



# New and Emerging Techniques - Surgical

## Procedure Brief

# Intradiscal Electrothermal Therapy (IDET)



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Royal Australasian  
College of Surgeons

<b>NET-S Procedure Brief Summary</b>
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**Intradiscal Electrothermal Therapy (IDET)**

- Low back pain is common, and may be due to torn or herniated discs.
- Intradiscal Electrothermal Annuloplasty, or IDET may be a treatment option for patients who fail to respond to non-invasive treatments.
- IDET may also be a minimally invasive alternative to spinal fusion.
- IDET is performed by inserting a catheter with a thermal resistive coil at the end, into the affected disc. The coil is then heated, to 90°C, for 15 to 17 minutes, which kills the nerves causing the pain and also “tightens” the collagen fibres that form the wall of the disc.
- Indications for IDET include patients who; fail to respond to six months of conservative treatment and have small herniations, internal disc tears or mild disc degeneration limited to one or two levels.
- Contraindications include: severe disc degeneration, spinal stenosis, neurological symptoms (e.g. leg weakness) and large disc herniations.
- Evidence indicates that IDET is safe, with minimal morbidities reported.
- IDET appears to be effective in 60-80% of cases, as indicated by VAS (visual analogue scales) and short form-36 (SF-36) surveys, although there is a lack of high quality evidence and long-term follow-up.
- IDET is not widely available in Australia.

***NET-S Classification***

IDET (Intradiscal Electrothermal Annuloplasty) is an emerging technique, which has recently been introduced into Australasian health care, and is currently not widely available.

## Background

Lower back pain occurs in up to 90% of people and is often due to damage to intervertebral discs.<sup>1</sup> Discs are rubber-like structures that lie between the bones of the spine, separating one vertebra from another. They act as ‘shock absorbers’ and are made up of a gelatinous core (nucleus pulposus) and surrounded by a circular fibrous wall (annulus fibrosus). The fibrous wall may weaken or tear, and irritation of small nerves in the damaged outer wall of the disc or irritation and pressure on nerves that invade the damaged disc produce pain (discogenic pain).<sup>1</sup>

Intradiscal electrothermal annuloplasty (IDET) may be an alternative to long-term pain management or spinal fusion surgery. Alternative acronyms for IDET include IDEA and IDTA.

## The Technology

The procedure involves passing a flexible catheter (SpineCath, Oratec Interventions, Inc., Menlo Park, CA designed by Saal *et al.*<sup>2</sup>) with a five centimetre long, thermal resistive coil (TRC) at the end, through a six-inch needle into the affected disc (Figure 1).

The patient is first lightly sedated and local anaesthesia is applied to the skin of the back. With x-ray (fluoroscopic) guidance, the needle is inserted into the disc to be treated. The catheter is then passed through the needle and positioned along the inner wall of the disc. It is slowly heated up to 90°C, for 15 to 17 minutes (Figure 2). It is normal to feel pain with heating and this indicates that treatment is being applied in the appropriate place.



Figure 1. Needle and Catheter.<sup>3</sup>

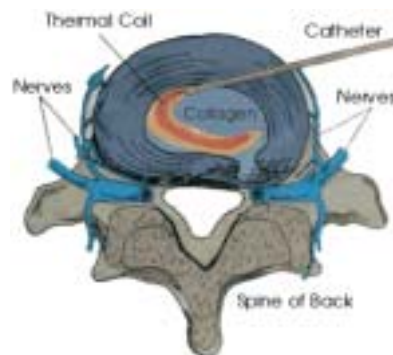


Figure 2. Cross section of herniated disc.<sup>3</sup>

The heat causes thermal destruction of nerves and contraction of the collagen fibres by denaturation of the protein molecules.<sup>4</sup> IDET takes about an hour to complete and the patient is allowed to go home after a short period of observation.

### ***Post-procedural Care***

For most patients, there is a period of pain and this may be relieved with rest, medication and ice. A lumbar support is worn under the clothing for six to eight weeks, followed by physical therapy. Patients are warned to avoid lifting and bending to allow for adequate healing of the disc. They are also encouraged to keep active with light walking and to begin this a few days

after the procedure. If their jobs do not involve physical exertion, patients may be able to return to work in one to five days. Maximal healing may take as long as four to six months.<sup>1</sup>

### Patient Group

IDET is suitable for patients with discogenic back pain that is refractory to conservative treatments. IDET can be performed on patients with one or two damaged discs and includes discs with small herniations, internal disc tears and mild disc degeneration.<sup>5</sup>

#### *Preliminary Evaluation*

Screening is needed before IDET, to confirm that lower back pain is disc-related, and should consist of a physical examination and an interview. Information gathered from the patient's history of pain, x-rays and magnetic resonance imaging (MRI) scans help determine the location of pain. Discography, where contrast dye is injected into the disc, helps confirm which disc is affected. If disc tears are present, the contrast dye fills these tears.

