NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of percutaneous electrothermal treatment of the intervertebral disc annulus 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 by inserting a narrow tube into the affected disc annulus and delivering heat to stiffen the annulus and to reduce the sensation of pain from the nerves within it.

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 March 2015.

Procedure name

- Percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica

Specialist societies

- British Association of Spine Surgeons
- Society of British Neurological Surgeons

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, pain in the leg (sciatica), 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 less invasive alternatives using percutaneous approaches.

What the procedure involves

Percutaneous electrothermal treatment aims to relieve back pain and sciatica by applying thermal energy to the annulus of a damaged intervertebral disc in order to stiffen the annulus and disrupt nerve endings within it. Thermal treatment of the annulus can be performed using a variety of techniques which use radiofrequency energy. These include Intradiscal Electrothermal Therapy (IDET), biacuplasty, and Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT). PIRFT can be used to treat the intervertebral disc annulus and/or the disc nucleus. This overview considers only thermal treatment of the annulus.

Percutaneous electrothermal treatment is usually done with the patient under sedation and using local anaesthesia. The damaged disc is identified by lumbar discography. If the patient feels pain when contrast is injected into the disc (provocative discography), this is usually taken as evidence that the disc is symptomatic. Under fluoroscopic guidance, 1 or 2 introducer needles are inserted into the disc. If 1 introducer needle is used, a monopolar electrode or catheter is then passed into the disc and positioned next to its posterior wall. If 2 introducer needles are used, bipolar electrodes are inserted through each introducer into contralateral sides of the disc. Once in position, electrodes heat the annulus for 2 to 15 minutes, depending on the technique being used. The aim is to contract collagen fibres and promote closure of any tears and cracks. In addition, treatment may destroy nociceptive pain fibres.

Outcome measures

The Oswestry Disability Index (ODI) measures the degree of disability due to 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 electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica. The following databases were searched, covering the period from their start to 27 March 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 and sciatica
Intervention/test	Percutaneous electrothermal treatment
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 2878 patients from 1 systematic review, 2 randomised controlled trials, 3 non-randomised comparative studies, 1 case series, 1 conference abstract and 3 case reports.

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 electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica

Study 1 Appleby D (2006) – included in the 2009 overview

Details

Study type	**Systematic review and meta-analysis**
Country	USA
Recruitment period	1998 to 2005
Study population and number	Patients with discogenic low back pain n=**805 patients treated by Intradiscal Electrothermal Therapy (IDET) from 17 studies (16 case series and 1 randomised controlled trial)**
Age and sex	Not reported
Patient selection criteria	Inclusion criteria: studies that recruited patients with discogenic low back pain that lasted for more than 3 months and failed to respond to 6 weeks of conservative treatment were included. Exclusion criteria: patients with abnormal neurological findings, severe disc degeneration, segmental instability or previous low back surgery were excluded. Animal studies, cadaveric or biomechanical studies, case reports, reviews of previously published literature, and studies that reported non-clinical outcomes were excluded.
Technique	All patients were treated by IDET. Techniques varied between included studies
Follow-up	**6 to 34 months**
Conflict of interest/source of funding	The first author is an employee of the manufacturer

Analysis

Follow-up issues: there was heterogeneity in the follow-up periods of included studies. Patients were followed-up at 6 months (n=5 studies), 12 months (n=3 studies), 15 months (n=1study), 22 months (n=1study) and 24 months (n=6 studies). One study did not report a mean follow-up period; instead, it reported a range from 3 to 27 months.

Study design issues: IDET techniques varied between included studies. Authors state that outcomes reported in fewer than 3 studies were not evaluated. Three of the included studies used invalidated, arbitrary measurements of efficacy and were only included in the meta-analysis of complication rates. A Random effects meta-analysis was performed.

Study population issues: Patient selection criteria varied between included studies.

Other issues:

- Pain was evaluated by pooling visual analogue scales scores. Scores ranged from 0 (indicating no pain) to 10 (indicating the worst possible pain).
- SF-36 subscale scores ranged from 0 to 100 with higher scores indicating better outcomes.
- ODI scores ranged from 0 to 100 with lower scores indicating less disability.
- It is unclear whether statistical tests were performed to assess the degree of heterogeneity between included studies.
- Eleven studies actively monitored the incidence of adverse events.
- The timing of occurrence of adverse events was not reported.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **805 patients from 17 studies**

Outcome	Number of studies	Number of patients	Mean improvement	95% Confidence interval
VAS scores for pain (0–10 scale)	13	503	2.9	2.5 to 3.4
SF-36 bodily pain scores	4	196	21.1	13.4 to 28.8
SF-36 physical function scores	4	196	18.0	11.9 to 24.1
ODI scores	3	79	7.0	2.0 to 11.9

Safety

Meta-analysis of adverse events, which included 486 patients from 11 studies, revealed a complication rate of 0.8% (95% CI: 0.2% to 1.4%)

Complication	Number of patients	Status
Burning sensation in 1 leg	1	Resolved
Paraesthesia and numbness in thighs	2	Resolved
Foot drop	1	Resolved
Increasing back and thigh pain	1	Fusion
Increasing lower leg pain	1	Lost to follow up
Headache	1	Resolved
Increasing radicular pain	5	Resolved in 4, surgery in 1
Cerebral spinal fluid visualised	1	Resolved
Device failure due to scar tissue	1	Interbody fusion
Increasing low back pain	1	Fusion
Nerve root injury	1	Resolved
Increased disc herniation	2	Fusion in both patients
Decreased sphincter tone/ faecal incontinence	1	Resolved
Non-dermatomal leg pain	2	Resolved
Discitis	1	Fusion
Anterolisthesis	1	Fusion

Abbreviations used: ODI, Oswestry disability index; VAS, visual analogue scale

Study 2 Kapural L (2014)

Details

Study type	**Randomised controlled trial**
Country	USA
Recruitment period	2007 to 2011
Study population and number	Patients with discogenic low back pain n= **59 (29 Intradiscal biacuplasty [IDB] versus 30 Sham)**
Age and sex	Mean age: IDB group, 40.4 years; Sham group, 38.4 years Sex: IDB group 56% female; Sham group, 50% female
Patient selection criteria	Inclusion criteria: patients ≥18 years with a history of chronic low back pain that was unresponsive to non-surgical treatment (physiotherapy and/or anti-inflammatory medication) for more than 6 months were included. Patients presented with predominant low back pain with or without referred leg pain; pain was exacerbated by sitting. Furthermore, pain could be induced by provocative lumbar discography. All patients had evidence of disc degeneration at 1 or 2 levels. The height of degenerated discs had to be at least 50% of adjacent control discs. Exclusion criteria: patients with prior lumbar surgery, nucleus pulposus herniation, disc bulges >5 mm, presence of free disc fragments, evidence of more than 2 levels of disc degeneration, spondylolisthesis, evidence of compressive radiculopathy with permanent leg pain, presence of concordant cervical or thoracic pain, symptoms or signs of lumbar canal stenosis, chronic severe conditions (such as rheumatoid arthritis, fibromyalgia, immunosuppression and cancer), history of coagulopathy, progressive neurological deficits, a Beck depressive inventory score>20, a history of opioid abuse or a body mass index >30 kg/m^2 were excluded.
Technique	All procedures were performed under local anaesthesia and moderate sedation. IDB was performed under fluoroscopic guidance by inserting 2 radiofrequency probes in the posterior annulus using a posterolateral, oblique approach. Bipolar radiofrequency energy was applied at 45ºC (n=13 patients) or 50ºC (n=16 patients) for 15 minutes. Subsequently, monopolar radiofrequency energy was applied at each electrode at 60 ºC for 2 minutes and 30 seconds. Sham procedures mimicked IDB procedures, except that probes were positioned outside the intervertebral disc and no radiofrequency energy was applied. All patients were given lumbar back braces that were worn for the first 4 weeks. They were also provided with a recovery guide that outlined activities and exercises that were meant to be followed for 6 weeks. Patients were offered prescriptions for analgesics and/or muscle relaxants.
Follow-up	**6 months**
Conflict of interest/source of funding	Authors state that financial support was provided by the manufacturer in order to cover coordinator time, administrative costs and study treatments. Authors also state that no conflicts of interest were stated by participating study physicians or staff.

