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Evidence-informed management of chronic low back pain with minimally invasive nuclear decompression

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Abstract **EDITORS' PREFACE:** The management of chronic low back pain (CLBP) has proven very challenging in North America, as evidenced by its mounting socioeconomic burden. Choosing among available nonsurgical therapies can be overwhelming for many stakeholders, including patients, health providers, policy makers, and third-party payers. Although all parties share a common goal and wish to use limited health-care resources to support interventions most likely to result in clinically meaningful improvements, there is often uncertainty about the most appropriate intervention for a particular patient. To help understand and evaluate the various commonly used nonsurgical approaches to CLBP, the North American Spine Society has sponsored this special focus issue of *The Spine Journal*, titled Evidence Informed Management of Chronic Low Back Pain Without Surgery. Articles in this special focus issue were contributed by leading spine practitioners and researchers, who were invited to summarize the best available evidence for a particular intervention and encouraged to make this information accessible to nonexperts. Each of the articles contains five sections (description, theory, evidence of efficacy, harms, and summary) with common subheadings to facilitate comparison across the 24 different interventions profiled in this special focus issue, blending narrative and systematic review methodology as deemed appropriate by the authors. It is hoped that articles in this special focus issue will be informative and aid in decision making for the many stakeholders evaluating nonsurgical interventions for CLBP.

Keywords: Discogenic pain; Minimally invasive nuclear decompression; Chronic low back pain

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Description

History

Although advances in imaging and improved understanding of its innervation have been helpful in identifying the intervertebral disc as a potential source of chronic low back pain (CLBP) in many patients, innovative new treatments aimed at the disc have not improved clinical outcomes. This failure is perhaps the result of the lack of agreement in methods used to diagnose discogenic pain. However, there has been a gradual shift toward less invasive treatments for discogenic pain in recent decades including chymopapain, automated percutaneous disc decompression, and laser nuclear decompressions. More recently, there have been attempts to develop interventions using thermal treatment of the disc. Such methods include intradiscal electrothermal annuloplasty (IDET) and intradiscal radiofrequency treatment—reviewed elsewhere in this supplement—and minimally invasive nuclear decompression using a bipolar radiofrequency device. This review will focus exclusively on the latter method.

General description

A minimally invasive bipolar radiofrequency device for vaporizing disc nucleus was introduced by ArthroCare (Sunnyvale, CA). The technique, named disc nucleoplasty, was patterned after existing devices for knee debridement

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FDA device/drug status: approved for this indication (Smith and Nephew SpineCath and Acutherm catheter, Radionics DiscTrode Catheter, Arthrocare Spinewand [RMB]; Nucleoplasty, IDET [intradiscal electrothermocoagulation], Discography [C-HL]).

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and marketed as a percutaneous technique to ablate nuclear tissue by creating channels within the nucleus. During the procedure, a ‘‘wand’’ is introduced through a 17-G needle placed into the annular-nuclear junction using standard posterior-lateral access techniques. The nuclear tissue is then ablated by high voltage (typically 100–300 V) delivered at a frequency of 120 KHz using bipolar radiofrequency energy. In hydrated-tissue conductive medium containing normal saline, this current creates a plasma field approximately 75 μm thick that is composed of highly ionized particles with sufficient energy to break organic molecular bonds and thus vaporize tissue. By advancing the Perc-DL Spine Wand in ablation mode and retracting the probe while delivering a bipolar RF coagulation, 1-mm channels are created in the nucleus. This mechanism was confirmed by histological examination after channel ‘‘coblation’’ (coagulation ablation) in harvested sheep discs in which there was no evidence of collateral tissue or cell destruction [1].

Reimbursement

Pertinent CPT codes include 62287: aspiration or decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method, single or multiple levels, lumbar (eg, manual or automated percutaneous discectomy, percutaneous laser discectomy). Performed in an outpatient surgery center with a relatively inexpensive disposable apparatus, the facility and physician expense in time, labor, equipment, and facility overhead are between 5 and 10 times less than a comparable fusion or arthroplasty.

Theory

Mechanism of action

The percutaneous removal of nuclear tissue by thermal energy is thought to lower nuclear pressure, thereby reducing nerve root tension and allowing a protrusion to implode inward. This implosion or retraction of the protrusion may reduce contact pressure between the protruding disc and the nerve root. Although pressure on a nerve root is considered a primary cause of radicular low back pain (LBP), only a few studies have validated this mechanism, an etiology for mechanical CLBP.

