A Systematic Review

TREATMENT OF INTRACTABLE DISCOGENIC LOW BACK PAIN. A SYSTEMATIC REVIEW OF SPINAL FUSION AND INTRADISCAL ELECTROTHERMAL THERAPY (IDET)

Gunnar B. J. Andersson, MD, PhD, Nagy A. Mekhail, MD, PhD, and Jon E. Block, PhD

Background: A growing number of patients suffer from severe low back pain of discogenic origin that is not responsive to conservative medical management. These patients must consider the option of surgical spinal fusion or minimally-invasive intradiscal electrothermal therapy (IDET).

Objective: To conduct a systematic review of clinical outcomes in patients undergoing spinal fusion or the intradiscal electrothermal therapy (IDET) procedure for intractable discogenic low back pain.

Design: Systematic literature review.

Methods: English-language journal articles published from January 1995 to December 2005 were identified through computerized searches of the PubMed database and bibliographies of identified articles and review papers. Articles were selected if disc degeneration or disruption was the primary indication for spinal fusion or the IDET procedure and if follow-up outcome data included evaluations of back pain severity, condition-specific functional impairment and/or health-related quality of life. The literature review encompassed 33 spinal fusion articles: 10 randomized controlled trials, 1 nonrandomized controlled trial, 9 before-after trials, and 13 case series. There were 18 IDET articles: 2 randomized controlled trials, 2 nonrandomized controlled trials, 11 before-after trials, and 3 case series. Data were extracted and summarized on patient characteristics, surgical methods, and clinical outcomes.

Results: Overall, there were similar median percentage improvements realized after spinal fusion and the IDET procedure, respectively, for 2 of the 3 outcomes evaluated: pain severity (50%, 51%), back function (42%, 14%) and quality of life (46%, 43%). There was an identifiable randomized controlled trials trend of both treatments reporting a smaller magnitude of improvement in all 3 primary outcomes (pain severity, back function, quality of life) compared to other types of trials. Perioperative complications were commonly associated with spinal fusion (median: 14%, range: 2% to 54%, n=31 study groups) whereas adverse events were rarely experienced with the IDET procedure (median: 0%, range: 0% to 16%, n=14 studies). Randomized controlled trials of spinal fusion, in particular, had important methodological limitations.

Conclusion: The majority of patients reported improvement in symptoms following both spinal fusion and the IDET procedure. The IDET procedure appears to offer sufficiently similar symptom amelioration to spinal fusion without the attendant complications."

Key words: Spinal fusion, intradiscal electrothermal therapy, back pain.
current preference has emerged toward en masse disc excision combined with instrumented interbody fusion to provide stabilization (20, 21). Patients with imaging and discographic evidence of internal disc disruption may have another option — percutaneous intradiscal electrothermal therapy (IDET), the minimally-invasive technique which uses a navigable catheter to provide targeted thermal energy within the disc (2, 22, 23).

The primary purpose of this report is to present a systematic review of the published literature regarding clinical outcomes after spinal fusion and IDET in patients with intractable discogenic low back pain. Emphasis was placed on 3 primary outcomes: pain severity, condition-specific functional impairment and health-related quality of life. Qualitative outcome comparisons were made between spinal fusion and IDET, as well as between each intervention, and non-operative conservative management.

Methods

Data Sources

A computerized search of the PubMed database from January 1995 to December 2005 for English-language publications was conducted using the key words disc and interbody coupled separately with fusion or arthrodesis for studies of spinal fusion, and intradiscal or IDET for published reports of IDET studies. The reference lists of the retrieved articles were reviewed for additional studies, as were review articles on the subject. The initial article inclusion date of 1995 was chosen based on the finding that the earliest publication date for a study of the IDET procedure was 1996 and spinal fusion articles published prior to this date often failed to provide adequate clinical outcome data with respect to pain severity or functional impairment. Additionally, spinal fusion articles published subsequent to 1995 were more likely to include patients treated with newer pedicle screw fixation and interbody fusion cage devices for disc disease (24). Only IDET studies that specifically used the SpineCATH® device (Smith & Nephew Endoscopy, Andover, MA) were included in this review. This device is a navigable intradiscal catheter that can be deployed directly adjacent to the posterior or posterolateral annulus and provides temperature-controlled conductive heating using a thermal resistive coil (23).

Study Selection

All articles were triaged for inclusion by one of the authors (JEB) for suitability prior to review. Studies were selected for inclusion in this synthesis if the methods section clearly indicated that disc degeneration or disruption was the primary indication for spinal fusion or the IDET procedure, and if follow-up outcome data included evaluations of back pain severity, condition-specific functional impairment and/or health-related quality of life. Reports of patients described as having nonspecific chronic low back pain were included if there was discographic evidence of concordant pain provocation. Studies evaluating patients for other back pain-related indications such as spinal/foraminal stenosis, spondylolisthesis, failed back syndrome, scoliosis, fracture, spondylosis or nonspecific degenerative instability were excluded.

A total of 229 articles were located from all sources and triaged for inclusion. Fifty one articles (22%) met the stated requirements for inclusion in this systematic review: most excluded articles were either clinical studies that did not evaluate at least 1 of the 3 primary outcomes or were studies that intermingled patients with multiple diagnoses and failed to report outcomes separately for cases with disc degeneration. All published articles of the IDET procedure were included in this review. Three studies (25-27) were excluded that used a distinctly different intradiscal device consisting of a radiofrequency needle probe inserted directly into the center of the nucleus. Experimentally this device has been shown to be unable to access the broad expanse of the posterior or annular wall, the site of symptomatic disc disruption (12), and the device also fails to provide sufficient annular heating and tissue coagulation to achieve the desired clinical benefit.

