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A Systematic Review

Treatment Of Intractable Discogenic Low Back Pain. A Systematic Review Of Spinal Fusion And Intradiscal Electrothermal Therapy (IDET)

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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 reviewed 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 trial, 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.

Almost every individual, at some point in life, will suffer an episode of low back pain of sufficient severity to disrupt normal daily activities including work and recreation (1). Fortunately, the vast majority of patients will experience complete symptom amelioration with time and conservative medical management (2). Even refractory cases of severe back pain respond reasonably well to intensive nonoperative multidisciplinary management (3). However, approximately 5% of patients will continue to experience severe pain and functional impairment chronically (4). Almost 90% of the health care costs for low back pain are consumed by this group of patients with intractable pain (5).

A number of biomechanical and neurologic components have been putatively implicated in the etiology of chronic low back pain (6, 7). Internal disc disruption is associated directly with chronic pain in an estimated 40% of patients reporting persistent symptoms of unknown origin (8). Posterior annular fissuring, the delamination and degeneration of the intervertebral disc, in particular, is a potential cause of back pain because mechanical loading to areas of degenerated and disrupted lamellae causes sensitization of the annular receptors (9, 10). Histological studies suggest that in response to disc degeneration and lamellar disruption, neovascularization, neuronal penetration with unmyelinated nerve fibers, and ingrowth of Schwann cells occur (11-13). It has been observed that at least a portion of this neoinnervation provides a sensory function, potentially acting as a pain generator (12, 13).

Patients with chronic, intractable low back pain of discogenic origin often must face the harsh reality that the prognosis for recovery with conservative, nonoperative management alone is not good (4, 14, 15). Consequently, this patient group is confronted with the option of living with persistent back pain and possible narcotic dependency or electing to undergo open surgical spinal fusion. A number of fusion procedures are available for treatment of degenerative disc disease (16-19). Because the intervertebral disc is often the primary source of pain in these patients, a

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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 nonoperative 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 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 (28).

Data Extraction

All studies were classified as follows: randomized controlled trial, nonrandomized 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 (360°) (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.

Table 1. *Summary of Selected Demographic and Study-Related Characteristics*

Characteristic	Spinal Fusion			IDET*		
	no. of 33	**median**	(range)	no. of 18	**median**	(range)
Age (years)	32	**44**	(37-58)	16	**41**	(35-45)
Female (%)	30	**47**	(24-92)	18	**47**	(13-59)
Duration of Symptoms (months)	20	**43**	(3-115)	16	**38**	(6-92)
Length of Follow-up (months)	33	**24**	(12-68)	18	**12**	(3-28)

IDET indicates intradiscal electrothermal therapy.