#### *Indications for Surgery*

Indications include a history of function-limiting low back pain of at least six months' duration despite conservative treatment, which includes intradiscal corticosteroid injection or oral anti-inflammatory medication. Other criteria include normal findings on neurological examination, negative results on the straight leg raise (SLR) test and MRI scans to exclude a neural compressive lesion. Reproduction of the patient's typical pain symptoms should occur with provocative discography.<sup>2</sup>

IDET is contraindicated with conditions such as inflammatory arthritis, severe disc degeneration, spinal stenosis, large disc herniations and the presence of neurological symptoms such as leg weakness.<sup>1, 2, 5</sup>

IDET should not be recommended to patients who are unwilling to commit to substantial post-procedure activity restrictions and therapy.<sup>1</sup>

### Current Treatment and Alternatives

Some patients with discogenic pain respond well to conservative treatment, which include a combination of medication, rest and activity modification. Some relief may be achieved with injection of corticosteroids directly into the painful disc, but this does not provide long lasting effects due to the limited life span of the injected drug.<sup>6</sup>

Conservative methods should always be pursued first. However, if patients continue to suffer severe pain then more invasive treatment may be necessary.

Other more invasive treatments include:

- Radiofrequency ablation of the posterior annulus from within the disc which acts to modify collagen in an effort to strengthen the structure of the disc. However, the treatment zone is small and high temperatures produced may injure healthy tissues.<sup>4</sup>

- A minimally invasive technique known as Coblation-assisted Nucleoplasty™ can be carried out through the skin using a Perc-D SpineWand (ArthroCare Corporation<sup>i</sup>, Sunnyvale, CA, USA), which removes and destroys tissue of the disc at low temperatures. This is alternated with thermal energy for coagulation, resulting in the formation of a firmer, less painful, disc.<sup>7</sup>
- Spinal fusion surgery uses grafts to fuse the bones on each side of the treated disc, in an attempt to make them grow together in order to relieve stress. It is commonly performed, although it is very costly and permanently alters the structure of the spine.

### Literature Search Methodology and Results

A systematic search of MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed, Cochrane Library and Science Citation Index using Boolean search terms was conducted, from the inception of the databases until October 2002. The York Centre for Reviews and Dissemination, Clinicaltrials.gov, National Research Register, SIGLE, Grey Literature Reports (2002), relevant online journals and the Internet were also searched in October 2002. Searches were conducted without language restriction.

Articles were obtained on the basis of the abstract containing safety and efficacy data on Intradiscal Electrothermal Therapy in the form of randomised controlled trials (RCTs), other controlled or comparative studies, case series and case reports. Conference abstracts and manufacturer's information were included if they contained relevant safety and efficacy data. Foreign language papers were included if they contained safety and efficacy data and were considered to add substantively to the English language evidence base. In the case of duplicate publications, the latest, most complete study was included.

Data were extracted from one randomised controlled trial (RCT) and one conference abstract. One potentially biased comparative study was also included, as were all case series and case studies. Extracted data are tabulated in Appendix A.

#### List of studies found

Total number of studies: 22

Systematic reviews	0
RCTs (conference abstract)	1
Non-randomised comparative studies	1
Case series	18
Case reports	2

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<sup>i</sup> [www.arthrocare.com](http://www.arthrocare.com)

## RCTs in progress

A UK-based multi-centre RCT is to compare the performance of Intradiscal Electrothermal Therapy using the SpineCath followed by a standardised physical therapy program versus a standardised physical therapy program alone. The trial is to include 80 patients with chronic discogenic low back pain and will have a 40-month study period with completion expected by 2004. (Mr Colin Natali, Department of Orthopaedic Surgery, Royal London Hospital, Luckes Home, Whitechapel, London, E1 1BB, UK, Telephone: 0171 377 7197, Fax: 0171 377 7302.)

An Australian based RCT was ceased after pressure from Oratec to change the protocol half way through the study. The study recruited 55 patients who are still being followed, and the results are pending.

Another non-randomised Australian trial is being planned; A Prospective Clinical Outcome Study to Evaluate the Use of Intradiscal Electrothermal Annuloplasty (IDETA) with The SpineCATH™ Followed By A Standardised Physical Therapy Program For Chronic Discogenic Low Back Pain. The primary objectives of this trial are to study pre- and postoperative outcomes at 3, 6, 12, 24 and 60 months after IDET. Pain, function, health care utilisation and cost effectiveness will be studied.

## Summary of Key Efficacy and Safety Findings

Evidence for the safety and efficacy of intradiscal electrothermal annuloplasty (IDET) exists from one randomised controlled trial (RCT), one non-randomised comparative study, eighteen case series, and two case reports (see tables in Appendix A). From the evidence currently available, IDET appears safe with a very low incidence of morbidities. It appears to be effective, in the short-term, in 60% to 80% of cases (based on success or patient satisfaction), but sufficient high quality evidence and long-term data are presently not available.