Takahashi et al. measured the contact pressure between the nerve and annulus in patients under general anesthesia in a prone position before and after removing a herniated disc [2]. Pressures ranged from 7 to 256 mm Hg (mean, 54.2) before discectomy and was 0 mm after, and was directly correlated with the amount of trunk list and degree of neurological deficits before the operation. Because nerve edema can be induced by pressure of only 50 mm for 2 minutes, this study suggests that compression could in fact contribute to CLBP [3].

Thus, although one might logically conclude that percutaneously removing a herniated nucleus from an inside-out or outside-in approach would likewise relieve pressure on a nerve root, the effect of lowering nuclear pressure by removing a small amount of nucleus from the center of the disc is conceptually harder to understand, especially if the desired effect is to lower annular tension for the purpose of decreasing axial CLBP.

Pressure theory

The concept of lowering pressure was postulated by surgeons to justify nuclear decompression using laser heat ablation. Case et al. measured a rapid rise in the pressure of cadaver discs while slowly infusing normal saline into the disc nucleus [4]. These findings were consistent with the concept that the nucleus, surrounded by a relatively inelastic annulus and solid vertebral end plates, acts like a tight hydraulic space where large pressure rises occur with a small increase in volume. On the basis of these findings, it was suggested that small decreases in volume must lead to large decreases in intradiscal pressure [4]. In a follow-up study using a 1,000 Joules (J) Nd:YAG, 1.32 micron laser delivered through a quartz fiber, the mean intradiscal pressure in cadaver discs was decreased by 43% [5,6]. Likewise, using a 350 Nd:YAG laser, Yonezawa et al. vaporized central nuclear tissue in rabbit discs, creating a hole in the nucleus that over an 8-week period gradually filled with fibrous tissue and lowered the vertically measured disc pressure by ~50% [7]. Removing even less nuclear material by creating six channels in the nucleus of cadaver discs, Chen and Lee showed a 100% drop in pressure in normal discs in young cadavers, but only a negligible drop in degenerated discs.

In addition to direct pressure measurements in animal models, Hellinger et al. indirectly studied disc pressure changes in 21 patients by comparing the disc densities in computed tomography scans before and after nonendoscopic Nd:YAG laser nuclear ablation [8]. Density within disc protrusions showed a statistical difference of 66.3 Houndsfield units, corresponding to a 20% postoperative density reduction. Therapeutic results were attributed to reduced improved flow of venous and cerebrospinal fluid.

Although these studies suggest that pressure is lowered within the nucleus immediately after ablation, little is known about the effect on tensional forces in the outer annulus or the duration of decreased pressure. Because injecting the disc with fluid will increase outer annular pressure when radial annular tears extend to the outer annulus, one might reasonably conclude that lowering the fluid pressure would decrease annular tension [9]. Several studies suggest that it may be preferable to remove a smaller amount of nuclear material through ablation. Mochida et al. performed percutaneous discectomy on 47 young (27.3 average age) patients with herniations causing radicular pain [10]. They compared results of 25 cases in which an average of 3.8 g of tissue was removed from the central nucleus to 22 cases in which an average of only 1 g of tissue was removed from the posterior protrusion. Although 2-year favorable outcomes were comparable at about 70% in both groups, 10-year results were favorable in 71% for the group that had less tissue removed compared with 36% in those having more tissue removed. More importantly, disc space collapse greater than 30% was observed in 57% of the group with more tissue removed, compared with 20% of the group with less tissue removed. A decrease in disc herniation size did not correlate with outcome. Further supporting these findings, another study showed that in elite athletes a more extensive arthroscopic removal of tissue was associated with an acute worsening of symptoms and a delayed return to sports activity [11]. Similarly, Carragee et al. had better outcomes after open surgical removal of herniated discs when less nuclear material was removed [12]. The study compared removal of all the free fragments through an annulotomy incision to a more limited removal of the herniated mass alone. Although recurrent herniation rate was higher in the limited removal group, clinical outcomes measured by satisfaction, pain, and function were superior.

