

# **NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE**

## **INTERVENTIONAL PROCEDURES PROGRAMME**

### **Interventional procedures overview of percutaneous intradiscal electrothermal therapy for lower back pain**

#### ***Introduction***

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

#### ***Date prepared***

This overview was prepared in April 2003. It is based on an earlier overview presented to the committee on intradiscal electrothermal therapy.

#### ***Procedure names***

- Intradiscal Electrothermal Annuloplasty (IDETA).
- Intradiscal electrothermal anuloplasty (IDTA)
- Intradiscal Electrothermal Therapy (IDET)
- Intradiscal Electroannuloplasty (IDEA)

#### ***Specialty societies***

- British Orthopaedic Association.
- Association of Anaesthetists of Great Britain and Ireland.
- British Society of Skeletal Radiology.

#### ***Description***

##### **Indication(s)**

Chronic back pain is a common condition that affects a considerable proportion of the population. In the majority of individuals pain resolves spontaneously within several months. However, for some people pain persists, despite specific causes of back pain such as herniated discs, osteoporosis and fractures being excluded. Increasingly this pain is being attributed to degeneration of the intervertebral disc, and referred to as discogenic back pain<sup>1</sup>.

## **Current treatment and alternatives**

Few treatment options exist for individuals with chronic back pain. First-line treatment is typically a conservative management strategy, consisting of pharmacotherapy and/or a multidisciplinary programme. Patients who fail to respond to this regime then have the choice to continue with conservative management or to undergo surgery (spinal fusion).

The procedure is only indicated for patients with chronic low back pain due to annular disruption of contained herniated discs.

## **Summary of procedure**

Percutaneous intradiscal electrothermal therapy is performed under a mild local anaesthetic and light sedation. Under fluoroscopic guidance, a needle is inserted into the disc to be treated.

The electrode or flexible catheter is then introduced into the disc. The catheter is passed through the needle and guided to cover the entire posterior wall of the disc. Once in position the catheter is slowly heated up to 90°C for 15 to 17 minutes.

## **Efficacy**

The published evidence on percutaneous intradiscal electrothermal therapy indicated that the majority of patients reported a decrease in pain following the procedure as measured by a visual analogue scale. In the published randomised control trial, 78% (25/32) of patients reported an improvement in pain 6 months after the procedure, compared with 46% (11/24) of patients in the control group. But only 38% (12/32) of patients treated with the procedure experienced more than 50% pain relief, compared with 33% (8/32) of patients who underwent the sham procedure.

The reporting of improvement in pain varied among the case series from 48% (38/79) of patients reporting more than 50% pain relief at 6 months to 72% (42/58) of patients experiencing at least a 2-point improvement in pain at 24 months as measured by a visual analogue scale. The case series evidence also indicated that, although a substantial proportion of patients experienced improvement in pain following the procedure, there is still a significant number who experienced no appreciable benefit.

There was also some evidence to indicate that patients experienced an improvement in physical function, bodily pain and disability scores following the procedure.

Most of the studies report on small numbers of highly selected patients. There is limited good-quality comparative data on this procedure. This lack of comparative data makes it difficult to distinguish between treatment effect and the natural history of this disease. The one randomised controlled trial on this procedure reported on 64 patients with 6 months follow up.

The Specialist Advisors expressed uncertainty regarding the efficacy of this procedure. The Advisors felt that the current published evidence had not demonstrated the benefits of the procedure.

## **Safety**

Complications were described in six of the seven studies, with no reference made to complications in one study. Most of these complications were of a transient nature. The incidence of complications ranged from 0% (0/58) to 15% (5/33) and included increasing radicular pain (5/33), parasthesia and numbness in the thighs (2/79), and foot drop (1/79). In

one of the studies one patient developed a cerebro-spinal fluid leak. There have also been two case reports of cauda equina syndrome and two cases of vertebral osteonecrosis following percutaneous intradiscal electrothermal therapy.

The Specialist Advisors did not report any particular safety concerns, although persisting pain, nerve root damage and infection were noted as potential complications of intradiscal therapy.

## **Literature review**

### **Rapid review of literature**

The medical literature was searched to identify studies and reviews relevant to percutaneous intradiscal electrothermal therapy for lower back pain. Searches were conducted via the following databases from their commencement to October 2003 (with an update in May 2004): MEDLINE, PREMEDLINE, EMBASE, Cochrane Library, Current Contents and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

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

**Table 1 Inclusion criteria for identification of relevant studies**

<b>Characteristic</b>	<b>Criteria</b>
Publication type	Clinical studies included. Emphasis was placed on identifying good quality comparative studies. Abstracts were excluded where no clinical outcomes were reported; or where the paper was a review, editorial, technical or animal study. Case reports were excluded. Case series with fewer than 10 patients were excluded. Conference abstracts were also excluded due to the difficulty in appraising methodology.
Patient	Patients with lower back pain.
Intervention/test	Percutaneous intradiscal thermocoagulation.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

### **List of studies included in the overview**

This overview is based on seven studies (nine publications).<sup>2-10</sup> This includes one randomised controlled trial, one non-randomised controlled trial and five case series studies.

Five additional studies were identified that were relevant to the safety of this procedure.

Appendix A includes a list of studies not included in the summary tables.

### **Existing reviews on the procedure**

Since 1998 nine health technology assessments or systematic reviews have been undertaken on percutaneous intradiscal electrothermal therapy (Canadian Coordinating Office for Health Technology Assessment, 2003). Differing inclusion criteria led to different studies being assessed within each of the reviews. In addition, many of the existing health technology

assessments or systematic reviews do not report on the more recent studies, including the one published randomised controlled trial on this procedure.