An RCT<sup>8</sup> between IDET and a placebo showed a statistically significant improvement in pain (measured by visual analogue scale and SF-36 bodily pain), an improvement in disability and a decrease in depression. There was potential for bias, and study details were not elaborated upon as results were presented as a conference abstract. The comparative study<sup>9</sup>, comparing IDET and rehabilitation, showed that most patients who underwent IDET improved. Improvement in pain was statistically significant but this study may have been biased due to the method of patient selection. Case series results indicated improvement in pain, decreases in disability, improvements in general activity, sitting, standing and walking, and return to work. Patients were generally satisfied with the outcome.

Studies such as Saal and Saal 2000a<sup>10</sup> have shown an improvement rate of 70%. This study and other such studies (except Karasek and Bogduk 2000<sup>9</sup> which has a control group that may have selection bias) lack a control group. It is important to realise that approximately 70% of patients with unoperated discogram-positive low back pain (i.e. natural history with bed rest for exacerbations, non-steroidal anti-inflammatory drugs, weight loss and physical therapy evaluation for exercise and modalities) can improve.<sup>11</sup> Therefore, randomised studies with appropriate controls, such as natural history and minimally invasive treatment as stated above, need to be conducted to determine the true effect of IDET.

IDET appears safe with complications occurring infrequently. Reported complications included radiculopathy, discitis, bladder dysfunction and nerve root injuries. Two case reports detailed major complications of vertebral osteonecrosis<sup>12</sup> and cauda equina syndrome.<sup>13</sup>

### Availability in Australia

Evidence suggests that IDET is being practiced in Australia, although it is not widely available to patients. The Medicare Services Advisory Committee (MSAC) has recently evaluated IDET (MSAC application 1048). Since there was currently insufficient evidence pertaining to IDET, public funding was not supported for the procedure at this time (<http://www.health.gov.au/msac/pdfs/msac1048.pdf>). Previously, the IDET procedure has been claimed or potentially claimed on the Medicare Benefits Schedule (MBS) under item 48363 (percutaneous lumbar discectomy). Item 48636 was amended on 1 May 2003 to exclude its use for any IDET procedure.

### Summary

Intradiscal electrothermal annuloplasty (IDET) is a minimally invasive procedure for the treatment of disc-related lower back pain. It may be suitable for patients whose condition is refractory to conservative treatments. From the available evidence the procedure appears to be safe, with few morbidities reported in the literature. However, occasional serious complications such as radiculopathy, discitis, bladder dysfunction and nerve root injuries have been known to occur. There is short-term evidence that the procedure can improve most patients' condition, but its effectiveness in the long term is yet to be studied. Randomised controlled trials are necessary to determine the procedure's effectiveness compared with other treatments and natural history.

*Horizon Scanning Classification:* IDET is an emerging technique, which has recently been introduced into Australasian health care, and is currently not widely available.

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<b>APPENDIX A</b>
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**TABLE OF KEY SAFETY AND EFFICACY FINDINGS****Abbreviations used in tables:**

BDI	beck depression inventory
IDET	intradiscal electrothermal therapy
NASS	North American Spine Society
MDR	Medical Device Report
MRC	Medical Research Council
MRI	magnetic resonance imaging
SF-36	short-form 36
VAS	visual analogue scale

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
<b>Randomised Controlled Trials</b>			
<p><b>Pauza et al. 2002<sup>8</sup>, USA</b></p> <p>55 patients (after 9 protocol violations were removed) Follow-up: 6 months</p> <p><i>Comparison:</i> Group 1: 32 patients, IDET Group 2: 23 patients, placebo</p> <p><i>Selection criteria:</i> Randomised, prospective, double-blind clinical trial evaluating the efficacy of IDET compared with a placebo for the treatment of chronic discogenic low back pain. Patients initially screened by telephone interview. 64 patients included in study were computer randomised at a 3:2 ratio (IDET:Placebo).</p>	<p><u>Pain relief:</u> A statistically significant greater improvement in pain (VAS p=0.0327 and Bodily Pain p=0.0327) was demonstrated by the IDET treatment group when compare to the placebo group. Pain was worse in 6% of the subjects in the treatment group and in 30% in the control group (p=0.0132). The bodily pain scale demonstrated a mean improvement in 61.1% in the treatment group and a mean improvement of 29.8% in the control group (p=0.0377).</p> <p><u>Oswestry Disability Index:</u> A statistically significant improvement in the treatment group compared with the control group was seen for the Oswestry Disability Index (p not stated).</p> <p><u>Beck Depression Inventory:</u> The IDET treatment group demonstrated a statistically significant improvement in the Beck Depression Inventory (p=0.0296), no change was seen in the control group (p=0.3871). The IDET group reported a greater improvement in the mean BDI compared to the control group (p=0.0192).</p> <p><u>SF-36:</u> Overall there was no difference in the level of improvement in the Physical Function (SF-36 subscale) between IDET and control groups, but among those patients with physical functioning limitations at pre-treatment there was a statistically significant improvement in Physical Function in the IDET treated group when compared to the control (p=0.0224).</p> <p>Trends suggested a greater improvement for IDET patients in SF-36 Social Function, Role Emotional and Mental Health subscales, but were not statistically significant.</p>	None stated.	<p><i>Potential for bias:</i> Conference abstract. The use of computer randomisation should reduce bias, but the reason for the 3:2 ratio was not given. Staff (Sierra Yearsley and Kathryn Dawson) from Oratec assisted with the investigation. Protocol adherence was met by 56/64 (88%) of enrolled patients.</p> <p><i>Outcome measures and their validity:</i> Validation of VAS, SF-36, Oswestry Disability Index, Beck Depression Inventory and Work Status Questionnaire not stated.</p>