Data Extraction

All studies were classified as follows: randomized controlled trial, non-randomized controlled trial, before-after trial (prospective), or case series (retrospective). The literature reviewed encompassed 33 spinal fusion articles: 10 randomized controlled trials (29-38), 1 nonrandomized controlled trial (39), 9 before-after trials (40-48), and 13 case series (49-61). Randomized controlled trials of spinal fusion were further subcategorized as studies comparing spinal fusion with conservative management (n=2) (31, 37) and studies comparing various fusion techniques (n=8) (29, 30, 32-36, 38). Six of the spinal fusion articles provided outcomes on similar or equivalent patient groups (33, 34, 42, 43, 51, 52).

There were 18 IDET articles: 2 randomized controlled trials (62, 63), 2 nonrandomized controlled trials (64, 65), 11 before-after trials (66-76), and 3 case series (77-79). The 2 nonrandomized controlled trials reported outcomes on the same patient population with different lengths of follow-up (64, 65). Five of the before-after trials likewise reported outcomes on the same patient population with different lengths of follow-up (67, 68, 70-72).

The quality of all reports of randomized controlled trials was graded using the 5-point Jadad Score with a score of “1” representing poor quality and a score of “5” reflecting excellent quality (80). This scoring system rates study quality on 3 fundamental methodological criteria: randomization, blinding, and completeness of follow-up. Results of randomized controlled trials of spinal fusion versus conservative management, and of the IDET procedure versus sham control were analyzed per protocol. Post hoc intention-to-treat analyses
were not conducted.

The following information was abstracted from each of the selected articles: age, gender distribution, duration of symptoms, length of follow-up, indication, type of procedure, sample size, outcome(s), and complication rate. For spinal fusion, the type of procedure was recorded as posterolateral (PLF), posterior lumbar interbody (PLIF), anterior lumbar interbody (ALIF), or circumferential (360º) (CF) fusion.

This synthesis focused on 3 primary clinical outcomes: pain severity as measured by visual analog scale (normally 10-point), condition-specific functional impairment as measured by the Oswestry disability index (100-point), and health-related quality of life as measured by the SF-36 questionnaire instrument (100-point) (81). Findings from the Roland-Morris disability questionnaire were included only if the Oswestry was not used, and results for the physical functioning domain of the SF-36 were summarized. For spinal fusion studies, results with respect to the percentage of patients achieving good or excellent clinical results (or highest equivalent rating) also were included. This outcome was defined variously but generally reflected moderate to complete pain relief (54, 82, 83). For studies of the IDET procedure, results for the percentage of patients demonstrating at least a 2-point improvement in pain severity were included as an improvement of this magnitude has been shown to be clinically significant (84).

### Statistical Methods

For the three primary outcomes, the estimated percentage improvement from baseline to final follow-up was computed from mean values reported in each article (85). For pain severity and back impairment, decreases in scores reflected improvement whereas for quality of life, increases in scores reflected improvement. In all cases, the median percentage improvement and associated range for each outcome was presented for all studies by type of treatment (i.e., spinal fusion or IDET). For spinal fusion articles, the median percentage improvement in each outcome also was provided for each type of fusion procedure (e.g., PLF, PLIF, ALIF, etc.) separately. Lastly, the median percentage improvement in each outcome grouped by hierarchy of study design was presented for both types of treatments separately. No adjustments were made to median summary scores for sample size, length of followup, or other factors. Significance values were abstracted directly from the text and not computed post hoc. For controlled trials, P values reflect comparisons in improvement between study groups. For single-arm before-after trials and case series, P values reflect paired comparisons within study groups. If provided, the major complication or adverse event rate was abstracted directly from each report. If complications were only listed, then the total number of complications was divided by the number of procedures to arrive at percentage estimate for adverse events.

### Results

Table 1 summarizes selected demographic and study-related characteristics for all investigations of spinal fusion and the IDET procedure separately. While there were no noteworthy differences between treatments for age or gender distribution, the median duration of symptoms and the length of follow-up were somewhat longer for patients treated with spinal fusion compared to patients treated with the IDET procedure. The primary presenting clinical symptom, back pain severity, also was fairly similar between treatments. Adjusted to a 10-point scale, the median baseline pain severity scores were 7.9 (range: 6.2 to 8.9) and 6.6 (range: 5.9 to 8.0) for studies of spinal fusion and the IDET procedure, respectively.

Complete findings grouped by study design into the categories of indication, type of procedure, baseline, final follow-up values for 3 primary outcomes, the percentage good or excellent results, and complication rates are all presented in Table 2 for spinal fusion. There were 10 reports (30%) of patients treated with PLF, 7 (21%) with PLIF, 12 (36%) with ALIF, and 6 (18%) with CF. There were 28 studies (85%) reporting pain severity results, 17 studies (52%) reporting Oswestry results and 5 studies (15%) reporting SF-36 results. The overall median percentage improvement after spinal fusion in pain severity was 50% (range: 24% to 77%), in Oswestry was 42% (range: 17% to 77%), and in SF-36 was 46% (range: 21% to 123%).