These reviews are listed in Appendix B of this document.

## Summary of key efficacy and safety findings

Study details	Key efficacy findings	Key safety findings	Comments																																																																															
<p><b>Pauza et al (2004)</b><sup>2</sup></p> <p>Texas</p> <p>Randomised controlled trial</p> <p>September 2000–April 2002.</p> <p>IDET: 37 patients (32 included in analysis)</p> <p>Sham: 27 patients (24 included in analysis)</p> <p>Selection criteria 18–65 years of age; pain present for more than 6 months; failure to improve after at least 6 weeks of care; a score of less than 20 on the Beck depression scale; no surgical treatments within last 3 months.</p> <p>IDET: heated to a temperature of 90°C</p> <p>Follow up: 6 months</p>	<p><b>Outcomes reported:</b> pain and disability, Short Form (SF)-36 and the Oswestry disability scale.</p> <table border="1"> <thead> <tr> <th>Pain (VAS 1–10)</th> <th>IDET (32) Mean (SD)</th> <th>Sham (24) Mean (SD)</th> <th>p-value</th> </tr> </thead> <tbody> <tr> <td>Pre-treatment</td> <td>6.6 (1.4)</td> <td>6.5 (1.9)</td> <td>p = 0.758</td> </tr> <tr> <td>6 months</td> <td>4.2 (2.6)</td> <td>5.4 (2.7)</td> <td>p = 0.089</td> </tr> <tr> <td>Change</td> <td>2.4 (2.3)</td> <td>1.1 (2.6)</td> <td>p = 0.045</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th></th> <th>IDET (32)</th> <th>Sham (24)</th> </tr> </thead> <tbody> <tr> <td>Pain worse</td> <td>2 (6%)</td> <td>8 (33%)</td> </tr> <tr> <td>Pain same</td> <td>5 (16%)</td> <td>5 (21%)</td> </tr> <tr> <td>Improvement</td> <td>25 (78%)</td> <td>11 (46%)</td> </tr> <tr> <td>Change &gt; 50%</td> <td>12 (38%)</td> <td>8 (33%)</td> </tr> </tbody> </table> <p><b>SF-36 (0-100)</b></p> <p><b>Bodily pain</b></p> <table border="1"> <thead> <tr> <th></th> <th>IDET (32)</th> <th>Sham (24)</th> <th>p-value</th> </tr> </thead> <tbody> <tr> <td>Pre-treatment</td> <td>36 (12)</td> <td>35 (12)</td> <td>p = 0.765</td> </tr> <tr> <td>6 months</td> <td>53 (19)</td> <td>44 (20)</td> <td>p = 0.085</td> </tr> <tr> <td>Change</td> <td>17 (19)</td> <td>9 (15)</td> <td>p = 0.086</td> </tr> </tbody> </table> <p><b>SF-36 (0–100)</b></p> <p><b>Physical funct.</b></p> <table border="1"> <thead> <tr> <th></th> <th>IDET (32)</th> <th>Sham (24)</th> <th>p-value</th> </tr> </thead> <tbody> <tr> <td>Pre-treatment</td> <td>56 (24)</td> <td>49 (21)</td> <td>p = 0.236</td> </tr> <tr> <td>6 months</td> <td>71 (22)</td> <td>60 (24)</td> <td>p = 0.079</td> </tr> <tr> <td>Change</td> <td>15 (27)</td> <td>11 (17)</td> <td>p = 0.548</td> </tr> </tbody> </table> <p><b>Oswestry (0–100)</b></p> <table border="1"> <thead> <tr> <th></th> <th>IDET (32)</th> <th>Sham (24)</th> <th>p-value</th> </tr> </thead> <tbody> <tr> <td>Pre-treatment</td> <td>31 (10)</td> <td>33 (11)</td> <td>p = 0.485</td> </tr> <tr> <td>6 months</td> <td>20 (12)</td> <td>28 (15)</td> <td>p = 0.023</td> </tr> <tr> <td>Change</td> <td>11 (11)</td> <td>4 (12)</td> <td>p = 0.050</td> </tr> </tbody> </table> <p>Further analysis was also undertaken of the main outcomes, stratified according to baseline scores. These results are not presented here.</p>	Pain (VAS 1–10)	IDET (32) Mean (SD)	Sham (24) Mean (SD)	p-value	Pre-treatment	6.6 (1.4)	6.5 (1.9)	p = 0.758	6 months	4.2 (2.6)	5.4 (2.7)	p = 0.089	Change	2.4 (2.3)	1.1 (2.6)	p = 0.045		IDET (32)	Sham (24)	Pain worse	2 (6%)	8 (33%)	Pain same	5 (16%)	5 (21%)	Improvement	25 (78%)	11 (46%)	Change > 50%	12 (38%)	8 (33%)		IDET (32)	Sham (24)	p-value	Pre-treatment	36 (12)	35 (12)	p = 0.765	6 months	53 (19)	44 (20)	p = 0.085	Change	17 (19)	9 (15)	p = 0.086		IDET (32)	Sham (24)	p-value	Pre-treatment	56 (24)	49 (21)	p = 0.236	6 months	71 (22)	60 (24)	p = 0.079	Change	15 (27)	11 (17)	p = 0.548		IDET (32)	Sham (24)	p-value	Pre-treatment	31 (10)	33 (11)	p = 0.485	6 months	20 (12)	28 (15)	p = 0.023	Change	11 (11)	4 (12)	p = 0.050	<p><b>Complications:</b> Authors note that “no patient had any adverse effects attributable to their treatment”.</p>	<p>Patients were recruited from authors’ private practice, colleagues and newspaper advertisements.</p> <p>Exclusion criteria clearly stated.</p> <p>Before randomisation, patients who were potentially eligible had to undergo a provocation discography – patients had to have a posterior tear of the annulus fibrosus. All consecutive patients were invited to participate.</p> <p>Randomisation: Computer generated random numbers.</p> <p>Participants were unblinded at 6 months – authors stated that it was expected that outcomes at 6 months would be stable and would be predictive of outcomes at 12 and 24 months.</p> <p>After treatment both groups underwent an exercise programme and received medication (blinded clinicians). Outcomes assessment blinded.</p> <p>Study was intended to recruit 40 patients to IDET and 27 patients to Sham (power 80%). Authors note difficulty recruiting– power 60%.</p> <p>Authors comment that IDET would seem to be more effective in patients with poor physical function and high disability, but in patients with low disability and good function benefits were minimal.</p>
