NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of percutaneous coblation of the intervertebral disc for low back pain and sciatica

The tough covering of a spinal disc (annulus) can sometimes break, allowing the soft centre to bulge through. This is called herniation, also known as 'slipped disc'. This may cause pain in the back, pain in the leg (sciatica), and numbness and weakness in the leg. This procedure aims to relieve low back pain and sciatica by inserting a narrow tube into the affected disc and delivering radiofrequency energy to remove excess tissue.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) 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 IP overview was prepared in May 2015 and updated in November 2015.

Procedure name

- Percutaneous coblation of the intervertebral disc for low back pain and sciatica
- Nucleoplasty
- Plasma disc decompression

Specialist societies

- British Association of Spinal Surgeons
- British Pain Society Interventional Pain Management Special Interest Group

- British Society of Interventional Radiologists

Description

Indications and current treatment

Lumbar disc herniation occurs when the nucleus pulposus of an intervertebral disc protrudes through a tear in the surrounding annulus fibrosus. Symptoms include pain in the back or leg, and numbness or weakness in the leg. Serious neurological sequelae may sometimes occur.

Conservative treatments include analgesics, non-steroidal anti-inflammatory medication, manual therapy and acupuncture. Epidural corticosteroid injections can also be used to reduce nerve pain in the short term. Lumbar discectomy is considered if there is evidence of severe nerve compression or persistent symptoms that are unresponsive to conservative treatment. Surgical techniques include open discectomy or minimally invasive alternatives using percutaneous approaches.

Potential candidates for percutaneous coblation of the intervertebral disc are those patients with pain caused by contained herniated discs that has not responded to conservative treatment, but who are not yet considered to be candidates for open surgery.

What the procedure involves

Percutaneous coblation of the intervertebral disc for low back pain and sciatica is usually performed on an outpatient basis under sedation and local anaesthesia. Under fluoroscopic guidance, a needle is inserted into the affected disc. A probe-like device that uses radiofrequency energy is then introduced into the disc. The device is heated up to 40–70°C, ablating the centre of the disc and creating a channel. After stopping at a pre-determined depth, the probe is then removed, coagulating the tissue as it is withdrawn. Around 6 channels are created during the procedure, the number of channels depending on the amount of tissue reduction needed. The aim is that the procedure provides targeted removal of tissue from the disc nucleus without damaging surrounding structures.

Outcome measures

The Oswestry Disability Index (ODI) measures degrees of disability in a person with low back pain. The index is scored from 0 to 100, with 0 indicating no disability and 100 indicating maximum disability.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to percutaneous coblation of the intervertebral disc for low back pain and sciatica. The following databases were searched, covering the period from their start to 23 September 2015: 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 low back pain or sciatica.
Intervention/test	Percutaneous coblation of an intervertebral disc.
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 IP overview

This IP overview is based on approximately 4000 patients from 1 systematic review (including a randomised controlled trial and case series that have been described separately in table 2), 2 randomised controlled trials, 1 non-randomised comparative study, 2 case series and 1 case report[1–9].

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 coblation of the intervertebral disc for low back pain and sciatica

Study 1 Eichen PM (2014)

Details

Study type	**Systematic review and meta-analysis**
Country	Germany
Recruitment period	Search date: 30 September 2012
Study population and number	27 studies were included: 4 randomised controlled trials, 18 prospective non-randomised studies and 5 retrospective studies. **n=3211 patients treated by nucleoplasty (percutaneous coblation)** 21 studies included patients with lumbar disc herniation and 6 included patients with cervical disc herniation.
Age and sex	Mean age ranged from 38 to 52 years (not specified in 5 studies). Sex not reported.
Patient selection criteria	Patients treated by nucleoplasty for intervertebral disc conditions. Studies were only included if they scored at least 2 on the modified Jadad scale (used for making a qualitative assessment of the methodology of studies conducted in pain research - score ranges from 0 to 8, with questions pertaining to randomisation, blinding, study dropouts, inclusion and exclusion criteria, side effects, and statistical methods). Only English language publications were included.
Technique	Systematic search used the terms 'nucleoplasty' and 'plasma disc decompression'.
Follow-up	**24 months**
Conflict of interest/source of funding	Research was funded by an unrestricted scientific grant from ArthroCare (Deutschland) AG. None of the authors had a conflict of interest.

Analysis

Study design issues: 22 of the studies were prospective and 5 were retrospective; 7 were controlled. Outcome measures included in the meta-analysis were pain (visual analogue scale 0 to 10, where 0 is no pain and 10 is the greatest imaginable pain) and the Oswestry Disability Index (scale 0 to 100, where 0 is minimal impairment and 100 is maximal impairment). The studies were heterogeneous and a minimum score of 2 on the Jadad scale was applied to obtain homogeneity. A random effects model was used for the meta-analysis. If no information pertaining to complications was found, the study was deleted from the meta-analysis calculation. A control group called 'conservative therapy (including epidural steroid injection)' was generated from the control groups of the 27 studies. Three of the 7 controlled studies used microdiscectomy or 'disc dekompressor' as the comparative treatments.

Study population issues: The included studies described patients with intervertebral disc herniation, regardless of level. Of the 27 studies, 6 included patients with cervical disc herniation rather than lumbar disc herniation. Patients with higher grade spinal degenerations and disc extrusions were also included in the studies.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **3211 patients treated by percutaneous coblation**

Pain reduction measured using a visual analogue score (VAS) or numeric pain scale (NPS) (range 0–10 where 0 is no pain and 10 is the greatest imaginable pain)

17 studies were included in analysis (n=971 patients treated by percutaneous coblation; 4 studies were comparative and included 230 control patients treated by conservative therapy).

Patients treated by percutaneous coblation				
Random effects analysis	**n**	**VAS/NPS**	**95% CI**	**p values in comparison to baseline**
Baseline	971	7.27	7.03 to 7.51	
3 months	612	2.84	2.45 to 3.23	<0.001
6 months	790	3.06	2.60 to 3.53	<0.001
12 months	702	3.03	2.15 to 3.92	<0.001
18 months	73	1.54	1.16 to 1.91	<0.001
24 months	92	3.69	3.34 to 4.04	<0.001
Patients treated by conservative therapy (including epidural steroid injection)				
Random effects analysis	**n**	**VAS/NPS**	**95% CI**	**p values in comparison to percutaneous coblation**
Baseline	98	6.98	5.91 to 8.04	0.599
3 months	88	4.87	3.86 to 5.89	<0.001
6 months	85	4.25	2.61 to 5.90	0.173
12 months	57	3.85	3.77 to 3.92	0.073

The difference in pain relief between patients with cervical or lumbar disc herniation was not significant at any time point.

Functional mobility measured using Oswestry Disability Index(6 studies, n=318 versus 105; all patients had lumbar disc herniations)

Patients treated by percutaneous coblation				
Random effects analysis	**n**	**ODI**	**95% CI**	**p values in comparison to baseline**
Baseline	318	58.95	45.47 to 72.43	
6 weeks	40	30.00	24.42 to 35.58	<0.001
3 months	153	18.30	8.40 to 28.19	<0.001
6 months	256	22.54	10.94 to 34.13	<0.001
12 months	264	24.43	13.08 to 35.79	<0.001
18 months	73	12.82	9.16 to 16.47	<0.001
24 months	92	36.98	31.63 to 42.33	<0.005
Patients treated by conservative therapy (including epidural steroid injection)				
Random effects analysis	**n**	**ODI**	**95% CI**	**p values in comparison to percutaneous coblation**
Baseline	40	43	37.73 to 48.27	<0.05
6 weeks	33	38	33.22 to 42.78	<0.05
3 months	30	40	33.92 to 46.08	<0.001
6 months	28	49	43.44 to 54.56	<0.001

Safety

Complication rate (pooled value from meta-analysis)

- Percutaneous coblation (n=3069)=1.5% (range 0.7– 3.0%); cervical discs=0.8% (n=638), lumbar discs=1.8% (n=2237)
- Control procedures (n=168)=4.0% (range 0.9–16.2%)

The most frequent complications were postoperative discitis and tingling or numbness, and leg pain.

The review states that most studies reported no or no significant complications.

Abbreviations used: CI, confidence interval; NPS, numerical pain scale; ODI, Oswestry Disability Index; VAS, visual analogue score

Study 2 Gerszten PC (2010) – also included in Eichen PM et al, 2014 (study 1)

Details

Study type	**Randomised controlled trial**
Country	USA
Recruitment period	2005–7
Study population and number	**n=90 (46 percutaneous coblation vs 44 transforaminal epidural steroid injections)** Patients with sciatica associated with a single-level lumbar contained disc herniation.
Age and sex	Mean age (years): 46 vs 42 (p=0.13) 51% female
Patient selection criteria	Age 18–75 years; body mass index less than 40; radicular pain score of 50 or more (measured on a visual analogue scale 0–100); treated by epidural corticosteroid injection for the same symptoms between 3 weeks and 6 months previously. Patients with evidence of extruded or sequestered disc herniation were not included. Exclusion criteria included having sciatica originating from more than 1 disc level, more severe axial (back) pain than radicular (leg) pain, clinical evidence of cauda equine syndrome, progressive neurological deficit, radiological evidence of spondylolisthesis or moderate or severe stenosis at the level to be treated, history of previous spinal surgery at or directly adjacent to the level to be treated, spinal fracture, tumour or infection.
Technique	Device for percutaneous coblation: Coblation DLR or DLG SpineWand device (ArthroCare Corporation). All procedures were done on an outpatient basis. Patients assigned to the epidural steroid injections were scheduled to receive up to 2 injections, 3 weeks apart. Patients in both treatment groups were allowed to receive additional conservative therapies, including bed rest, braces, physical therapy, narcotic analgesics, or non-steroidal anti-inflammatories, at the discretion of the treating investigator.
Follow-up	**2 years (6 months for RCT part of study)**
Conflict of interest/source of funding	Financial support was provided by the ArthroCare Corporation. In addition, 4 authors were consultants for ArthroCare Corporation and 1 author received financial support from the company for non-study-related clinical or research effort overseen by him.

Analysis

Follow-up issues: 4 patients were lost to follow-up at 6 months (1 in the percutaneous coblation group and 3 in the epidural steroid injection group. A total of 12 patients were lost to follow-up at 2 years (6 in each treatment group). Of the 90 patients randomised, 5 did not receive treatment (1 assigned to percutaneous coblation and 4 assigned to steroid injections): 3 patients did not return for treatment, 1 patient died and 1 patient no longer met the study eligibility criteria. During the study follow-up, 1 patient from each group died (1 from a myocardial infarction and 1 as a result of acute pyelonephritis).

