on outcome with the solid-state, pulsed-wave, mid-infrared laser angioplasty system: Final multicenter registry report. Lasers in Surgery and Medicine 22: 228–39.

8 Margolis JR and Mehta S. (7-5-1992) Excimer laser coronary angioplasty. American Journal of Cardiology 69: 3F–11F.

9 Bittl JA, Sanborn TA, Yardley DE et al. (1994) Predictors of outcome of percutaneous excimer laser coronary angioplasty of saphenous vein bypass graft lesions. American Journal of Cardiology 74: 144–8.

Appendix A: Additional papers on percutaneous laser coronary angioplasty

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
Ajani AE, Waksman R, Kim H-S et al. (2001) Excimer laser coronary angioplasty and intracoronary radiation for in-stent restenosis: Six-month angiographic and clinical outcomes. Cardiovascular Radiation Medicine 2 (3) 191–196.	n = 208 (33 laser) Follow-up (FU) = 6 months	Radiation therapy with laser angioplasty significantly reduces angiographic binary restenosis at 6 months in patients with diffuse in-stent restenosis, driven predominantly by reduced percutaneous target vessel revascularisation	Larger studies are included in table 2
Babalik E, Gurmen T, Gulbaran M et al. (2003) Revascularization of chronic coronary artery occlusions using laser debulking followed by stent implantation. Acta Cardiologica 58 (2) 149–153	n = 48 FU = 6 months	The high rates of restenosis and target vessel revascularization in our study suggest that laser debulking before stent implantation does not improve clinical and angiographic outcomes in chronic total occlusions	Larger studies are included in table 2
Batchelor WB, Chisholm RJ, and Strauss BH. (1996) Dissections following excimer laser-assisted angioplasty of saphenous vein bypass grafts: Analysis of incidence and effect of adjunctive balloon angioplasty. Journal of Interventional Cardiology 9 (3) 265-269.	n = 118 FU = not reported	Further techniques, such as multiplex catheters or saline infusion, aimed at minimizing vessel wall injury from laser ablation, may be required to reduce the occurrence of laser-induced dissections	Larger studies are included in table 2
Baumbach A, Oswald H, Kvasnicka J et al. (1994) Clinical results of coronary excimer laser angioplasty: report from the European Coronary Excimer Laser Angioplasty Registry. European Heart Journal 15 (1) 89–96.	n = 470 FU = not reported	Complications included vasospasm (13.4%), dissection (14.7%), flow limiting dissection (4%), reclosure (7.8%), and perforation (1.9%). Myocardial infarction occurred in 2.1%, CABG was requested in 1.9%, and the mortality was 1.5%.	Larger studies are included in table 2
Bittl JA and Sanborn TA. (1992) Excimer laser-facilitated coronary angioplasty. Relative risk analysis of acute and follow-up results in 200 patients. Circulation 86 (1) 71–80.	n = 200 FU = 6 months	This analysis, which defines the profile of risk for excimer laser angioplasty, provides a sound basis for rigorous comparison of adjunctive excimer laser with balloon angioplasty for ostial narrowings, long lesions, and saphenous vein graft stenoses	Larger studies are included in table 2 Possibly some same patients as Bittl (1994)
Bittl JA, Ryan TJ Jr, Keaney JF Jr et al. (1993) Coronary artery perforation during excimer laser coronary angioplasty. The percutaneous Excimer Laser	n = 764 FU = not reported	Most lesions thought to be suitable for excimer laser treatment are not at increased risk of perforation. The	Larger studies are included in table 2 Possibly some