Analysis

Follow-up issues: A total of 64 patients (32 patients randomised to each group) were recruited but due to eligibility breaches 59 had treatment (29 IDB versus 30 Sham). Two patients from the IDB group were excluded from analysis; one patient dropped out shortly after having treatment and another was excluded after admitting to abusing controlled substances. Two patients in the sham group were excluded from analysis after dropping out at 3 months.

Study design issues: The procedure was performed at pain management centres. Physicians who performed the procedures were aware of group allocations. Patients and assessors were blinded to treatment allocations. Patients were randomly assigned to each study arm using computer-generated maintained in sequentially numbered opaque envelopes. Patients were offered prescriptions for analgesics and/or muscle relaxants. Patients who underwent the sham procedure were offered the real IDB procedure, upon completion of the study.

Study population issues: Power calculations revealed that a sample size of 64 patients, randomised on a 1:1 basis, was needed to detect a 15 point difference in SF-36 scores between groups at 6-month follow-up.

Other issues:

- SF-36 subscale scores for physical function ranged from 0 to 100 with higher scores indicating better physical function.

- Numerical rating scale scores ranged from 0 to 10 with lower scores indicating less back pain.
- ODI scores ranged from 0 to 100 with lower scores indicating less disability.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **55 (27 IDB versus 28 Sham)**

Mean changes in physical function, pain, disability scores and daily opioid use

	IDB			Sham			
Outcome measure	Baseline	6 months	Mean change	Baseline	6 months	Mean change	p value between groups
SF-36 physical function scores	47.04	62.04	15.00	46.03	48.67	2.63	0.012
Numerical rating scale scores for pain	7.13	4.94	−2.19	7.18	6.58	−0.64	0.014
ODI scores	40.37	32.94	−7.43	40.93	41.17	0.53	0.005
Daily opioid use (mg)	52.47	36.87	−15.60	50.85	49.48	0.26	0.264

Mean changes in physical function, pain and disability scores in patients who had IDB at 1 or 2 disc levels

	1 level			2 levels			
Outcome measure	Baseline	6 months	Mean change	Baseline	6 months	Mean change	p value between groups
SF-36 physical function scores	48.75	66.88	18.13	44.55	55.00	10.45	0.248
Numerical rating scale scores for pain	7.47	4.69	−2.78	6.64	5.32	−1.32	0.126
ODI scores	38.88	28.88	−10.00	42.55	38.85	−3.70	0.113

Safety

- A change in pain characteristic, shifting from the right side to the left side, was reported in 1 patient who had IDB.

Abbreviations used: IDB, Intradiscal biacuplasty; ODI, Oswestry disability index

Study 3 Freeman BJC (2005) – included in the 2009 overview

Details

Study type	**Randomised controlled trial**
Country	Australia
Recruitment period	1999 to 2001
Study population and number	Patients with chronic discogenic low back pain n=**57 (38 IDET versus 19 Sham)**
Age and sex	Mean age: IDET group, 37.5 years; Sham group, 40.2 years Sex: IDET group 34% (13/38) female; Sham group, 11% (2/19) female
Patient selection criteria	Inclusion criteria: patients ≥18 years with chronic low back pain that lasted for more than 3 months and failed to respond to a minimum of 6 weeks of conservative treatment (physiotherapy and/or anti-inflammatory medication) were included. Patients presented with predominant low back pain with or without referred leg pain and had evidence of disc degeneration at 1 or 2 levels (determined by provocative lumbar discography). The height of degenerated discs had to be at least 50% of adjacent control discs. Exclusion criteria: patients with evidence of a large contained or sequestered herniation, severely disrupted discs, neurogenic claudication due to spinal stenosis, 3 or more levels of disc degeneration, a history of previous back surgery or spondylolisthesis at a symptomatic were excluded
Technique	All procedures were performed under local anaesthesia and moderate sedation. IDET was performed under fluoroscopic guidance by inserting a 17 gauge introducer into the symptomatic disc using a posterolateral approach. A catheter, with an electrothermal tip, was then inserted and the heating protocol commenced at 65ºC and rose to 90ºC, over 12.5 minutes. The temperature was maintained at 90ºC for 4 minutes. Cefazolin (antibiotic) was injected into the disc after heat treatment. Sham procedures mimicked IDET procedures, except that probes heat was applied. All patients followed a rehabilitation programme that involved Pilates-based exercises
Follow-up	**6 months**
Conflict of interest/source of funding	Authors state that financial support was provided by the manufacturer.

Analysis

Follow-up issues: 5% (2/38) of patients in the IDET group broke protocol and were excluded from analysis.

Study design issues: Authors state that the study sample was obtained by recruiting consecutive patients that attended the clinics of 3 spinal surgeons. Patients were then randomised on a 2:1 (IDET:Sham) basis. Patients and assessors were blinded to treatment allocations. Patients who underwent the sham procedure were offered the real IDB procedure, upon completion of the study.

Study population issues: The proportion of female participants was greater in the IDET group (34.2%) in comparison to the sham group (10.5%). The mean duration of symptoms was considerably lower in the IDET group (41.54 months) compared against the sham group (66.07 months).