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<p><b>Bogduk,N and Karasek, M. (2002)</b> <sup>3</sup>  <b>Karasek &amp; Bogduk (2000)</b> <sup>4</sup>  <b>USA</b></p> <p>Non-randomised controlled trial.</p> <p>May 1998–November 1998</p> <p>36 patients IDET  17 patients control (rehabilitation).</p> <p>Selection criteria:  3 months who underwent discography, unresponsive to conservative management, No evidence disc prolapse, CT discography</p> <p>IDET: heated to a temperature of 90°C, 80°C, or 85°C</p> <p>Follow up: 24 months</p>	<p><b>Outcomes assessed:</b> pain, return to work, and medication use.</p> <p><b>Pain</b> (Visual analogue scale 1–10)  <b>Median Pain scores,</b></p> <table border="1" data-bbox="510 438 1243 606"> <thead> <tr> <th></th> <th>n</th> <th>IDET</th> <th>n</th> <th>Control Group</th> <th></th> </tr> </thead> <tbody> <tr> <td>Baseline</td> <td>36</td> <td>8 (7-9)</td> <td>17</td> <td>8 (5-8)</td> <td>p = 0.071</td> </tr> <tr> <td>3 months</td> <td>36</td> <td>4 (1-5)</td> <td>17</td> <td>8 (7-8)</td> <td>p = 0.000</td> </tr> <tr> <td>6 months</td> <td>36</td> <td>3 (1-6)</td> <td>-</td> <td>-</td> <td></td> </tr> <tr> <td>12 months</td> <td>35</td> <td>3 (1-7)</td> <td>12</td> <td>7.5 (5-8)</td> <td>p = 0.005</td> </tr> <tr> <td>24 months</td> <td>35</td> <td>3 (1-7)</td> <td>10</td> <td>7.5 (4-8)</td> <td>p = 0.028</td> </tr> </tbody> </table> <p><b>Improvement (pain)</b>  IDET</p> <ul style="list-style-type: none"> <li>• 3 months; 8% had complete relief; 64% had obtained 50% relief; remaining patients (16/17) obtained minimal or no relief.</li> <li>• 12 months 60% had at least 50% relief, and 23% had complete relief.</li> <li>• 24 months 57% had at least 50% relief, and 20% had complete relief.</li> </ul> <p>Control</p> <ul style="list-style-type: none"> <li>• 3 months; 0% had complete relief; 1 (5.9%) patient obtained 80% relief; remaining patients obtained minimal or no relief.</li> <li>• 12 months 2 patients had complete relief; none were pain free.</li> <li>• 24 months 2 patients had complete relief</li> </ul> <p><b>Return to work</b>  IDET – 1/5 patients not working had returned to work, 3/10 patients working before treatment had ceased to work.</p> <p><b>Medication</b>  7 patients still used opioids, five stopped, four started using opioids.</p>		n	IDET	n	Control Group		Baseline	36	8 (7-9)	17	8 (5-8)	p = 0.071	3 months	36	4 (1-5)	17	8 (7-8)	p = 0.000	6 months	36	3 (1-6)	-	-		12 months	35	3 (1-7)	12	7.5 (5-8)	p = 0.005	24 months	35	3 (1-7)	10	7.5 (4-8)	p = 0.028	<p><b>Complications:</b>  The authors make no statements regarding complications.</p>	<p>Setting: private practice.</p> <p>Patients who were potentially eligible had to undergo a provocation discography.</p> <p>Control group consisted of patients whose insurance company refused to reimburse.</p> <p>Authors stated that control group did not remain under the care of the practice so there is a lack of complete full follow-up for this group: 3 patients treated with IDET; 1 patient died (unrelated); 1 declined to provide data; 2 could not be contacted.</p> <p>Thermal electrode was navigated within the annulus of the disc rather than intradiscally</p> <p>Success was defined as a 50% reduction in pain, return to work/normal duties, and no longer required opioids for pain.</p> <p>Pain was not measured independently (blinded).</p> <p>Authors reported that there seem to be two patient groups: (1) those who failed to show any response immediately/those that showed some improvement but relapsed at 6 months; (2) those who showed significant improvements that were maintained .</p>
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Study details	Key efficacy findings	Key safety findings	Comments
<p><b>Saal &amp; Saal (2000a) (2002b)</b> <sup>5-6,11,</sup></p> <p>Case-series</p> <p>November 1997 – October 1998.</p> <p>58 patients</p> <p>Symptoms: Mean duration of preoperative symptoms was 60.7 months, median duration was 48 months (10-17 years).</p> <p>30 (48%) patients treated as a single disc level</p> <p>Selection criteria: Pain &gt; 6 months, no improvement following conservative management, normal neurological findings, negative straight leg raising results, negative MRI scan</p> <p>Follow up: minimum 2 years (mean 28 months)</p>	<p><b>Outcomes assessed:</b> pain, sitting tolerance and SF-36.</p> <p><b>Mean pain</b> visual analogue Mean <math>\pm</math> SD reduction in 10 point pain scale Baseline <math>6.57 \pm 1.85</math>, 12-month follow up <math>3.52 \pm 2.30</math> <math>p &lt; 0.001</math> 24-month follow up <math>3.41 \pm 1.96</math> <math>p &lt; 0.01</math></p> <p>24 months post treatment 72% of the patients experienced at least 2-point improvement in pain and 50% exhibited at least 4-point reduction in pain.</p> <p><b>Return to work, all patients</b> 37/38 (97%) of privately paying and 17/20 (83%) of workers compensation patients returned to work</p> <p><b>Sitting tolerance (minutes)</b> Baseline <math>32.64 \pm 47.52</math>, 24 months <math>85.34 \pm 61.19</math></p> <p><b>SF-36 all patients, 24 month follow-up</b> <b>Physical function subscale</b>, 100-point scale, mean <math>\pm</math> SD Baseline <math>40.5 \pm 25.0</math>, 12 month follow-up <math>60.34 \pm 22.2</math> <math>p &lt; 0.001</math> 24 months <math>71.8 \pm 22.8</math> <math>p &lt; 0.0001</math></p> <p>81% patients showed at least a 7-point improvement. 45% patients showed at least a 28-point improvement.</p> <p><b>Bodily pain subscale</b> 100-point scale, mean <math>\pm</math> SD Baseline <math>29.8 \pm 16.0</math> 12 month follow-up <math>46.93 \pm 19.17</math> <math>P &lt; 0.001</math> 24 months <math>51.7 \pm 22.6</math> <math>p &lt; 0.0001</math></p> <p>In all subscales of the SF-36 there was an improvement at 24 months.</p>	<p><b>Complications</b> Authors note that no IDET-treated patients in this study had a complication. There were no nerve injuries and no infections and no patient had a neurologic deficit.</p>	<p>Authors describe as consecutive patients.</p> <p>Originally 62 patients at 1 year follow-up (6) - 4/58 (7%) patients lost to follow-up.</p> <p>Small study numbers.</p> <p>38 private pay patients and 20 workers compensation patients.</p> <p>Saal and Saal are the inventors of the SpineCath catheter and are also cofounders of the manufacturing company Oratec Interventions Inc.</p> <p>Data were collected and entered by clerical personnel.</p> <p>Authors made a comparison with IDET patients and previously published quality of life values/pain scores.</p>