Coronary Angioplasty Registry. Journal of the American College of Cardiology 21 (5) 1158–1165.		complication may be avoided by improved patient and laser catheter size selection	same patients as Bittl (1994)
Chen C-P, Huang C-L, Fong C-C et al. (2008) Six-month angiographic and clinical outcomes after successful eccentric excimer laser coronary angioplasty with adjunctive cutting balloon angioplasty for recurrent in-stent restenosis. Acta Cardiologica Sinica 24 (1) 15–20.	n = 35 FU = not reported	Laser angioplasty plus balloon angioplasty can be safely and effectively used in patients with recurrent focal in-stent restenosis	Larger studies are included in table 2
Dangas G, Mehran R, Lansky AJ et al. (2000) Acute and long-term results of treatment of diffuse in-stent restenosis in aortocoronary saphenous vein grafts. American Journal of Cardiology 86 (7) 777–779.	n = 83 FU = 1 year	Despite an adequate procedural result, treatment of SVG diffuse in-stent restenosis has a high clinical recurrence rate and the population is characterized by significant long-term mortality.	Larger studies are included in table 2
de Marchena E, Larrain G, Posada JD et al. (1995) Holmium laser-assisted coronary angioplasty in acute ischemic syndromes. Clinical Cardiology 19 (4) 315–319.	n = 85 FU = 6 months	Holmium laser-assisted balloon angioplasty appears promising in the treatment of acute ischaemic syndromes and thrombotic coronary lesions	Larger studies are included in table 2
Dorr M, Vogelgesang D, Hummel A et al. (2007) Excimer laser thrombus elimination for prevention of distal embolization and no-reflow in patients with acute ST elevation myocardial infarction: results from the randomized LaserAMI study. International Journal of Cardiology 116 (1) 20–26.	n = 27 (14 laser) FU = not reported	Laser angioplasty is feasible and safe for the treatment of patients with ST elevation acute MI. Procedural results were at least on par with conventional treatment. Further randomised controlled trials are needed to assess the benefit of laser angioplasty in acute MI	Larger studies are included in table 2
Foley DP, Melkert R, Umans VA et al. (1995) Differences in restenosis propensity of devices for transluminal coronary intervention. A quantitative angiographic comparison of balloon angioplasty, directional atherectomy, stent implantation and excimer laser angioplasty. CARPORT, MERCATOR, MARCATOR, PARK, and BENESTENT Trial Groups. European Heart Journal 16 (10) 1331–1346.	n = 3660 (116 laser) FU = 6 months	These findings indicate that propensity to restenosis after apparently successful intervention is influenced not only by the degree of luminal enlargement achieved at intervention, but by the device used to achieve it	Larger studies are included in table 2
Geschwind HJ, Nakamura F, Kvasnicka J et al. (1993)	n = 86	Technical improvements are required to ablate	Larger studies are included in table 2

Excimer and holmium yttrium aluminum garnet laser coronary angioplasty. American Heart Journal 125 (2:Pt 1) t-22.	FU = not reported	more tissue to possibly reduce the restenosis rate. Further studies are needed to elucidate the mechanism of side effects and to reduce the restenosis rate	
Gim RD, Bokhari SW and Winters RJ (2005) Novel use of a peripheral, self-expanding nitinol stent in adjunct to excimer laser coronary atherectomy in the treatment of degenerated vein graft disease. Reviews in Cardiovascular Medicine 6 (3) 173–179.	n = 1 FU = not reported	The procedure was tolerated well without any short- or long-term complications	Larger studies are included in table 2
Hamburger JN, Foley DP, de Feyter PJ et al. (2000) Six-month outcome after excimer laser coronary angioplasty for diffuse in-stent restenosis in native coronary arteries. American Journal of Cardiology 86 (4) 390–394.	n = 16 FU = 6 months	Despite satisfactory acute angiographic results, the recurrence of significant restenosis in all patients suggests that laser angioplasty plus balloon angioplasty is not a suitable stand-alone therapy for diffuse in-stent restenosis of long stented segments	Larger studies are included in table 2
Heuser, R. R. and Mehta, S. S. (1991) Holmium laser angioplasty after failed coronary balloon dilation: use of a new solid-state, infrared laser system. Catheterization & Cardiovascular Diagnosis 23 (3) 187-189	n = 1 FU = 4 months	The holmium laser has several advantages over excimer systems and may prove an effective adjunct or alternative to coronary balloon angioplasty	Larger studies are included in table 2
Ilkay E, Karaca I, Yavuzkir M et al. (2005) The effect of interventional treatment in acute myocardial infarction on ST resolution: a comparison of coronary angioplasty with excimer laser angioplasty. Angiology 56 (4) 377–384.	n = 80 (36 laser) FU = 5 to 7 days	These findings should be supported by large randomised studies	Larger studies are included in table 2
Karaca I, Ilkay E, Akbulut M et al. (2002) Treatment of in-stent restenosis with excimer laser coronary angioplasty. Japanese Heart Journal 44 (2) 179–186.	n = 23 FU = 6 months	Laser angioplasty is a safe and efficient debulking technology for treating diffuse in-stent restenosis	Larger studies are included in table 2
Karsch KR, Haase KK, Wehrmann M et al. (1991) Smooth muscle cell proliferation and restenosis after stand alone coronary excimer laser angioplasty. Journal of the American College	n = 1 FU = 2 months	Postmortem histologic examination revealed 80% restenosis at the lesion site without plaque disruption or thrombosis	Larger studies are included in table 2