Procedures involving an interbody fusion showed somewhat greater median percentage improvement in pain severity than PLF although the ranges were overlapping: PLF (median: 37%, range: 30% to 77%, n=9 study groups), PLIF (median: 57%, range: 52% to 61%, n=4 study groups), ALIF (median: 50%, range: 31% to 75%, n=11 study groups), and CF (median: 41%, range: 24% to 70%, n=6 study groups). Similar results by type of fusion procedure also were observed for the median percentage improvement in the Oswestry disability index: PLF (median: 38%, range: 21% to 73%, n=7 study groups), PLIF (median: 54%, range: 24% to 58%, n=3 study...
Table 2. Study Background Characteristics and Clinical Findings of Published Reports of Spinal Fusion for the Treatment of Discogenic Low Back Pain

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Characteristics</th>
<th>Sample Size</th>
<th>Outcome</th>
<th>Baseline Value</th>
<th>Final Follow-up Value</th>
<th>Δ from Baseline Value</th>
<th>% GE</th>
<th>% AE</th>
</tr>
</thead>
<tbody>
<tr>
<td>France et al 1999</td>
<td>RCT</td>
<td>J.S. = 1</td>
<td>DDD</td>
<td>PLF</td>
<td>PS</td>
<td>NR</td>
<td>4.0</td>
<td>NR</td>
</tr>
<tr>
<td>Boden et al 2000</td>
<td>RCT</td>
<td>J.S. = 3</td>
<td>DDD</td>
<td>ALIF**</td>
<td>OS</td>
<td>39</td>
<td>14</td>
<td>25</td>
</tr>
<tr>
<td>Fritzell et al 2001</td>
<td>RCT</td>
<td>J.S. = 3</td>
<td>DDD/DH</td>
<td>V</td>
<td>PS</td>
<td>64</td>
<td>43</td>
<td>21</td>
</tr>
<tr>
<td>Boden et al 2002</td>
<td>RCT</td>
<td>J.S. = 2</td>
<td>DDD</td>
<td>PLF***</td>
<td>OS</td>
<td>47</td>
<td>36</td>
<td>11</td>
</tr>
<tr>
<td>Burks et al 2002</td>
<td>RCT</td>
<td>J.S. = 2</td>
<td>DDD</td>
<td>ALIF**</td>
<td>PS</td>
<td>16</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>Burks et al 2002</td>
<td>RCT</td>
<td>J.S. = 2</td>
<td>DDD</td>
<td>ALIF**</td>
<td>OS</td>
<td>54</td>
<td>24</td>
<td>29</td>
</tr>
<tr>
<td>Fritzell et al 2002</td>
<td>RCT</td>
<td>J.S. = 3</td>
<td>DDD</td>
<td>PLF#</td>
<td>PS</td>
<td>64</td>
<td>45</td>
<td>19</td>
</tr>
<tr>
<td>Gibson et al 2002</td>
<td>RCT</td>
<td>J.S. = 1</td>
<td>DDD</td>
<td>PLF*</td>
<td>RM</td>
<td>18</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>Ivar Brox et al 2003</td>
<td>RCT</td>
<td>J.S. = 3</td>
<td>DDD</td>
<td>ALIF**</td>
<td>OS</td>
<td>51</td>
<td>30</td>
<td>21</td>
</tr>
<tr>
<td>Sasso et al 2004</td>
<td>RCT</td>
<td>J.S. = 2</td>
<td>DDD</td>
<td>ALIF**</td>
<td>OS</td>
<td>8.4</td>
<td>5.3</td>
<td>3.1</td>
</tr>
<tr>
<td>Madan et al 2003</td>
<td>NCT</td>
<td>DDD</td>
<td>PLF</td>
<td>OS</td>
<td>64</td>
<td>39</td>
<td>25</td>
<td>39</td>
</tr>
<tr>
<td>Gertzbein et al 1996</td>
<td>BA</td>
<td>DDD</td>
<td>CF</td>
<td>PS</td>
<td>7.1</td>
<td>2.1</td>
<td>5</td>
<td>(70)</td>
</tr>
<tr>
<td>Hall et al 1996</td>
<td>BA</td>
<td>DDD</td>
<td>PLF</td>
<td>PS</td>
<td>5.0</td>
<td>2.9</td>
<td>2.1</td>
<td>(42)</td>
</tr>
<tr>
<td>Kuslich et al 1998</td>
<td>BA</td>
<td>DDD</td>
<td>ALIF/PLIF</td>
<td>PS</td>
<td>4.0</td>
<td>2.0</td>
<td>1.7</td>
<td>(46)</td>
</tr>
</tbody>
</table>