Study details	Key efficacy findings	Key safety findings	Comments
<p><b>Lutz, Lutz &amp; Cooke (2003)<sup>7</sup></b></p> <p>Case series</p> <p>33 patients</p> <p>Patients recruited from an academic-affiliated private physiatric practice of one of the authors</p> <p>16 (52%) of patients treated as a single disc level</p> <p>Follow up: mean 15 months</p>	<p><b>Outcomes assessed:</b> pain, disability, patient satisfaction, return to work.</p> <p><b>Mean Pain visual analogue scale (VAS)</b> Mean ± SD reduction in 10 point pain scale Baseline 7.5 follow up 3.9. Mean change was 3.9 p &lt; 0.001</p> <p><b>Mean Pain Visual Analogue – Lower Extremity (VAS- LE)</b> Mean ± SD reduction in 10 point pain scale Baseline 5.7 follow up 2.0. Mean change was 3.7 p &lt; 0.001</p> <p>Overall VAS scores improved by ≥ 3 in 23/33 (69.6%) of cases</p> <p><b>Mean Roland Morris Disability Questionnaire (RMDQ)</b> Mean Baseline 13.9 follow up 6.6 Mean change was 7.3 p &lt; 0.001</p> <p><b>NASS Patient satisfaction, all patients, 12-month follow up</b> 22/33 (77%) of patients stated the procedure met their expectations and they would undergo it again for the same outcome.</p> <p><b>Return to work, all patients</b> 4/8 (50%) of patients who were not working returned to work</p>	<p><b>Complications</b> 5 patients experience increased radicular pain (4 cases resolved with injection of epidural steroid injection).</p>	<p><b>Comments</b> 15 were workers' compensation or no-fault cases.</p> <p>Unclear about return to work for people on workers' compensation.</p> <p>The treatment was considered a success if patients had a 2-point reduction on the VAS and Roland Morris Disability Questionnaire (RMDQ) and a positive North American Spine Society (NASS) response.</p>