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*

Reference	Study Characteristics				Outcome[§]	Baseline Value	Final Follow-up Value	Δ from Baseline			% GE[‖]	% AE[¶]
	Design[*]	Indication[†]	Procedure[‡]	Sample Size				value	(%)	P value		
France et al 1999	RCT J.S. = 1	DDD	PLF PLF[#]	41 42	PS	NR NR	4.0 4.0	NR NR		NS	63 73	NR
Boden et al 2000	RCT J.S. = 3	DDD	ALIF[**] ALIF[††]	11 3	OS	39 35	14 20	25 15	(64) (43)	.12	100 67	21
					SF	48 30	86 67	38 37	(79) (123)	NR		
Fritzell et al 2001	RCT J.S. = 3	DDD/DH	V CM	222 72	PS	64 63	43 58	21 5	(33) (8)	.0002	NR	17
					OS	47 48	36 46	11 2	(24) (6)	.015		
Boden et al 2002	RCT J.S. = 2	DDD	PLF[††] PLF[**] PLF[**#]	5 11 9	PS	17 16 13	11 11 3	6 5 10	(35) (31) (77)	.025	60 60 100	12
					OS	54 49 40	31 36 11	23 13 29	(43) (27) (73)	NR		
					SF[‡‡]	26 29 31	32 35 48	6 6 17	(23) (21) (55)	.07		
Burkus et al 2002	RCT J.S. = 2	DDD	ALIF[**] ALIF[††]	143 136	PS	16 16	7 8	9 8	(56) (50)	NR	NR	10
					OS	54 55	24 24	29 30	(54) (55)	NR		
Burkus et al 2002	RCT J.S. = 2	DDD	ALIF[**] ALIF[††]	24 22	PS	16.3 16.3	7.4 10.9	9 5	(56) (31)	.05	83 55	4 18
					OS	52 55	19 33	33 22	(63) (40)	.04		
					SF[‡‡]	30 30	45 40	15 10	(50) (33)	NS		
Fritzell et al 2002	RCT J.S. = 3	DDD	PLF[#] PLF CF	73 74 75	PS	64 63 66	45 40 46	19 23 20	(30) (36) (30)	NS	41 50 46	6 16 31
					OS	47 48 47	37 34 39	10 14 8	(21) (29) (17)	NS		
Gibson et al 2002	RCT J.S. = 1	DDD	PLF[††] PLF[§§]	32 37	RM	18 17	11 15	7 2	(39) (12)	.04	NR	NR
Ivar Brox et al 2003	RCT J.S. = 3	CNLBP/ DDD	PLF CM	37 27	PS	62 64	39 49	23 15	(37) (23)	.14	NR	18
					OS	42 43	26 30	16 13	(38) (30)	.33		
Sasso et al 2004	RCT J.S. = 2	DDD	ALIF[‖‖] ALIF[§§]	77 62	OS	51 53	30 32	21 21	(41) (40)	NS	NR	44 36
					SF[‡‡]	28 29	40 37	12 8	(43) (28)	NS		
Madan et al 2003	NCT	IDD	PLF PLIF	36 35	PS	8.4 8.4	5.3 4	3.1 4.4	(37) (52)	NS	64 80	8 11
					OS	64 67	39 31	25 36	(39) (54)	NS		
Gertzbein et al 1996	BA	DDD	CF	67	PS	7.1	2.1	5	(70)	.006	NR	10
Hall et al 1996	BA	DDD	PLF	120	PS	NR	NR	2.6	NR	<.0001	65	13
Kuslich et al 1998	BA	DDD	ALIF/PLIF	947	PS	5.0	2.9	2.1	(42)	.001	NR	2
Simmons et al 1998	BA	DDD	PLF	213	PS	3.7	2.0	1.7	(46)	<.0001	NR	22

Table 2 continued to p. 171.

Table 2 continued

Reference	Study Characteristics				Outcome[§]	Baseline Value	Final Follow-up Value	Δ from Baseline			% GE[‖]	% AE[¶]
	Design[*]	Indication[†]	Procedure[‡]	Sample Size				value	(%)	P value		
Kuslich et al 2000	BA	DDD	ALIF/PLIF	196	PS	5.1	2.8	2.3	(45)	<.05	NR	14
Kleeman et al 2001	BA	DDD	ALIF	22	PS OS SF	7.7 47 40	1.9 11 84	5.8 36 44	(75) (77) (110)	<.001 <.001 NR	NR	9
Lowe et al 2002	BA	DDD/DH	PLIF	40	PS	8.3	3.2	5.1	(61)	<.0001	80	10
Pellise et al 2002	BA	DDD	ALIF	12	PS	7.2	2.2	5	(69)	<.01	92	NR
Folman et al 2003	BA	DDD	PLIF	87	PS OS	8.5 31	3.3 13	5.2 18	(61) (58)	<.01 <.01	NR	3
Buttermann et al 1998	CS	DDD	V	35	PS OS	8.5 63	4.5 32	4 31	(47) (49)	<.05 <.05	NR	NR
Gertzbein et al 1998	CS	DDD	CF	51	PS	7.4	4.4	3	(41)	<.001	17	27
Grob and Humke 1998	CS	IDD/DH	PLF	173	PS	7.6	2.9	4.7	(62)	NR	76	10
Humke et al 1998	CS	DH	PLF	173	PS	7.6	2.9	4.7	(62)	NR	76	10
Whitecloud et al 1998	CS	DDD	CF	35	PS	7.2	5.5	1.7	(24)	.0002	NR	54
Leufven and Nordwall 1999	CS	DDD	PLIF	29	PS	8.6	4.0	4.6	(53)	<.001	52	7
Tandon et al 1999	CS	CNLBP	PLIF	53	OS	51	39	12	(24)	<.001	NR	13
Barrick et al 2000	CS	DDD/DH	ALIF	18	PS OS	7.9 56	4.7 48	3.2 8	(41) (17)	<.001 .03	NR	NR
Thalgott et al 2000	CS	DDD/IDD	CF	46	PS	NR	NR	NR	(56)	NR	76	NR
Madan and Boeree 2001	CS	DDD	ALIF	27	PS OS	8.2 60	4.1 34	4.1 26	(50) (43)	<.0001 <.0001	NR	11
Thalgott et al 2002	CS	DDD/IDD	ALIF	50	PS	8.9	3.8	5.1	(57)	NR	90	16
Thalgott et al 2002	CS	DDD	CF	20	PS OS	8.9 64	3.4 35	5.5 29	(62) (45)	NR	80	15
Beutler and Peppelman 2003	CS	DDD	ALIF	104	OS	58	34	24	(41)	NR	NR	NR