Table 2 continued on p. 171.
<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Characteristics</th>
<th>Outcome</th>
<th>Baseline Value</th>
<th>Final Follow-up Value</th>
<th>∆ from Baseline Value</th>
<th>% GE</th>
<th>% AE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kuslich et al 2000</td>
<td>BA DDD ALIF/PLIF</td>
<td>PS</td>
<td>5.1</td>
<td>2.8</td>
<td>2.3 (45) &lt;.05</td>
<td>NR</td>
<td>14</td>
</tr>
<tr>
<td>Kleeman et al 2001</td>
<td>BA DDD ALIF</td>
<td>OS</td>
<td>7.7</td>
<td>4.7</td>
<td>11 (84) &lt;.001</td>
<td>NR</td>
<td>9</td>
</tr>
<tr>
<td>Lowe et al 2002</td>
<td>BA DDD/DH PLIF</td>
<td>PS</td>
<td>8.3</td>
<td>3.2</td>
<td>5.1 (61) &lt;.001</td>
<td>80</td>
<td>10</td>
</tr>
<tr>
<td>Pellise et al 2002</td>
<td>BA DDD ALIF</td>
<td>PS</td>
<td>7.2</td>
<td>2.2</td>
<td>5 (69) &lt;.01</td>
<td>NR</td>
<td>92</td>
</tr>
<tr>
<td>Folman et al 2003</td>
<td>BA DDD PLIF</td>
<td>OS</td>
<td>8.5</td>
<td>3.3</td>
<td>5.2 (61) &lt;.01</td>
<td>NR</td>
<td>3</td>
</tr>
<tr>
<td>Buttermann et al 1998</td>
<td>CS DDD V</td>
<td>PS</td>
<td>8.5</td>
<td>4.5</td>
<td>13 (63) &lt;.05</td>
<td>NR</td>
<td>92</td>
</tr>
<tr>
<td>Gertzbein et al 1998</td>
<td>CS DDD CF</td>
<td>PS</td>
<td>7.4</td>
<td>4.4</td>
<td>4 (41) &lt;.001</td>
<td>17</td>
<td>27</td>
</tr>
<tr>
<td>Grob and Humke 1998</td>
<td>CS IDD/DH PLF</td>
<td>PS</td>
<td>7.6</td>
<td>2.9</td>
<td>4.7 (62) NR</td>
<td>76</td>
<td>10</td>
</tr>
<tr>
<td>Humke et al 1998</td>
<td>CS DH PLF</td>
<td>PS</td>
<td>7.6</td>
<td>2.9</td>
<td>4.7 (62) NR</td>
<td>76</td>
<td>10</td>
</tr>
<tr>
<td>Whitecloud et al 1998</td>
<td>CS DDD CF</td>
<td>PS</td>
<td>7.2</td>
<td>5.5</td>
<td>1.7 (24) .0002</td>
<td>NR</td>
<td>54</td>
</tr>
<tr>
<td>Leufven and Nordwall 1999</td>
<td>CS DDD PLIF</td>
<td>OS</td>
<td>8.6</td>
<td>4.0</td>
<td>4.6 (53) &lt;.01</td>
<td>52</td>
<td>7</td>
</tr>
<tr>
<td>Tandon et al 1999</td>
<td>CS CNLBP PLIF</td>
<td>OS</td>
<td>51</td>
<td>39</td>
<td>12 (24) &lt;.001</td>
<td>NR</td>
<td>13</td>
</tr>
<tr>
<td>Barrick et al 2000</td>
<td>CS DDD/DH ALIF</td>
<td>PS</td>
<td>7.9</td>
<td>4.7</td>
<td>3.2 (41) &lt;.001</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Thalgott et al 2000</td>
<td>CS DDD/IDD CF</td>
<td>PS</td>
<td>NR</td>
<td>NR</td>
<td>NR (56) NR</td>
<td>76</td>
<td>NR</td>
</tr>
<tr>
<td>Madan and Boeree 2001</td>
<td>CS DDD ALIF</td>
<td>OS</td>
<td>8.2</td>
<td>4.1</td>
<td>4.1 (26) &lt;.0001</td>
<td>NR</td>
<td>11</td>
</tr>
<tr>
<td>Thalgott et al 2002</td>
<td>CS DDD/IDD ALIF</td>
<td>OS</td>
<td>8.9</td>
<td>3.8</td>
<td>5.1 (57) NR</td>
<td>90</td>
<td>16</td>
</tr>
<tr>
<td>Thalgott et al 2002</td>
<td>CS DDD CF</td>
<td>OS</td>
<td>8.9</td>
<td>3.4</td>
<td>5.5 (62) NR</td>
<td>80</td>
<td>15</td>
</tr>
<tr>
<td>Beutler and Peppelman 2003</td>
<td>CS DDD ALIF</td>
<td>OS</td>
<td>58</td>
<td>34</td>
<td>24 (41) NR</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

NS, not significant; NR, not reported.
* RCT indicates randomized controlled trial; NCT, nonrandomized controlled trial; BA, prospective before-after trial; CS, retrospective case series. J.S. indicates Jadad score (1 to 5) for methodological quality.
* DDD indicates degenerative disc disease; IDD, internal disc disruption; DH, disc herniation; CNLBP, chronic nonspecific low back pain.
* PLF indicates posterolateral fusion; PLIF, posterior lumbar interbody fusion; ALIF, anterior lumbar interbody fusion; IF, interbody fusion; CF, combined anterior-posterior or 360° fusion; CM, conservative management; V, various fusion techniques.
* PS indicates pain severity; OS, Oswestry disability index; SF, SF-36 physical functioning domain (unless otherwise indicated); RM, Roland-Morris disability questionnaire.
* GE indicates good or excellent clinical results.
* AE indicates adverse events.
* Fusion procedure performed without instrumentation.
* Graft material consisted of rhBMP-2.
* Graft material consisted of autologous bone.
* Results provided for the SF-36 physical component summary score.
* Graft material consisted of allogeneic bone or femoral ring allograft.
* Cylindrical threaded titanium cage device.
Sixteen of 33 (48%) spinal fusion studies reported on the percentage of patients achieving good or excellent results (Table 2). The overall median percentage value of good or excellent results was 67% but the range was wide (17% to 100%). There was a somewhat lower median percentage of good or excellent results for patients treated with PLF or CF although the ranges were overlapping: PLF (median: 64%, range: 41% to 100%, n=10 study groups), PLIF (median: 80%, range: 52% to 80%, n=3 study groups), ALIF (median: 85%, range 55% to 100%, n=6 study groups), and CF (median: 61%, range: 17% to 80%, n=4 study groups).