Although removing nuclear tissue will decrease disc pressure in the inner and middle annular fibers, little effect is seen on the outer and more commonly innervated collagenous layers [13]. In addition, during creep loading the reduced nuclear tension allows the inner layers to bulge inward, reducing height, and compressive strength, and potentially leading to lateral segmental instability [14]. Reduced nuclear pressure shifts load to the relatively thin outer annulus [14–16] causing high, irregular stress concentrations that may cause pain [17,18]. In addition, the lowered pressure in the nucleus and the elevated pressures in the annulus will suppress chondrocyte metabolism leading to further disc dehydration and reduction of osmotic forces [19,20]. Wognum et al. showed that decreased osmotic pressure exposes the tips of annular tears to increased stress concentrations, causing cracks to open and potentially increasing the risk of herniation [21].

In addition, a drop in nuclear pressure will cause disc space narrowing and disc bulging. In hydrated cadaver discs, Brinckmann et al. showed a significant drop of pressure when up to 3 g of nuclear material was removed. For every gram of tissue removed from the nucleus, disc height collapsed by an average of 0.8 mm and the disc bulge by 0.02 mm. Similarly, Castro et al. showed that removal of 4.6 g of nuclear material by aspiration percutaneous lumbar discectomy (APLD) narrowed the disc space by 1.42 mm and increased the disc bulge by 0.45 mm [22].

Interpreting findings of decreased pressure is challenging, because the majority of discs selected for this procedure may already have lowered nuclear pressures from end-plate injury or disc herniations. With the nucleus already decompressed, the benefits of further decompression may be questionable but removing less material would perhaps cause less harm in such cases. Interestingly, studies have suggested that elevating nuclear pressures may be theoretically beneficial in those cases where an annular tear alone is present in an otherwise healthy hydrated nucleus [13]. Although elevated pressure will increase the risk of disruption, decreased chondrocyte metabolism should eventually relieve the pressure [23]. Furthermore, nuclear decompression typically occurs after injuries such as an end-plate fracture, annular tear with herniation, outer rim lesion, or concentric annular tears [24,25]. One could postulate that minimal nuclear decompression might initiate, assist, or hasten this response. Further studies, however, are required to understand the effects of nucleoplasty on disc pressure.

Implosion theory

Another goal of central nuclear decompression is to allow room for the herniated fragment to implode inward and reduce the tension on the nerve root and annulus. There is little evidence to support this theory. In fact, Delamarter et al. reviewed the magnetic resonance imaging scans of 33 patients with radicular pain as the result of a disc herniation before and after APLD and saw no measurable changes at 6 weeks [26]. At the L4–5 level and above, a more lateral approach will allow a more posterior needle placement [27] and more targeted tissue removal (Fig. 1).

Chemical theory

The application of heat through nucleoplasty may also enhance the chemical environment within the disc. Coblation in cultured disc cells [28] increased inflammatory mediators in normal nuclear and annular cells, but decreased inflammatory mediators in abnormal nuclear cells.

Nucleoplasty

Smaller protrusions are postulated to cause both axial and referred extremity pain as the result of neural inflammation, and axial pain as the result of the combination of a sensitized outer annulus and increased outer annular tension [29]. During percutaneous endoscopic discectomy, surgeons often see an inflamed outer annulus adjacent to the disc protrusion [30]. Directly removing the herniated disc within the protrusion should remove the source of inflammation and pressure on the innervated outer annulus and adjacent posterior longitudinal ligament and nerve roots. Percutaneous techniques using medium and smaller diameter cannulae were not, however, designed to remove nucleus directly behind the protrusion and unless the protrusion lies in the path of the posterior-lateral approach, directly removing the source of inflammation is typically not achieved.

Unlike larger 3 to 5 mm outer diameter cannulae used for ‘‘surgical’’ percutaneous disc decompression, those performed though smaller 2.5 to 3 mm cannulae (APLD, Laser, SpineJet MicroResector) and even small diameter 1.5 mm cannulae (nucleoplasty) are designed to allow easy access only to the disc nucleus and not to herniated nucleus