Other issues:

- Low back outcome scores ranged from 0 to 75 with higher scores indicating less impact of back pain on a person's daily activities.
- SF-36 subscale scores ranged from 0 to 100 with higher scores indicating better outcomes.
- ODI scores ranged from 0 to 100 with lower scores indicating less disability.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **57 (38 IDET versus 19 Sham)**

Changes outcome measures (mean±SD)

	IDET		Sham	
Outcome measure	Baseline	6 months	Baseline	6 months
Low back outcome score	39.51±5.25	38.31±3.61	36.71±3.00	37.45±1.60
ODI scores	41.42±14.80	39.77±16.28	40.74±11.84	41.58±11.29
SF-36 bodily pain scores	33.13±15.97	38.28±21.37	24.2±13.45	31.47±15.29
SF-36 physical function scores	41.86±23.01	44.72±24.20	35.00±15.37	36.58±20.14

Mean changes in outcome measures at 6-month follow-up

	Mean change (95% Confidence Interval)		
Outcome measure	IDET	Sham	p value
Low back outcome score	−0.971 (−2.3337 to 0.394)	0.737 (−0.765 to 2.238)	0.111
ODI scores	−1.314 (−4.171 to 1.543)	0.842 (−6.149 to 7.833)	0.489
SF-36 bodily pain scores	5.056 (−7.99 to 10.910)	7.053 (0.963 to 13.142)	0.819
SF-36 physical function scores	2.624 (−2.675 to 7.922)	1.579 (−6.416 to 9.574)	0.659

Safety

- No serious adverse events were reported in either study group
- Transient radiculopathy, which lasted for less than 6 weeks, was reported in 11% (4/38) of patients in the IDET group and 5% (1/19) of patients in the placebo group

Abbreviations used: IDET, intradiscal electrothermal therapy; ODI, Oswestry disability index

Study 4 Derby R (2004)

Details

Study type	**Non-randomised comparative study**
Country	USA
Recruitment period	2000 to 2002
Study population and number	Patients with chronic discogenic low back pain n=**109 (74 IDET versus 35 restorative injection)**
Age and sex	Mean age: IDET group, 41.6 years; restorative injection group, 42.0 years Sex: IDET group 57% (42/72) female; restorative injection group, not reported
Patient selection criteria	Inclusion criteria for the IDET group: patients with discogenic low back pain that failed to respond to conservative treatment (including nerve blocks) were included. Discogenic pain was confirmed by provocative lumbar discography within the previous 6 months of study participation. All patients had disc protrusion <2 mm, single level pathology and a positive discogram confirming an annular tear. The height of degenerated discs had to be at least 50% of adjacent control discs Exclusion criteria: patients with segmental instability, spondylolisthesis or severe spinal stenosis were excluded.
Technique	IDET was performed under fluoroscopic guidance by inserting a 17-gauge introducer into the symptomatic disc using a posterolateral approach. A catheter, with an electrothermal tip, was then inserted and heated to 90ºC, over 16.5 minutes. Cefazolin (antibiotic) was injected into the disc after heat treatment. After the procedure patients were given a lumbar support brace and instructed to perform rehabilitation exercises for 6 months. Authors did not report the type, nature and frequency of restorative injections.
Follow-up	**7.7 to 15.5 months**
Conflict of interest/source of funding	None reported

Analysis

Follow-up issues: Mean follow-up was 15.5 months in the IDET group and only 7.7 months in the restorative injection group.

Study design issues: Study was included in the systematic review (Appleby, 2005) that is included in table 2. Analysis was performed by retrospectively reviewing data from a prospectively collected database.

Study population issues: There is a potential for selection bias as patients in the restorative injection group may have had more severe back pain than patients in the IDET group. Patients who had restorative injections had low back pain that failed to respond to physiotherapy, multiple analgesics, ligament prolotherapy, laminectomy (n=3), fusion (n=3) and IDET (n=7). Furthermore, no patients in the IDET group had disc degeneration at more than 3 levels whereas 69% (24/35) of patients in the restorative injections group had disc degeneration at more than 3 levels.

Other issues: none identified.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **109 (74 IDET versus 35 restorative injections)** • Visual analogue scale scores for pain (scores ranged from 0 to 10 with lower scores indicating less pain) decreased by 1.3 points in the IDET group and 2.2 points in the restorative injection group (p value between groups=0.01). • Pain flare-up was reported in 69% of patients in the IDET group and 81% of patients in the restorative injection group. No numerators were reported. • Patient satisfaction was reported in 47.8% of patients in the IDET group and 65.6% of patients in the restorative injection group	**The study did not actively assess the occurrence of adverse events**
Abbreviations used: IDET, intradiscal electrothermal therapy	

Study 5 Fukui S (2012)

Details

Study type	**Non-randomised comparative study**
Country	Japan
Recruitment period	2003 to 2011
Study population and number	Patients with chronic discogenic low back pain n=**31 (16 IDET versus 15 Pulsed-radiofrequency)**
Age and sex	Mean age: IDET group, 41.7 years; Pulsed-radiofrequency group, 39.3 years Sex: IDET group 31% (5/11) female; Pulsed-radiofrequency group, 33% (5/15) female
Patient selection criteria	Inclusion criteria: patients with chronic discogenic low back pain that lasted for more than 6 months and was unresponsive to conservative treatment (including corticosteroid injections, physiotherapy and oral anti-inflammatory medication) were included. Pain decreased considerably, for more than 3 days, after administration of 1ml of 2% lidocaine. Exclusion criteria: patients with disc extrusion or a sequestered fragment, severe spinal canal narrowing, segmental instability, localised infection (at the treatment site), systemic infection, chronic lower extremity radiculopathy or a history of opioid abuse were excluded.
Technique	All procedures were performed under fluoroscopic guidance. Authors do not describe the technique in which IDET was performed. Pulsed-radiofrequency was performed by inserting a probe into the degenerated disc using a posterior oblique approach. Pulsed-radiofrequency was applied at a frequency of 5 Hz, pulse width of 5 seconds, amplitude of 60 V, and a maximum temperature of 40ºC, for a duration of 15 minutes.
Follow-up	**6 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: none identified

Study design issues: Analysis was performed by retrospectively reviewing the records of patients treated at 1 pain medical centre.

Study population issues: none identified.

Other issues:

- Numerical rating scale scores for pain ranged from 0 to 10 with lower scores indicating less pain.
- Roland Morris disability questionnaire scores ranged from 0 to 18 with lower scores indicating less disability.

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>Number of patients analysed: 31 (16 IDET versus 15 Pulsed-radiofrequency)

Mean numerical rating scale and Roland Morris Disability Questionnaire scores
<table>
<tr><td></td><td colspan="3">IDET</td><td colspan="3">Pulsed-radiofrequency</td></tr>
<tr><td>Outcome measure</td><td>Baseline</td><td>3 months</td><td>6 months</td><td>Baseline</td><td>3 months</td><td>6 months</td></tr>
<tr><td>Numerical rating scale scores for pain</td><td>7.5</td><td>3.1</td><td>1.7</td><td>7.2</td><td>2.6</td><td>2.5</td></tr>
<tr><td>Roland Morris Disability Questionnaire scores</td><td>10.4</td><td>5.8</td><td>2.8</td><td>10.8</td><td>2.9</td><td>2.3</td></tr>
</table>

Significant improvements in numerical rating scale scores and Roland Morris disability questionnaire scores were observed within groups (p values<0.01).
No significant differences in numerical rating scale scores and Roland Morris disability questionnaire scores were observed between groups at 6-month follow-up (p values>0.05).
Pain flare-up was reported in 87.5% (14/16) of patients in the IDET group and 0% of patients in the pulsed-radiofrequency group.
An increase in the amount (amount not reported) or type of pain medication was reported in 87.5% of patients in the IDET group and 0% of patients in the pulsed-radiofrequency group, within 8 weeks of treatment.
</td><td>No adverse events were reported in either study group.</td></tr>
<tr><td colspan="2">Abbreviations used: IDET, Intradiscal electrothermal therapy</td></tr>
</table>