Study design issues: Patients were randomly assigned to the treatment groups using sealed envelopes. Patients were not blinded to their treatment allocation. Analysis was by intention to treat. The primary outcome was pain reduction, assessed using a visual analogue scale (VAS, 0 was 'no pain' and 100 was 'worst pain imaginable'). Self-reported function and quality of life were assessed using the Oswestry Disability Index (ODI), the SF-36 questionnaire, and satisfaction with treatment. Minimum clinically important changes were considered to be ≥25 points for leg pain VAS scores, ≥13 points for back pain scores, ≥12 points for ODI scores, and ≥5 points for SF-36 scores.

Study population issues: The 2 groups were similar with regard to age, sex, body mass index and employment status. All baseline status measures were statistically similar between treatment groups except for duration of leg pain, which was significantly longer in the epidural steroid injection group.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **85 (45 vs 40)**

Mean % change in VAS pain scores and ODI scores (95% confidence intervals)

Measure and follow-up period	Percutaneous coblation	Epidural steroid injection	p value
Leg pain VAS score			
6 weeks	-53 (-40 to -67)	-28 (-15 to -40)	0.007
3 months	-63 (-49 to -76)	-31 (-16 to -46)	0.003
6 months	-67 (-52 to -83)	-30 (-18 to -43)	0.0008
Back pain VAS score			
6 weeks	-7 (-51 to 37)	10 (-19 to 39)	0.01
3 months	-9 (-55 to 33)	28 (-5 to 62)	0.01
6 months	-29 (-67 to 9)	24 (-34 to 83)	0.003
ODI score			
6 weeks	-29 (-16 to -42)	-8 (-18 to 3)	0.03
3 months	-23 (-7 to -40)	0.3 (-14 to 14)	0.07
6 months	-37 (-16 to -58)	-11 (-22 to 0)	0.04

Leg pain VAS scores were significantly reduced from baseline in both treatment groups (p<0.001). Back pain VAS and ODI scores were significantly reduced from baseline in the percutaneous coblation group but not the epidural steroid injection group.

Quality of life

Both treatments were associated with significant improvements in the SF-36 components of physical function, bodily pain, physical components summary, and social function at 6 months. The percutaneous coblation group also had significant improvement for the role physical and role emotional components. There were significant differences between treatment groups for physical function (p=0.0016), bodily pain (p=0.0039), physical components summary (p=0.004) and social function (p=0.0312).

The number of patients working full or part-time at 6 months follow-up was similar in both treatment groups (69–70%). Reduction in the use of pain relief medication did not differ significantly between the groups.

Patient satisfaction at 6 months follow-up

	Percutaneous coblation	Epidural steroid injection
Extremely satisfied	38%	15%
Very satisfied	24%	18%
Somewhat satisfied	31%	26%
Somewhat dissatisfied	3%	15%
Very dissatisfied	3%	15%
Extremely dissatisfied	0%	11%

During the 2-year follow-up, 25 patients in the percutaneous coblation group and 11 patients in the epidural steroid injection group remained free from having a secondary procedure.

Safety

Procedure-related adverse events

- Percutaneous coblation=11% (5/45) (7 events)
- Epidural steroid injection=18% (7/40) (14 events)

Pain at the injection site

- Percutaneous coblation=4.4% (2/45)
- Epidural steroid injection=5.0% (2/40)

Increased radicular pain

- Percutaneous coblation=2.2% (1/45)
- Epidural steroid injection=12.5% (5/40)

Increased weakness

- Percutaneous coblation=2.2% (1/45)
- Epidural steroid injection=0% (0/40)

Increased back pain

- Percutaneous coblation=2.2% (1/45)
- Epidural steroid injection=10.0% (4/40)

Lightheadedness

- Percutaneous coblation=0% (0/45)
- Epidural steroid injection=2.5% (1/40)

Muscle tightness or spasms

- Percutaneous coblation=4.4% (2/45)
- Epidural steroid injection=2.5% (1/40)

Acute low back pain with muscle spasms

- Percutaneous coblation=2.2% (1/45)
- Epidural steroid injection=2.5% (1/40)

Proportion of patients attaining literature-based minimum clinically important changes for leg pain, back pain, ODI and SF-36 scores, n(%)

Measure and follow-up period	Percutaneous coblation	Epidural steroid injection	p value
Leg pain VAS score change ≥25 points (n=43 vs 39)			
6 months	21 (49)	8 (21)	0.0074
1 year	19 (44)	7 (18)	0.0195
2 years	18 (42)	8 (21)	0.0380
Back pain VAS score change ≥12 points (n=39 vs 36)			
6 months	19 (49)	8 (22)	0.0169
1 year	15 (39)	4 (11)	0.0065
2 years	15 (39)	6 (17)	0.0357
ODI score change ≥13 points (n=44 vs 40)			
6 months	14 (32)	6 (15)	0.0707
1 year	11 (25)	4 (10)	0.0730
2 years	13 (30)	4 (10)	0.0260
SF-36 score change ≥5 points (n=43 vs 39)			
6 months	16 (37)	8 (21)	0.0970
1 year	14 (33)	5 (13)	0.0344
2 years	14 (33)	5 (13)	0.0344

Patients who had a secondary procedure were counted as not having achieved the literature-based minimum clinically important difference threshold.

Abbreviations used: ODI, Oswestry Disability Index; VAS, visual analogue scores

Study 3 Chitragran R (2012)

Details

Study type	**Randomised controlled trial**
Country	Thailand
Recruitment period	2007–9
Study population and number	**n=64** (32 percutaneous coblation vs 32 conservative treatment) Patients with radicular or axial low back pain secondary to contained herniated discs.
Age and sex	Age not reported; 56% (36/64) female
Patient selection criteria	Inclusion criteria were the presence of discogenic low back pain or leg pain for six weeks or more, absence of neurological deficit, lack of response to conservative management and fluoroscopically guided injection therapies. The diagnosis was confirmed by MRI. Exclusion criteria included heavy opioid use and uncontrolled psychological disorders. Contraindications for the procedure were evidence of infection, disc herniation with sequestration, large contained herniation occupying one-third or more of the spinal canal, marked spinal stenosis due to extensive osteophytosis, and equivocal discography results.
Technique	Device for percutaneous coblation: Perc-DLE wand (ArthroCare Inc., USA). All procedures were done on an outpatient basis under monitored anaesthesia care in the operating room.
Follow-up	**up to 12 months**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: There were no losses to follow-up.

Study design issues: Randomisation was done by computer. Outcome measures included self-reported pain score on a numeric pain scale (with 0 being no pain and 10 being the most severe pain) and functional improvement, based on patients reported ability to sit, stand and walk without significant or intolerable pain for less than 15 minutes, 15 to 30 minutes, 30 to 45 minutes, 45 minutes to 1 hour, 1 to 2 hours, and greater than 2 hours. Preoperative and postoperative MRI were used to assess the reduction of the bulging disc.

Study population issues: The conclusion of the paper notes that these patients were not considered candidates for open surgical intervention.

Other issues: Some of the results section is lacking in clarity and was difficult to interpret.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **64 (32 vs 32)** Pain reduction was statistically significant in the treatment group at 15 days follow up and this reduction was sustained at 12 months follow up (p≤0.001). There was no significant reduction in the control group. Pain reduction was significantly greater in the treatment group compared with the control group at 15 days follow-up. Functional status was improved at 1, 3, 6 and 12 months after percutaneous coblation (p≤0.001 for all time periods). Mean disc bulge in treatment group • Baseline=5.09 mm • 3 month follow-up=1.81 mm (p<0.001)	There were no infections or nerve root injuries.

Study 4 Adam D (2013)

Details

Study type	**Non-randomised comparative study**
Country	Romania
Recruitment period	2009–10
Study population and number	**n=160** (80 percutaneous coblation versus 80 open discectomy) Patients with radicular symptoms and lumbar disc protrusions.
Age and sex	Age range 20–81 years (mean 43 versus 47 years); 44% (70/160) female
Patient selection criteria	Inclusion criteria for percutaneous coblation: radicular pain more intense than back pain and resistant to previous conservative treatment for a period of at least 6 weeks; MRI evidence of contained disc; herniation ≤6 mm in antero-posterior diameter. Exclusion criteria: disc protrusion >6 mm or sequestration, spondylolisthesis, spinal fractures, infections, tumours. Inclusion criteria for open discectomy: radicular pain that has not responded to medical treatment after 6 weeks; motor deficit and MRI evidence of disc protrusion >6 mm in antero-posterior diameter. Exclusion criteria: back pain as a chief complaint and disc protrusion <6 mm. Common inclusion criteria: 1 level protrusion and 'virgin' spine at the level of interest.
Technique	Percutaneous coblation was done in an outpatient setting. Open discectomy was done using a posterior lumbar approach through the interlaminar space, with small unilateral laminectomy and medial facetectomy. The herniated fragment was removed, followed by subtotal discectomy with intradisc curettage without end-plate lesion.
Follow-up	**12 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: There were no losses to follow-up.

Study design issues: Outcome measures included pain score (visual analogue scale range 0 to 10, with 0 being no distress and 10 being agonising pain) and the Rolland-Morris disability questionnaire (a health status measure for low back pain, score ranges from 0 to 24 with higher scores indicating a greater level of disability).

Study population issues: There were different inclusion criteria for the 2 different treatment groups.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **160 (80 vs 80)**

Pain reduction measured using a visual analogue scale

Follow-up period	Percutaneous coblation	Open discectomy
Baseline	7.9	8.0
3 months	5.0	2.8
6 months	3.7	2.0
12 months	2.2	1.8

Improvement in disability (Rolland-Morris questionnaire)

Follow-up period	Percutaneous coblation	Open discectomy
Baseline	-	-
3 months	40%	60%
6 months	45%	70%
12 months	60%	78%

General clinical outcome at 1-year follow-up

Grade	Percutaneous coblation, n (%)	Open discectomy, n (%)
Excellent	31 (38.75)	29 (36.25)
Good	27 (33.75)	26 (32.50)
Fair	21 (26.25)	22 (27.50)
Poor	1 (1.25)	3 (3.75)

'Excellent' and 'good' define the success rate

Proportion of patients who returned to work

Follow-up period	Percutaneous coblation	Open discectomy
1 month	99% (64/65)	3.1% (2/64)
3 months	99% (64/65)	10.9% (7/64)
6 months	99% (64/65)	21.8% (14/64)
12 months	99% (64/65)	31.2% (20/64)

Patients' opinion of outcome for percutaneous coblation

- Successful (improvement of more than 75%)=40% (32/80)
- Partially successful (improvement between 25% and 75%)=31.3% (25/80)
- Failure (less than 25% improvement)=28.8% (23/80)

67% of patients would recommend percutaneous coblation to other patients, 32% of patients would not recommend it.