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.

groups), ALIF (median: 43%, range: 17% to 77%, n=12 study groups), and CF (median: 31%, range: 17% to 45%, n=2 study groups). There were too few studies reporting SF-36 results to subcategorize the findings by spinal fusion procedure.

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*

Reference	Study Characteristics				Outcome§	Baseline Value	Final Follow-up Value	Δ from Baseline			% Δ PS ≥ 2 points‖	% AE¶
	Design*	Indication†	Procedure‡	Sample Size				value	(%)	p value		
Pauza et al 2004	RCT	IDD	SC	37	PS	6.6	4.2	2.4	(36)	.045	56	0
	J.S. = 5		sSC	27		6.5	5.4	1.1	(17)			
					OS	31	20	11	(35)	.05		
						33	28	4	(12)			
					SF	56	71	15	(27)	.55		
						49	60	11	(22)			
Freeman et al 2005	RCT	DDD	SC	38	OS	41	40	1	(4)	.5	NR	0
	J.S. = 5		sSC	19		41	42	1	(2)			
					SF	42	45	3	(7)	.8		
						35	37	2	(6)			
Karasek and Bogduk 2000	NCT	IDD	SC	36	PS	8.0	3.0	5	(63)	<.0001	NR	0
			CM	17		8.0	8.0	0	(0)			
Bogduk and Karasek 2002	NCT	IDD	SC	36	PS	8.0	3.0	5	(63)	.03	***NR***	0
			CM	17		8.0	7.5	.5	(6)			
Derby et al 2000	BA	IDD/DDD	SC	32	PS	***NR***	***NR***	1.84	***NR***	NR	***NR***	0
					RM	***NR***	***NR***	4.03	***NR***	NR		
Saal and Saal 2000	BA	CNLBP	SC	62	PS	6.6	3.7	3.0	(45)	<.001	***NR***	0
					SF	39	59	20	(51)	<.001		
Saal and Saal 2000	BA	CNLBP	SC	25	PS	7.3	3.6	3.7	(51)	<.0001	***NR***	0
					SF	40	55	15	(38)	.001		
Singh 2000	BA	IDD	SC	21	PS	6.2	3.9	2.3	(37)	.0001	***NR***	***NR***
Welch et al 2001	BA	DDD	SC	23	OS	34	26	8	(24)	NR	***NR***	8.6
					SF	31	47	16	(52)	NR		
Gerszten et al 2002	BA	DDD	SC	27	OS	34	30	4	(7)	NR	***NR***	0
					SF	32	47	15	(47)	NR		
Saal and Saal 2002	BA	CNLBP	SC	58	PS	6.6	3.4	3.2	(48)	.0001	72	0
					SF	41	72	31	(76)	<.0001		
Spruit and Jacobs 2002	BA	DDD	SC	20	PS	65	51	14	(22)	<.05	***NR***	***NR***
					OS	43	37	6	(14)	NS		
					SF	45	55	10	(22)	NS		
Lutz et al 2003	BA	CNLBP	SC	33	PS	7.5	3.9	3.9	(52)	<.001	70	0
					RM	13.9	6.6	7.3	(53)	<.001		
Kapural et al 2004	BA	DDD	SC	17	PS	7.4	2.5	4.9	(66)	<.001	***NR***	***NR***
Mekhail and Kapural 2004	BA	IDD	SC	32	PS	8.0	2.3	5.7	(71)	<.001	***NR***	***NR***
Endres et al 2002	CS	DDD	SC	54	PS	***NR***	***NR***	***NR***		<.001	65	0
Cohen et al 2003	CS	DDD	SC	79	PS	5.9	2.1	3.8	(64)	NR	***NR***	10
Freedman et al 2003	CS	CNLBP	SC	31	PS	***NR***	***NR***	***NR***		NR	52	16

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

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

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

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.

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

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 nonrandomized 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.