The 2 randomized controlled trials of spinal fusion versus conservative management had conflicting findings (31, 37). Fritzell et al (31) demonstrated significantly better improvement in pain severity (33% vs. 8%, P = 0.0002) and back function (24% vs. 6%, P = 0.015) among patients treated with fusion compared to patients assigned to nonoperative management. On the other hand, Ivar Brox et al (37) failed to show a difference in improvement in pain severity (37% vs. 23%, P = 0.14) or back function (38% vs. 30%, P = 0.33) between fusion and conservative management, respectively.

Perioperative complications were commonly associated with spinal fusion (median: 14%, range: 2% to 54%, n=31 study groups) with a tendency for a higher percentage of adverse events among patients treated with circumferential (360°) fusion. Two randomized controlled trials of spinal fusion were rated as having poor methodological quality (Jadad score: 1) (29, 36), 4 were rated fair (Jadad score: 2) (32-34, 38), and 4 were rated good (Jadad score: 3) (30, 31, 35, 37). Due to the distinct characteristics of these surgical interventions, the patient was generally unblinded to treatment assignment in randomized controlled trials and this adversely affected the methodological quality ratings of these studies.

Table 3 provides comparable findings for the IDET procedure regarding indication, type of procedure as well as baseline and final follow-up values for the 3 primary outcomes and complication rates. There were 15 studies (83%) reporting pain severity results, 5 studies (28%) reporting Oswestry results, and 8 studies (44%) reporting SF-36 results. The overall median percentage improvement after the IDET procedure in pain severity was 51% (range: 22% to 71%), in Oswestry was 14% (range: 4% to 35%), and in SF-36 was 43% (range: 7% to 76%). In 5 IDET studies (28%) the median percentage of patients experiencing at least a 2-point improvement in pain severity on a 10-point visual analog scale was 65% (range: 52% to 72%).

The two randomized controlled trials of the IDET procedure versus a sham control also had conflicting findings (62, 63). Pauza et al (62) demonstrated significantly better improvement in pain severity (36% vs. 17%, P = 0.045) and back function (35% vs. 12%, P < 0.05) among patients treated with the IDET procedure compared to patients randomly assigned to sham control. These improvements were realized in spite of a notable placebo response among sham-treated patients (Table 3). Alternatively, Freeman et al (63) reported an almost uniform lack of effectiveness in either treatment group on any outcome over 6 months. For example, subjects randomly treated with the IDET procedure experienced an approximate 4% average improvement in back function compared to their sham-treated counterparts who had an approximate 2% decline (P = 0.50).

Adverse events were rarely experienced with the IDET procedure. Of 14 IDET studies reporting perioperative complications, 11 studies (79%) reported no complications. In the 3 IDET studies reporting adverse events, the rate was comparatively low (range: 9% to 16%). Both randomized controlled trials of the IDET procedure were rated as having excellent methodological quality (Jadad score: 5) and a successfully executed blinded sham control (62, 63).

The median percentage improvement from baseline and the associated range for the 3 primary outcomes categorized by study design are presented in Table 4. There was an identifiable trend for randomized controlled trials to report a smaller magnitude of improvement in all outcomes compared to other types of trials. This trend was apparent for studies of both spinal fusion and the IDET procedure. For example, there was an approximate 36% median reduction in pain severity realized after spinal fusion in randomized controlled trials compared to a median reduction of 61% reported in before-after trials. The median pain severity reduction (36%) for one of the randomized controlled trials of the IDET procedure compared favorably with trials of spinal fusion. Similarly, the median percentage improvement in pain severity was higher (50%) in before-after trials of IDET (Table 4).

**Discussion**

This systematic review provides a comparative evaluation of clinical outcome and complication rates for published studies of spinal fusion and the IDET procedure. Patients included in these studies suffered from severe intractable back pain of discogenic origin. These patients uniformly experienced inadequate pain amelioration, exhausting the entire range of conservative medical interventions including pain medications, physical therapy, epidural injections, and psychological interventions. Patients eligible for the IDET procedure have specific imaging and discographic evidence of internal disc disruption. These patients represent a subset of cases presenting with the more general diagnosis of severe disc degeneration that are managed operatively with spinal fusion and,
### Table 3. Study Background Characteristics and Clinical Findings of Published Reports of Intradiscal Electrothermal Therapy (IDET) for the Treatment of Discogenic Low Back Pain