Reoperation

- Percutaneous coblation, n=1 (patient had open discectomy 3 months after percutaneous coblation because of severe pain)
- Open discectomy, n=3.

Safety

There were no complications in the group of patients treated by percutaneous coblation.

The following complications were reported in the open discectomy group:

- CSF fistula, n=1
- Discitis, n=1
- Superficial infections, n=3

Study 5 Wu S (2013)

Details

Study type	**Randomised controlled trial**
Country	China
Recruitment period	2009–11
Study population and number	**n=118 (39 percutaneous coblation vs 39 percutaneous coblation combined with nerve root injection vs 40 transforaminal lumbar epidural injection)** Patients with lumbar disc herniation confirmed by MRI
Age and sex	Mean age 42 vs 41 vs 41 years; 31% (36/118) female
Patient selection criteria	Age range 20–60 years; radicular pain, resulting from disc herniation at a single segmental level, continuing over a 6-month period; MRI evidence of small-sized or medium-sized herniated discs correlating with the clinically identified segment (contained disc herniation <6 mm with the disc height ≥50% compared with normal adjacent discs; no neurological deficits; failure to get any improvement by conservative treatment (physical, manual therapy, and non-opioid medication); pain intensity ≥5 of maximum 10 and clear clinical signs of nerve root ganglion irritation; no previous surgical intervention. Exclusion criteria included infection; spinal tumour or fracture; history of drug abuse; multilevel symptoms or MRI evidence; a psychological or cognitive disturbance or somatic disorder that could affect the outcome; structural spinal deformities or vertebral canal stenosis, and severe degenerative disc material or complete annular disruption on MRI; intervertebral disc herniations ≥6 mm or sequestered intervertebral disc herniations, and greater back pain than leg pain; pregnancy; allergy to contrast media or drugs used in the procedure.
Technique	Device for percutaneous coblation: Perc-DLE Spine wand (ArthroCare Inc., USA). For the nerve root injection, the needle was withdrawn adjacent to the nerve root under CT fluoroscopic guidance after the coblation procedure and 2 ml of steroid solution with 1 ml of 1.0% lidocaine were injected. All patients were advised to start lumbar stabilisation exercises 3 weeks after the procedure.
Follow-up	**12 months**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: 5 patients were lost to follow-up and 8 patients underwent surgery after their initial procedure: these patients were excluded from the analysis. In addition, 5 patients in the epidural injection group received a repeat injection and these were also excluded from the analysis.

Study design issues: Patients were randomly allocated into 3 groups by a research nurse, with the help of a computer-generated table of random numbers. The treatment allocation was sealed in an envelope, which was opened by a staff nurse before the procedure. The patients were blinded to their group assignment. Outcome measures included a numeric rating scale for pain from 0 (no pain) to 10 (worst possible pain) and the Chinese version of the Oswestry Disability Index (10 questions covering different dimensions of daily living).

Study population issues: There were no significant differences between the groups with regard to sex, age, duration of symptoms, and involved disc before the procedure.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **97 (33 vs 35 vs 29)**

Numeric Rating Scale for pain

Follow-up	Group A: percutaneous coblation	Group B: percutaneous coblation combined with nerve root injection	Group C: epidural injection	1-way ANOVA	Post Hoc comparison	Least significant difference (LSD) p value
Baseline	7.15±1.15	7.29±1.02	7.31±1.00	0.812		
1 week	4.97±1.02*	3.86±1.09*	4.10±1.01*	<0.001	A vs B A vs C B vs C	<0.001# 0.002# 0.349
1 month	3.36±0.74*	2.51±0.85*	3.21±0.76*	<0.001	A vs B A vs C B vs C	<0.001# 0.432 0.001#
3 months	2.33±0.78*	2.29±0.62*	3.30±0.78*	<0.001	A vs B A vs C B vs C	0.787 <0.001# <0.001#
12 months	2.27±0.57*	2.14±0.73*	3.44±0.58*	<0.001	A vs B A vs C B vs C	0.401 <0.001# <0.001#

* p<0.001 compared with baseline, # significant differences in 1-way ANOVA and LSD tests (p<0.05)

Oswestry Disability Index scores (%)

Follow-up	Group A: percutaneous coblation	Group B: percutaneous coblation combined with nerve root injection	Group C: epidural injection	1-way ANOVA	Post Hoc comparison	Least significant difference (LSD) p value
Baseline	47.73±10.31	47.71±11.65	48.10±11.29	0.998		
1 week	40.75±8.58*	34.57±8.43*	36.21±8.86*	0.011	A vs B A vs C B vs C	0.004# 0.039# 0.448
1 month	31.96±6.72*	27.14±8.51*	32.41±5.92*	0.006	A vs B A vs C B vs C	0.007# 0.809 0.005#
3 months	25.30±6.49*	24.29±6.32*	30.52±5.57*	<0.001	A vs B A vs C B vs C	0.498 0.001# <0.001#
12 months	22.73±6.26*	22.85±5.32*	27.76±4.93*	0.001	A vs B A vs C B vs C	0.923 0.001# 0.001#

* p<001 compared with baseline, # significant differences in 1-way ANOVA and LSD tests (p<0.05)

The 12-month follow-up MRI correlated with the clinical outcome, demonstrating a reduction in the disc lesions in nearly 70% of patients treated by percutaneous coblation. None of the patients with poor pain relief displayed obvious degeneration of the treated disc. No change in the involved disc was observed in the patients treated by epidural injection.

Safety

No safety outcomes were reported.

Abbreviations used: ANOVA, analysis of variance; LSD, least significant difference

Study 6 Kallas JL (2013)

Details

Study type	**Case series (retrospective)**
Country	Brazil
Recruitment period	2004–8
Study population and number	**n=396** Patients with lumbar disc herniation related pain
Age and sex	Median age 46 years
Patient selection criteria	Pain with clinical-radiological correlation; MRI showed disc protrusions or contained hernia; at least two-thirds of intervertebral space height preservation; previous treatment with short rest period, pain medications and motor physiotherapy, without satisfactory improvement. Exclusion criteria: presence of obvious disc fragment sequestration; loss of more than one-third of the intervertebral space height; diffuse or multilevel degenerative disc changes on imaging; no signs of radicular involvement or axial pain associated with the degenerated level; previous diagnosis or antecedents of psychological and/or psychiatric disorders; uncontrolled systemic diseases, as well as active infection or neoplasm.
Technique	Patients were conscious throughout the procedure and sedation was given on an on-demand basis. After the procedure, patients remained in bed rest with local cold compresses for about 20 minutes in 3-hour breaks, with constipation prevention diet and hospital discharge scheduled for the next 12 hours.
Follow-up	**Up to 3 years (mean 1 year)**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: No losses to follow-up were described.

Study design issues: Retrospective study. The main outcome measure was a visual analogue scale for pain (not described).

Study population issues: The most frequent affected level was L4-L5, followed by L5-S1.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **396** ***Improvement in pain after the procedure (VAS)*** • 100% (complete pain remission)=26% of patients • 90% pain improvement=13% of patients • 80% pain improvement=15% • At least 50% pain improvement=75% of patients The median pain improvement was about 67% according to the VAS scores. There was no improvement in symptoms in 6.3% (25/396) of patients.	**Complications=2%** • Radicular paraesthesia=0.5% (2/396) • Bradycardia=1.0% (4/396) • Discitis=0.25% (1/396) • Worsening of pain=0.25% (1/396) • Convulsive crisis=0.25% (1/396) All bradycardia episodes were related to poor tolerance to minor pain by the patients. The convulsive episode occurred as a result of prolonged pain-induced bradycardia in a patient receiving dexmedetomidine as sedative. The authors note that this led them to avoid using bradycardia inducing sedatives for this procedure.
Abbreviations used: VAS, visual analogue scale	

Study 7 Cincu R (2015)

Details

Study type	**Case series (retrospective)**
Country	Spain
Recruitment period	Not reported
Study population and number	**n=50** Patients with symptomatic contained disc herniations or bulging discs.
Age and sex	Mean age 52 years; 46% (23/50) female
Patient selection criteria	Age 18–75 years; 1 symptomatic contained, focal herniated lumbar disc; visual analogue score for radicular pain 7 or greater (on a scale 0–10); symptoms refractory to conservative management, including medication, physical therapy and epidural steroid injections. The radicular pain must be concordant with image findings (MRI or CT) and the disc herniation no more than a third of the sagittal diameter of the spinal canal. Exclusion criteria: previous spinal surgery at the level to be treated; morbid obesity (body mass index >40); spinal fracture, tumour or infection; back pain greater than radicular (leg) pain or radicular pain originating from more than 1 disc level or radiological evidence of severe stenosis at the level to be treated; radiological evidence of spondylolisthesis at the level to be treated; severe disc degeneration (with >50% loss of disc height); evidence of extruded or sequestered disc herniation on MRI; clinical evidence of cauda equina syndrome or progressive neurological deficit; allergy to the contrast media or drugs to be used in the procedure.
Technique	The procedure was done under local anaesthesia. In all patients, intervention was done at L4-L5 level.
Follow-up	**Mean 114 months (range 103–130)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: No losses to follow-up were described.

Study design issues: Retrospective study. Outcome measures included a visual analogue scale for pain (range 0–10), the Oswestry Disability Index, subjective global rating of overall satisfaction, and reduction in analgesic treatment; these were recorded and analysed every year. The report does not include the pain and disability scores at baseline. There are some discrepancies between the text and the table of the report, with regard to the pain and disability scores at different follow-up periods.

Study population issues: Patients presented with intermittent or continuous radicular pain with or without low back pain. 9 patients had previous L5-S1 surgery (discectomy or arthrodesis).