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
<b>Non-randomised comparative studies</b>			
<p><b>Karasek and Bogduk 2000<sup>9</sup>, USA</b></p> <p>53 patients Follow-up: 12 months</p> <p><i>Comparison:</i> Group 1: 36 patients, IDET Group 2: 17 patients, control (rehabilitation)</p> <p><i>Selection criteria:</i> 110 patients consented to provocative discography, of whom 53 were eligible for IDET. 36 patients obtained insurance authority and constituted the IDET treatment group. The remaining 17 were denied authority and constituted a concurrent convenience control group.</p>	<p><u>Improvement:</u> Group 1 4/36 (11%) no appreciable relief. Group 2 (3 months) 1/17 (6%) dramatically improved, 3/17 (18%) modestly improved, 4/17 (24%) no improvement.</p> <p><u>Pain:</u> Group 1 VAS pain scores improved with statistical significance (p=0.000*) and were statistically different from the control group. Patients maintained their response at 6 and 12 months follow up, and there were no statistically significant differences between the scores at 3, 6 and 12 months. Group 2 9/17 (53%) deteriorated, as a group showed no improvement in their VAS pain scores.</p> <p><u>Opioid use:</u> Group 1 significantly associated with VAS after treatment, 18/36 (50%) were working before treatment and continued to work. 3/36 (8%) were home-makers, 15/36 (42%) were not working before treatment and 9/15 (60%) had returned to work by 12 month follow-up. Success was graded with all grades requiring a 50% reduction in pain and return to work. Grades differed in final VAS score where grade I is complete relief of pain – Grade I (23%), Grade II (23%), Grade III (14%) – combined total of 60% with Grade III or better. Group 2 7/17 (41%) still used, 5/17 (29%) discontinued use, 4/17 (24%) began using.</p>	<p>None stated</p>	<p><i>Potential for bias:</i> The division of the patient group on the basis of insurance company consent or denial introduced selection bias and immediate dissatisfaction within the control group as indicated by lack of follow-up of the control group after 3 months.</p> <p><i>Outcome measures and their validity:</i> VAS validation not stated and it was unclear whether the Oswestry Disability Questionnaire was validated (this outcome measure was only used for 14/26 IDET patients and was not reported on in detail).</p>
* p value as presented in article.			

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
<b>Case series</b>			
<b>Derby et al. 1999<sup>14</sup>, USA</b>  31 patients Follow-up: 1 year  <i>Selection criteria:</i> Not stated.	<u>VAS:</u> Improvement (p<0.05).  <u>Roland Morris questionnaire:</u> Decrease in disability (p<0.05).  <u>NASS Patient Satisfaction index:</u> 77% satisfied; 23% same or worse after procedure.  <u>Activity of Daily Living variables:</u> 59% reported improvement in general overall activity; 41% in sitting; 50% in standing; 45% in walking; 41% in sleeping.	None stated	<i>Potential for bias:</i> Small study numbers. Method of patient selection not given.  <i>Outcome measures and their validity:</i> Validation of VAS, Roland Morris questionnaire and NASS Patient Satisfaction index not stated.  <i>Other comments:</i> Conference abstract, scant detail and patients may have been reported in Derby et al. 2000a <sup>5</sup> and Derby et al. 2000b <sup>6</sup> .
<b>Derby and O'Neill, 2000a<sup>15</sup>, USA</b>  24 patients Follow-up: 8 months  <i>Selection criteria:</i> Patients were retrospectively selected to complete a follow-up questionnaire.	<u>Overall patient satisfaction:</u> 73%  <u>Pain relief:</u> 77% patients felt that overall pain level was better or much better; 68% felt their activity level was better or much better.  <u>Symptom relief:</u> 90% had an average of 71% relief of leg symptoms; 55% had an average of 64% relief of their back symptoms.  A reduction in VAS was observed.	None stated	<i>Potential for bias:</i> Small study numbers. 2/24 (8%) patients were lost to follow-up.  <i>Outcome measures and their validity:</i> Validity of follow-up questionnaire and VAS not stated.  <i>Other comments:</i> Conference abstract, scant detail and patients may have been reported in Derby et al. 2000b <sup>5</sup> .