Study 6 Finch PM (2005)

Details

Study type	**Non-randomised comparative study**
Country	Australia
Recruitment period	Not reported
Study population and number	Patients with chronic discogenic low back pain n=**46 (31 Percutaneous Intradiscal Radiofrequency Thermocoagulation [PIRFT] of the annulus versus 15 Controls [patients who had conservative treatment])**
Age and sex	Mean age: PIRFT group, 38.1 years; Control group, 37.8years Sex ratios not reported.
Patient selection criteria	Inclusion criteria: patients with discogenic low back pain who had conservative treatment (including physiotherapy, cognitive behavioural therapy and pain medication) were included. Patients presented with predominant low back pain with or without referred leg pain. MRI scans revealed single-level lumbar disc degeneration. The height of degenerated discs was at least 70% of adjacent control discs. Exclusion criteria: patients with disc bulges >5 mm, compressive lesions of the spinal canal, malignancy, infection, coagulopathy, and a history of previous spinal surgery were excluded.
Technique	All PIRFT procedures were performed with the patient under local anaesthesia and conscious sedation. Under fluoroscopic guidance, a 17-gauge introducer was inserted from the contralateral side to the annular tear and steered around the lateral border of the superior articular facet into the outer annulus. A radiofrequency probe was then inserted and positioned along the posterolateral portion of the disc. Heat was applied, reaching a maximum of 65ºC over 10 minutes. Antibiotic was injected into the disc after heat treatment. After the procedure patients were supervised by a physiotherapist in a gradual but increasing exercise programme that lasted for 3 months. Control patients had physiotherapy, cognitive behavioural therapy and pain medication. The type and amount of pain medication was not reported.
Follow-up	**1 year**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: Four patients in the PIRFT group withdrew from the study: three patients elected to have spinal fusion surgery and another patient elected to have steroid injections.

Study design issues: none identified.

Study population issues: Control patients declined treatment by PIRFT or did not have funding approval from their health insurance providers.

Other issues:

- Visual analogue scale scores for pain ranged from 0 to 10 with lower scores indicating less pain.
- ODI scores ranged from 0 to 100 with lower scores indicating less disability.
- The range and direction of medication quantification scores was not reported.

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>Number of patients analysed: 42 (27 PIRFT versus 15 Controls)

Changes in outcome measures (mean±SD)
<table>
<tr><td></td><td colspan="3">PIRFT</td><td colspan="3">Controls</td></tr>
<tr><td>Outcome measure</td><td>Baseline</td><td>1 year</td><td>p value</td><td>Baseline</td><td>1 year</td><td>p value</td></tr>
<tr><td>Visual analogue scale scores for pain</td><td>7.2±1.3</td><td>4.5±2.5</td><td><0.001</td><td>6.2±1.2</td><td>6.3±1.5</td><td>NS</td></tr>
<tr><td>ODI scores</td><td>48.1±11.5</td><td>35.5±16.6</td><td><0.001</td><td>46.1±15.0</td><td>46.0±14.0</td><td>NS</td></tr>
<tr><td>Medication quantification scale scores</td><td>16.8±10.5</td><td>13.5±11.8</td><td>NS</td><td>15.9±14.9</td><td>19.3±13.6</td><td>NS</td></tr>
</table>
• No p values for comparisons between groups were reported</td><td>• No adverse events were reported in either study group.</td></tr>
<tr><td colspan="2">Abbreviations used: NS, not significant; ODI, Oswestry disability index.</td></tr>
</table>

Study 7 Tsou HSI (2010)

Details

Study type	**Case series**
Country	Taiwan
Recruitment period	2004 to 2007
Study population and number	Patients with chronic discogenic low back pain n=**93 patients treated by IDET**
Age and sex	Mean age: 46.1 years Sex: 46% (43/93) female
Patient selection criteria	Inclusion criteria: patients ≥ 18 years with chronic discogenic low back pain that lasted for more than 6 months and was unresponsive to conservative treatment (including pain medication and physiotherapy) were included. Patients presented with predominant low back pain with or without referred leg pain and had evidence of disc degeneration at 1, 2 or 3 levels (determined by provocative lumbar discography). Exclusion criteria: patients with spondylolisthesis, evidence of large contained or sequestered herniation, loss of more than 50% of target disc height, severely disrupted discs, neurogenic claudication due to spinal stenosis, disc degeneration at more than 3 levels or a history of previous back surgery were excluded.
Technique	IDET was performed with the patient under local anaesthesia. Under fluoroscopic guidance a 20 cm catheter, with a 5 cm electrothermal tip was inserted anteriorly into the disc via a 17-gauge introducer. Heating began at 65ºC and was increased by 1ºC increments every 30 seconds to achieve a final temperature of 90ºC. The final temperature was maintained for 4 minutes, resulting in a total treatment time of 16.5 minutes.
Follow-up	**3 years**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: A total of 4, 23 and 70 patients were lost to follow-up at 1-, 2- and 3-year assessments.

Study design issues: patients were recruited from 2 treatment centres.

Study population issues: none identified.

Other issues:

- Visual analogue scale scores for pain ranged from 0 to 100 with lower scores indicating less pain.
- ODI scores ranged from 0 to 100 with lower scores indicating less disability.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **89 patients; however, the number of patients assessed varied at each follow-up assessment.**

Changes in outcome measures

	Mean scores			
Outcome measure	Baseline	1 year	2 years	3 years
VAS scores for back pain	69.3	29.0[a]	28.0[a]	34.9
VAS scores for leg pain	64.0	29.0[a]	30.0[a]	32.1
ODI scores	31.7	NR	NR	16.7

[a] results were obtained from a graph

- Significant improvements in VAS scores for back pain, leg pain and ODI scores were observed at 3-year follow-up (p values<0.05).

Proportion of patients who had improvements in VAS sores for back pain (%) [n/N]

Degree of improvement	1 year (n=89 patients)	2 years (n=70 patients)	3 years (n=23 patients)
Worse	0	0	0
0% (No improvement)	19 [17/89]	18.5 [13/70]	26.0 [6/23]
Between 1 and 49% improvement	18 [16/89]	21.4 [15/70]	26.0 [6/23]
Between 50 and 99% improvement	58 [52/89]	52.8 [37/70]	39.1 [9/23]
100% (Symptom free)	4 [4/89]	7.1 [5/70]	8.7 [2/23]

- The satisfaction rate was 63%, 60% and 47% at 1, 2 and 3 year follow-up assessments.

Proportion of patients who had improvements in VAS sores for leg pain (%) [n/N]

Degree of improvement	1 year (n=75 patients)	2 years (n=59 patients)	3 years (n=19 patients)
Worse	0	0	0
0% (No improvement)	22.7 [17/75]	20.3 [12/59]	31.5 [6/19]
Between 1 and 49% improvement	17.3 [13/75]	22.0 [13/59]	26.3 [5/19]
Between 50 and 99% improvement	53.3 [40/75]	44.0 [26/59]	31.5 [6/19]
100% (Symptom free)	6.7 [5/75]	13.6 [8/59]	1.1 [2/19]

Safety

- No adverse events were reported in any patients.