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>
Number of patients analysed: 50

Pain score (visual analogue scale, VAS 0–10)
<table>
<tr><th>Follow-up period</th><th>Mean Difference</th><th>Standard error</th><th>p value</th><th>95% CI</th></tr>
<tr><td>Baseline</td><td></td><td></td><td></td><td></td></tr>
<tr><td>1 month</td><td>5.2</td><td>0.2</td><td><0.0001</td><td>4.8 to 5.6</td></tr>
<tr><td>6 months</td><td>4.0</td><td>0.2</td><td><0.0001</td><td>3.5 to 4.5</td></tr>
<tr><td>12 months</td><td>5.1</td><td>0.3</td><td><0.0001</td><td>3.5 to 4.6</td></tr>
<tr><td>24 months</td><td>4.2</td><td>0.3</td><td><0.0001</td><td>4.8 to 6.0</td></tr>
<tr><td>72 months</td><td>4.8</td><td>0.3</td><td><0.0001</td><td>4.8 to 6.0</td></tr>
</table>
The text states that the VAS was 4.0 at 24 months follow-up, 4.2 at 48 months and 4.8 at 72 months.

Oswestry low back pain disability Index score (ODI)
<table>
<tr><th>Follow-up period</th><th>Mean Difference</th><th>Standard error</th><th>p value</th><th>95% CI</th></tr>
<tr><td>6 months</td><td>35.6</td><td>15.6</td><td><0.0001</td><td>31.4 to 39.8</td></tr>
<tr><td>12 months</td><td>35.1</td><td>16.7</td><td><0.0001</td><td>30.5 to 39.7</td></tr>
<tr><td>24 months</td><td>43.2</td><td>18.0</td><td><0.0001</td><td>38.3 to 48.5</td></tr>
<tr><td>72 months</td><td>43.6</td><td>18.0</td><td><0.0001</td><td>38.2 to 48.2</td></tr>
</table>
The text states that the ODI was 7.2 at 24 months follow-up, 7.0 at 48 months and 7.0 at 72 months.

15 patients had recurrence of pain within 30 days and needed another type of treatment.

At 12 months follow-up, 27 patients had improvement in pain VAS and 24 patients had improvement in ODI. Analgesic consumption was stopped or reduced in 90% of these cases after 1 year.

Coblation was repeated in 3 patients at 36 months follow-up.

Analgesic consumption was reintroduced in 80% of the patients after 7 years follow-up.

20% (10/50) of patients continued to be asymptomatic after 114 months. 54% of patients had mild pain that could be managed with smaller doses of medication than before the procedure.
</td><td>
The report states ‘There were no complications with the procedure including nerve root injury, discitis or allergic reaction.’
</td></tr>
<tr><td colspan="2">Abbreviations used: ODI, Oswestry Disability Index; VAS, visual analogue scale</td></tr>
</table>

Study 8 Alexandre A (2005) - also included in Eichen PM et al, 2014 (study 1) and in the 2006 overview

Details

Study type	**Case series**
Country	Italy
Recruitment period	2001–3
Study population and number	**n=1390** Patients with chronic lumbar pain, with or without radicular pain, due to disc bulging or partially contained disc herniation (989 L4-L5, 234 L3-L4, 167 L5-S1)
Age and sex	57% female
Patient selection criteria	Age 18–65 years; chronic lumbar pain, with or without radicular pain, lasting more than 3 months and with failure of medical and physical conservative treatments; absence of neurological deficit; 1 level positive provocative discography and negative control level. Exclusion criteria included disc herniation with sequestration, large contained herniation occupying one-third or more of the spinal canal, severe spinal stenosis due to extensive osteophytosis, presence of secondary pain issues, psychological disorders, gait disorders depending on different neurological or orthopaedic pathology. Contraindications were evidence of infection, severe coagulopathies or impossibility of interrupting anticoagulation treatment.
Technique	Percutaneous coblation device: Spine Wand (ArthroCare). After the procedure, patients were instructed to limit bending, rotating, and lifting more than 5 kg for 2 weeks. Physical exercises were started after this period.
Follow-up	**1 year**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: No losses to follow-up were described.

Study design issues: The baseline scores were not reported. Outcomes were assessed using the Japanese Orthopaedic Association (JOA) score.

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>Number of patients analysed: 1390
Functional outcomes
<table>
<tr><th>Follow-up</th><th>‘Excellent’</th><th>‘Good’</th><th>‘Scanty’</th><th>‘None’</th></tr>
<tr><td>15 days</td><td>50.8%</td><td>23%</td><td>13.9%</td><td>12.3%</td></tr>
<tr><td>1month</td><td>53.3%</td><td>26.6%</td><td>10%</td><td>10%</td></tr>
<tr><td>6 months</td><td>51.5%</td><td>31.5%</td><td>8.5%</td><td>8.5%</td></tr>
<tr><td>1 year</td><td>55.8%</td><td>24.9%</td><td>12.4%</td><td>6.9%</td></tr>
</table>
‘Excellent’ – total resolution of the clinical picture, and full re-uptake of daily activities.
‘Good’ – Fairly total resolution of pain, with rather good quality of life.
‘Scanty’ – Insignificant pain resolution and inability to take up normal daily activities.
‘None’ – No results both on pain and clinical field.

Radiological evaluation
MRI or CT were done 6 months after the procedure and showed that bulging was eliminated in 34% of patients, significantly reduced in 48% and unchanged in 18% of patients.</td><td>Operative complications
There were no complications related to the procedure, and no patients suffered radiculopathy

Postoperative complications
5% of patients complained of lateralised postural lumbar pain and hypertone (contraction of paravertebral muscles) for up to 10 days.</td></tr>
</table>

Study 9 Smuck M (2007)

Details

Study type	**Case report**
Country	USA
Recruitment period	not reported
Study population and number	**n=1** Patient with low back pain radiating to his leg, disc protrusion at L5-S1
Age and sex	46 year old male
Patient selection criteria	Not reported
Technique	Percutaneous disc decompression with coblation was done under mild conscious sedation.
Follow-up	**2 years**
Conflict of interest/source of funding	None

Key efficacy and safety findings

Epidural Fibrosis

A 46-year old man had percutaneous coblation after having previous epidural steroid injections. Within an hour of treatment, the patient reported improvement in his leg and back pain. The improvements continued over the following days to near complete relief. Within 6 weeks, he had resumed his usual activities.

Three months later, the patient had recurrence of pain in his left lower extremity and lower back. Physical examination showed a change in his reflexes. An MRI showed a large new soft tissue mass encasing the left S1 nerve root, consistent with epidural fibrosis.

The patient's symptoms spontaneously resolved after the MRI and no further treatment was given. Currently, more than 2 years since the procedure, the patient continues without complaints of back pain or leg pain.

Efficacy

Pain reduction

A systematic review of 27 studies, 17 of which were included in the efficacy analysis, reported that pain measured on a visual analogue scale (VAS, range 0–10, in which 0 is no pain and 10 is the greatest imaginable pain) decreased after percutaneous coblation from 7.27 (n=971) at baseline to 2.84 at 3 months (n=612, p<0.001), 3.03 at 12 months (n=702, p<0.001) and 3.69 at 24 months (n=92, p<0.001). In the group of patients treated by conservative therapy, the mean pain score decreased from 6.98 at baseline (n=98) to 3.85 at 12 months follow-up (n=57, p=0.073 compared with percutaneous coblation)[1]. A non-randomised study of 160 patients treated by percutaneous coblation or open discectomy reported that the VAS score for pain reduced from 7.9 and 8.0 at baseline to 2.2 and 1.8 respectively at 12-month follow-up[4]. A randomised controlled trial of 118 patients treated by percutaneous coblation alone, percutaneous coblation combined with nerve root steroid injection, or epidural steroid injection reported that the mean numeric rating scale for pain decreased from 7.15, 7.29, and 7.31 at baseline to 2.27, 2.14 and 3.44 respectively at 12-month follow-up (p<0.001 for all 3 compared with baseline)[5]. The reduction in pain was significantly greater in the percutaneous coblation group compared with the epidural injection group (p<0.001). A case series of 396 patients reported that 75% of patients had at least a 50% improvement in pain after the procedure (mean follow-up 1 year)[6]. A case series of 50 patients reported that 20% (10/50) of patients were asymptomatic after a mean follow-up of 114 months after the procedure, and 54% of patients had mild pain that could be managed with smaller doses of medication than before the procedure[7].

Functional outcomes

The systematic review of 27 studies reported that functional mobility measured using the Oswestry Disability Index (ODI) improved after percutaneous coblation from 58.95 (n=318) at baseline to 18.30 at 3 months (n=153, p<0.001), 24.43 at 12 months (n=264, p<0.001) and 36.98 at 24 months (n=92, p<0.005)[1]. In the group of patients treated by conservative therapy, the mean disability score increased from 43 at baseline (n=40) to 49 at 12-month follow-up (n=28, p<0.001 compared with percutaneous coblation). The non-randomised study of 160 patients treated by percutaneous coblation or open discectomy reported improvements in disability of 60% and 78%, respectively, at 12-month follow-up[4]. The randomised controlled trial of 118 patients treated by percutaneous coblation alone, percutaneous coblation combined with nerve root steroid injection, or epidural steroid injection reported that the mean ODI scores decreased from 47.73, 47.71, and 48.10 at baseline to 22.73, 22.85 and 27.76 respectively at 12-month follow-up (p<0.001 for all 3 compared with baseline)[5]. The improvement was significantly greater in the percutaneous coblation group compared with the epidural injection group (p<0.001).

Quality of life

A randomised controlled trial of 90 patients treated by percutaneous coblation or epidural steroid injection, which was included in the systematic review of 27 studies, reported that both treatments were associated with significant improvements in quality of life measured on the SF-36 questionnaire; there were significant improvements in components of physical function, bodily pain, physical components summary, and social function at 6 months[2]. The percutaneous coblation group also had significant improvement for the role physical and role emotional components. There were significant differences between treatment groups in favour of percutaneous coblation for physical function (p=0.0016), bodily pain (p=0.0039), physical components summary (p=0.004) and social function (p=0.0312).

Patient satisfaction

The randomised controlled trial of 90 patients reported that 62% of patients treated by percutaneous coblation were extremely or very satisfied at 6-month follow-up compared with 33% of patients treated by epidural steroid injection (absolute numbers and p value not reported)[2]. The non-randomised study of 160 patients reported that 67% of patients would recommend percutaneous coblation to other patients, 32% of patients would not recommend it[4].