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
<p><b>Derby et al. 2000b</b><sup>16</sup>, USA</p> <p>32 patients Follow-up: 1 year</p> <p><i>Selection criteria:</i> Not stated.</p>	<p>No significant difference between overall outcomes at 6 and 12 month follow-up.</p> <p><u>VAS:</u> Mean decrease was 1.84.</p> <p><u>Roland Morris:</u> Mean decrease was 4.03.</p> <p>Procedures met the expectations of 78.1% of patients; 53.1% patients activity level better or much better; 34.4% same; 9.4% worse; 3.1% much worse.</p> <p>41% reported improvement in sitting; 50% in standing; 45% in walking; 41% in sleeping (also reported in Derby et al 1999). Overall, 62.5% favourable outcome; 12.5% unfavourable; 25% no change. One patient underwent a spine fusion due to persistent discogenic back pain.</p> <p>73% with excellent or good catheter position had a favourable outcome. 16.7% with a fair catheter position had a favourable outcome.</p> <p>68% without previous surgery had a favourable outcome, 42.8% with previous surgery had a favourable outcome.</p>	<p>All patients experienced a flare in their typical pain following the procedure, with a mean duration of 5 days.</p> <p>No infections, neurologic or bleeding complications.</p>	<p><i>Potential for bias:</i> Small study numbers. Patients undergoing IDET were consecutively enrolled from May 1997 to December 1997.</p> <p><i>Outcome measures and their validity:</i> Validation of VAS, Roland Morris questionnaire and NASS Patient Satisfaction index not stated.</p> <p><i>Other comments:</i> Conference abstract, not much detail given and patients may have been reported in Derby et al 1999<sup>3</sup> and Derby et al 2000<sup>4</sup>.</p>

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
<p><b>Endres et al. 2002<sup>17</sup>, USA</b></p> <p>54 patients Follow-up: 3 to 29 months</p> <p><i>Selection criteria:</i> Review of patients who underwent IDET since April 1998 excluding those that were &lt;3 month follow-up.</p>	<p><u>VAS:</u> 25/54 (52%) showed a decrease in VAS by 3 or more points, 31/54 (65%) by 2 points, 6/54 (13%) by 1 point, 7/54 (15%) no change, 4/54 (8%) worse than pre-IDET.</p> <p>Overall significant reduction in VAS (p&lt;0.001). 29/54 (56%) showed at least a 40% increase in sitting tolerance in a car, 24/54 (46%) showed at least a 40% increase in sitting tolerance on a firm surface, 31/54 (57%) showed at least a 40% increase in walking tolerance. 43/54 (80%) patients improved at least 40% in one function, 28/54 (52%) in two functions, 11/54 (20%) did not improve in any function. Significant improvement in sitting tolerance – car (p&lt;0.001), sitting tolerance – firm surface (p=0.005), walking tolerance (p&lt;0.001).</p> <p><u>Return to work:</u> 35/54 (66%) patients returned to work, 37/54 (76%) said they would do the procedure again.</p>	<p>No complications were noted.</p>	<p><i>Potential for bias:</i> Small study numbers.</p> <p><i>Outcome measures and their validity:</i> Validation of VAS not stated.</p>
<p><b>Laguttuta et al. 2000<sup>18</sup>, USA</b></p> <p>122 patients Follow-up: 6-18 months</p> <p><i>Selection criteria:</i> Patient selection not stated except that patients were discogram positive.</p>	<p>Study to evaluate the frequency of spinal fusion (ie. inability for IDET to successfully treat) in patients after IDET.</p> <p>4/122 (3.2%) required spinal surgery in the 6-18 months after IDET.</p> <p><u>Return to work after IDET:</u> 3 patients (2.5%) retired, 5 patients (4%) applied for disability benefit, 12 patients (9.8%) had not returned to work, 100 patients (82% or 89% from potential workers) were given permission to return to work.</p>	<p>No complications requiring hospitalisation in the follow-up period.</p>	<p><i>Potential for bias:</i> Inclusion criteria not stated, method of retrospective chart review may be biased.</p> <p><i>Other comments:</i> Conference abstract, not much detail given.</p>