of Cardiology 17 (4) 991–994.			
Koster R, Hamm CW, Seabra-Gomes R et al. (1999) Laser angioplasty of restenosed coronary stents: results of a multicenter surveillance trial. The Laser Angioplasty of Restenosed Stents (LARS) Investigators. Journal of the American College of Cardiology 34 (1) 25–32.	n = 440 FU = 1 to 23 days	Excimer laser angioplasty with adjunctive balloon angioplasty is a safe and efficient technology to treat in-stent restenoses. These data justify a randomised comparison with balloon angioplasty	Larger studies are included in table 2
Koster R, Hamm CW, Terres W et al. (1997) Treatment of in-stent coronary restenosis by excimer laser angioplasty. American Journal of Cardiology 80 (11) 1424–1428	n = 70 FU = not reported	Laser angioplasty is an efficient and safe technique to debulk tissue in restenotic lesions and total occlusions within stents. The incidence of procedure-related complications was low	Possibly the same patients as Koster (1999) Larger studies are included in table 2
Kuntz RE, Safian RD, Levine MJ et al. (1992) Novel approach to the analysis of restenosis after the use of three new coronary devices. Journal of the American College of Cardiology 19 (7) 1493–1499.	n = 223 (11 laser) FU = not reported	Although the apparent restenosis rates differed significantly among the three interventions (19% for stents, 31% for atherectomy and 50% for laser balloon angioplasty; p = 0.02), late loss among the three interventions was equivalent (average 1 mm; p = 0.91).	Larger studies are included in table 2
Lawson CS, Cooper IC and Webb-Peploe MM. (1993) Initial experience with excimer laser angioplasty for coronary ostial stenoses. British Heart Journal 69 (3) 255–259.	n = 9 FU = 20 months	With a mean follow-up of 19.7 months the overall success rate was 67%	Larger studies are included in table 2
Linnemeier TJ, Rothbaum DA, Cumberland DC et al. (1990) Percutaneous laser-assisted thermal coronary angioplasty in native coronary arteries and saphenous vein grafts: initial results and angiographic follow-up. Journal of Invasive Cardiology 2 (4) 133–138.	n = 27 FU = 6 months	Further evaluation of coronary laser systems should be continued only with catheters that are capable of creating channels closer to the size of the vessel treated	Larger studies are included in table 2
Litvack F, Grundfest WS, Goldenberg T et al. (1989) Percutaneous excimer laser angioplasty of aortocoronary saphenous vein grafts. Journal of the American College of Cardiology 14 (3) 803–808.	n = 2 FU = 1 to 8 months	These cases demonstrate the feasibility of safely performing percutaneous coronary excimer laser angioplasty. Additional studies are indicated to determine the clinical role and potential benefits of this procedure in relation	Larger studies are included in table 2