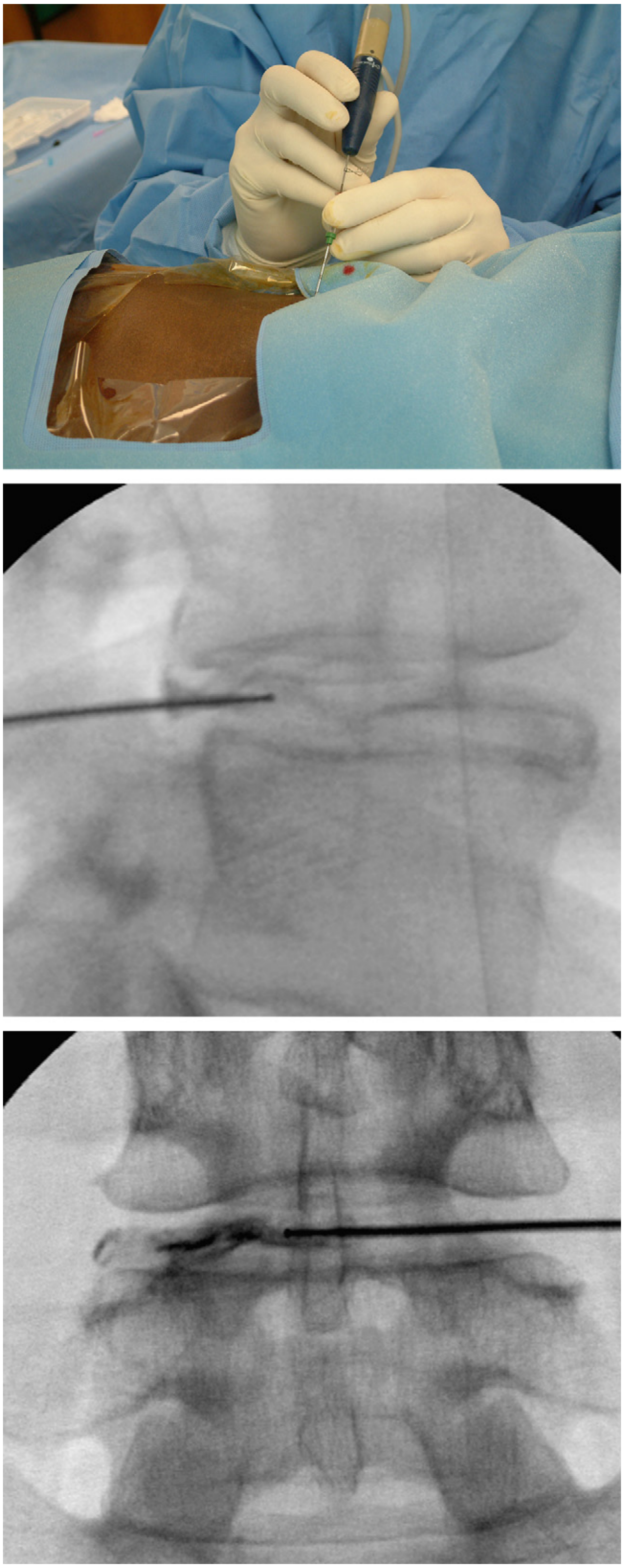

Fig. 1. Lumbar nucleoplasty procedure (Top). Lateral view with needle purposely placed posteriorly to achieve decompression behind the central disc protrusion (Middle). AP view (Bottom).

within posterior annular fissures and protrusions. These techniques primarily remove tissue by cutting and aspirating, removing, or vaporizing nucleus within the center of the disc and do not necessarily remove nuclear material within the protrusion unless the protrusion is located along its access path.

Evidence of efficacy

Review methods

Numerous observational studies were identified pertaining to nucleoplasty for CLBP, including nonrandomized controlled trials, prospective case series, and retrospective case series. Evidence from these studies was synthesized according to previously proposed classes of evidence (Table 1). Study populations are summarized in Tables 2 and 3 and results are summarized in Tables 4 and 5 according to study design. Overall results are summarized in Table 6. Only articles that were presented or published before September 2006 are included in this review; more recent evidence is also available.

Observational studies

There are many case series providing Level 3 evidence, but most have a small study size, incomplete or short follow-up data, and none have a validated control group. The lack of acceptable evidence is demonstrated by wide variation in published successes. This ranges from 80% favorable results in 1,300 patients reported by two Italian neurosurgeons [31] compared with less than 20% average pain relief in several small American case series [32–34].