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<p><b>Wetzel <i>et al.</i> 2001a<sup>19</sup>, USA</b></p> <p><b>Wetzel <i>et al.</i> 2001b<sup>20</sup>, USA</b></p> <p><b>Lee <i>et al.</i> 2001<sup>20, 21</sup>, USA</b></p> <p>78 patients*</p> <p>Follow-up: 2 year follow-up</p> <p><i>Selection criteria:</i> Intent to treat group in a prospective multi-institution cohort study.</p>	<p><u>Wetzel <i>et al.</i> 2001a<sup>9</sup>:</u> 5/70 (7%) failures, 4 went to fusion and one received a second IDET. Change in VAS was significant at 3, 6 and 12 months (p=0.00066), American Academy of Orthopedic Surgery (AAOS) scales for Bodily pain, Physical function, Role physical, Social function, Vitality, Reported health transitions, Physical health and pain, Treatment expectation, patient satisfaction and pain disability changed significantly at 3 months follow-up, all correlations held at 6 months except for vitality. All correlations held at 1 year follow-up (20 patients). Significant changes in Work ability were seen at 1 year (p=0.00117, 18 patients). Significant changes in sitting and walking ability were seen at 6 months and 1 year (p=0.04 and p=0.0009 respectively).</p> <p><u>Wetzel <i>et al.</i> 2001b<sup>11</sup>:</u> At 2 years post-treatment, 88% of patients would “definitely” or “probably” choose the same treatment, 61% were performing 100% of their jobs at 2 years post-IDET compared to 23% pre-IDET, 8.7% were performing 50% or less of their job at 2 years post-IDET compared to 38% pre-IDET. VAS significantly improved (p&lt;0.0001). SF-36 significantly improved in Physical function (p&lt;0.0001), Bodily pain (p&lt;0.0001) Role physical (p&lt;0.0002), Social function (p&lt;0.0004), Mental health (p&lt;0.0169) and vitality (p&lt;0.0009).</p> <p><u>Lee <i>et al.</i> 2001<sup>10</sup>:</u> Statistically significant improvements in VAS, SF-36 (physical function, bodily pain, role physical, social function, vitality, but not role emotional, general health or mental health), Improvement in Pain/disability score (p&lt;0.0001) and Neurogenic symptom scores (leg pain (p=0.0139) and weakness in leg and/or foot (p=0.0123) but not numbness or tingling in leg and/or foot (p=0.2287)). Significantly fewer locations of pain postoperative (p=0.0035).</p> <p>Patients were originally fusion candidates and 18% required further back surgery.</p>	<p>None stated.</p>	<p><i>Potential for bias:</i> Small study numbers. Conference abstracts. Also see *</p> <p><i>Outcome measures and their validity:</i> Validation of VAS, American Academy of Orthopaedic Surgeons (AAOS) lumbar spine instrument (which includes the Pain/disability score and Neurogenic symptom scores) were not stated. SF-36 is validated.</p> <p><i>Other comments:</i> *All three abstracts appear to be reporting the same study and all were presented in the same year. There is some confusion as to patient numbers and withdrawals.</p>

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<p><b>Maurer et al. 2000<sup>22</sup>, USA</b></p> <p><b>Maurer &amp; Squillante, 2001<sup>23</sup>, USA</b></p> <p>2000 - 36 patients Follow-up: 3 and 6 months</p> <p>2001 – 78 patients Follow-up: 24 months</p> <p><i>Selection criteria:</i> Prospective enrolment of consecutive patients with chronic lower back pain who have failed at least 6 weeks of conservative treatment, but excluded if they had previous back surgery.</p>	<p><u>Results for 24 month follow-up only:</u> 71% successful treatments (all scales <math>p &lt; 0.0001</math>), 29% failure (where failure is defined as <math>&lt; 2</math> point VAS improvement or <math>&lt; 10</math> point increase in either bodily pain or physical function SF-36 subscales).</p>	No complications were observed.	<p><i>Potential for bias:</i> Small study numbers. Maurer is a consultant to Oratec Interventions.</p> <p><i>Outcome measures and their validity:</i> Validation of VAS was not stated.</p> <p><i>Other comments:</i> Conference abstract, not much detail given.</p>
<p><b>McGraw et al. 2001<sup>24</sup>, USA</b></p> <p>30 patients. Follow-up: 10 months (mean 4.2 months).</p> <p><i>Selection criteria:</i> Not stated</p>	<p>Procedure was technically successful in 29/30 (97%) patients. 21/30 (72%) reported significant improvement in back pain with a decrease in VAS score of 4 or more points, VAS improvement was statistically significant (<math>p &lt; 0.0001</math>). 21/30 (72%) were satisfied and would have the procedure again.</p>	Right leg radiculopathy 1/30 (3%)	<p><i>Potential for bias:</i> Small study numbers. Method of patient selection not stated.</p> <p><i>Outcome measures and their validity:</i> Validation of VAS not stated.</p> <p><i>Other comments:</i> Conference abstract, not much detail given.</p>
<p><b>Peloza 2000<sup>25</sup>, USA</b></p> <p>23 patients Follow-up: 12 months</p> <p><i>Selection criteria:</i> Consecutive enrolment of patients with low back pain lasting longer than 6 months, with disc disruption confirmed by x-ray, MRI, discography and failed 6 weeks conservative treatment.</p>	<p><u>Statistically significant improvements in:</u> VAS (56%, <math>p = 0.035</math>); SF-36 subscales measuring Bodily pain (<math>p = 0.011</math> at 6 months), Physical functioning (<math>p = 0.035</math>) and Role physical (<math>p = 0.020</math>). Overall, 80% of patients were satisfied (<math>p = 0.004</math>).</p>	None stated.	<p><i>Potential for bias:</i> Small study numbers.</p> <p><i>Outcome measures and their validity:</i> Validation of VAS not stated.</p> <p><i>Other comments:</i> Conference abstract, not much detail given. Patients may have been reported by Lee et al. 2001<sup>8</sup>, Wetzel et al. 2001a<sup>7</sup> and Wetzel et al. 2001b<sup>9</sup>.</p>