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References

1. Deyo RA, Cherkin D, Conrad D, Volinn E. Cost, controversy, crisis: low back pain and the health of the public. *Annu Rev Public Health* 1991;12:141-156.
2. Brodke DS, Ritter SM. Nonoperative management of low back pain and lumbar disc degeneration. *J Bone Joint Surg Am* 2004;86-A:1810-1818.
3. Guzman J, Esmail R, Karjalainen K, Malmivaara A, Irvin E, Bombardier C. Multidisciplinary rehabilitation for chronic low back pain: Systematic Review. *BMJ* 2001;322:1511-1516.
4. Carey TS, Garrett JM, Jackman AM. Beyond the good prognosis. Examination of an inception cohort of patients with chronic low back pain. *Spine* 2000;25:115-120.
5. Nachemson AL. Newest knowledge of low back pain. A critical look. *Clin Orthop* 1992;279:8-20.
6. Bogduk N. The lumbar disc and low back pain. *Neurosurg Clin N Am* 1991;2:791-806.
7. Kuslich SD, Ulstrom CL, Michael CJ. The

tissue origin of low back pain and sciatica: a report of pain response to tissue stimulation during operations on the lumbar Spine using local anesthesia. *Orthop Clin North Am* 1991;22:181-187.

8. Schwarzer AC, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. The prevalence and clinical features of internal disc disruption in patients with chronic low back pain. *Spine* 1995;20:1878-1883.
9. Osti OL, Vernon-Roberts B, Fraser RD. 1990 Volvo Award in experimental studies. Anulus tears and intervertebral disc degeneration. An experimental study using an animal model. *Spine* 1990;15:762-767.
10. Osti OL, Vernon-Roberts B, Moore R, Fraser RD. Annular tears and disc degeneration in the lumbar *Spine*. A postmortem study of 135 discs. *J Bone Joint Surg Br* 1992;74:678-682.
11. Coppes MH, Marani E, Thomeer RT, Groen GJ. Innervation of "painful" lumbar discs. *Spine* 1997;22:2342-2349.
12. Freemont AJ, Peacock TE, Goupille P, Hoyland JA, O'Brien J, Jayson MI. Nerve ingrowth into diseased intervertebral disc in chronic back pain. *Lancet* 1997;350:178-181.
13. Johnson WE, Evans H, Menage J, Eisenstein SM, El Haj A, Roberts S. Immunohistochemical detection of Schwann cells in innervated and vascularized human intervertebral discs. *Spine* 2001;26:2550-2557.
14. Rhyne AL, Smith SE, Wood KE, Darden BV. Outcome of unoperated discogram-positive low back pain. *Spine* 1995;20:1997-2000.
15. Wahlgren DR, Atkinson JH, Epping-Jordan JE, Williams RA, Pruitt SD, Klapow JC, Patterson TL, Grant I, Webster JS, Slater MA. One-year follow-up of first onset low back pain. *Pain* 1997;73:213-221.
16. Haid RW, Jr., Dickman CA. Instrumentation and fusion for discogenic disease of the lumbosacral *Spine*. *Neurosurg Clin N Am* 1993;4:135-148.
17. Herkowitz HN, Sidhu KS. Lumbar *Spine* fusion in the treatment of degenerative conditions: current indications and recommendations. *J Am Acad Orthop Surg* 1995;3:123-135.
18. Abraham DJ, Herkowitz HN, Katz JN. Indications for thoracic and lumbar *Spine* fusion and trends in use. *Orthop Clin North Am* 1998;29:803.
19. Nachemson A, Zdeblick TA, O'Brien JP. Lumbar disc disease with discogenic pain. What surgical treatment is most effective? *Spine* 1996;21:1835-1838.
20. McAfee PC. Interbody fusion cages in reconstructive operations on the Spine. *J Bone Joint Surg Am* 1999;81:859-880.
21. Hanley EN, Jr., David SM. Lumbar arthrodesis for the treatment of back pain. *J Bone Joint Surg Am* 1999;81:716-730.
22. Bridwell KH, Anderson PA, Boden SD, Vaccaro AR, Zigler JE. What's new in *Spine* surgery. *J Bone Joint Surg Am* 2004;86-A:1587-1596.
23. Saal JA, Saal JS. Intradiscal electrothermal therapy for the treatment of chronic discogenic low back pain. *Clin Sports Med* 2002;21:167-187.
24. Bono CM, Lee CK. Critical analysis of trends in fusion for degenerative disc disease over the past 20 years: influence of technique on fusion rate and clinical outcome. *Spine* 2004;29:455-463.