In 2001, Sharps et al. were reported outcomes after nucleoplasty in 49 patients after 1 month, 41 patients after 3 months, 24 patients after 6 months, and 13 patients after 12 months [35]. Participants had CLBP (mean duration 38 mo) with or without leg pain, and protrusions greater than 1/3 the sagittal canal diameter were excluded. The procedure was performed as recommended by the device manufacturer. The 1- through 12-month outcomes based on visual analog scale (VAS) pain score showed a relatively consistent drop in VAS pain score of between 4.3 (54%) and 3.6 (45%) from a preoperative average of 7.9. Despite the reported near 50% drop in VAS pain score, mean post-procedural patient satisfaction (0 = unsatisfactory,

Table 1
Classes of evidence

Class	Supporting evidence
I	One or more well-designed, randomized controlled clinical trials, including overviews of such trials.
II	One or more well-designed comparative clinical studies, such as nonrandomized cohort studies, case-control studies, and other comparable studies, including less well-designed randomized controlled trials.
III	Case series, comparative studies with historical controls, case reports, and expert opinion, as well as significantly flawed randomized controlled trials.

Reference: Neurosurgery, Vol. 50, No. 3, March 2002 Supplement S2–6.

Table 2
Nonrandomized controlled trials and prospective cohort study populations

Reference	Sample size (final)	Follow-up period	Pain indication	Pain duration	Performed by	WC/litigation*
[50]	N: 64 (60) CAM: 13	12 mo	CLBP w/wo RP	1.3 y	SURG	NR
[34] (ongoing)	N: 92 I: 63	12.7 mo 14.9 mo	Discogenic, W/WO leg pain	37.5 mo	INT	WC & LT: N: 79.8% I: 73.9%
[39]	67	6 mo	More leg, contained, discogenic	NR	SURG	NR
[35]	53	2 wk	Contained, discogenic or leg pain	NR	SURG	NR
[31]	64	1 y	CLBP w/wo RP, discogenic	>3 mo	NR	NR
[51]	47 (37)	12 mo	Discogenic	6.3 y	INT	EX
[37]	80 (69)	12 mo	Discogenic and/or leg pain, small herniation	5.5 y	INT	EX
[36]	67	12 mo	Contained, discogenic, and/or leg pain	5.4 y	INT	EX
[52]	49 (13)	12 mo	More leg, contained, discogenic	38 mo	SURG	NR
[53]	14	NR	CFP	58.4 mo	INT	NR

CLBP=chronic low back pain; CAM=coblation-assisted microdiscectomy; CFP=central focal protrusion; EX=excluded; I=IDET procedure; INT=interventionalist; LT=litigation; NR=not reported; SURG=surgeon; W=working before IDET; WC=worker's compensation.

* Includes workers' compensation, claims, or litigation.

4 = excellent) was only 2.14. Nonetheless, authors reported a 79% success rate based on patient satisfaction change of greater than 1 in a group of patients with relatively severe pain secondary to small disc protrusions.

In the following year, Sing et al. reported results on a group of 67 patients with CLBP and leg pain of long duration (5.4 ± 5.6 y) [36]. Outcomes were available in 61 patients at 6 months and 41 patients at 12 months. The average decrease in numeric pain score was 38%, from a preoperative average score of 6.80. Numerical pain rating score (NPRS) decreased greater than 50% in 59% at 6 months and 56% at 12 months. The authors also presented improvements in self-reported sitting and standing tolerance.

The same group extended their study, and in 2003 published results of a consecutive series of 84 LBP patients with or without leg pain. The patients presumably included the original 67 patients, though this was unclear [37]. Although not specifically stated in their first published report, the second study excluded any patient with "secondary gain issues" and therefore left open to the authors' discretion which patients would be included in the consecutive series. At 12 months, there was a 34% decrease in the NPRS; only 15% of the patients unemployed before nucleoplasty returned to work after the study intervention.

In 2005, Reddy et al. reported on 67 patients undergoing nucleoplasty for LBP and leg pain. Follow-up data were available for 16 patients at 3 months, 22 patients at 6 months, and 11 patients at 12 months. Small but statistically significant improvements were reported in a five-point impairment score for work and leisure activities, with 56%, 64%, and 45% of patients achieving greater than 50% pain relief at 3, 6, and 12 months, respectively. However, there was only a 15% (7.1–5.2) decrease in NPRS reported by the 11 patients followed to 12 months, consistent with five responders having greater than 50% relief and six nonresponders having no relief [38].

Despite the inclusion of patients who presented with contained disc protrusions primarily with radicular pain rather than CLBP, Gerszten et al. in 2006 reported outcomes on 23 patients and found a decrease in VAS pain score from 5.4 to 4.8 (11%), which was not statistically significant. Although the authors reported significant improvement in several quality-of-life outcome measures, this conclusion was based on only 20 of 67 patients enrolled in a prospective cohort and authors did not comment on missing data for the other 47 participants [39].