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
<p><b>Saal et al. 2001<sup>26</sup>, USA</b></p> <p>1675 patients (1675 IDET procedures) and analysis of MDR's (FDA) related to the 35000 SpineCath intradiscal catheters that have been used during IDET procedures Follow-up: not applicable</p> <p><i>Selection criteria:</i> Questionnaires were sent to 5 centres performing IDET.</p>	<p>Not stated</p>	<p>6/1675 (0.4%) nerve root injuries (5 or 6 completely resolved and 1 case at 2.5 months was resolving but had not completely resolved at time of report). 0/1675 discitis. 6/1675 (0.4%) post-IDET disc herniation 2-12 months post-treatment (4 resolved, 2 required disc excision). 1/1675 (0.06%) bladder dysfunction. 8/1675 (0.5%) superficial skin burn at needle puncture site.</p> <p>19/35,000 (0.05%) catheters have had a catheter breakage (not associated with patient morbidity*).</p>	<p><i>Potential for bias:</i> Conference abstract. Survey response rate not reported. Reason for selection of practices not stated.</p> <p><i>Other comments:</i> *information from a separate MDR</p>
<p><b>Saal &amp; Saal 2000a<sup>2</sup>, USA</b></p> <p>Preliminary report</p> <p>25 patients Follow-up: mean 7 (range 6-12 months)</p> <p><i>Selection criteria:</i> Consecutive patients who met the stated inclusion and exclusion criteria after a feasibility study of 10 patients (not reported).</p>	<p><u>Pain relief:</u> Statistically significant reduction in VAS pain scores (p&lt;0.0001). 20/25 (80%) patients reported a reduction in VAS pain scores of at least 2 points, 18/25 (72%) reported improvement in sitting tolerance (means significant at p=0.0002) and 19/25 were taking analgesia before IDET, 10/19 eliminated use after IDET and 4/19 reduced by more than 50%.</p> <p><u>SF-36:</u> 18/25 (72%) patients improved via the SF-36 physical function scale (p=0.001) and bodily pain subscale p=0.004)</p> <p>1/25 (4%) had an epidural injection during 8 weeks of postoperative recovery. No patients had intradiscal injections.</p>	<p>No patients developed a neurologic deficit or radicular pain. No adverse events or complications. No patient's condition was worsened by the procedure.</p>	<p><i>Potential for bias:</i> Small study numbers. Saal and Saal are the inventors of the SpineCath catheter and are also cofounders of the manufacturing company Oratec Interventions Inc.</p> <p><i>Outcome measures and their validity:</i> Validation of VAS not stated.</p> <p><i>Other comments:</i> These patients may overlap with those reported in Saal and Saal, 2000b<sup>12</sup></p>
<p><b>Saal &amp; Saal 2000b<sup>10</sup>, USA</b></p> <p>62 patients Follow-up: 1 year</p> <p><i>Selection criteria:</i> Patients who were referred to authors with unremitting chronic discogenic back pain , unresponsive to nonoperative care and discogram positive.</p>	<p>Improvement in VAS (p&lt;0.001), improvement in SF-36 Physical function (p&lt;0.001) and Bodily pain (p&lt;0.001) subscales. 97% of the patients with private payers and 83% of those receiving worker's compensation, returned to work. All patients, who had private payers, who were working prior to treatment returned to work. Of 20 who were not working prior to treatment, 19 returned to work. 3/62 (5%) patients had an epidural injection during 8 weeks of postoperative recovery, no patients had intradiscal injections.</p>	<p>No patients exhibited a neurologic deficit or new radicular pain during the follow-up period. No adverse events or complications were reported in the study group. No patient's condition was worsened by the procedure.</p>	<p><i>Potential for bias:</i> Small study numbers. Saal and Saal are the inventors of the SpineCath catheter and are also cofounders of the manufacturing company Oratec Interventions Inc.</p> <p><i>Outcome measures and their validity:</i> Validation of VAS not stated.</p>