25. Barendse GA, van Den Berg SG, Kessels AH, Weber WE, van Kleef M. Randomized controlled trial of percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic back pain: lack of effect from a 90-second 70 C lesion. *Spine* 2001;26:287-292.
26. Ercelen O, Bulutcu E, Oktenoglu T, Sasani M, Bozkus H, Cetin Saryoglu A, Ozer F. Radiofrequency lesioning using two different time modalities for the treatment of lumbar discogenic pain: a randomized trial. *Spine* 2003;28:1922-1927.
27. van Kleef M, Barendse GA, Wilmink JT. Percutaneous intradiscal radio-frequency thermocoagulation in chronic non-specific low back pain. *Pain Clinic* 1996;9:259-268.
28. Houpt JC, Conner ES, McFarland EW. Experimental study of temperature distributions and thermal transport during radiofrequency current therapy of the intervertebral disc. *Spine* 1996;21:1808-1812.
29. France JC, Yaszemski MJ, Lauerman WC, Cain JE, Glover JM, Lawson KJ, Coe JD, Topper SM. A randomized prospective study of posterolateral lumbar fusion. Outcomes with and without pedicle screw instrumentation. *Spine* 1999;24:553-560.
30. Boden SD, Zdeblick TA, Sandhu HS, Heim SE. The use of rhBMP-2 in interbody fusion cages. Definitive evidence of osteoinduction in humans: a preliminary report. *Spine* 2000;25:376-381.
31. Fritzell P, Hagg O, Wessberg P, Nordwall A. 2001 Volvo Award Winner in Clinical Studies: Lumbar fusion versus nonsurgical treatment for chronic low back pain: a multicenter randomized controlled trial from the Swedish Lumbar Spine Study Group. *Spine* 2001;26:2521-2532.
32. Boden SD, Kang J, Sandhu H, Heller JG. Use of recombinant human bone morphogenetic protein-2 to achieve posterolateral lumbar Spine fusion in humans: a prospective, randomized clinical pilot trial: 2002 Volvo Award in clinical studies. *Spine* 2002;27:2662-2673.
33. Burkus JK, Gornet MF, Dickman CA, Zdeblick TA. Anterior lumbar interbody fusion using rhBMP-2 with tapered interbody cages. *J Spinal Disord Tech* 2002;15:337-349.
34. Burkus JK, Transfeldt EE, Kitchel SH, Watkins RG, Balderston RA. Clinical and radiographic outcomes of anterior lumbar interbody fusion using recombinant human bone morphogenetic protein-2. *Spine* 2002;27:2396-2408.
35. Fritzell P, Hagg O, Wessberg P, Nordwall A. Chronic low back pain and fusion: a comparison of three surgical techniques: a prospective multicenter randomized study from the Swedish lumbar Spine study group. *Spine* 2002;27:1131-1141.
36. Gibson S, McLeod I, Wardlaw D, Urbaniak S. Allograft versus autograft in instrumented posterolateral lumbar spinal fusion: a randomized control trial. *Spine* 2002;27:1599-1603.
37. Ivar Brox J, Sorensen R, Friis A, Nygaard O, Indahl A, Keller A, Ingebrigtsen T, Eriksen HR, Holm I, Koller AK, Riise R, Reikeras O. Randomized clinical trial of lumbar instrumented fusion and cognitive intervention and exercises in patients with chronic low back pain and disc degeneration. *Spine* 2003;28:1913-1921.
38. Sasso RC, Kitchel SH, Dawson EG. A prospective, randomized controlled clinical trial of anterior lumbar interbody fusion using a titanium cylindrical threaded fusion device. *Spine* 2004;29:113-122.
39. Madan SS, Harley JM, Boeree NR. Circumferential and posterolateral fusion for lumbar disc disease. *Clin Orthop* 2003;409:114-123.
40. Gertzbein SD, Betz R, Clements D, Errico T, Hammerberg K, Robbins S, Shepherd E, Weber A, Kerina M, Albin J, Wolk D, Ensor K. Semirigid instrumentation in the management of lumbar spinal conditions combined with circumferential fusion. A multicenter study. *Spine* 1996;21:1918-1925.
41. Hall BB, Asher MA, Zang RH, Quinn LM. The safety and efficacy of the Isola Spinal Implant System for the surgical treatment of degenerative disc disease. A prospective study. *Spine* 1996;21:982-994.
42. Kuslich SD, Ulstrom CL, Griffith SL, Ahern JW, Dowdle JD. The Bagby and Kuslich method of lumbar interbody fusion. History, techniques, and 2-year follow-up results of a United States

prospective, multicenter trial. *Spine* 1998;23:1267-1278.