Abbreviations used: NR, not reported; ODI, Oswestry disability index; VAS, visual analogue scale

Study 8 Saal JA (2001)

Details

Study type	**Case series (Conference abstract)**
Country	USA
Recruitment period	1997 to 2001
Study population and number	Patients with chronic discogenic low back pain n=**1675 patients treated by IDET**
Age and sex	Mean age: not reported Sex: not reported
Patient selection criteria	Not reported
Technique	Not reported
Follow-up	**Not reported**
Conflict of interest/source of funding	Not reported
Safety	Data from 5 centres were pooled and assessed to evaluate the occurrence of adverse events. • Nerve root injuries were reported in 6 patients. Five cases completely resolved while 1 partially resolved. • No discitis was reported. • Disc herniation at the treated level was reported in 6 patients, 2 to 12 months after treatment. Four resolved with non-operative care, 2 needed disc excision. • Catheter breakage was reported 19 times. They were all associated repeated catheter manipulation resulting in catheter kinking. Two broken tips were retrieved by percutaneous methods, 1 was removed surgically, 16 were left in the disc and 1 was left in subcutaneous tissues. None of the cases were associated with any morbidity. • Superficial burns, at needle puncture sites, were reported in 8 patients. • Bladder dysfunction was reported in 1 patient. The treating physician noted that the catheter was positioned in the extra-discal space.

Study 9 Tang (2013)

Details

Study type	**Case report**
Country	USA
Study population	A 42-year-old female with discogenic low back pain treated by Percutaneous Intradiscal Radiofrequency Thermocoagulation [PIRFT] of the annulus
Technique	PIRFT was performed at the L4–L5 level. No further details were provided.
Follow-up	**Unclear**
Conflict of interest/source of funding	None reported
Summary	The patient presented with complaints of pain in both feet 3 months after having PIRFT. The patient reported that her low back pain decreased within the first week, after having PIRFT, but both feet became painful and swollen. She described her foot pain as a burning, pinprick-like sensation, with an intensity of 10/10. Physical examination revealed swelling and local hyperthermia extending from 'both ankles to feet'. Significant allodynia to touch and heat stimuli were also noted. The patient was diagnosed with complex regional pain syndrome type 1. Authors suspected that the corresponding spinal nerve adhering to the damaged annulus was injured during PIRFT. Medical therapy (including oxycodone, pregabalin, amitriptyline and mecobalamin) was immediately initiated. Furthermore, a CT-guided continuous lumbar sympathetic trunk block with patient-controlled analgesia was performed. Three months after discharge, the patient had minimal pain (Visual analogue score of 1/10) on her feet during walking but it did not restrict her daily activities.

Study 10 Orr RD (2005) – included in the 2009 overview

Details

Study type	**Case report**
Country	USA
Study population	A 46 year old female with discogenic low back pain treated by IDET. The patient had back pain that was refractory to conservative treatment using analgesics and nonsteroidal anti-inflammatory drugs. Provocative discography showed abnormalities at L5–S1 level.
Technique	Not reported
Follow-up	**9 months**
Conflict of interest/source of funding	Not reported
Summary	Three catheters were employed during IDET. On the third attempt, adequate positioning was obtained but the tip of the catheter had become kinked. During removal the tip broke off inside the disc space. The patient reported increased axial back pain shortly after the procedure. At 6-month follow-up, the patient reported left leg paraesthesia and dysaesthesia. X-ray and CT scans showed migration of the tip. Electromyography showed sensory neuropathy affecting the L5 nerve root; however, the CT scan showed that the tip was positioned in the extradural space and was unlikely to be the cause of the patient's lower extremity symptoms. A wide laminectomy was performed in order to locate and remove the tip of the catheter but it could not be found. A longitudinal durotomy was then performed and the tip was located inside the dural sac, having migrated from the disc space. Three months after removal, the axial back pain remained unchanged but dysaesthetic symptoms in the left leg had resolved.

Study 11 Scholl BM (2003) – included in the 2009 overview

Details

Study type	**Case report**
Country	USA
Study population	A 36-year-old male with discogenic low back pain treated by IDET. The patient had back pain that was refractory to conservative treatment using chiropractic therapy, nonsteroidal anti-inflammatory drugs and physiotherapy.
Technique	Heat was applied at 90ºC for 4 minutes at L4–L5 and L5–S1 levels. Five months later, IDET was performed at L2–L3 and L3–L4 levels.
Follow-up	**12 months**
Conflict of interest/source of funding	None reported
Summary	The patient's pain intensified after having IDET. At 3-month follow-up, MRI scanning revealed diffuse narrow oedema of the L2 vertebral body consistent with osteonecrosis. At 7 months, the patient's pain persisted in the mid lumbar region (no significant lower extremity symptoms were reported) and was managed with narcotic analgesics. MRI scans at 12 months showed an intervertebral decrease in size and signal at the L2 lesion. A small amount of increased T2 signal and enhancement within the subchondral lesion remained but the diffuse narrow oedema of the L2 vertebral body that was consistent with osteonecrosis had resolved.

Efficacy

Pain relief

In a systematic review of 17 studies that included patients treated by Intradiscal Electrothermal Therapy (IDET), 13 studies (503 patients) reported visual analogue scale scores for pain (scores ranged from 0 to 10 with lower scores indicating less pain). Meta-analysis revealed that visual analogue scale scores for pain improved by a mean of 2.9 points (95% confidence interval [CI] 2.5 to 3.4; no p value reported). Meta-analysis of 4 studies (n=196 patients) that reported SF-36 bodily pain scores (scores ranged from 0 to 100 with higher scores indicating less pain) revealed that scores improved by a mean of 21.1 points (95% CI 13.4 to 28.8; no p value reported)[1].

In a case series of 93 patients treated by IDET, mean visual analogue scale scores for back pain (scores ranged from 0 to 100 with lower scores indicating less pain) improved from 69.3 to 34.9 at 3-year follow-up ($p<0.05$). In the same study, visual analogue scale scores for leg pain improved from 64.0 to 32.1 at 3-year follow-up ($p<0.05$)[7].

In a randomised controlled trial of 59 patients treated by intradiscal biacuplasty (n=29) or sham (n=30), mean numerical rating scale scores for pain (scores ranged from 0 to 10 with lower scores indicating less pain) improved from 7.13 to 4.94 and 7.18 to 6.58, respectively, at 6-month follow-up (p value between groups=0.014)[2].

In a non-randomised comparative study of 46 patients treated by Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT) of the annulus (n=31) or conservative treatment (n=15), mean visual analogue scale scores for pain (scores ranged from 0 to 10 with lower scores indicating less pain) changed from 7.2 to 4.5 ($p<0.001$) and 6.2 to 6.3 (not significant), respectively, at 1-year follow-up. No p value for inter-group comparisons was reported[6].