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Characteristics</th>
<th>Outcome</th>
<th>Baseline Value</th>
<th>Final Follow-up Value</th>
<th>Δ from Baseline</th>
<th>%Δ PS ≥ 2 points</th>
<th>% AE†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pauza et al 2004</td>
<td>RCT IDD SC 37 J.S. = 5</td>
<td>PS</td>
<td>6.6</td>
<td>4.2</td>
<td>2.4 (36) .045</td>
<td>56 0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6.5</td>
<td>5.4</td>
<td>1.1 (17)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OS</td>
<td>31 20</td>
<td>11 (35) .05</td>
<td>4 (12)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>33 28</td>
<td>15 (27) .55</td>
<td>11 (22)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>SF</td>
<td>36 71</td>
<td>6 (2)</td>
<td>2 (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>49 60</td>
<td>1 (4)</td>
<td>5 NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Freeman et al 2005</td>
<td>RCT DDD SC 38 J.S. = 5</td>
<td>OS</td>
<td>41 40</td>
<td>5 (63) &lt;.0001</td>
<td>0 NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>41 42</td>
<td>0 (0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>SF</td>
<td>42 45</td>
<td>3 (7)</td>
<td>.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>35 37</td>
<td>2 (6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Karasek and Bogduk 2000</td>
<td>NCT IDD SC 36 CM 17</td>
<td>PS</td>
<td>8.0</td>
<td>3.0</td>
<td>5 (63) .03</td>
<td>0 NR</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>8.0</td>
<td>7.5</td>
<td>5 (63) .03</td>
<td>0 NR</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>PP</td>
<td>8.0</td>
<td>7.5</td>
<td>5 (63) .03</td>
<td>0 NR</td>
<td></td>
</tr>
<tr>
<td>Derby et al 2000</td>
<td>BA IDD/DDD SC 32</td>
<td>OS</td>
<td>34 26</td>
<td>8 (24) NR</td>
<td>0 NR</td>
<td>8.6</td>
<td></td>
</tr>
<tr>
<td>Saal and Saal 2000</td>
<td>BA CNLBP SC 62</td>
<td>OS</td>
<td>6.6</td>
<td>3.7</td>
<td>5 (51) &lt;.0001</td>
<td>0 NR</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>39 39</td>
<td>20 (51) &lt;.0001</td>
<td>0 NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saal and Saal 2000</td>
<td>BA CNLBP SC 25</td>
<td>PS</td>
<td>7.3</td>
<td>3.6</td>
<td>15 (52) &lt;.0001</td>
<td>0 NR</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>40 55</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Singh 2000</td>
<td>BA IDD SC 21</td>
<td>PS</td>
<td>6.2</td>
<td>3.9</td>
<td>1.4 (37) .0001</td>
<td>0 NR</td>
<td></td>
</tr>
<tr>
<td>Welch et al 2001</td>
<td>BA DDD SC 23</td>
<td>OS</td>
<td>34 26</td>
<td>4 (7) NR</td>
<td>0 NR</td>
<td>8.6</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>31 47</td>
<td>16 (52) NR</td>
<td>0 NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gerszten et al 2002</td>
<td>BA DDD SC 27</td>
<td>OS</td>
<td>34 26</td>
<td>4 (7) NR</td>
<td>0 NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>32 47</td>
<td>15 (47) NR</td>
<td>0 NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saal and Saal 2002</td>
<td>BA CNLBP SC 58</td>
<td>PS</td>
<td>6.6</td>
<td>3.4</td>
<td>3.2 (48) .0001</td>
<td>0 NR</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>41 72</td>
<td>31 (76) &lt;.0001</td>
<td>0 NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spruit and Jacobs 2002</td>
<td>BA DDD SC 20</td>
<td>PS</td>
<td>6.5</td>
<td>5.1</td>
<td>14 (22) &lt;.05</td>
<td>0 NR</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>43 37</td>
<td>6 (14) NS</td>
<td>0 NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OS</td>
<td>45 55</td>
<td>10 (22) NS</td>
<td>0 NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lutz et al 2004</td>
<td>BA CNLBP SC 33</td>
<td>PS</td>
<td>7.5</td>
<td>3.9</td>
<td>3.9 (52) &lt;.001</td>
<td>0 NR</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>13.9 6.6</td>
<td>7.3 (53) &lt;.001</td>
<td>0 NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kapural et al 2004</td>
<td>BA DDD SC 17</td>
<td>PS</td>
<td>7.4</td>
<td>2.5</td>
<td>4.9 (66) &lt;.001</td>
<td>0 NR</td>
<td></td>
</tr>
<tr>
<td>McKhail and Kapural 2004</td>
<td>BA IDD SC 32</td>
<td>PS</td>
<td>8.0</td>
<td>2.3</td>
<td>5.7 (71) &lt;.001</td>
<td>0 NR</td>
<td></td>
</tr>
<tr>
<td>Endres et al 2002</td>
<td>CS DDD SC 54</td>
<td>PS</td>
<td>8.0</td>
<td>2.3</td>
<td>5.7 (71) &lt;.001</td>
<td>0 NR</td>
<td></td>
</tr>
<tr>
<td>Cohen et al 2003</td>
<td>CS DDD SC 79</td>
<td>PS</td>
<td>5.9</td>
<td>2.1</td>
<td>3.8 (64) NR</td>
<td>0 NR</td>
<td></td>
</tr>
<tr>
<td>Freedman et al 2003</td>
<td>CS CNLBP SC 31</td>
<td>PS</td>
<td>8.0</td>
<td>2.3</td>
<td>5.7 (71) &lt;.001</td>
<td>0 NR</td>
<td></td>
</tr>
</tbody>
</table>

NS, not significant; NR, not reported.
* RCT indicates randomized controlled trial; NCT, nonrandomized controlled trial; BA, prospective before-after trial; CS, retrospective case series. J.S. indicates Jadad score (1 to 5) for methodological quality.
† DDD indicates degenerative disc disease; IDD, internal disc disruption; CNLBP, chronic nonspecific low back pain.
‡ SC, SpineCATH device; sSC, sham SpineCATH device; CM, conservative management.
§ PS indicates pain severity; OS, Oswestry disability index; SF, SF-36 physical functioning domain; RM, Roland-Morris disability questionnaire.
|| Adjusted to a standard 10-point visual analog scale (VAS).
¶ AE indicates adverse events.