43. Kuslich SD, Danielson G, Dowdle JD, Sherman J, Fredrickson B, Yuan H, Griffith SL. Four-year follow-up results of lumbar Spine arthrodesis using the Bagby and Kuslich lumbar fusion cage. *Spine* 2000;25:2656-2662.
44. Simmons JW, Andersson GB, Russell GS, Hadjipavlou AG. A prospective study of 342 patients using transpedicular fixation instrumentation for lumbosacral Spine arthrodesis. *J Spinal Disord* 1998;11:367-374.
45. Kleeman TJ, Michael Ahn U, Talbot-Kleeman A. Laparoscopic Anterior Lumbar Interbody Fusion With rhBMP-2: A Prospective Study of Clinical and Radiographic Outcomes. *Spine* 2001;26:2751-2756.
46. Lowe TG, Tahernia AD, O'Brien MF, Smith DA. Unilateral transforaminal posterior lumbar interbody fusion (TLIF): indications, technique, and 2-year results. *J Spinal Disord Tech* 2002;15:31-38.
47. Pellise F, Puig O, Rivas A, Bago J, Villanueva C. Low fusion rate after L5-S1 laparoscopic anterior lumbar interbody fusion using twin stand-alone carbon fiber cages. *Spine* 2002;27:1665-1669.
48. Folman Y, Lee SH, Silvera JR, Gepstein R. Posterior lumbar interbody fusion for degenerative disc disease using a minimally invasive B-twin expandable spinal spacer: a multicenter study. *J Spinal Disord Tech* 2003;16:455-460.
49. Buttermann GR, Garvey TA, Hunt AF, Transfeldt EE, Bradford DS, Boachie-Adjei O, Ogilvie JW. Lumbar fusion results related to diagnosis. *Spine* 1998;23:116-127.
50. Gertzbein SD, Hollopeter M, Hall SD. Analysis of circumferential lumbar fusion outcome in the treatment of degenerative disc disease of the lumbar Spine. *J Spinal Disord* 1998;11:472-478.
51. Grob D, Humke T. Translaminar screw fixation in the lumbar Spine: technique, indications, results. *Eur Spine* J 1998;7:178-186.
52. Humke T, Grob D, Dvorak J, Messikommer A. Translaminar screw fixation of the lumbar and lumbosacral Spine. A 5-year follow-up. *Spine* 1998;23:1180-1184.
53. Whitecloud TS, 3rd, Castro FP, Jr., Brinker MR, Hartzog CW, Jr., Ricciardi JE, Hill C. Degenerative conditions of the lumbar *Spine* treated with intervertebral titanium cages and posterior instrumentation for circumferential fusion. *J Spinal Disord* 1998;11:479-486.
54. Leufven C, Nordwall A. Management of chronic disabling low back pain with 360 degrees fusion. Results from pain provocation test and concurrent posterior lumbar interbody fusion, posterolateral fusion, and pedicle screw instrumentation in patients with chronic disabling low back pain. *Spine* 1999;24:2042-2045.
55. Tandon V, Campbell F, Ross ER. Posterior lumbar interbody fusion. Association between disability and psychological disturbance in noncompensation patients. *Spine* 1999;24:1833-1838.
56. Barrick WT, Schofferman JA, Reynolds JB, Goldthwaite ND, McKeehen M, Keaney D, White AH. Anterior lumbar fusion improves discogenic pain at levels of prior posterolateral fusion. *Spine* 2000;25:853-857.
57. Thalgott JS, Chin AK, Ameriks JA, Jordan FT, Giuffre JM, Fritts K, Timlin M. Minimally invasive 360 degrees instrumented lumbar fusion. Eur *Spine* J 2000;9 Suppl 1:S51-56.
58. Thalgott JS, Giuffre JM, Klezl Z, Timlin M. Anterior lumbar interbody fusion with titanium mesh cages, coralline hydroxyapatite, and demineralized bone matrix as part of a circumferential fusion. *Spine* J 2002;2:63-69.
59. Thalgott JS, Klezl Z, Timlin M, Giuffre JM. Anterior lumbar interbody fusion with processed sea coral (coralline hydroxyapatite) as part of a circumferential fusion. *Spine* 2002;27:E518-525.