Oswestry Disability Index (ODI) scores

In the systematic review of 17 studies that included patients treated by IDET, 3 studies (79 patients) reported ODI scores (scores ranged from 0 to 100 with lower scores indicating less disability). Meta-analysis revealed that ODI scores improved by a mean of 7.0 points (95% CI 2.0 to 11.9; no p value reported)[1].

In the case series of 93 patients treated by IDET, mean ODI scores improved from 31.7 to 16.7 at 3-year follow-up ($p<0.05$)[7].

In the randomised controlled trial of 59 patients treated by intradiscal biacuplasty (n=29) or sham (n=30), mean ODI scores changed from 40.37 to 32.94 and 40.93 to 41.17 respectively at 6-month follow-up (p value between groups=0.005)[2].

In the non-randomised comparative study of 46 patients treated by PIRFT of the annulus (n=31) or conservative treatment (n=15), mean ODI scores improved from 48.1 to 35.5 ($p<0.001$) and 46.1 to 46.0 (not significant), respectively, at 1-year follow-up. No p value for inter-group comparisons was reported[6].

Physical function

In the systematic review of 17 studies that included patients treated by IDET, 4 studies (196 patients) reported SF-36 physical function scores (scores ranged from 0 to 100 with higher scores indicating better physical function). Meta-analysis revealed that scores improved by a mean of 18.0 points (95% CI 11.9 to 24.1; no p value reported)[1].

In the randomised controlled trial of 59 patients treated by intradiscal biacuplasty (n=29) or sham (n=30), mean SF-36 physical function scores changed from 47.04 to 62.04 and 46.03 to 48.67 respectively at 6-month follow-up (p value between groups=0.012)[2].

Use of analgesia

In the randomised controlled trial of 59 patients treated by intradiscal biacuplasty (n=29) or sham (n=30), mean amount of opioids taken each day changed from 52.47 mg to 36.87 mg and 50.85 mg to 49.48 mg respectively at 6-month follow-up[2].

Safety

Catheter breakage was reported in 19 patients (involving 20 tips which fractured and separated) in a case series (conference abstract) of 1675 patients treated by IDET. Two broken tips were retrieved using percutaneous methods, 1 was removed surgically, 16 were left in the disc and 1 was left in subcutaneous tissues. None of the cases were associated with any morbidity[8]. A case report of 1 patient treated by IDET described paraesthesia and dysaethesia in the left leg, 6 months after a procedure in which 3 different catheters had to be used because of catheter breakage. On the third attempt, the tip of the catheter broke off inside the disc space and was not retrieved. After the patient's complaints the tip was surgically removed and the patient reported no dysaesthetic symptoms 3 months after removal[10].

Transient radiculopathy, which lasted for less than 6 weeks, was reported in 11% (4/38) of patients in the IDET group and 5% (1/19) of patients in the sham procedure group in a randomised controlled trial of 57 patients[3].

Bladder dysfunction was reported in 1 patient in the case series (conference abstract) of 1675 patients treated by IDET. During IDET the treating physician noted that the catheter was positioned in the extra-discal space. No further details were provided[8].

Type 1 complex regional pain syndrome was reported at 3-month follow-up in a case report of 1 patient treated by PIRFT of the annulus. The patient reported that their back pain decreased after having PIRFT but both feet became extremely painful and swollen. The patient was treated by medical therapy and a CT-guided lumbar sympathetic trunk block[9].

Increased axial back pain was reported in a case report of 1 patient treated by IDET. MRI scans at 3-month follow-up revealed diffuse 'marrow oedema' of the L2 vertebral body consistent with osteonecrosis; this resolved at 12-month follow-up[11].

In a systematic review of 17 studies that included patients treated by IDET, 11 studies (486 patients) reported the incidence of adverse events. Meta-analysis revealed an adverse event rate of 0.8% (95% CI 0.2% to 1.4%)[1]. Adverse events included:

- A burning sensation in the leg of 1 patient; this resolved.
- Paraesthesia and numbness in the thighs of 2 patients; both resolved.
- Foot drop in 1 patient; this resolved.
- Increasing lower leg pain in 1 patient; the patient was subsequently lost to follow-up.
- Increasing back and thigh pain in 1 patient; this was treated by spinal fusion.
- Headache in 1 patient; this resolved.
- Increasing radicular pain in 5 patients; pain resolved in 4 patients, 1 patient needed surgery.
- Device failure in 1 patient due to scar tissue around the treatment site; the patient was treated by interbody fusion.
- Increasing low back pain in 1 patient; this was treated by spinal fusion.
- Nerve root injury in 1 patient; this resolved.
- Increased disc herniation in 2 patients; both were treated by spinal fusion.
- Decreased anal sphincter tone and faecal incontinence in 1 patient; this resolved.
- Non-dermatomal leg pain in 2 patients; both resolved.
- Discitis in 1 patient; this was treated by spinal fusion.
- Anterolisthesis in 1 patient; this was treated by spinal fusion.

Validity and generalisability of the studies

- The heating protocols used for treatment varied between studies.
- The majority of studies included patients that had back pain which was refractory to conservative treatment[1,2,3,4,5,6,7,10].
- Four studies stated that investigators included patients with 1- or 2-level disc degeneration[2,3,4,6].
- In 4 studies, the height of degenerated discs was at least 50% of adjacent control discs[2,3,4,7].
- Only 1 study differentiated between low back pain and low leg pain (sciatica)[7].
- Few objective efficacy outcomes are reported.
- The longest follow-up period was 3 years[7].

Existing assessments of this procedure

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

Related NICE guidance

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

Interventional procedures

- Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. NICE Interventional Procedure Guidance 83 (2004). This guidance is currently under review and is expected to be updated in 2015. Available from: http://www.nice.org.uk/guidance/ipg83
- Percutaneous disc decompression using coblation for low back pain NICE Interventional Procedure Guidance 173 (2006). This guidance is currently under review and is expected to be updated in 2015. Available from: http://www.nice.org.uk/guidance/ipg173
- Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedure guidance 300 (2009). This guidance is currently under review and is expected to be updated in 2015. Available from: http://www.nice.org.uk/guidance/ipg300

- Percutaneous intradiscal laser ablation in the lumbar spine. NICE interventional procedure guidance 357 (2010). Available from: http://www.nice.org.uk/guidance/ipg357
- Automated percutaneous mechanical lumbar discectomy. NICE interventional procedure guidance 141 (2005). Available from: http://www.nice.org.uk/guidance/ipg141
- 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
- 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

NICE guidelines

- Low back pain: Early management of persistent non-specific low back pain. NICE clinical guideline 88 (2009). This guidance is currently under review and is expected to be updated in 2016. 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. Four Specialist Advisor Questionnaires for percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica were submitted and can be found on the NICE website [INSERT HYPER LINK TO MAIN IP PAGE].