Study details	Key efficacy findings	Key safety findings	Comments
<p><b>Derby, Eek, Chen, O'Neill, &amp; Ryan (2000)<sup>8</sup></b></p> <p>California US (single Centre) 32 patients</p> <p>21 (66%) of patients treated as a single disc level</p> <p>Selection criteria: Pain &gt; 6 months No improvement following conservative management, normal neurological findings, negative straight leg raising results, negative MRI scan</p> <p>Follow up: 12 months</p>	<p><b>Outcomes assessed:</b> pain, disability, patients satisfaction and activity levels.</p> <p><b>Mean Pain visual analogue scale (VAS)</b> Mean <math>\pm</math> SD improvement from baseline <math>1.8 \pm 2.4</math></p> <p><b>Mean Roland Morris Disability Questionnaire (RMDQ)</b> Improvement from baseline <math>4.0 \pm 4.8</math> Patients improved in sitting (41%), standing (50%), walking (45%) and sleeping (41%)</p> <p><b>Patient satisfaction, all patients, 12 month follow-up</b> 78% of patients stated the procedure met their expectations and they would undergo it again for the same outcome.</p> <p><b>Self reported overall activity</b> level compared with before the procedure, 53% patients better or much better, 34.4% same, 9.4% worse, 3.1% much worse.</p>	<p><b>Complications</b> All patients experienced an increased in their typical pain following the procedure (transient).</p>	<p><b>Comments</b> Authors note that report is a pilot study. Variable electrode heating regime was also used on the first few patients.</p>

Study details	Key efficacy findings	Key safety findings	Comments								
<p><b>Cohen et al (2003)</b> <sup>9</sup></p> <p>US</p> <p>Case series</p> <p>80 consecutive patients (79 analysed)</p> <p>Mean age: 37.6 years (range 15-60)</p> <p>50 patients had one disc treated, 29 had two discs treated. 13 patients had undergone previous surgery.</p> <p><b>Selection criteria:</b> Pain &gt; 6 months No improvement following conservative management, normal neurological findings, absence of prominent radicular signs and symptoms; positive provocative discography. Follow up: 6 months</p>	<p><b>Outcomes assessed:</b> pain</p> <p><b>Pain – 6 months (visual analogue scale)</b></p> <table border="0"> <tr> <td>Positive outcome</td> <td>Negative outcome</td> </tr> <tr> <td>38 patients</td> <td>41 patients</td> </tr> <tr> <td><b>Pre:</b> 5.9 (SD 1.8)</td> <td>6.2 (SD 1.9)</td> </tr> <tr> <td><b>Post:</b> 2.1</td> <td>5.1 (SD 1.8)</td> </tr> </table> <p>After treatment, 48% (38/79) of patients reported more than 50% pain relief, with 10% (8/79) obtaining over 90% relief.</p>	Positive outcome	Negative outcome	38 patients	41 patients	<b>Pre:</b> 5.9 (SD 1.8)	6.2 (SD 1.9)	<b>Post:</b> 2.1	5.1 (SD 1.8)	<p><b>Complications</b></p> <ul style="list-style-type: none"> <li>▪ 8 patients reported complications (10%)</li> <li>▪ 1 patient burning sensation in one leg (lasted 2 weeks)</li> <li>▪ 2 patients new nondermatomal paresthesias and numbness in thighs (last 1 month)</li> <li>▪ 1 patient noted weakness in the L4 distribution ipsilateral to the trocar insertion site, manifested as food drop (resolved 6 weeks)</li> <li>▪ 1 patient considerable increase in back and thigh pain immediately following the procedure along with new paresthesias.</li> <li>▪ 1 patient increase in lower leg pain</li> <li>▪ 1 patient severe headache</li> <li>▪ 1 patient increased thigh and back pain</li> </ul>	<p>Retrospective</p> <p>Patient population comprised active duty/civilian patients. It was reported that there was no difference in outcomes between the groups.</p> <p>Outcome measure: more than 50% reduction in pain 6 months post-procedure was considered a success.</p> <p>Outcomes assessed, 1, 2, 6 monthly by visits, phone or email.</p> <p>Outcomes not reported well in the study.</p> <p>Trend for obesity to be associated with complication.</p>
Positive outcome	Negative outcome										
38 patients	41 patients										
<b>Pre:</b> 5.9 (SD 1.8)	6.2 (SD 1.9)										
<b>Post:</b> 2.1	5.1 (SD 1.8)										