		to established procedures and other experimental devices	
Madyoon H and Croushore L. (2001) Application of excimer laser coronary angioplasty (ELCA) in bifurcation lesions. Lasers in Medical Science 16 (2) 108–112.	n = 3 FU = to discharge	Laser angioplasty can be used safely and effectively in high-risk patients with bifurcation lesions, even in the presence of thrombus	Larger studies are included in table 2
Mintz GS, Pichard AD, Kent KM et al. (1993) Transcatheter device synergy: Preliminary experience with adjunct directional coronary atherectomy following high-speed rotational atherectomy or excimer laser angioplasty in the treatment of coronary artery disease. Catheterization and Cardiovascular Diagnosis 29 (SUPPL. 1) 37–44.	n = 16 (6 laser) FU = not reported	Thus, there seems to be a synergistic relationship between high-speed rotational atherectomy or excimer laser angioplasty and adjunct directional atherectomy in treating calcified coronary artery target lesions	Larger studies are included in table 2
Mintz GS, Kovach JA, Javier SP et al. (1995) Mechanisms of lumen enlargement after excimer laser coronary angioplasty. An intravascular ultrasound study. Circulation 92 (12) 3408–3414.	n = 190 FU = not reported	These findings support both photoablation and forced vessel expansion as mechanisms of lumen enlargement and plaque dissection after laser angioplasty	Larger studies are included in table 2
Natarajan MK, Bowman KA, Chisholm RJ et al. (1996) Excimer laser angioplasty vs. balloon angioplasty in saphenous vein bypass grafts: quantitative angiographic comparison of matched lesions. Catheterization & Cardiovascular Diagnosis 38 (2) 153–158.	n = 80 (41 laser) FU = not reported	In a matched population of successfully treated vein graft lesions, laser angioplasty plus did not reduce elastic recoil or improve immediate angiographic outcome, as compared with balloon angioplasty alone	Larger studies are included in table 2
Noble S and Bilodeau L. (2008) High energy excimer laser to treat coronary in-stent restenosis in an underexpanded stent. Catheterization and Cardiovascular Interventions 71 (6) 803–807.	n = 1 FU = 10 months	Laser technology represents a useful tool to overcome resistant lesions during percutaneous coronary interventions	Larger studies are included in table 2
Okmen E, Cakmak M, Celik S et al. (2001) Laser angioplasty in a right coronary artery stent restenosis with the guidance of left internal mammary artery contrast injection: Case report. Catheterization and Cardiovascular Interventions 53 (1) 71–74.	n = 1 FU = 7 months	We successfully used the left internal mammary artery contrast injections for guidance in all stages of the right coronary laser angioplasty intervention	Larger studies are included in table 2
Power JA and Schmidhofer M.	n = 43	We now have a	Larger studies are

(1992) Excimer laser coronary angioplasty for diseased saphenous vein bypass grafts. Clinical Laser Monthly 10 (3) 41–44.	FU = 6 months	procedure that significantly improves quality of life and, in certain instances, the length of life for these patients	included in table 2
Pizzulli L, Jung W, Pfeiffer D et al. (1996) Angiographic results and elastic recoil following coronary excimer laser angioplasty with saline perfusion. Journal of Interventional Cardiology 9 (1) 9–18.	n = 48 FU = not reported	Laser angioplasty with concomitant saline infusion is effective, safe, and easy to perform	Larger studies are included in table 2
Rechavia E, Federman J, Shefer A et al. (1995) Usefulness of a prototype directional catheter for excimer laser coronary angioplasty in narrowings unfavorable for conventional excimer or balloon angioplasty. American Journal of Cardiology 76 (16) 1144–1146.	n = 53 FU = 6 months	Further evaluation of this device using the now standard saline infusion technique is necessary to establish its ultimate role as a primary interventional device	Larger studies are included in table 2
Safian RD, Freed M, Reddy V et al. (1996) Do excimer laser angioplasty and rotational atherectomy facilitate balloon angioplasty? Implications for lesion-specific coronary intervention. Journal of the American College of Cardiology 27 (3) 552–559.	n = 1266 (237 laser) FU = not reported	Rotational atherectomy, extraction atherectomy and excimer laser angioplasty can facilitate the results of balloon angioplasty. However, the extent of facilitated angioplasty is dependent on the device and baseline lesion morphology, consistent with the need for lesion-specific coronary intervention	Larger studies are included in table 2
Sanborn TA, Torre SR, Sharma SK et al. (1991) Percutaneous coronary excimer laser-assisted balloon angioplasty: initial clinical and quantitative angiographic results in 50 patients. Journal of the American College of Cardiology 17 (1) 94–99.	n = 50 FU = 7 months	Percutaneous coronary excimer laser angioplasty appears to be a feasible and safe procedure in selected patients	Larger studies are included in table 2
Schofer J, Rau T, Schluter M et al. (1997) Short-term results and intermediate-term follow-up of laser wire recanalization of chronic coronary artery occlusions: A single-center experience. Journal of the American College of Cardiology 30 (7) 1722–1728.	n = 68 FU = 24 weeks	Successful recanalisation of a chronic coronary occlusion by using currently available laser wires can be expected in 50% of selected patients in whom attempts at mechanical revascularisation fail. Restenosis or reocclusion accounts for an overall 6-month	Larger studies are included in table 2