60. Madan S, Boeree NR. Containment and stabilization of bone graft in anterior lumbar interbody fusion: the role of the Hartshill Horseshoe cage. *J Spinal Disord* 2001;14:104-108.
61. Beutler WJ, Peppelman WC, Jr. Anterior lumbar fusion with paired BAK standard and paired BAK Proximity cages: subsidence incidence, subsidence factors, and clinical outcome. *Spine* J 2003;3:289-293.
62. Pauza KJ, Howell S, Dreyfuss P, Peloza JH, Dawson K, Bogduk N. A randomized, placebo-controlled trial of intradiscal electrothermal therapy for the treatment of discogenic low back pain. *Spine* J 2004;4:27-35.
63. Freeman BJ, Fraser RD, Cain CM, Hall DJ, Chapple DC. A randomized, double-blind, controlled trial: intradiscal electrothermal therapy versus placebo for the treatment of chronic discogenic low back pain. *Spine* 2005;30:2369-2377.
64. Karasek M, Bogduk N. Twelve-month follow-up of a controlled trial of intradiscal thermal anuloplasty for back pain due to internal disc disruption. *Spine* 2000;25:2601-2607.
65. Bogduk N, Karasek M. Two-year follow-up of a controlled trial of intradiscal electrothermal anuloplasty for chronic low back pain resulting from internal disc disruption. *Spine* J 2002;2:343-350.
66. Derby R, Eek B, Chen Y, O'Neill C, Ryan D. Intradiscal electrothermal annuloplasty (IDET): A novel approach for treating chronic discogenic back pain. *Neuromodulation* 2000;3:82-88.
67. Saal JS, Saal JA. Management of chronic discogenic low back pain with a thermal intradiscal catheter. A preliminary report. *Spine* 2000;25:382-388.
68. Saal JA, Saal JS. Intradiscal electrothermal treatment for chronic discogenic low back pain: a prospective outcome study with minimum 1-year follow-up. *Spine* 2000;25:2622-2627.
69. Singh V. Intradiscal electrothermal therapy: a preliminary report. *Pain Physician* 2000;3:367-373.
70. Welch WC, Gerszten PC, McGrath P. Intradiscal electrothermy: indications, techniques, and clinical results. *Clin Neurosurg* 2001;48:219-225.
71. Gerszten PC, Welch WC, McGrath PM. A prospective outcomes study of patients undergoing intradiscal electrothermy (IDET) for chronic low back pain. *Pain Physician* 2002;5:360-364.
72. Saal JA, Saal JS. Intradiscal electrothermal treatment for chronic discogenic low back pain: prospective outcome study with a minimum 2-year follow-up. *Spine* 2002;27:966-973.
73. Spruit M, Jacobs WC. Pain and function after intradiscal electrothermal treatment (IDET) for symptomatic lumbar disc degeneration. *Eur Spine* J 2002;11:589-593.
74. Lutz C, Lutz GE, Cooke PM. Treatment of chronic lumbar diskogenic pain with intradiskal electrothermal therapy: a prospective outcome study. *Arch Phys Med Rehabil* 2003;84:23-28.
75. Kapural L, Mekhail N, Korunda Z, Basali A. Intradiscal thermal annuloplasty for the treatment of lumbar discogenic pain in patients with multilevel degenerative disc disease. *Anesth Analg* 2004;99:472-476.
76. Mekhail N, Kapural L. Intradiscal thermal annuloplasty for discogenic pain: an outcome study. *Pain Practice* 2004;4:84-90.
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.
78. Cohen SP, Larkin T, Abdi S, Chang A, Stojanovic M. Risk factors for failure and complications of intradiscal electrothermal therapy: a pilot study. *Spine* 2003;28:1142-1147.
79. Freedman BA, Cohen SP, Kuklo TR,