Study details	Key efficacy findings	Key safety findings	Comments																												
<p><b>Gerszten et al (2002)</b> <sup>10</sup></p> <p>US</p> <p>Case-series</p> <p>27 patients 8 with private insurance 19 received workers compensation.</p> <p>16 patients treated at 1 disc level 11 patients at 2 or more disc levels.</p> <p>Duration of symptoms: 38 months (6 months–15 years). Follow up: 12 months</p>	<p><b>Outcomes assessed:</b> Quality of life (SF-36), disability.</p> <table border="0" data-bbox="504 311 1258 422"> <thead> <tr> <th><b>SF-36</b></th> <th><b>Baseline</b></th> <th><b>Post</b></th> <th><b>% change</b></th> </tr> </thead> <tbody> <tr> <td>Physical functioning</td> <td>32</td> <td>47</td> <td>47%</td> </tr> <tr> <td>Bodily pain</td> <td>27</td> <td>38</td> <td>41%</td> </tr> <tr> <td>Role functioning</td> <td>5</td> <td>16</td> <td>220%</td> </tr> </tbody> </table> <p>Authors note that at 1 year 45% of patients reported a significant improvement on the SF-36 survey.</p> <p><b>Disability – Oswestry low back pain</b></p> <table border="0" data-bbox="504 558 1258 646"> <tbody> <tr> <td>Baseline</td> <td>34</td> </tr> <tr> <td>Post-treatment</td> <td>30</td> </tr> <tr> <td>% Change</td> <td>12%</td> </tr> </tbody> </table> <p>Authors note that 75% of patients had improvement of their symptoms following the IDET procedure.</p> <p><b>Neurogenic symptoms</b></p> <table border="0" data-bbox="504 782 1258 857"> <tbody> <tr> <td>Baseline</td> <td>15</td> </tr> <tr> <td>Post-treatment</td> <td>14</td> </tr> <tr> <td>% Change</td> <td>7%</td> </tr> </tbody> </table>	<b>SF-36</b>	<b>Baseline</b>	<b>Post</b>	<b>% change</b>	Physical functioning	32	47	47%	Bodily pain	27	38	41%	Role functioning	5	16	220%	Baseline	34	Post-treatment	30	% Change	12%	Baseline	15	Post-treatment	14	% Change	7%	<p><b>Complications:</b> Authors note that no serious complications occurred.</p> <p>Cerebral spinal fluid was visualised in one case.</p> <p>1 patient the catheter could not be threaded into the disc space – this patient went onto surgery.</p>	<p>Authors state patients are consecutive.</p> <p>A significant improvement was defined as an improvement greater than 7 points.</p> <p>Pain was not measured in this study.</p> <p>Authors note that outcomes was not dependent upon number of levels treated, duration of symptoms or workers compensation status.</p>
<b>SF-36</b>	<b>Baseline</b>	<b>Post</b>	<b>% change</b>																												
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Study details	Key efficacy findings	Key safety findings	Comments																																		
<p>Davis et al (2004)<sup>18</sup></p> <p>Case series</p> <p>May 1999 – December 2000</p> <p>60 consecutive patients (referred from 17 centres) – 44 were evaluable</p> <p>Patients had a positive discogram and failed other conservative management.</p> <p>For evaluable patients</p> <p>Mean age: 40 (range 25-64 years)</p> <p>Follow-up: 20.4 months (range 6-38 months)</p>	<p><b>Outcomes reported:</b></p> <p>Within 1 year following procedure. 6 of the 44 (14%) patients who responded had undergone a post-IDET lumbar surgery.</p> <p>Data on patients who received no treatment (n=38)</p> <table border="0" data-bbox="524 523 994 995"> <tr> <td><b>No of patients</b></td> <td><b>38</b></td> </tr> <tr> <td>Continue to have pain</td> <td>37 (97%)</td> </tr> <tr> <td>Less pain</td> <td>15 (39%)</td> </tr> <tr> <td>Same amount</td> <td>11 (29%)</td> </tr> <tr> <td>More pain</td> <td>11 (29%)</td> </tr> <tr> <td>Medication use</td> <td></td> </tr> <tr> <td>None</td> <td>5 (13%)</td> </tr> <tr> <td>Less meds</td> <td>12 (32%)</td> </tr> <tr> <td>Same amount</td> <td>10 (26%)</td> </tr> <tr> <td>More meds</td> <td>11 (29%)</td> </tr> <tr> <td>Disability</td> <td></td> </tr> <tr> <td>Prior to IDET</td> <td>17 (45%)</td> </tr> <tr> <td>After IDET</td> <td>17 (45%)</td> </tr> <tr> <td>IDET outcome</td> <td></td> </tr> <tr> <td>Satisfied</td> <td>14 (37%)</td> </tr> <tr> <td>Dissatisfied</td> <td>19 (50%)</td> </tr> <tr> <td>Undecided</td> <td>5 (13%)</td> </tr> </table>	<b>No of patients</b>	<b>38</b>	Continue to have pain	37 (97%)	Less pain	15 (39%)	Same amount	11 (29%)	More pain	11 (29%)	Medication use		None	5 (13%)	Less meds	12 (32%)	Same amount	10 (26%)	More meds	11 (29%)	Disability		Prior to IDET	17 (45%)	After IDET	17 (45%)	IDET outcome		Satisfied	14 (37%)	Dissatisfied	19 (50%)	Undecided	5 (13%)	<p><b>Complications</b></p> <p>1 patient within 4 weeks of the procedure began experiencing pain similar to preprocedure.</p> <p>1 patient anterolisthesis.</p>	<p><b>This reference was identified during consultation (May 2003). It is not included in the efficacy summary of this overview.</b></p> <p>Information on original patients that refused the offered IDET were not available.</p> <p>Assessment of outcomes was undertaken by an independent reviewer (interview questionnaire).</p> <p>16 patients did not complete interview/questionnaire. Reasons for refusing to complete the interview were mostly due to pending Workers Compensation Claims.</p> <p>Outcomes only reported on some patients.</p> <p>Questionnaire.</p>
<b>No of patients</b>	<b>38</b>																																				
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Study details	Key efficacy findings	Key safety findings	Comments
<p>Lee et al (2003)<sup>19</sup></p> <p>Case-series</p> <p>1999 - 2001</p> <p>Patients were recruited from an academic affiliated private physiatric practice.</p> <p>62 patients met inclusion criteria – 51 patients were available for a minimum follow-up of 24 months.</p> <p>Mean age: 41.4 years (18 – 60 years)</p> <p>Average duration of symptoms 46 months (6-180 months)</p> <p>Average follow-up was 34 months (6-47 months)</p>	<p><b>Outcomes reported:</b> questionnaire containing information on lower back and lower extremity visual numeric pain scale; Roland Morris disability evaluation and North American Spine Society patient satisfaction index.</p> <p>There was a statistically significant improvement in lower back pain scores, Roland Morris score and lower extremity pain scores.</p> <p>On NASS patient satisfaction index, 63% (32/51) responded positively and would undergo the procedure again.</p> <p>A total of 7 patients (14%) underwent additional therapeutic procedures during the follow-up period. 2/51 patients underwent a spinal fusion procedure.</p> <p>In terms of medication usage 68% (30/44) reported using less or no pain medication and 25% reported using same amount. 7% were using more oral pain medication.</p>	<p><b>Complications:</b></p> <p>Authors not that there no peri or post procedural complications of dural puncture, infection or nerve injury.</p>	<p><b>This reference was identified during consultation (May 2003). It is not included in the efficacy summary of this overview.</b></p> <p>Questionnaires were administrated by an independent observer.</p> <p>Clinical improvement was defined as a change of more than 2 points on the pain scale and Roland Morris scale.</p> <p>11 patients had relocated out of area – lost to follow-up. Possible that these patients had additional surgery or poorer outcomes.</p> <p>Subgroup analyses undertaken.</p>