Cohen et al. reported on 16 active duty soldier patients with CLBP and leg pain (average 5.6 y [40]). Seven had nucleoplasty alone and nine had an IDET followed by nucleoplasty at the same level. The average decrease in VAS pain score was 16%, and only one patient reported greater than 50% relief of pain. There was no significant difference in outcome between the two groups [40].

Table 3
Retrospective case series study populations

Reference	Sample size (final)	Follow-up period	Pain indication	Pain duration	Performed by	WC/litigation*
[40]	N: 7 N+I: 9	9 mo	More leg, small herniation, radicular, discogenic	7.2 y 3.8 y	INT	MMC
[38]	49	>1 y	More leg, discogenic, contained	5 y	SURG	NR

INT=interventionalist; MMC=military medical compensation; NR=not reported; SURG=surgeon; WC=worker's compensation.

* Includes workers' compensation, claims, or litigation.

Table 4
Nonrandomized controlled trials and prospective cohort studies

Reference	Outcomes	Initial (mean±SD)	Follow-up (mean, SD)	% Improvement
[43]	Any improvement		N: 80%	
	VAS		CM: 20%	
[50]	Any improvement VAS		78%	
	Walking, standing, sitting		N: >75%	
			CAM: no conclusion	
[34] (ongoing)	VAS	N: 7.45±1.44	N: 5.02±2.21	33
		I: 7.60±1.78	I: 6.06±2.08	20
	Improvement VAS >10%		N: 80.4%	
			I: 55.5%	25
	Improvement VAS >50%		N: 27.59	
	BPI		I: 7.62	
	LPI		30.24%	
			17.86%	
	SAT		68.2%	
			44.4%	
[39]	VAS	0.63	0.5 (3 mo)	24
			0.48 (6 mo)	
	SF-36 PCS	33	37 (3 mo)	24
			41 (6 mo)	
	EQ5D	0.2	0.4 (3 mo)	200
			0.6 (6 mo)	
[35]	VAS—back	6.74	4.27	37
	VAS—right leg	5.14	3.59	30
	VAS—left leg	6.63	4.01	40
[31]	JOA—excellent		55.8%	
	JOA—good		24.9%	
	JOA—scanty		12.4%	
	JOA—none		6.9%	
	Overall excellent outcome		51.5%	
	Overall good outcome		31.5%	
[51]	VAS	6.7±1.1	4.4±2.3	34
	Improvement VAS >50%		53%	
	Sitting	11%	32%	
	Standing	13%	30%	
	Walking	15%	35%	
[37]	VAS	6.8	4.2 (6 mo)	34
			4.5 (12 mo)	38
	Any improvement VAS		75%	
	Improvement VAS >50%		54%	
	Sitting		54%	
	Standing		44%	
	Walking		49%	
[36]	VAS	6.8±1.1	4.1±2.5	40
	Any improvement VAS		80%	
	Improvement VAS >50%		56%	
	Sitting		62%	
	Standing		59%	
	Walking		60%	
[52]	VAS	7.9±1.3	4.3±2.8	46
	Any improvement VAS		OP: 67%	
			Non-OP: 82%	
			Overall: 79%	
	Improvement VAS >50%		56%	
[53]	Any improvement VAS		Overall: 64.3%	
			w/o CFP: 30%	

CFP=central focal protrusion; CM=conservative management; I=IDET procedure; VAS=Visual Analogue Pain scale.

Table 5
Retrospective case series

Reference	Outcomes	Initial (mean ± SD)	Follow-up (mean, SD)	% Improvement
[40]	VAS	N: 6.0±2.0	N: 4.8±1.8	20
	Improvement VAS >50%	N+I: 7.2±0.8	N+I: 6.3±1.0	13
			N: 20%	
	Return to work	N: 86%	N+I: 0%	
		N+I: 34%	N: 83%	
			N+I: 86%	
	Medication use		N: 71%	
			N+I: 34%	
[38]	VAS	Overall: 8.08	Overall: 4.41	45
		<6 mo: 8.1	<6 mo: 4.5	56.4
		6–12 mo: 8.0	6–12 mo: 3.9	64.6
		>1 y: 7.1	>1 y: 5.4	45
	SAT		<6 mo: 75%	
			6–12 mo: 73%	
			>1 y: 91%	
	Work impairment	<6 mo: 3.9	<6 mo: 2.7	
		6–12 mo: 3.7	6–12 mo: 2.2	
		>1 y: 4.2	>1 y: 3.0	
	Medication use	<6 mo: 3.8	<6 mo: 2.7	
		6–12 mo: 3.2	6–12 mo: 2.0	
		>1 y: 3.7	>1 y: 2.4	

I=IDET procedure; VAS=Visual Analogue Pain scale.