Lehman RA, Larkin P, Giuliani JR. Intradiscal electrothermal therapy (IDET) for chronic low back pain in active-duty soldiers: 2-year follow-up. *Spine* J 2003;3:502-509.

80. Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, McQuay HJ. Assessing the quality of reports of randomized clinical trials: is blinding necessary? *Control Clin Trials* 1996;17:1-12.
81. Deyo RA, Battie M, Beurskens AJ, Bombardier C, Croft P, Koes B, Malmivaara A, Roland M, Von Korff M, Waddell G. Outcome measures for low back pain research. A proposal for standardized use. *Spine* 1998;23:2003-2013.
82. Bombardier C. Outcome assessments in the evaluation of treatment of spinal disorders: summary and general recommendations. *Spine* 2000;25:3100-3103.
83. Greenough CG. Outcome of fusion: assessment techniques and comparison of anterior fusion with posterolateral fusion. *Bull Hosp Jt Dis* 1996;55:162-165.
84. Hagg O, Fritzell P, Nordwall A. The clinical importance of changes in outcome scores after treatment for chronic low back pain. *Eur Spine* J 2003;12:12-20.
85. Little DG, MacDonald D. The use of the percentage change in Oswestry Disability Index score as an outcome measure in lumbar spinal surgery. *Spine* 1994;19:2139-2143.
86. Turner JA, Ersek M, Herron L, Haselkorn J, Kent D, Ciol MA, Deyo R. Patient outcomes after lumbar spinal fusions. *JAMA* 1992;268:907-911.
87. Deyo RA, Andersson G, Bombardier C, Cherkin DC, Keller RB, Lee CK, Liang MH, Lipscomb B, Shekelle P, Spratt KF, Weinstein J.N. Outcome measures for studying patients with low back pain. *Spine* 1994;19:2032S-2036S.
88. Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne D, Gotzsche PC, Lang T. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med* 2001;134:663-694.
89. Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *JAMA* 1995;273:408-412.
90. Schulz KF, Chalmers I, Altman DG. The landscape and lexicon of blinding in randomized trials. *Ann Intern Med* 2002;136:254-259.
91. Turner JA, Deyo RA, Loeser JD, Von Korff M, Fordyce WE. The importance of placebo effects in pain treatment and research. *JAMA* 1994;271:1609-1614.
92. Wetzel FT, McNally TA, Phillips FM. Intradiscal electrothermal therapy used to manage chronic discogenic low back pain: new directions and interventions. *Spine* 2002;27:2621-2626.
93. Biyani A, Andersson GB, Chaudhary H, An HS. Intradiscal electrothermal therapy: a treatment option in patients with internal disc disruption. *Spine* 2003;28: S8-14.
94. Webster BS, Verma S, Pransky GS. Outcomes of workers' compensation claimants with low back pain undergoing intradiscal electrothermal therapy. *Spine* 2004;29:435-441.
95. Deyo RA, Cherkin DC, Loeser JD, Bigos SJ, Ciol MA. Morbidity and mortality in association with operations on the lumbar Spine. The influence of age, diagnosis, and procedure. *J Bone Joint Surg Am* 1992;74:536-543.
96. Deyo RA, Ciol MA, Cherkin DC, Loeser JD, Bigos SJ. Lumbar spinal fusion. A cohort study of complications, reoperations, and resource use in the Medicare population. *Spine* 1993;18:1463-1470.
97. Fritzell P, Hagg O, Nordwall A. Complications in lumbar fusion surgery for chronic low back pain: comparison of three surgical techniques used in a prospective randomized study. A report from the Swedish Lumbar Spine Study Group. *Eur Spine* J 2003;12:178-189.
98. Cohen SP, Larkin T, Polly DW, Jr. A giant herniated disc following intradiscal electrothermal therapy. *J Spinal Disord Tech* 2002;15:537-541.
99. Ackerman WE, 3rd. Cauda equina syndrome after intradiscal electrothermal therapy. *Reg Anesth Pain Med* 2002;27:622.
100. Hsia AW, Isaac K, Katz JS. Cauda equina syndrome from intradiscal electrothermal therapy. *Neurology* 2000;55:320.
101. Djurasovic M, Glassman SD, Dimar JR, 2nd, Johnson JR. Vertebral osteonecrosis associated with the use of intradiscal electrothermal therapy: a case report. *Spine* 2002;27:E325-328.
102. Scholl BM, Theiss SM, Lopez-Ben R, Kraft M. Vertebral osteonecrosis related to intradiscal electrothermal therapy: a case report. *Spine* 2003;28:E161-164.
103. Mochida J, Nishimura K, Nomura T, Toh E, Chiba M. The importance of preserving disc structure in surgical approaches to lumbar disc herniation. *Spine* 1996;21:1556-1563.
104. Dawson KS. The use of patient registries to measure effectiveness: a case study. Paper presented at: International Spinal Injection Society; September 9 - 11, 2004, 2004; Maui, Hawaii.
105. Hacker RJ. Comparison of interbody fusion approaches for disabling low back pain. *Spine* 1997;22:660-665.
106. Ray CD. Threaded fusion cages for lumbar interbody fusions. An economic comparison with 360 degrees fusions. *Spine* 1997;22:681-685.