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
<p><b>Saal &amp; Saal 2002<sup>27</sup>, USA</b></p> <p>58 patients Follow-up: 2 years (mean 28 months)</p> <p><i>Selection criteria:</i> Patients who were referred to authors with unremitting chronic discogenic back pain, unresponsive to nonoperative care and discogram positive.</p> <p>(1 year follow-up reported in Saal and Saal 2000b<sup>18</sup>)</p>	<p><u>Physical functioning:</u> (measured by the SF-36 physical functioning subscale and sitting tolerance) Significant improvements in both outcomes were detected at 6 months (p&lt;0.001). From 6 to 24 months, the magnitude of improvement significantly increased for both outcomes (p&lt;0.0001).</p> <p><u>Pain:</u> (Measured by SF-36 bodily pain subscale, and VAS) Significant improvements in pain at 6 months posttreatment (p&lt;0.0001). Improvements measured by SF-36 continued to increase through 24 months post-treatment (p=0.0017).</p> <p>Improvement of pain as measured by VAS remained constant from 6 months to 24 months (p=0.4960).</p> <p><u>Quality of life was measured by SF-36 scales:</u> (other than Physical functioning and Bodily pain) Significant improvement was detected at 24 months post-treatment (p=0.0001). One patient (2%) underwent interbody fusion surgery at 6 months post-IDET.</p>	<p>No IDET-treated patient in this study had a complication. There were no nerve injuries and no infections, and no patient had a neurologic deficit.</p>	<p><i>Potential for bias:</i> 4/58 (7%) patients lost to follow-up. Small study numbers. Saal and Saal are the inventors of the SpineCath catheter and are also cofounders of the manufacturing company Oratec Interventions Inc.</p> <p><i>Outcome measures and their validity:</i> Validation of VAS not stated.</p> <p><i>Other comments:</i> The return to work data is identical to that reported in Saal and Saal 2001b<sup>12</sup>, and was therefore not stated here.</p>
<p><b>Singh 2000<sup>28</sup>, USA</b></p> <p>23 patients Follow-up: 6 months</p> <p><i>Selection criteria:</i> Consecutive patients undergoing IDET from June 1999 through August 1999.</p>	<p>At least 50% pain relief in 67% of patients.</p> <p>Significant decrease in visual analogue pain scores.</p> <p>Narcotic use decreased by 29% but was not statistically significant (p=0.063).</p> <p>Statistically significant improvement in standing (p=0.0299) and walking (p=0.0046).</p> <p>Improvement in sitting but was not statistically significant.</p>	<p>No complications noted perioperative or postoperatively.</p>	<p><i>Potential for bias:</i> Limited information and therefore could not determine potential for bias. 2/23 (9%) patients lost to follow-up (1 died due to a cardiovascular event 5 months postoperative, 1 moved residence with no forwarding address.</p> <p><i>Outcome measures and their validity:</i> Validation of VAS pain not stated.</p>

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
<p><b>Thompson &amp; Eckel 2000<sup>29</sup>, USA</b></p> <p><b>Thompson &amp; Eckel 2001<sup>30</sup>, USA</b></p> <p>211 patients completed 12 month follow-up</p> <p>100 patients completed 24 month follow-up</p> <p><i>Selection criteria:</i> Voluntary participation in a prospective, uncontrolled study as part of a manufacturer sponsored registry.</p>	<p><u>12 month follow-up:</u> Improvements in VAS (p=0.0001), SF-36 Physical functioning, Role physical, Bodily pain, vitality, Social functioning, Role emotional, Mental health (p=0.0001), improvements in sitting, standing and walking time (p=0.0001). Workers Compensation patients had significantly lower in magnitude improvement in SF-36 physical function scores.</p> <p><u>24 month follow-up:</u> All SF-36 scales significantly improved (p&lt;0.05 or better), except General health (p=0.9620). Improvement in sitting time (&lt;0.0001), walking time (&lt;0.0001) and standing time (p&lt;0.0049). 81% reported health was “somewhat” or “much better” compared to prior IDET, 83% would “probably” or “definitely” choose the same treatment again, 66% reported using less medication at 24 months post IDET compared with pre IDET.</p>	<p>Not stated.</p>	<p><i>Potential for bias:</i> Registry sponsored by the manufacturer of the SpineCath catheter used for IDET. The sponsor was responsible for receiving and mailing follow-up questionnaires. The sponsor compiled the data and the sponsor and authors performed analysis. Patients were offered compensation for completion and return of the forms. Vested interest of study sponsor was recognised. The 2 year follow-up response rate was 67%.</p> <p><i>Outcome measures and their validity:</i> Validation of VAS and SF-36 not stated.</p> <p><i>Other comments:</i> Conference abstract, not much detail given.</p>
Study details	Key safety findings		
Case reports			
<p><b>Djurasovic et al. 2002<sup>12</sup>, USA</b></p> <p>1 patient Follow-up: 6 months</p>	<p>Vertebral osteonecrosis. Presented 5 month postoperative with worsening of pain and dysesthetic leg pain. Plain radiographs showed increased collapse of the L5-S1 disc, MRI showed oedema and changes similar to severe degenerative disc disease with disc space collapse (L5-S1). Patient underwent interbody fusion and biopsies of the L5 vertebral body and L5-S1 were obtained showing necrotic bone and disc material. At 6 month follow-up, patient still has significant back pain.</p>		
<p><b>Hsia et al., 2000<sup>13</sup>, USA</b></p> <p>1 patient Follow-up: 6 months</p>	<p>Cauda equina syndrome Catheter inappropriately placed in spinal canal during IDET at L4-L5. Patient demonstrated bilateral saddle anaesthesia with diminished rectal tone and diminished sensation over the posterior aspect of the left leg to the plantar surface of the foot. Left Achilles tendon reflex absent. MRC grade 4 weakness in hip extensors and knee and ankle flexors. Required daily self catheterisation and had bowel incontinence. Had not resolved 6 months postoperatively.</p>		