Radiological evaluation

A case series of 1390 patients, which was included in the systematic review of 27 studies, reported that bulging was eliminated in 34% of patients, significantly reduced in 48% and unchanged in 18% of patients at 6-month follow-up (visualised on CT or MRI scan)[8]. A randomised controlled trial of 64 patients treated by percutaneous coblation or conservative therapy reported a decrease in the mean disc bulge from 5.1 mm at baseline to 1.8 mm at 3-month follow-up (p<0.001) in the percutaneous coblation group[3].

Safety

Pain

Increased radicular pain was reported in 4% (2/45) of patients treated by percutaneous coblation and 13% (5/40) of patients treated by epidural steroid injection in a randomised controlled trial of 90 patients; increased back pain was reported in 2% (1/45) and 10% (4/40) of patients respectively[2]. Acute low back pain with spasms was reported in 1 patient in each group in the same study. Lateralised postural lumbar pain and hypertone (contraction of paravertebral muscles), which lasted up to 10 days after the procedure, was reported in 5% of patients in a case series of 1390 patients (actual numbers not reported)[8]. Worsening of pain was reported in 1 patient in a case series of 396 patients[6].

Muscle tightness or spasms

Muscle tightness or spasms were reported in 2% (1/45) of patients treated by percutaneous coblation and 3% (1/40) of patients treated by epidural steroid injection in the randomised controlled trial of 90 patients[2].

Bradycardia

Bradycardia was reported in 1% (4/396) of patients in the case series of 396 patients[7]. All the episodes were related to poor tolerance to pain by the patients. Prolonged pain-induced bradycardia led to 1 patient having a convulsive episode.

Discitis

Discitis was reported in 1 patient in the case series of 396 patients (no further information given)[6].

Radicular paraesthesia

Radicular paraesthesia was reported in <1% (2/396) of patients in the case series of 396 patients[6].

Weakness

Increased weakness was reported in 2% (1/45) of patients treated by percutaneous coblation and 0% (0/40) of patients treated by epidural steroid injection in the randomised controlled trial of 90 patients[2].

Epidural fibrosis

Epidural fibrosis, diagnosed by MRI 3 months after percutaneous coblation, was reported in a single case report. The patient had recurrence of pain in his left lower extremity and lower back, which spontaneously resolved after the MRI. No further treatment was given[9].

Validity and generalisability of the studies

- The systematic review included some patients with disc extrusions, which is a contraindication for nucleoplasty. This may have had a negative bias on the efficacy outcomes. The review also included some patients with cervical disc herniation; the safety and efficacy of percutaneous coblation may differ according to the level of the affected disc[1].
- Of the 27 studies included in the systematic review, 7 had a control group[1]. In 3 of these controlled studies, the comparative treatment was microdiscectomy

or mechanical disc decompression. In the remaining studies the comparator was conservative treatment (including epidural steroid injection).

- The non-randomised comparative study compared percutaneous coblation against open discectomy but the 2 patient groups were different with regard to inclusion criteria: the open discectomy group included patients with disc protrusion whereas this was a reason for excluding patients from the percutaneous coblation group[4].

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

- Insertion of an annular disc implant at lumbar discectomy. NICE interventional procedure guidance 506 (2014). Available from http://www.nice.org.uk/guidance/IPG506
- Peripheral nerve-field stimulation for chronic low back pain. NICE interventional procedure guidance 451 (2013). Available from http://www.nice.org.uk/guidance/IPG451
- Transaxial interbody lumbosacral fusion. NICE interventional procedure guidance 387 (2011). Available from http://www.nice.org.uk/guidance/IPG387
- Non-rigid stabilisation techniques for the treatment of low back pain. NICE interventional procedure guidance 366 (2010). Available from http://www.nice.org.uk/guidance/IPG366
- Percutaneous intradiscal laser ablation in the lumbar spine. NICE interventional procedure guidance 357 (2010). Available from http://www.nice.org.uk/guidance/IPG357

- Percutaneous intradiscal electrothermal therapy for low back pain. NICE interventional procedure guidance 319 (2009). Available from http://www.nice.org.uk/guidance/IPG319
- Lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine. NICE interventional procedure guidance 321 (2009). Available from http://www.nice.org.uk/guidance/IPG321
- Prosthetic intervertebral disc replacement in the lumbar spine. NICE interventional procedure guidance 306 (2009). Available from http://www.nice.org.uk/guidance/IPG306
- Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedure guidance 300 (2009). Available from http://www.nice.org.uk/guidance/IPG300
- Automated percutaneous mechanical lumbar discectomy. NICE interventional procedure guidance 141 (2005). Available from http://www.nice.org.uk/guidance/IPG141
- Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. NICE interventional procedure guidance 83 (2004). Available from http://www.nice.org.uk/guidance/IPG83
- Endoscopic laser foraminoplasty. NICE interventional procedure guidance 31 (2003). Available from http://www.nice.org.uk/guidance/IPG31

NICE guidelines

- Low back pain in adults: early management. NICE clinical guideline 88 (2009). Available from http://www.nice.org.uk/guidance/CG88

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 is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Three Specialist Advisor Questionnaires for percutaneous coblation of the intervertebral

disc for low back pain and sciatica were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme sent 50 questionnaires to 1 NHS trusts for distribution to patients who had the procedure (or their carers). NICE received 4 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

A Specialist Adviser noted that there are modifications of this procedure that combine percutaneous coblation with physical nucleotomy and annulus modulation, such as the Disc-FX system. Some studies that describe the use of Disc-FX are included in appendix A.

References

1. Eichen PM, Achilles N, Konig V et al. (2014) Nucleoplasty, a minimally invasive procedure for disc decompression: a systematic review and meta-analysis of published clinical studies. Pain Physician 17: E149–173
2. Gerszten PC, Smuck M, Rathmell JP et al. (2010) Plasma disc decompression compared with fluoroscopy-guided transforaminal epidural steroid injections for symptomatic contained lumbar disc herniation: a prospective, randomized, controlled trial. Journal of Neurosurgery Spine 12: 357–71
3. Chitragran R, Poopitaya S, Tassanawipas W. (2012) Result of percutaneous disc decompression using nucleoplasty in Thailand: a randomized controlled trial. Journal of the Medical Association of Thailand 95: S198–205
4. Adam D, Pevzner E, Gepstein R. (2013) Comparison of percutaneous nucleoplasty and open discectomy in patients with lumbar disc protrusions. Chirurgia (Bucuresti) 108: 94–8
5. Wu S, Li X, Lin C et al. (2015) CT-guided nucleoplasty with radiofrequency energy for the treatment of lumbar disk herniation. Journal of Spinal Disorders & Techniques 28: E9–16
6. Kallas JL, Godoy BL, Andraus CF et al. (2013) Nucleoplasty as a therapeutic option for lumbar disc degeneration related pain: a retrospective study of 396 cases. Arquivos de Neuro-Psiquiatria 71: 46–50
7. Cincu R, Lorente Fde A, Gomez J et al. (2015) One decade follow up after nucleoplasty in the management of degenerative disc disease causing low back pain and radiculopathy. Asian Journal of Neurosurgery 10: 21-25
8. Alexandre A, Coro L, Azuelos A et al. (2005) Percutaneous nucleoplasty for discoradicular conflict. Acta Neurochirurgica - Supplement 92: 83–6
9. Smuck M, Benny B, Han A et al. (2007) Epidural fibrosis following percutaneous disc decompression with coblation technology. Pain Physician 10: 691–6

Appendix A: Additional papers on percutaneous coblation of the intervertebral disc for low back pain and sciatica

The following table outlines the studies that are considered potentially relevant to the IP 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
Adakli B, Cakar Turhan KS, Asik I (2015) The comparison of the efficacy of radiofrequency nucleoplasty and targeted disc decompression in lumbar radiculopathy. Bosnian Journal of Basic Medical Sciences 15: 57-61	Retrospective non-randomised comparative study (36 nucleoplasty versus 37 decompression) n=73 Follow-up=12 months	Statistically significant improvement in visual analogue scale (VAS) and functional rating index was seen in both groups. VAS scores after 1, 6, and 12 months were slightly higher in the nucleoplasty group, compared with the decompression group. The overall procedure-related patient satisfaction ratio was 75% for nucleoplasty, compared with 68% for decompression. Both methods are effective therapies for lumbar radiculopathy, with targeted disc decompression showing long-term lower pain scores.	Small, non-randomised comparative study.
Al-Zain F, Lemcke J, Killeen T et al. (2008) Minimally invasive spinal surgery using nucleoplasty: a 1-year follow-up study. Acta Neurochirurgica 150: 1257–62	Case series n=69 FU=12 months	73% of treated patients experienced an improvement of more than 50% in their symptoms in the early post-operative VAS score. This was reduced to 61% at 6 months post-operatively and 58% after 1 year. A statistically significant reduction in analgesic consumption, disability and occupational incapacitation resulted from treatment with nucleoplasty.	Small case series with short follow-up.
Azzazi A, AlMekawi S, Zein M (2011) Lumbar disc nucleoplasty using coblation technology: clinical outcome. Journal of Neurointerventional Surgery 3: 288-292	Case series n=50 FU=12 months	Analgesic consumption was reduced or stopped in 90% of patients after 1 year. There was complete resolution of symptoms in 40 patients after 1 year. 4 patients underwent conventional microdiscectomy. Five patients had postoperative discitis which cleared clinically and radiologically within 2 months without sequelae in 4 of them. One patient had to undergo operative instrumental fusion at the affected level.	Small case series with short follow-up. Included in systematic review (Eichen PM et al., 2014)