## **Additional safety information**

In a paper by Eckel and Ortiz (2002) <sup>12</sup> a reference is made to the complications following percutaneous intradiscal electrothermal therapy as reported in a retrospective multi-centre registry of 1675 treated patients. Eckel and Ortiz (2002) state that there were 19 catheter breakages, 5 transient nerve root injuries, 1 partially resolved nerve root injury and 6 cases of post-IDET disc herniation. The authors also state that 'although disc infection is a potential risk, this complication has not yet been reported. Other risks include cerebrospinal fluid leak, hemorrhage and worsening of pain.' p.217.

There have also been several case reports published on complications following percutaneous intradiscal electrothermal therapy . This includes two cases of cauda equine <sup>13-14</sup> and two cases of vertebral osteonecrosis <sup>15-16</sup> due to intradiscal electrothermal therapy.

A search on the US Food and Drug Administration database - Manufacturer and User Facility Device Experience Database - (MAUDE) identified four reports of device events in respect to this procedure. All four incidents involved catheter breakages, no reports were made of adverse patient consequences as a result of the breakages <sup>17</sup>.

## **Validity and generalisability of results**

- The primary end point in the studies is pain relief. Given the lack of comparative data it is difficult to determine what influence the placebo effect has on reported outcomes.
- Similarly the lack of comparative data makes it difficult to distinguish between treatment effect and the natural history of this disease.
- Length of follow up varied from 6 months to 24 months. This would seem to be important given that the efficacy of the procedure would seem to decrease with time.
- Patients were typically a highly selected group. In the papers by Saal and coworkers quite specific inclusion and exclusion criteria were applied to study participants. Most of the other papers comment that there should be rigorous selection of patients.
- Selection bias would also seem to be an issue. For example in the study by Karasek and Bogduk (2000) <sup>4</sup> the control group consisted of patients whose insurance company refused to reimburse for the treatment.
- The inclusion of workers compensation cases in the studies may have an influence of the reported results, particularly when interpreting return to work rates.
- The SF-36 subscale of bodily pain has also been used to measure pain in some of the studies. It is unclear how valid this is to determine pain in this population.
- Much of the literature is US-based and set in private clinics. This may limit the generalisability of the findings.
- Limited safety data is reported in the studies.

## **Specialist advisors' opinions**

*Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.*

- The procedure is relevant to radiologists, orthopaedic surgeons and those versed in interventional pain techniques.
- Only skilled clinicians should undertake the procedure.
- There is some debate as to the efficacy of this procedure.
- The procedure could have an impact on the way discogenic low back pain is managed.
- Short-term results appear to be promising.

## **Issues for consideration by IPAC**

Manufacturer maintains a registry related to this procedure.

## References

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## Appendix A: Relevant studies not included in the data extraction tables.

Study details	Patients/ Follow up	Comments
Freeman, B.J.C. et al A randomised double-blind controlled efficacy study: intradiscal electrothermal therapy (IDET) versus placebo. <b>Abstract (no details)</b>	53 patients: 38 IDET and 19 placebo	Abstract.
Wetzel, F. et al. Intradiscal eletrothermal therapy to treat discogenic low back pain: two year results of a multicenter prospective cohort study. <i>The Spine Journal</i> 2002; 10S-11S	78 patients 2 years	Abstract also mentioned in a review paper {112}.
Shadid E, Kazala K, O'Neil C. <i>An independent assessment of the one to two year outcomes of intradiscal electrothermal anuloplasty (IDET) for discogenic low back pain.</i> ISIS 9 <sup>th</sup> Annual Scientific Meeting Syllabus, September 2001 pp1614-5.	Not known	Abstract.
Wetzel FT, McNally TA, Phillips FM. Intradiscal electrothermal therapy used to manage chronic discogenic low back pain: new directions and interventions. <i>Spine</i> 2002; 27,22: 2621-6.	Not relevant	Retrospective literature review.
Endres SM, Fiedler GA, Larson KL. Effectiveness of intradiscal electrothermal therapy in increased function and reducing chronic low back pain in selected patients. <i>Wisconsin Medical Journal</i> 2002; 101(1):31-34	54 patients	Retrospective review of patients.
Spruit M, Jacobs W. Pain and function after intradiscal electrothermal treatment (IDET) for symptomatic lumbar disc degeneration. <i>European Spine Journal</i> , 2002; 11:589-93.	20 patients 6 months	Small study, short-term follow up.
Sing V. Intradiscal Electrothermal Therapy: a preliminary report. <i>Pain Physician</i> , 2000; 3(4):367-73.	23 patients 6 months	Small study, short-term follow up.
Saal JS, Saal JA. Management of chronic discogenic low back pain with a thermal intradiscal catheter: a preliminary report. <i>Spine</i> 2000; 25(3):382-388.	25 patients 7 months	Preliminary results. Later papers.
Maurere P et al . <i>Is IDET effective treatment for discogenic low back pain? A prospective cohort outcome study (1-2 year follow-up). Identifying successfully patient selection criteria.</i> International Spinal Injection Society Annual Meeting, September 2002.	81 patients 20 months	Abstract..
Welch WC, Gerszten PC, McGrath P. Intradiscal electrotherapy: indications, techniques, and clinical results. <i>Clinical Neurosurgery</i> , 2001; 48:219-25	23 patients 3 month data (16 patients)	Case series. Small study, limited follow-up. SF-36 scores were measured.
Thompson KJ et al. <i>Two year results from the Intradiscal Electrothermal Therapy (IDET) Nationwide Registry.</i> North American Spine Society Annual Meeting, October 2001.	211 patients 24 months	Manufacturer registry.
Freedman et al. <i>Intradiscal electrothermal therapy (IDET) for chronic low back pain in active-duty soldiers: 2 year follow-up.</i> <i>The Spine Journal</i> , 2003; 3: 502-509.	41 patients 2 years	Select group of patients.
Webster et al. <i>Outcomes of Workers' Compensations Claimants with low back pain undergoing intradiscal electrothermal therapy.</i> <i>Spine</i> , 2004; 4: 435-441.	142 patients	Select group of patients