Patient commentators' opinions

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

Issues for consideration by IPAC

Ongoing trials:

NCT01263054: Safety and Efficacy of the TransDiscal System Versus Medical Management in Treating Chronic Discogenic Low Back Pain (COLD); location: United States; type: RCT; estimated enrollment: 60; estimated primary completion date: April 2015

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3. Freeman BJC, Fraser RD, Cain CMJ et al. (2005) A randomized, double-blind, controlled trial: intradiscal electrothermal therapy versus placebo for the treatment of chronic discogenic low back pain... including commentary by Carey TS. Spine 30: 2369-2379.
4. Derby R, Eek B, Lee S-H et al. (2004) Comparison of intradiscal restorative injections and intradiscal electrothermal treatment (IDET) in the treatment of low back pain. Pain Physician 7: 63-66.
5. Fukui S, Nitta K, Iwashita N et al (2012) Results of intradiscal pulsed radiofrequency for lumbar discogenic pain: comparison with intradiscal electrothermal therapy. Korean J Pain 25(3):155-60. doi:10.3344/kjp.2012.25.3.155.
6. Finch PM, Price LM, Drummond PD (2005) Radiofrequency heating of painful annular disruptions: one-year outcomes. J Spinal Disord Tech. 18(1): 6-13.
7. Tsou HK, Chao SC,Kao TH et al (2010) Intradiscal electrothermal therapy in the treatment of chronic low back pain: Experience with 93 patients. Surg Neurol Int 1: 37. doi:10.4103/2152-7806.67107
8. Saal J, Saal JS, Wetzel F, et al. (2001) IDET-related complications: a multicenter study of 1675 treated patients with a review of the FDA MDR database [Abstract] Presented at: 16th Annual Meeting of the North American Spine Society.
9. Tang YZ, Ni JX and An JX (2013) Complex Regional Pain Syndrome Type I Following discTRODE Radiofrequency Treated with Continuous Lumbar Sympathetic Trunk Block Using Patient-Controlled Analgesia. Pain Medicine 14(2): 309-310
10. Orr RD and Thomas SA. (2005) Intradural migration of broken IDET catheter causing a radiculopathy. Journal of Spinal Disorders & Techniques 18: 185-187.
11. Scholl BM, Theiss SM, Lopez-Ben R et al. (1-5-2003) Vertebral osteonecrosis related to intradiscal electrothermal therapy: a case report. Spine 28: E161-E164.

Appendix A: Additional papers on percutaneous electrothermal treatment of the intervertebral disc annulus 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
Kvarstein G, Måwe L, Indahl A et al. (2009) A randomized double-blind controlled trial of intra-annular radiofrequency thermal disc therapy--a 12-month follow-up. Pain. 145(3):279-86. doi: 10.1016/j.pain.2009.05.001.	Randomised controlled trial n=20 (20 PIRFT of the annulus versus 10 Sham) Follow-up: 1 year	SF-36 bodily pain scores (scores ranged from 0 to 100 with higher scores indicating less pain) increased by 39.5 to 51.6 in the PIRFT group and from 32.5 to 39.5 in the sham group at 1 year follow-up. SF-36 physical function scores (scores ranged from 0 to 100 with higher scores indicating improved physical function) improved from 49.0 to 65.0 in the PIRFT group and 52.5 to 57.5 in the sham group at	Larger studies that reported similar outcomes are included in table 2.
Pauza KJ, Howell S, Dreyfuss P et al (2004) A randomized, placebo-controlled trial of intradiscal electrothermal therapy for the treatment of discogenic low back pain. Spine J. 4(1):27-35.	Randomised controlled trial n=64 (37 IDET versus 27 Sham) Follow-up: 1 year	Mean visual analogue scale scores for pain (scores ranged from 1 to 10 with lower scores indicating less pain) improved from 6.6 to 4.2 in the IDET group and from 6.5 to 5.4 in the sham group at 6 month follow-up (p=0.89). Mean ODI scores improved from 31 to 20 in the IDET group and from 33 to 28 in the sham group at 6 month follow-up (p=0.23).	Larger studies that reported similar outcomes are included in table 2.
Kapural L, Hayek S, Malak O et al. (2005) Intradiscal thermal annuloplasty versus intradiscal radiofrequency ablation for the treatment of discogenic pain: a prospective matched control trial. Pain Medicine 6:425-431.	Non-randomised comparative study (Included in the previous guidance document) n=42 (21 IDET versus 21 Radiofrequency ablation)	Mean visual analogue scale scores for pain (scores ranged from 1 to 10 with lower scores indicating less pain) improved from 7.4 to 1.4 (p<0.001) in the IDET group and from 6.6 to 4.4 (p<0.001) in the radiofrequency	Larger studies that reported similar outcomes are included in table 2.

	Follow-up: median of 1 year	group at 1 year follow-up.	
Kapural L, Mekhail N, Korunda Z et al. (2004) Intradiscal thermal annuloplasty for the treatment of lumbar discogenic pain in patients with multilevel degenerative disc disease. Anesth Analg. 99(2):472-6	Non-randomised comparative study n=34 patients treated by IDET (17 with single-level disc degeneration matched with 17 patients who had multi-level disc degeneration) Follow-up: 1 year	Mean visual analogue scale scores for pain (scores ranged from 0 to 10 with lower scores indicating less pain) improved from 7.4 to 4 in patients with single-level disc degeneration ($p<0.001$). In patients with multi-level disc degeneration, visual analogue scale scores for pain improved from 7.7 to 5 at 1 year follow-up ($p<0.001$). Pain Disability Index scores (scores range	Larger studies that reported similar outcomes are included in table 2.
Karaman H, Tüfek A, Kavak GO et al. (2011) 6 month results of transdiscal buacuplasty on patients with discogenic low back pain: Preliminary findings (2011) International journal of medical sciences 8(1):1-8	Case series n=15 patients treated by PIRFT of the annulus Follow-up: 6 months	Mean visual analogue scale scores for pain scores (scores range from 0 to 10 with lower scores indicating less pain) improved from 8.3 to 4.6 at 6 month follow-up ($p<0.05$). ODI scores improved from 34.9 to 17.9 at 6 month follow-up ($p<0.05$). The proportion of patients who had a 10 point improvement in ODI scores was 78.6%	Larger studies that reported similar outcomes are included in table 2.
Saal JA1, Saal JS. (2000) Intradiscal electrothermal treatment for chronic discogenic low back pain: a prospective outcome study with minimum 1-year follow-up. Spine 25(20):2622-7.	Case series n=62 patients treated by IDET Follow-up: mean of 16 months	Mean visual analogue scale scores for pain (scores range from 0 to 10 with lower scores indicating less pain) improved from 6.6 to 3.7 at follow-up ($p<0.001$). Mean SF-36 physical function subscale scores improved from 39 to 59 at follow-up ($p<0.001$). Mean SF-36 pain subscale scores improved from 29 to 46.2 at follow-up ($p<0.001$).	Larger studies that reported similar outcomes are included in table 2.
Nunley PD, Jawahar A, Brandao SM et al. (2008) Intradiscal electrothermal therapy (IDET) for low back pain in worker's compensation patients: can it provide a potential answer? Long-term results.	Case series (Included in the previous guidance document) n=53 patients treated by IDET	Mean visual analogue scale scores for pain (scores ranged from 1 to 100 with lower scores indicating less pain) improved from 63.77 to 19.43 at 1 year follow-up. ODI scores	Larger studies that reported similar outcomes are included in table 2.