Consequently, may have somewhat different clinical characteristics at baseline. Inspection of comparative median pain severity scores (and ranges) suggests that the severity of back pain suffered by patients prior to spinal fusion was somewhat higher but with generally similar overlapping ranges, to the severity reported by patients undergoing the IDET procedure. Thus, the presenting symptomatology of patients included in both types of studies was fairly homogeneous. A primary goal of this literature review was to evaluate whether highly-selected patients with definitive evidence of internal disc disruption could benefit from the IDET procedure at a stage prior to undergoing operative intervention and, thus, markedly delay or obviate the need for subsequent spinal fusion.

The median percentage of patients reporting good or excellent results after spinal fusion surgery for discogenic low
back pain in the current synthesis was 67% (range: 17% to 100%). This finding is similar to results reported by Turner et al (86) in 1992, for the percentage of satisfactory outcomes after fusion for all indications (mean: 68%, range: 16% to 95%). Bono and Lee (24) likewise found no difference in good or excellent percentages in fusion studies of degenerative disc disease published in the 1980s (78%) and the 1990s (74%). This apparent lack of improvement in clinical outcome following spinal fusion is noteworthy in light of the significant technical and device-related advances in the surgical procedure during the last decade including pedicle screw instrumentation and interbody cage systems.

The current literature review included only studies of patients where disc degeneration was implicated as the primary cause of chronic pain and was stated as the indication for more aggressive intervention beyond nonoperative conservative medical management. While previous studies have generally found little association between surgical indication and outcome (49, 86), the focus on a single indication in this review allowed for a direct comparison of outcomes following spinal fusion and the IDET procedure. This report also has the advantage of providing results for both spinal fusion and the IDET procedure on a set of well-described clinical outcomes including pain severity, condition-specific functional impairment and health-related quality of life that previous reviews have not included (81, 87).

It remains unclear whether spinal fusion provides an advantage over conservative medical management with respect to symptomatic improvement among patients with intractable discogenic low back pain. The two randomized controlled trials comparing spinal fusion with conservative management provided conflicting findings in this regard for both pain severity and functional impairment of the back (31, 37). The subjects in these trials were unblinded to treatment assignment, subjecting them to ascertainment bias. This methodological shortcoming reduced the quality rating of these studies. Inadequate treatment allocation concealment and lack of double blinding can substantially inflate treatment effects, particularly with respect to psychologically-linked and subjective outcomes such as the perception of pain, its severity and the degree of associated functional impairment (88-90). Thus, it is impossible to estimate the contribution of nonspecific study effects, particularly placebo effect, on the reported improvements realized with spinal fusion (91). This may also explain, in large part, the often weak association shown between symptomatic improvement and whether the fusion surgery was technically successful in achieving a solid arthrodesis (91).

Previous reviews of the clinical literature regarding the IDET procedure have noted encouraging findings but cautioned that lack of controlled trials prevented definitive conclusions regarding treatment effectiveness (92, 93). Both randomized controlled trials of the IDET procedure included in this review were methodologically sound with appropriate treatment allocation concealment and the successful execution of a blinded sham control. Indeed, Pauza et al (62) reported that patients in either study group were unable to accurately guess whether they received the true intervention or the sham. Consequently, a placebo response amounting to an approximate 20% reduction in pain severity was demonstrated in this study. Nonetheless, Pauza et al (62) showed a significant improvement in back pain severity and functional impairment beyond the placebo response.

In sharp contrast, Freeman et al (63) failed to demonstrate either a treatment or a placebo response in their sham-controlled trial of the IDET procedure. These idiosyncratic results are particularly notable given the large body of evidence describing an identifiable placebo effect associated with sham procedures where the primary outcomes involve subjectivity, such as pain severity and its surrogates (91). It is plausible that inappropriate patient selection criteria may explain these

### Table 4. Summary of Percentage Improvement in Outcomes by Study Design for each Treatment Type

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Spinal Fusion</th>
<th>IDET</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>no. of 18</td>
<td>no. of 33</td>
</tr>
<tr>
<td></td>
<td>median (range)</td>
<td>median (range)</td>
</tr>
<tr>
<td>Pain Severity</td>
<td>RCT 6 36 (30-77)</td>
<td>1 36 (NA)</td>
</tr>
<tr>
<td></td>
<td>NCT 1 NA (37-52)</td>
<td>2 63 (NA)</td>
</tr>
<tr>
<td></td>
<td>BA 8 61 (42-75)</td>
<td>8 50 (22-71)</td>
</tr>
<tr>
<td></td>
<td>CS 11 53 (24-62)</td>
<td>1 64 (NA)</td>
</tr>
<tr>
<td>Back-Specific Impairment</td>
<td>RCT 8 40 (17-73)</td>
<td>2 20 (4-35)</td>
</tr>
<tr>
<td></td>
<td>NCT 1 NA (39-54)</td>
<td>0 NA</td>
</tr>
<tr>
<td></td>
<td>BA 2 NA (58-77)</td>
<td>3 14 (7-24)</td>
</tr>
<tr>
<td></td>
<td>CS 6 42 (17-49)</td>
<td>0 NA</td>
</tr>
<tr>
<td>Quality of Life</td>
<td>RCT 5 43 (21-123)</td>
<td>2 17 (7-27)</td>
</tr>
<tr>
<td></td>
<td>NCT 0 NA</td>
<td>0 NA</td>
</tr>
<tr>
<td></td>
<td>BA 1 110 (NA)</td>
<td>6 49 (22-76)</td>
</tr>
<tr>
<td></td>
<td>CS 0 NA</td>
<td>0 NA</td>
</tr>
</tbody>
</table>