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Bhagia SM, Slipman CW, Nirschl M et al. (2006) Side effects and complications after percutaneous disc decompression using coblation technology. American Journal of Physical Medicine & Rehabilitation 85: 6-13	Case series n=53 FU=2 weeks	Based on this preliminary data, nucleoplasty seems to be associated with short-term increased pain at the needle insertion site and increased preprocedure back pain and tingling numbness but without other side effects.	Small case series with short follow-up. Included in systematic review (Eichen PM et al., 2014)
Bokov A, Skorodumov A, Isrelov A et al. (2010) Differential treatment of nerve root compression pain caused by lumbar disc herniation applying nucleoplasty. Pain Physician 13: 469-480	Non-randomised comparative study n=138 FU=18 months	The size of the disc protrusion does not significantly affect the outcome of nucleoplasty. The rational guideline for choosing between the 2 types of surgery is the integrity of the annulus.	Included in systematic review (Eichen PM et al., 2014)
Bokov A, Isrelov A, Skorodumov A et al. (2011) An analysis of reasons for failed back surgery syndrome and partial results after different types of surgical lumbar nerve root decompression. Pain Physician 14: 545-557	Non-randomised comparative study n=138 FU=18 months	The results show that an analysis of the reasons for failures and partial effects of applied interventions for nerve root decompression may help to understand better the efficacy of the interventions and could be helpful in improving surgical strategies, otherwise the validity of the conclusion could be limited because not all sources of residual pain illustrate the applied technology efficacy.	Same patient population as Bokov A et al., 2010 (see above).
Calisaneller T, Ozdemir O, Karadeli E et al. (2007) Six months post-operative clinical and 24 hour post-operative MRI examinations after nucleoplasty with radiofrequency energy. Acta Neurochirurgica 149: 495-500	Case series n=29 FU=6 months	Although, nucleoplasty appeared to be a safe minimally invasive procedure, the value of this new technique for the treatment of discogenic low-back pain remains as yet unproven. Further randomised placebo-controlled studies with longer follow-up are needed to elucidate the effects of nucleoplasty on discogenic low back and leg pain.	Small case series with short follow-up. Included in systematic review (Eichen PM et al., 2014)
Ceylan D, Koktekir E, Tatarli N et al. (2015) Intracranial Bilateral Subdural Hematoma as a Complication of Lumbar Nucleoplasty. Neurosurgery Quarterly 25: 346-348	Case report n=1	Case report: bilateral subdural haematoma Bilateral intracranial subdural hematoma should be included in the list of potential complications of nucleoplasty and taken into account in the case of patients who present with headache after nucleoplasty.	Case report.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Cohen SP, Williams S, Kurihara C et al. (2005) Nucleoplasty with or without intradiscal electrothermal therapy (IDET) as a treatment for lumbar herniated disc. Journal of Spinal Disorders & Techniques 18 Suppl-24	Case series n=16 FU=9 months	We conclude that with use of the present selection criteria, nucleoplasty is not an effective long-term treatment for lumbar radiculopathy, either alone or with IDET. Before conducting future clinical trials, we recommend modifying these criteria to include only those patients with small (<6-mm) contained disc herniations whose annular integrity is documented by computed tomography discography and corresponding radicular symptoms confirmed by either selective nerve root blocks or electromyography and nerve conduction studies.	Small case series with short follow-up.
Cuellar VG, Cuellar JM, Vaccaro AR et al. (2010) Accelerated degeneration after failed cervical and lumbar nucleoplasty. Journal of Spinal Disorders & Techniques 23 (8) 521-524.2010.	Case series n=16 (lumbar) FU=6–52 weeks	Of the 17 lumbar procedures in 16 patients, 4 seemed to show progressive degeneration (25% of the patients) and 1 developed a new spondylolisthesis (6%).	Small case series with short follow-up.
Ebrahim KS, AlShehaby A, AlWardany MA et al. (2010) Percutaneous image guided lumbar disc nucleoplasty: A minimal invasive technique for lumbar disc decompression. Pan Arab Journal of Neurosurgery 14: 51-55	Case series n=29 FU=1 year	The mean visual analogue score (VAS) for the treated patients preoperative was 8.3 and there was significant reduction in VAS in follow-up visits with the mean VAS=3.4, 3.2, 2.5, 3.1, 3.5 at 1 week, 1 month, 3 months, 6 months, and 1 year duration respectively. All patients were satisfied with the procedure and the degree of pain relief at all follow-up visits.	Small case series with short follow-up.
Gerges FJ, Lipsitz SR, Nedeljkovic SS (2010) A systematic review on the effectiveness of the Nucleoplasty procedure for discogenic pain. Pain Physician 13: 117-132	Systematic review 14 studies (1 RCT, 13 observational)	Observational studies suggest that nucleoplasty is a potentially effective minimally invasive treatment for patients with symptomatic disc herniations who are refractory to conservative therapy. The recommendation is a level 1C, strongly supporting the therapeutic efficacy of this procedure. However, prospective randomized controlled trials with higher quality of evidence are necessary to confirm efficacy and risks, and to determine ideal patient selection for this procedure.	A more recent systematic review is included (Eichen PM et al., 2014)

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Gerszten PC, Welch WC, King JT, Jr. (2006) Quality of life assessment in patients undergoing nucleoplasty-based percutaneous discectomy. Journal of Neurosurgery Spine 4: 36-42	Case series n=67 FU=6 months	Nucleoplasty-based percutaneous disc decompression in patients with symptomatic contained disc herniations is safe and improves QOL as measured by the SF-36, EQ5D, and VAS for pain. Nucleoplasty is an effective minimally invasive surgical treatment alternative in patients with symptomatic contained disc hemiations. Further follow-up evaluation is underway to determine the durability of QOL improvement after nucleoplasty.	Studies with more patients or longer follow-up are included. Included in systematic review (Eichen PM et al., 2014)
He L, Hu X, Tang Y et al. (2015) Efficacy of coblation annuloplasty in discogenic low back pain: a prospective observational study. Medicine 94: e846	Case series n=17 Follow-up=6 months	At 1, 3, and 6 months postoperatively, the numbers of patients with "excellent" or "good" ratings were 13 (77%), 11 (65%), and 10 (59%) according to the modified MacNab criteria. No serious complications were observed.	Studies with more patients or longer follow-up are included in table 2.
Hellinger S. (2011) Disc-FX – a treatment for discal pain syndromes combining a maual and radiofrequency-assisted posterolateral microtubular decompressive nucleotomy. European Musculoskeletal review 6: 100–4	**Disc-FX** n=72 FU=6 months	Back and leg pain recorded with the Visual Analogue Scale (VAS) showed a significant improvement, from an average of 8.5 to 2 (post-operatively), 3.5 (after 6 weeks) and 3.3 (after 6 months). The original McNab Index shows 90% excellent and good post-operative results. After 6 weeks and 6 months, the results were still >70%. All patients would undergo a similar procedure again if necessary and would recommend such a procedure to others.	Study describes a combination of techniques (Disc-FX)
Karaman H, Tufek A, Olmez Kavak G et al. (2011) Effectiveness of nucleoplasty applied for chronic radicular pain. Medical Science Monitor 17: CR461-CR466	Case series n=56 FU=24 months	Mean VAS that was 8.7+/-1.1 before the procedure was 3.4+/-1.9 at 24 months follow-up. At the latest follow-up, 88% of the patients reported a 30% or higher decrease in their pain. While Oswestry scores were 76.1+/-10.2 in the beginning, they went down to 33.9+/-14.9 at the end of 2 years. The percent of those stating "good" and "excellent" satisfaction was 66% (n=23) at the last follow-up.	Small case series. Included in systematic review (Eichen PM et al., 2014)

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Kumar N, Kumar A, Siddharth MS et al. (2014) Annulo-nucleoplasty using Disc-FX in the management of lumbar disc pathology: early results. International Journal of Spine Surgery 8	**Disc-FX** Case series n=24	Early results after the Disc-FX procedure suggest that it is a reasonable treatment option for patients with back pain due to lumbar disc disease, especially for those with degenerative disc disease who fail conservative treatment. It could be an alternative to procedures like fusion or disc replacement.	Small case series. Study describes a combination of techniques (Disc-FX)
Kumar NS, Shah SM, Tan BW et al. (2013) Discogenic axial back pain: is there a role for nucleoplasty? Asian Spine Journal 7: 314-321	Case series n=30 FU=12 months	Nucleoplasty produced statistically significant improvements in pain, functional disability and quality of life in patients with discogenic low back pain at 6 months and at 12 months. Concordant pain during provocative discography, annular tear and loss of disc height did not influence any of the outcomes after nucleoplasty in patients with discogenic axial back pain.	Small case series.
Lee SH, Derby R, Sul D et al. (2015) Effectiveness of a new navigable percutaneous disc decompression device (L'DISQ) in patients with lumbar discogenic pain. Pain Medicine 16: 266-273	Case series n=98 Follow-up=48 weeks	The success rates of the procedure were 55% at 48 weeks. There were no complications with the exception of a minor venous bleeding at the site of needle puncture.	Studies with more patients or longer follow-up are included in table 2.
Lee D, Loh E, Kueh C et al. (2013) Radiofrequency-induced intradiscal nucleoplasty chronic low back pain secondary to lumbar disc herniation. Malaysian Orthopaedic Journal 7:18-20	Case series n=36	Patients reported statistically significant reduction of pain intensity and disability level after the procedure. The authors conclude that radiofrequency induced intradiscal nucleoplasty is an acceptable alternative minimally invasive procedure in relieving the symptoms of patients with lumbar disc herniation.	Small case series.
Lemcke J, Al-Zain F, Mutze S et al. (2010) Minimally invasive spinal surgery using nucleoplasty and the Dekompressor tool: a comparison of two methods in a one year follow-up. Minimally Invasive Neurosurgery 53: 236-242	Non-randomised comparative study n=126 FU=12 months	Both Nucleoplasty and Disc Dekompressor are effective therapies for chronic, discogenic back pain. Regardless of the different mechanism no significant differences in the outcomes were found. Both techniques result in significant reductions in levels of disability and incapacity for work as well as decreased analgesic consumption.	Included in systematic review (Eichen PM et al., 2014)