## Appendix B: Existing or in progress health technology assessments

Study details	Studies included	Direction of the conclusions
<b>MSAC Report 2002</b> <b>Literature search:</b> Intradiscal electrothermal anuloplasty: a treatment for patients with chronic low back pain due to anular disruption of contained herniated findings	Karasek and Bodduk (2000) Derby et al (2000) Singh, V (2000) Saal and Saal (2000) (2002) Endres (2002)	<i>Limited evidence on efficacy</i>
<b>TEC Access Program</b> <b>Literature search</b> Percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic low back pain	Karasek and Bodduk (2000) Derby et al (2000) Singh, V (2000) Saal and Saal (1999) (2000) (2002)	<i>Limited evidence on efficacy</i>  'The evidence does not permit conclusions on whether percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic low back pain improves health outcomes or is as beneficial as established alternatives'
<b>Institute for Clinical Systems Improvement 2002</b> <b>Literature search</b> Intradiscal electrothermal therapy (IDET) for low back pain	Saal and Saal (1999) Derby et al (2000) Karasek and Bodduk (2000) Saal and Saal (2000)	<i>Limited evidence on efficacy</i>  'There is no convincing evidence that shows the short or long term clinical efficacy of this procedure...'  'The procedure is acceptably safe when performed by a physician trained in IDET....short term studies have indicated few adverse events of IDET, but information on long-term effects is limited.'
<b>ASERNIP-S 2002</b> <b>Literature search:</b> Intradiscal electrothermal annuloplasty	Pauza et al (2002). Karasek and Bogduk (2000) Derby et al (2000) Singh, V (2000) Saal and Saal (2000) (2001) (2002) Thompson KJ and Eckel TS (2000)	<i>Safe and short-term efficacy</i> 'It appears safe with a very low incidence of morbidities. It appears that to be effective in the short-term in 60-80% of cases (based on success or patient satisfaction), but long-term data are presently not available.
<b>National Horizon Scanning Centre</b> <b>Literature search:</b> Intradiscal electrothermal therapy for chronic discogenic back pain.	Saal and Saal (1999) Derby et al (2000) Karasek and Bogduk (2000) Saal and Saal (2000) Thompson KJ and Eckel TS (2000) Singh, V. (2000).	No relevant conclusions.
<b>Minnesota Health Technology Advisory Committee 2001</b> <b>Literature search:</b> Intradiscal electrothermal therapy (IDET) for lower back pain.	Karasek and Bogduk (2000) Derby et al (2000) Singh, V (2000) Saal and Saal (1999) (2000) Wetzal (2000)	<i>Limited evidence on efficacy</i>  'Published literature is limited and unrefined due to small sample size, poor study quality, and lack of long-term data...pain relief, which varies is experienced by some patients, but not all. Pain may results due to new or pre-existing disc damage.
<b>Canadian Coordinating Office for Health Technology Assessment. 2003</b> <b>Literature search</b> Intradiscal electrothermal therapy (IDET) for the treatment for chronic, discogenic low back pain`	Not available	Summary of other HTA reports.
<b>DACEHTA Danish Centre for Evaluation and Health Technology Assessment. 2003-Literature search:</b> Intradiscal electrocoagulation for chronic back pain	Not available	Forthcoming report. Currently not in English.

Study details	Studies included	Direction of the conclusions
<b>Hayes Inc 2000</b> <b>Literature search:</b> Intradiscal electrothermal therapy	Not available	Report only available for purchase.
<b>ECRI 2002</b> <b>Literature search:</b> Intradiscal electrothermal therapy for discogenic pain.	Not available	Report only available for purchase.

## Appendix C: Literature search

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PredMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

	Search history	Results
1	intradiscal.mp.	370
2	exp Catheter Ablation/	4866
3	thermocoagulation.mp. or *Electrocoagulation/	3777
4	Electrothermal Therapy.mp.	16
5	Electrothermal Anuloplasty.mp.	2
6	or/1-5	8972
7	exp Low Back Pain/	4811
8	exp Intervertebral Disk Displacement/	9263
9	7 or 8	13633
10	6 and 9	177