		success rate of 35%	
Strauss BH, Natarajan MK, Batchelor WB et al. (1995) Early and late quantitative angiographic results of vein graft lesions treated by excimer laser with adjunctive balloon angioplasty. Circulation 92 (3) 348–356.	n = 125 (lesions) FU = not reported	Excimer laser angioplasty with adjunctive balloon angioplasty can be safely and successfully performed in diseased, old saphenous vein bypass graft lesions considered at high risk for reintervention	Larger studies are included in table 2
Strikwerda S, Van Swijndregt EM, Foley D et al. (1995) Immediate and late outcome of excimer laser and balloon coronary angioplasty: A quantitative angiographic comparison based on matched lesions. Journal of the American College of Cardiology 26 (4) 939–946.	n = 106 (53 laser) FU = not reported	Quantitative angiographic analysis of a matched group of 106 successfully treated coronary lesions showed a similar immediate outcome but reduced long-term efficacy of excimer laser-assisted balloon angioplasty compared with that after balloon angioplasty alone	Larger studies are included in table 2
Sunew J, Chandwaney RH, Stein DW et al. (2001) Excimer laser facilitated percutaneous coronary intervention of a nondilatable coronary stent. Catheterization and Cardiovascular Interventions 53 (4) 513–517	n = 1 FU = 3 months	The use of excimer laser facilitated full expansion of the stent with a balloon	Larger studies are included in table 2
Topaz, O., Bailey, N. T., and Mohanty, P. K.(1998) Application of solid-state pulsed-wave, mid-infrared laser for percutaneous revascularization in heart transplant recipients. Journal of Heart & Lung Transplantation 17 (5) 505-510	n = 5 FU = 2 to 28 months	In selected heart transplant recipients laser-assisted angioplasty can provide safe and successful acute revascularization	Larger studies are included in table 2 Atypical indication
Topaz O, Rozenbaum EA, Battista S et al. (1993) Laser facilitated angioplasty and thrombolysis in acute myocardial infarction complicated by prolonged or recurrent chest pain. Catheterization & Cardiovascular Diagnosis 28 (1) 7–16.	n = 9 FU = up to 6 months	This initial clinical experience demonstrates the feasibility and safety of holmium/thulium:YAG laser application in thrombolysis and plaque ablation in selected patients who experience acute myocardial infarction complicated by prolonged or recurrent ischaemia and chest pain	Larger studies are included in table 2 Combined intervention with thrombolysis
Topaz O, Ebersole D, Das T et al. (2004) Excimer laser angioplasty in acute myocardial infarction (the CARMEL multicenter trial). American Journal of Cardiology 93 (6) 694–701.	n = 151 FU = not reported	The presence of thrombus does not adversely affect procedural success; however, cardiogenic shock remains a predictor of major adverse events during	Larger studies are included in table 2