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Manchikanti L, Falco FJ, Benyamin RM et al. (2013) An update of the systematic assessment of mechanical lumbar disc decompression with nucleoplasty. Pain Physician 16: SE25–54	Systematic review 15 studies (1 RCT, 14 observational studies)	This systematic review illustrates Level II-3 evidence for mechanical lumbar percutaneous disc decompression with nucleoplasty in treatment of leg pain. However, there is no evidence available in managing axial low back pain.	A more recent systematic review is included (Eichen PM et al., 2014)
Marin FZ (2005) CAM versus nucleoplasty. Acta Neurochirurgica - Supplement 92: 111-114	Non-randomised comparative study n=64 FU=1–12 months	At 6 to 12 months, 80% of the patients demonstrated an improvement in pain scores (75% very good, 5% good, 15% improved but not good, and 5% no effect). None of the patients was worse. Results indicate that Nucleoplasty may be an efficacious minimally invasive technique for the treatment of symptoms associated with contained herniated disc.	Included in systematic review (Eichen PM et al., 2014)
Masala S, Massari F, Fabiano S et al. (2007) Nucleoplasty in the treatment of lumbar diskogenic back pain: one year follow-up. Cardiovascular & Interventional Radiology 30: 426-432	Case series n=72 FU=1 year	Average preprocedural pain level for all patients was 8.2 (on a visual analog scale of 1 to 10), while the average pain level at 12 months follow-up was 4.1. At the 1 year evaluation, 79% of patients demonstrated a statistically significant improvement in numeric pain scores ($p<0.01$): 17% (12 patients) were completely satisfied with complete resolution of symptoms, and 62% (43 patients) obtained a good result.	Included in systematic review (Eichen PM et al., 2014)
Mirzai H, Tekin I, Yaman O et al. (1992) The results of nucleoplasty in patients with lumbar herniated disc: a prospective clinical study of 52 consecutive patients. Spine Journal: Official Journal of the North American Spine Society 7: 88-92	Case series n=52 FU=1 year	Mean VAS reduced from preprocedure 7.5 to 3.1 at postprocedure 6 months and to 2.1 at the latest follow-up. Mean Oswestry index decreased from 42.2 to 24.8 at 6 months and to 20.5 at the latest examination. Analgesic consumption was stopped or reduced in 42 patients (85%) at 6 months and in 46 patients (94%) 1 year after the procedure. Overall patient satisfaction was 81% at 2 weeks, 85% at 6 months, and 88% at the latest follow-up. There were no complications related to the procedures.	Small case series. Included in systematic review (Eichen PM et al., 2014)
Ogbonnaya S, Kaliaperumal C, Qassim A et al. (2013) Outcome of nucleoplasty in patients with radicular pain due to lumbar intervertebral disc herniation. Journal of Natural Science Biology & Medicine 4:187-190	Case series n=33 FU=6 months	Nucleoplasty has been shown to be a safe and minimal-access procedure. Less than half of our selected cohort of patients reported symptomatic improvement at 1-month follow-up. We no longer offer this procedure to our patients.	Studies with more patients or longer follow-up are included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Reddy AS, Loh S, Cutts J et al. (2005) New approach to the management of acute disc herniation. Pain Physician 8: 385-390	Case series n=49	Significant pain relief, functional improvement, and a decrease in medication use were achieved following nucleoplasty. There were no complications associated with the procedure.	Small case series. Included in systematic review (Eichen PM et al., 2014)
Ren D-J, Liu X-M, Du S-Y et al. (2015) Percutaneous nucleoplasty using coblation technique for the treatment of chronic nonspecific low back pain: 5-year follow-up results. Chinese Medical Journal128: 1893-1897	Case series n=172 Follow-up: 41 patients were followed up for a mean of 67 months	Although previously published short- and medium-term outcomes after percutaneous nucleoplasty appeared to be satisfactory, these long-term follow-up results show a significant decline in patient satisfaction over time. Percutaneous nucleoplasty is a safe and simple technique, with therapeutic effectiveness for the treatment of chronic low back pain in selected patients.	Table 2 already includes a study of 50 patients with a mean follow-up of 114 months.
Shabat S, David R, Folman Y (2012) Nucleoplasty is effective in reducing both mechanical and radicular low back pain: a prospective study in 87 patients. Journal of Spinal Disorders & Techniques 25: 329-332	Case series n=87 FU=1 year	At 12 months of follow-up, 55 patients (65%) showed good results and 30 patients (35%) had no effect. In the case of the 39 patients who were followed for 24 months, 23 patients (59%) had significant pain relief. A statistically significant reduction in the Oswestry index was also noted for the series in all intervals. Minor complication occurred in 23 patients (26%) who had transient discomfort and burning pain at the insertion site of the nucleoplasty wire.	Included in systematic review (Eichen PM et al., 2014)
Shamov T, Roussoff RT, Ivanov P et al. (2015) Effectiveness of manual and radiofrequency-assisted posterolateral microtubular decompressive nucleotomy (Disc-FX) in patients with chronic discogenic low back pain. Journal of Spine & Neurosurgery 4: 2 *[in press]*	**Disc-FX** Non-randomised comparative study n=58 FU=6 months	There were statistically significant differences between the 2 groups (Disc-FX versus conservative treatment) at 1 and 3 months but the difference was no longer significant at 6 months follow-up.	Study describes a combination of techniques (Disc-FX)
Sharps LS, Isaac Z (2002) Percutaneous disc decompression using nucleoplasty. Pain Physician 5: 121-126	Case series n=49 FU=12 months	Overall, there was a 79% success rate, with 67% success in the group of patients that had previous surgery and 82% success in the group that had no prior surgical intervention.	Small case series. Included in systematic review (Eichen PM et al., 2014) Note: Included in table 2 of the 2006 overview.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Sinan T, Sheikh M, Buric J et al. (2011) Percutaneous coblation nucleoplasty in patients with contained lumbar disc prolapse: 1 year follow-up in a prospective case series. Acta Neurochirurgica - Supplement 108: 107-112	Case series n=83 FU=12 months	This disc decompression procedure was a safe and effective treatment option for carefully selected patients affected by low back and leg pain due to contained disc herniation	Included in systematic review (Eichen PM et al., 2014)
Singh V, Piryani C, Liao K et al. (2002) Percutaneous disc decompression using coblation (nucleoplasty) in the treatment of chronic discogenic pain. Pain Physician 5: 250-259	Case series n=67 FU=12 months	At 1 year, 80% of the patients demonstrated statistically significant improvement in numeric pain scores. Average pre-procedure pain level for all patients was reported as 6.8 while average pain level was 4.1 at the 12 month follow-up period. Statistically significant improvement was observed in 62%, 59%, and 60% of patients in sitting, standing, and walking ability at 12 months, respectively.	Included in systematic review (Eichen PM et al., 2014)
Singh V, Piryani C, Liao K (2003) Evaluation of percutaneous disc decompression using coblation in chronic back pain with or without leg pain. Pain Physician 6: 273-280	Case series n=80 FU=12 months	A total of 54% of patients indicated pain relief of 50% or more at twelve months. Additionally, significant improvement was reported by 54%, 44%, and 49% of patients in sitting, standing and walking abilities, respectively, at 12 months. There were no instances of complications.	Included in systematic review (Eichen PM et al., 2014) Note: Included in table 2 of the 2006 overview.
Singh V, Piryani C, Liao K (2004) Role of percutaneous disc decompression using coblation in managing chronic discogenic low back pain: a prospective, observational study. Pain Physician 7: 419-425	Case series n=47 FU=12 months	The proportion of patients who reported 50% or more pain relief was 80%, 74%, 63% and 53% at the 1, 3, 6 and 12 months follow-up time periods, respectively. Functional improvements were reported by 46% of patients for sitting ability, 41% for standing ability, and 49% for walking ability at 12 months. There were no complications.	Small case series. Included in systematic review (Eichen PM et al., 2014)
Slipman CW, Bhat AL, Gilschrist RV et al. (2002) Preliminary results for axial low back pain treated with coblation: a comparison of patients with and without a central focal protrusion. European Spine Journal 11:416-7	Case series n=14 FU=6 months	5/7 patients with central focal protrusion showed a statistically and clinically significant improvement in each of the outcome measures. 1/7 patients without central focal protrusion had clinical improvement.	Small case series. Note: Included in table 2 of the 2006 overview.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Yakovlev A, Tamimi MA, Liang H et al. (2007) Outcomes of percutaneous disc decompression utilizing nucleoplasty for the treatment of chronic discogenic pain. Pain Physician 10: 319-328	Case series n=22 FU=12 months	Reported pain and medication use were significantly decreased and functional status was improved at 1, 3, 6, and 12 months following Nucleoplasty (p values< or =0.001 for all outcome measures at all time periods). There were no complications associated with the procedure and we found continued improvements over time.	Small case series. Included in systematic review (Eichen PM et al., 2014)
Zhang W, Wang H, Jiao J et al. (2011) Primary results of the 3-in-1 technique of Disc-FX system for the discogenic low back pain. Chinese Journal of Orthopaedics 31: 1049–55	**Disc-FX** Case series n=40 FU=14 months	The postoperative VAS of limb pain decreased significantly compared with the preoperative value. The evaluation of Macnab score were excellent in 20 patients, good in 17, fair in 2, and poor in 1, suggesting an effective rate of 93% (37/40).	Study describes a combination of techniques (Disc-FX)
Zhu H, Zhou XZ, Cheng MH et al. (2011) The efficacy of coblation nucleoplasty for protrusion of lumbar intervertebral disc at a two-year follow-up. International Orthopaedics 35: 1677-1682	Case series n=42 FU=2 years	There was significant improvement rate of VAS: defined as 66% in back pain, 68% in leg pain, and 86% in numbness at 1-week after the operation; 53%, 58%, 81% at 1-year; and 46%, 51%, 75% at 2-year follow-up. One week after the operation, obvious amelioration occurred in all the patients, but the tendency decreased. Before operation, the mean value of ODI was 68.2 +/- 11%. The value at 1 week was 28.6 +/- 8%; 1-year at 35.8 +/- 6.5%; and 2-years at 39.4 +/- 6%	Small case series. Included in systematic review (Eichen PM et al., 2014)

Appendix B: Related NICE guidance for percutaneous coblation of the intervertebral disc for low back pain and sciatica