Journal of Spinal Disorders & Techniques 21:11-18.	Follow-up: 1 year	improved from 24.83 to 5.15 at 1 year follow-up. The proportion of patients requiring narcotic analgesic medication decreased from 51% at baseline to 13% at 12 month follow-up (measurement of significance not reported)	
Jawahar A, Brandao SM, Howard C, Nunley PD (2008) Intreadiscal Electrothermal Therapy (IDET): A viable alternative to surgery for low back pain in workers' compensation patients. Journal of the low back pain. Journal of the Louisiana State Medical Society. 160(5):280-5.	Case series n=53 treated by IDET Follow-up: 2 years	Mean visual analogue scale scores for pain (scores ranged from 1 to 100 with lower scores indicating less pain) improved from 63.77 to 19.43 at 2 year follow-up. ODI scores improved from 24.83 to 5.15 at 2 year follow-up. No p value reported	Larger studies that reported similar outcomes are included in table 2.
Assietti R, Morosi M, Migliaccio G et al. (2011) Treatment of discogenic low back pain with Intradiscal Electrothermal Therapy (IDET): 24 months follow-up in 50 consecutive patients. Acta Neurochir Suppl. 108:103-5. doi: 10.1007/978-3-211-99370-5_15.	Case series n=50 treated by IDET Follow-up: 2 years	Mean ODI scores improved from 59.0 to 20.1 at 2 year follow-up ($p<0.0001$)	Larger studies that reported similar outcomes are included in table 2.
Freedman BA, Cohen SP, Kuklo TR et al. (2003) Intradiscal electrothermal therapy (IDET) for chronic low back pain in active-duty soldiers: 2-year follow-up. Spine J. 3(6):502-9.	Case series n=41 treated by IDET Follow-up: 2 years	Improvements in back pain were reported in 29% (9/31) of patients at 2 year follow-up. 23% (7/31) of patients initially reported improvements in back pain; however pain returned to baseline levels at 2 year follow-up. No change in pain was reported in 29% (9/31) of patients, throughout the 2 year follow-up period. Worsening back pain was reported in 19% (6/31) of patients at 2 year follow-up. The following adverse events were reported: nerve root injury (n=1), increased disc herniation (n=1), decreased sphincter tone resulting in faecal incontinence (n=1) and	Larger studies that reported similar outcomes are included in table 2. The results of this study were included in the systematic review (Appleby, 2006) in Table 2.

		increased nondermatomal leg pain (n=2).	
Saal JS, Saal JA. (2000) Management of chronic discogenic low back pain with a thermal intradiscal catheter. A preliminary report. Spine 25(3):382-8.	Case series n=25 treated by IDET Follow-up: 7 months	Mean visual analogue scale scores for pain (scores ranged from 1 to 10 with lower scores indicating less pain) improved from 7.32 to 3.58 ($p<0.0001$) at mean follow-up of 7 months. SF-36 bodily pain scores improved from 28.48 to 42.24 at mean follow-up of 7 months. SF-36 physical function scores improved from 40.12 to 42.24 at mean follow-up of 7 months.	Larger studies that reported similar outcomes are included in table 2.

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

Guidance	Recommendations
Interventional procedures	**Percutaneous intradiscal electrothermal therapy for low back pain. NICE Interventional Procedure Guidance 319 (2009)** (Current guidance) 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. **Percutaneous intradiscal radiofrequency thermocoagulation for low back pain. NICE Interventional Procedure Guidance 83 (2004).** (Current guidance) 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. **Percutaneous disc decompression using coblation for low back pain NICE Interventional Procedure Guidance 173 (2006).** (Current guidance) 1.1 Current evidence suggests that there are no major safety concerns associated with the use of percutaneous disc decompression using coblation for lower back pain. There is some evidence of short-term efficacy; however, this is not sufficient to support the use of this procedure without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake percutaneous disc decompression using coblation 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 disc decompression using coblation for lower back pain. 1.3 Further research will be useful in reducing the current uncertainty, and clinicians are encouraged to collect long-term follow-up data. The Institute may review the procedure upon publication of further evidence. **Percutaneous endoscopic laser lumbar discectomy. NICE**

	interventional procedure guidance 300 (2009). (Current guidance) 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. **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. **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. **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. **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.
NICE guidelines	**Low back pain: Early management of persistent non-specific low back pain. NICE clinical guideline 88 (2009).** **(Current guidance)** 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 electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	27/03/2015	Issue 3 of 12, March 2015
HTA database (Cochrane Library)	27/03/2015	Issue 1 of 4, January 2015
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	27/03/2015	Issue 2 of 12, February 2015
MEDLINE (Ovid)	27/03/2015	1946 to March Week 4 2015
MEDLINE In-Process (Ovid)	27/03/2015	March 26, 2015
EMBASE (Ovid)	27/03/2015	1974 to 2015 Week 12
PubMed	27/03/2015	n/a
BLIC	27/03/2015	n/a

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

1	Low Back Pain/
2	(low* adj4 back pain*).tw.
3	(low* adj4 back ache*).tw.
4	(low* adj4 backache*).tw.
5	LBP.tw.
6	lumbago*.tw.
7	Sciatica/
8	sciatic*.tw.
9	(chronic* adj4 back pain*).tw.
10	Intervertebral Disk Displacement/
11	Intervertebral Disc Degeneration/
12	(Intervertebr* adj4 (Disk* or disc*) adj4 (Displace* or degenerat*)).tw.
13	((slipped or hernia* or prolaps* or an?ulus) adj4 (disc* or disk*)).tw.
14	((discogenic* or diskogenic*) adj4 pain*).tw.
15	(radicular adj4 pain*).tw.
16	Radiculopathy/
17	(lumbar adj4 radiculopath*).tw.

18	or/1-17
19	(intradisc* or intradisk*).tw.
20	Electrocoagulation/
21	electrocoagulat*.tw.
22	Electric Stimulation Therapy/
23	(electric* adj4 stimulat* adj4 therap*).tw.
24	Catheter Ablation/
25	(catheter adj4 ablation).tw.
26	electrotherm*.tw.
27	(electroannuloplast* or electroanuloplast* or anuloplast* or annuloplast*).tw.
28	(thermocoag* or electrocoag*).tw.
29	Electrodes/
30	electrode*.tw.
31	biacuplast*.tw.
32	coblat*.tw.
33	Radio Waves/
34	(Radiofrequenc* or radio-frequenc*).tw.
35	RF.tw.
36	((disc* or disk*) adj4 annulus).tw.
37	or/20-36
38	19 and 37
39	IDET.tw.
40	38 or 39
41	18 and 40
42	SpineCATH.tw.
43	"Disk IT".tw.
44	(Transdisc* adj4 Cooled adj4 RF).tw.
45	(Transdisc* adj4 System*).tw.
46	or/41-45
47	Animals/ not Humans/
48	46 not 47