Derby compared 67 patients undergoing IDET to 92 patients undergoing nucleoplasty [33,34]. Both groups had similar eligibility criteria and included a large percentage of patients with workers compensation or litigation claims. Axial LBP was worse than leg pain in 60% to 70% of patients. At an average 1-year follow-up, NPRS had decreased 17% (7.6–6.06) in the IDET group and 32% (7.45–5.02) in the nucleoplasty group. An index rating improvement in axial LBP and leg pain showed approximately equal improvement in the nucleoplasty group. Patient satisfaction based on a standard questionnaire was 44% in the IDET group and 68.2% in the nucleoplasty group.

Harms

Bhagia et al. recorded the short-term side effects and complications in a series of 53 patients after percutaneous disc decompression using nucleoplasty [35,41]. The most common side effect was soreness at the needle insertion site (76%), new numbness and tingling (26%), increased intensity of preprocedure back pain (15%), and new areas of back pain (15%). These symptoms resolved over 2 weeks except for a 15% incidence of new numbness and tingling and 4% incidence of increased LBP.

Performed by an experienced spine interventionalist, nucleoplasty is relatively safe. One can expect the same unlikely incidence of infection and nerve root injury inherent in any disc access procedure. The use of intradiscal and preoperative intravenous antibiotics will significantly reduce the incidence of infection. Because the introducer needle is only 17 G and the patient is (or should be) awake, prolonged nerve root injury should also be uncommon. Common to any procedure that uses heat within the intervertebral disc, there is the risk of end-plate damage and neural injury may occur. Nau and Diederich measured temperature maximums and thermal doses along the channels created in cadaver human discs [42]. Their data showed transient peak temperatures of 80°C to 90°C along the channel paths and temperatures greater than 65°C at radial distances of 3 to 4 mm from the channels and thermal doses of greater than 250 minutes up to 6 mm from the probes. Because operators cannot always guarantee the exact path of the advancing wand in relation to its transient proximity to the end plate, end-plate damage is possible. If the probe was to be passed outside the disc, injury to neural structures could occur.

Probably, the most significant risk that would be difficult to recognize is the inadvertent destruction of normal annulus. Typically, the advancing probe will not penetrate normal annulus. If one is trying to achieve a more posterior placement closer to the protrusion, there would be a risk that one would create channels in normal annulus on either side of the annular tear because the probe will be advanced roughly perpendicular to the annular tear.

Summary

We have yet to discover the cure for CLBP. If one relies on the published literature, we conclude that for the treatment of CLBP caused by a disrupted and mildly protruding disc there is no treatment that stands head and shoulders above the rest. Nucleoplasty and other minimally invasive nuclear decompression devices are trying to bridge the gap between noninvasive treatment modalities and surgical

Table 6
Summary of percentage improvement in outcomes by study design for each treatment type

		Pain severity				Function				QOL			
Procedure	Data	RCT	NCT	BA	CS	RCT	NCT	BA	CS	RCT	NCT	BA	CS
Spinal fusion	#Studies (33 total)	6	1	8	11	8	1	2	6	5	0	0	0
	Median %	36	NA	61	53	40	NA	NA	42	43	NA	110	NA
	Range	30–77	37–52	42–75	24–62	17–73	39–54	58–77	17–49	21–123	NA	NA	NA
IDET	#Studies (29 total)	3	3	12	2	3	1	2	0	3	0	7	0
	Patients	129	148	548	115	129	53	47		149	292		
	Median %	14	63	46	29	4	41	45		4	47		22–69
	Range	−9 to 36	63–81	22–71	29	−6 to 35	41		14–75	−16 to 35	–		22–69
	>50% Improvement Mean %	19	66	62	32								
	>50% Improvement Median %	19	60	67	32								
	>50% Improvement Range	0.08–38	57–81	50–70	16–48								
Nucleoplasty	#Studies (13 total)	0	0	7	2								
	Patients			531	65								
	Mean %			35	33								
	Median %			34	33								
	Range			25–46	20–45								
	>50% Improvement Mean			49	20								
	>50% Improvement Median			54	20								
	>50% Improvement Range			25–56	20								
DeKompressor	#Studies (3 total)	0	0	1	1	0	0	0	0	0	0	0	0
	Patients			50	60								
	Mean %			58									
	Median %			58									
	>50% Improvement Mean				76								