Guidance	Recommendations
Interventional procedures	**Insertion of an annular disc implant at lumbar discectomy. NICE interventional procedure guidance 506 (2014).** 1.1 Current evidence on the safety and efficacy of insertion of an annular disc implant at lumbar discectomy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake insertion of an annular disc implant at lumbar discectomy should take the following actions: •Inform the clinical governance leads in their NHS trusts. •Ensure that patients and their carers 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 the public is recommended. 1.3 NICE encourages further research on insertion of an annular disc implant at lumbar discectomy, particularly comparative trials. All studies should report details of patient selection and recurrence rates. 1.4 Clinicians should enter details about all patients undergoing insertion of an annular disc implant at lumbar discectomy onto the British Spine Registry and review clinical outcomes locally. **Peripheral nerve-field stimulation for chronic low back pain. NICE interventional procedure guidance 451 (2013).** 1.1 Current evidence on the efficacy of peripheral nerve-field stimulation (PNFS) for chronic low back pain is limited in both quantity and quality, and duration of follow-up is limited. Evidence on safety is also limited and there is a risk of complications from any implanted device. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake PNFS for chronic low back pain 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 the public is recommended. 1.3 Patient selection for treatment using PNFS for chronic low back pain should be done by a multidisciplinary team, including specialists in pain management and neurosurgery. 1.4 Clinicians should enter details about all patients undergoing PNFS

	for chronic low back pain onto the UK Neuromodulation Register when it is available. They should audit and review clinical outcomes locally. 1.5 NICE encourages collaborative data collection and publication of comparative studies on PNFS for chronic low back pain. Outcomes should include measures of pain, function and quality of life, particularly in the long term. Full details of any complications and adjunctive or subsequent treatments should be recorded. **Transaxial interbody lumbosacral fusion. NICE interventional procedure guidance 387 (2011).** 1.1 Current evidence on the efficacy of transaxial interbody lumbosacral fusion is limited in quantity but shows symptom relief in the short term in some patients. Evidence on safety shows that there is a risk of rectal perforation. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake transaxial interbody lumbosacral fusion should take the following actions. •Inform the clinical governance leads in their Trusts. •Ensure that patients and their carers understand the uncertainty about the procedure's efficacy and its risks, specifically including the small risk of rectal perforation in patients with higher bowel disease, or a history of pelvic disease or previous pelvic surgery. They should provide patients with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended. •Audit and review clinical outcomes of all patients having transaxial interbody lumbosacral fusion (see section 3.1). 1.3 This procedure should only be carried out by surgeons with expertise in the surgical management of spinal disease and specific training in the technique. They should perform their initial procedures with an experienced mentor. 1.4 NICE encourages further research into transaxial interbody lumbosacral fusion. Research outcomes should include fusion rates, pain and functional scores, quality of life measures and the frequency of both early and late complications. NICE may review this procedure on publication of further evidence. **Non-rigid stabilisation techniques for the treatment of low back pain. NICE interventional procedure guidance 366 (2010).** 1.1 Current evidence on the efficacy of non-rigid stabilisation techniques for the treatment of low back pain shows that these procedures are efficacious for a proportion of patients with intractable back pain. There are no major safety concerns. Therefore these procedures may be used provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 Patient selection should be carried out by specialist spinal surgeons

	who are able to offer patients a range of surgical treatment options. **Percutaneous intradiscal laser ablation in the lumbar spine. NICE interventional procedure guidance 357 (2010).** 1.1 Current evidence on the safety and efficacy of percutaneous intradiscal laser ablation in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 Patients selected for the procedure should be limited to those with severe pain refractory to conservative treatment, in whom imaging studies show bulging of an intact disc, and who do not have neurological deficit requiring surgical decompression. **Percutaneous intradiscal electrothermal therapy for low back pain. NICE interventional procedure guidance 319 (2009).** 1.1 Current evidence on the safety and efficacy of percutaneous intradiscal electrothermal therapy for low back pain is inconsistent. 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 intradiscal electrothermal therapy for low back pain should take the following actions. •Inform the clinical governance leads in their Trusts. •Ensure that patients and their carers 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. •Audit and review clinical outcomes of all patients having percutaneous intradiscal electrothermal therapy for low back pain (see section 3.1). 1.3 NICE encourages further research into percutaneous intradiscal electrothermal therapy for low back pain. Research should describe patient selection, use validated measures of long-term pain relief and quality of life, address the role of the procedure in avoiding major surgery, and measure long-term safety outcomes. **Lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine. NICE interventional procedure guidance 321 (2009).** 1.1 Current evidence on the safety and efficacy of lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake lateral interbody fusion in the lumbar spine should take the following actions. •Inform the clinical governance leads in their Trusts.

	•Ensure that patients and their carers 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. •Audit and review clinical outcomes of all patients having lateral interbody fusion in the lumbar spine (see section 3.1). 1.3 This procedure should only be carried out by surgeons with specific training in the technique, who should perform their initial procedures with an experienced mentor. 1.4 NICE encourages further research into lateral interbody fusion in the lumbar spine. Research outcomes should include fusion rates, pain and functional scores, quality of life measures and the frequency of both early and late complications. NICE may review the procedure on publication of further evidence. **Prosthetic intervertebral disc replacement in the lumbar spine. NICE interventional procedure guidance 306 (2009).** 1.1 Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 A multidisciplinary team with specialist expertise in the treatment of degenerative spine disease should be involved in patient selection for prosthetic intervertebral disc replacement in the lumbar spine. The procedure should only be carried out in patients for whom conservative treatment options have failed or are contraindicated. 1.3 The current evidence includes studies with a maximum follow-up of 13 years, but the majority of evidence is from studies with shorter durations of follow-up. NICE encourages clinicians to continue to collect and publish data on longer-term outcomes, which should include information about patient selection and the need for further surgery. **Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedure guidance 300 (2009).** 1.1 Current evidence on the safety and efficacy of percutaneous endoscopic laser lumbar discectomy is inadequate in quantity and quality. 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 endoscopic laser lumbar discectomy should take the following actions. •Inform the clinical governance leads in their Trusts. •Ensure that patients and their carers 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. •Audit and review clinical outcomes of all patients having percutaneous endoscopic laser lumbar discectomy (see section 3.1).

	1.3 Surgeons undertaking this procedure should have specific training in the use of lasers and in endoscopy of the spinal canal. 1.4 NICE encourages further research into percutaneous endoscopic laser lumbar discectomy and may review the procedure on publication of further evidence. Research studies should provide long-term outcome data. **Automated percutaneous mechanical lumbar discectomy. NICE interventional procedure guidance 141 (2005).** 1.1 Current evidence suggests that there are no major safety concerns associated with automated percutaneous mechanical lumbar discectomy. There is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, but evidence from small randomised controlled trials shows conflicting results. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake automated percutaneous mechanical lumbar discectomy should take the following actions. •Inform the clinical governance leads in their Trusts. •Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, use of the Institute's information for the public is recommended. •Audit and review clinical outcomes of all patients having automated mechanical percutaneous lumbar discectomy. The Institute may review the procedure upon publication of further evidence. **Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain.** NICE interventional procedure guidance 83 (2004). 1.1 Current evidence on the safety and efficacy of percutaneous intradiscal radiofrequency thermocoagulation for lower back pain does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake percutaneous intradiscal radiofrequency thermocoagulation for lower back pain should take the following actions. •Inform the clinical governance leads in their Trusts. •Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. Use of the Institute's information for the public is recommended. •Audit and review clinical outcomes of all patients having percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. 1.3 Further research will be useful in reducing the current uncertainty and clinicians are encouraged to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence.

	Endoscopic laser foraminoplasty. NICE interventional procedure guidance 31 (2003). 1.1 Current evidence of the safety and efficacy of endoscopic laser foraminoplasty does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake endoscopic laser foraminoplasty should inform the clinical governance leads in their Trusts. They should ensure that patients offered the procedure understand the uncertainty about its safety and efficacy and should provide them with clear written information. Use of the Institute's information for the public is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Further research into safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.
NICE guidelines	**Low back pain: Early management of persistent non-specific low back pain. NICE clinical guideline 88 (2009).** *1.5 Other non-pharmacological therapies* Electrotherapy modalities 1.5.1 Do not offer laser therapy. 1.5.2 Do not offer interferential therapy. 1.5.3 Do not offer therapeutic ultrasound. Transcutaneous nerve stimulation 1.5.4 Do not offer transcutaneous electrical nerve simulation (TENS). Lumbar supports 1.5.5 Do not offer lumbar supports. Traction 1.5.6 Do not offer traction. *1.6 Invasive procedures* 1.6.1 Consider offering a course of acupuncture needling comprising up to a maximum of 10 sessions over a period of up to 12 weeks. 1.6.2 Do not offer injections of therapeutic substances into the back for non-specific low back pain. *1.9 Referral for surgery* 1.9.1 Consider referral for an opinion on spinal fusion for people who: • have completed an optimal package of care, including a combined physical and psychological treatment programme (see section 1.7) and

	• still have severe non-specific low back pain for which they would consider surgery. 1.9.2 Offer anyone with psychological distress appropriate treatment for this before referral for an opinion on spinal fusion. 1.9.3 Refer the patient to a specialist spinal surgical service if spinal fusion is being considered. Give due consideration to the possible risks for that patient. 1.9.4 Do not refer people for any of the following procedures: •intradiscal electrothermal therapy (IDET) •percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) •radiofrequency facet joint denervation.

Appendix C: Literature search for percutaneous coblation of the intervertebral disc for low back pain and sciatica

Databases	Date searched	Version/files	No. retrieved
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	23/09/2015	Issue 9 of 12, September 2015	5
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	23/09/2005	Issue 9 of 12, September 2015	56
HTA database (Cochrane Library)	23/09/2015	Issue 9 of 12, September 2015	17
MEDLINE (Ovid)	23/09/2015	1946 to September week 2	13
MEDLINE In-Process (Ovid)	23/09/2015	September 22, 2015	74
EMBASE (Ovid)	23/09/2015	1974 to Week 38	20
PubMed	23/09/2015		1
JournalTOCS	23/09/2015	-	0

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

1	nucleoplast*.tw.
2	coblat*.tw.
3	Diskectomy, Percutaneous/
4	(percutan* adj4 (nucleotom* or nucleoplast* or discect* or disect* or diskect* or coblat* or decompress*)).tw.
5	PCN.tw.
6	or/1-5
7	Low Back Pain/
8	(low* adj4 back pain*).tw.
9	(low* adj4 back ache*).tw
10	Lbp.tw.
11	(low* adj4 backache*).tw.
12	lumbago*.tw.
13	Sciatica/
14	sciatic*.tw.
15	(chronic* adj4 back pain*).tw.
16	Intervertebral Disk Displacement/
17	Intervertebral Disc Degeneration/
18	(Intervertebr* adj4 (Disk* or disc*) adj4 (Displace* or degenerat*)).tw.

19	((slipped or hernia* or prolaps*) adj4 (disc* or disk*)).tw.
20	((discogenic* or diskogenic*) adj4 pain*).tw.
21	(radicular adj4 pain*).tw.
22	Radiculopathy/
23	(lumbar adj4 radiculopath*).tw.
24	annulu*.tw.
25	or/7-24
26	6 and 25
27	Animals/ not Humans/
28	26 not 27
29	limit 28 to english language