NA, not applicable.
- Categorized by study design: RCT indicates randomized control trial; NCT, nonrandomized control trial; BA, prospective before-after trial; CS, retrospective case series.
- IDET indicates intradiscal electrothermal therapy.
- Measured by visual analog scale (VAS).
- Measured by Oswestry disability index.
- Measured by either SF-36 physical functioning domain or physical component summary score.
findings. Specifically, study subjects had markedly severe disc degeneration with up to 50% disc height loss, full thickness annular tears, and a maximum duration of symptoms of 20 years. Also, greater than 50% of the subjects were recipients of worker’s compensation, a group with a notoriously high rate of recidivism and poor outcomes (94). The IDET procedure is considered more appropriate in the acute phase of injury with pain localized to the annulus and not the endplates or facet joints, as commonly occurs with advanced disc degeneration (75).

Spinal fusion is a complex and arduous surgical intervention. This review found that perioperative complications occur frequently. Deyo et al (95, 96) estimated that the complication rate associated with fusion surgery was more than 2 times greater than for back surgery without fusion. Likewise, in a randomized controlled trial, Fritzell et al (97) reported a relatively high complication rate for instrumented PLF (22%) and CF (40%) with a significantly lower complication rate among subjects treated with uninstrumented PLF (12%). In sharp contrast, this review found few complications associated with the IDET procedure with most studies reporting no adverse events at all. There have been several isolated case reports of IDET-related complications which included a herniated disc (98), cauda equina syndrome (99, 100) and vertebral osteonecrosis (101, 102).

IDET is a minimally-invasive percutaneous procedure that has the advantage of preserving the native disc structure (103). Consequently, undergoing the IDET procedure does not eliminate the possibility for surgery at a later time if severe symptoms persist. However, among a subset of properly selected chronic back pain sufferers with definitive imaging and discographic evidence of internal disc disruption, the IDET procedure may obviate the need for surgery completely.

The overall median percentage of patients exhibiting a clinically significant 2-point reduction in pain severity in this synthesis was 65%. In a randomized controlled trial, Pauza et al (62) likewise found that 56% of subjects treated with the IDET procedure reported a reduction in pain severity of at least 2 points. In this same trial, 22% of IDET subjects reported a 75% or greater pain severity reduction with 9% of subjects reported to be pain free. In a non-randomized controlled trial, Bogduk and Karasek (65) reported that 20% of patients were pain free 24 months after treatment with the IDET procedure. The 36-month follow-up in a registry of approximately 400 patients treated with IDET showed that only 17% of patients required spinal fusion surgery due to persistent symptoms (104). Assuming a clinically relevant reduction in pain severity following the IDET procedure would obviate the need for spinal fusion, it could be postulated that between 56% and 65% of properly selected patients with intractable discogenic low back pain would be spared fusion surgery with its attendant costs, complications and risks.

The direct periprocedural costs associated with the IDET procedure have been estimated at $7,000 US (77). In contrast, estimates of the direct perioperative costs associated with spinal fusion have been reported in excess of $50,000 US with more complex procedures involving greater costs (105, 106). Importantly, these estimates do not include costs associated with the management of postoperative complications which can be substantial in spinal fusion. Thus, based on the comparable clinical improvements realized with either spinal fusion or the IDET procedure, particularly with respect to pain severity and functional impairment, and with the estimate that more than half of IDET-treated patients could avoid surgery, it may be prudent to offer the IDET procedure prior to spinal fusion among all patients who meet strict eligibility criteria for this procedure.

ACKNOWLEDGMENT

This study was supported, in part, by Smith & Nephew Endoscopy (Andover, MA).

AUTHOR AFFILIATION:

Gunnar J. Andersson, MD, PhD
Professor and Chairman
Department of Orthopedic Surgery
Rush University Medical Center
1653 West Congress Parkway
Chicago, IL  60612
Gunnar_Andersson@rush.edu

Nagy A. Mekhail, MD, PhD
Chairman
Department of Pain Management
Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44195
MEKHAIN@ccf.org

Jon E. Block, PhD
2210 Jackson Street, Suite 401
San Francisco, CA 94115
jonblock@jonblockphd.com

REFERENCES

7. Kuslich SD, Ulstrom CL, Michael CJ. The


Andersson et al • A Systematic Review of Spinal Fusion and IDET


77. Endres SM, Fiedler GA, Larson KL. Effectiveness of intradiscal electrothermal therapy in increasing function and reducing chronic low back pain in selected patients. WMJ 2002;101:31-34.