BA=prospective before-after trial; CS=retrospective case series; NCT=non-randomized controlled trial; NA=not applicable; IDET=intradiscal electrothermal annuloplasty; RCT=randomized control trial.

(Spinal Fusion data from Andersson et al. in Pain Physician, 2006).

fusion. The techniques are a first iteration and will probably not be around in the same form 5 years from now. The scientific rational for the three procedures is wanting but not hopeless. Targeted removal of herniated nucleus behind a protrusion is a more logical strategy for achieving the desired effect of removing the source of inflammation and relieving tension on the adjacent irritated annulus. Future designs will allow better navigate into protrusions and incorporate enhanced methods to safely remove herniated nuclear material. For example, the anterior approach in cervical nucleoplasty allows decompression directly behind a protrusion and early favorable outcome reports after nucleoplasty for small cervical disc protrusions lend support for better access strategies [41,43].

Despite variable results, nucleoplasty is appealing because it is simple, relatively safe, and destroys minimal tissue. Disc height should therefore be maintained, or collapse more slowly and allow the body time to adapt. In addition, the 17-G introducer needle should cause significantly less collateral damage to normal annulus compared with surgical arthroscopic decompression techniques that remove herniations from inside the disc.

Because surgical decompression outcome for small protrusions causing axial pain is inconsistent and patients often would like fusion or arthroplasty to be the last resort, nuclear decompression using a minimally invasive technique would seem to be a reasonable ‘‘next option’’ for hydrated discs with relatively well-maintained disc heights. For patients with CLBP and referred leg pain, outcomes of nucleoplasty are comparable to those of IDET. The average mean percent relief after IDET reported in the literature is 14% in randomized controlled trials, 63% in nonrandomized controlled trial, 46% in before and after case series, and 29% in retrospective case series studies. The average mean percentage relief after nucleoplasty is 45% in prospective before and after series and 43% in retrospective case series. In the only unpublished study that specifically compared outcome between the two procedures, nucleoplasty had better patient satisfaction and somewhat better pain relief than IDET [33].

Comparing nucleoplasty to fusion surgery, the reported median decreases in pain scores including both leg and back pain after nucleoplasty are 54%, and median improvement in back-specific impairment scores is 42% after fusion. Nucleoplasty is, however, generally safer, considerably less expensive, and should have significantly less morbidity than fusion. Although the authors personally feel that surgical reconstruction is the definitive treatment that is more likely to provide better long-term functional outcome, once an artificial disc or fusion instrumentation is inserted, there is no turning back. Finally, we again remind the reader that nucleoplasty was designed and marketed specifically for treating leg pain. Relief of axial CLBP is commonly less than 50%.

Based on our review, minimally invasive nuclear decompression using nucleoplasty is one of the options that can be considered before fusion or arthroplasty, but the evidence as of September 2006 does not yet support the current device iteration use for the treatment of back pain alone. The procedure is better suited for the improvement of referred extremity pain in patients with protrusions less than 4 to 6 mm, minimal stenosis, and relatively well-maintained disc heights.

In conclusion, finding a safe, inexpensive, and effective interventional treatment of CLBP is a focus of ongoing research and development. Nonendoscopic techniques for removing herniated tissue will improve, however. The next wave of treatments for discogenic pain will likely also target tissue restoration. Noncommercial options may include injectable solutions like hypertonic saline and dextrose [44] that transiently lower disc pressure and will be used alone or combined with inexpensive chemicals that may either promote regeneration or otherwise favorably affect the chemical environment [9,45,46]. Products will include injectable solutions that are combined with growth factors, cultured chondrocytes, or gene vectors. Finally, various collagen fillers have already been used clinically and are under patent and investigation [47,48]. These filler substances will be used to fill annular tears with the hope that the injected fillers will provide scaffolding for healing, and the hope that attached substances will accelerate both the healing and regeneration process [49].

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