		hospitalisation	

Appendix B: Related NICE guidance for percutaneous laser coronary angioplasty

Guidance	Recommendations
Interventional procedures	**Percutaneous laser revascularisation for refractory angina pectoris. NICE interventional procedures guidance 302 (2009)** 1.1 Current evidence on percutaneous laser revascularisation (PLR) for refractory angina pectoris shows no efficacy and suggests that the procedure may pose unacceptable safety risks. Therefore, this procedure should not be used **Transmyocardial laser revascularisation for refractory angina pectoris. NICE interventional procedures guidance 301 (2009)** 1.1 Current evidence on transmyocardial laser revascularisation (TMLR) for refractory angina pectoris shows no efficacy, based on objective measurements of myocardial function and survival. Current evidence on safety suggests that the procedure may pose unacceptable risks. Therefore, this procedure should not be used
Technology appraisals	**Guidance on the use of drugs for early thrombolysis in the treatment of acute myocardial infarction. NICE technology appraisal 052 (2002)** 1.1 It is recommended that, in hospital, the choice of thrombolytic drug (alteplase, reteplase, streptokinase or tenecteplase) should take account of: • the likely balance of benefit and harm (for example, stroke) to which each of the thrombolytic agents would expose the individual patient • current UK clinical practice, in which it is accepted that patients who have previously received streptokinase should not be treated with it again • the hospital's arrangements for reducing delays in the administration of thrombolysis. 1.2 Where pre-hospital delivery of thrombolytic drugs is considered a beneficial approach as part of an emergency-care pathway for AMI (for example, because of population geography or the accessibility of acute hospital facilities), the practicalities of administering thrombolytic drugs in pre-hospital settings mean that the bolus drugs (reteplase or tenecteplase) are recommended as the preferred option.

Appendix C: Literature search for percutaneous laser coronary angioplasty

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	23/02/2010	Issue 1, 2010
Database of Abstracts of Reviews of Effects – DARE (CRD website)	23/02/2010	N/A
HTA database (CRD website)	23/02/2010	N/A
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	23/02/2010	Issue 1, 2010
MEDLINE (Ovid)	23/02/2010	Ovid MEDLINE(R) 1950 to February Week 2 2010
MEDLINE In-Process (Ovid)	23/02/2010	February 23, 2010
EMBASE (Ovid)	23/02/2010	EMBASE 1980 to 2010 Week 07
CINAHL (NLH Search 2.0)	23/02/2010	Cinahl 1981 to present
BLIC (Dialog DataStar)	18/02/2010	Searched for angioplasty in title - Non relevant
Zetoc (for update searches only)	N/A	N/A

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

1	Coronary Disease/ 119074 Advanced Display
2	Myocardial Infarction/ 120031 Advanced Display
3	Atherosclerosis/ 10146 Advanced Display
4	Angina Pectoris/ 28606 Advanced Display
5	Coronary Artery Bypass/ 35817 Advanced Display
6	(coronary adj3 (bypass or artery)).tw. 108927 Advanced Display
7	(coronary adj3 arterioscleros?s).tw. 837 Advanced Display
8	or/1-7 314233 Advanced Display

9	Saphenous Vein/ 11897 Advanced Display
10	Coronary Restenosis/ 4451 Advanced Display
11	Stents/ 34616 Advanced Display
12	Catheter Ablation/ 13954 Advanced Display
13	Atherectomy, Coronary/ 1306 Advanced Display
14	(balloon adj3 failure).tw. 143 Advanced Display
15	(saphenous adj3 vein*).tw. 10260 Advanced Display
16	(in-stent adj3 restenosis).tw. 1989 Advanced Display
17	((intracoronary or intra coronary) adj3 thrombosis).tw. 124 Advanced Display
18	(atheroma* adj3 (ablation or restenosis or calcification or stenosis or lesion or obstruction or debulking)).tw. 452 Advanced Display
19	(plaque* adj3 (ablation or restenosis or calcification or stenosis or lesion or obstruction or debulking)).tw. 1174 Advanced Display
20	or/9-19 67299 Advanced Display
21	8 and 20 16307 Advanced Display
22	exp Angioplasty, Laser/ 903 Advanced Display
23	Angioplasty, Balloon, Laser Assisted/ 311 Advanced Display
24	Lasers,Excimer/ 2738 Advanced Display
25	(percutaneous adj3 laser).tw. 502 Advanced Display
26	((Excimer or eximer or catheter) adj3 laser).tw. 3609 Advanced Display
27	dymer 200.tw. 2 Advanced Display
28	(ecla or extracorporeal lung assist).tw. 141 Advanced Display
29	or/22-28 6201 Advanced Display
30	21 and 29 220 Advanced Display
31	animals/ 4487711 Advanced Display
32	humans/ 11001391 Advanced Display
33	31 not (31 and 32) 3345663 Advanced Display
34	30 not 33 218 Advanced