ORIGINAL ARTICLE

Percutaneous Lumbar Discectomy: One-Year Follow-Up in an Initial Cohort of Fifty Consecutive Patients with Chronic Radicular Pain

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Pain Practice
Volume 5 Issue 2 Page 116 - June 2005

STUDY OBJECTIVE

Describe the 1-year follow-up response with the Dekompressor® 1.5-mm Percutaneous Lumbar Discectomy (PLD) probe in the initial cohort of 50 consecutive patients.

BACKGROUND

Discogenic leg pain is a primary cause of health care expenditure in the U.S.A., afflicting nearly 10 million people at an estimated cost of over $20 billion.(1,2) This pain is often due to herniation of the intervertebral disc (3-5) and clinically characterized as compressive or noncompressive. (3) Compressive herniations have been treated with open surgical discectomy/decompression when a progressive motor, sensory, and/or reflex change (ie, radiculopathic pattern) is noted on serial neurologic exam. (6,7) In that setting, surgical disc decompression has produced clinical improvement by reducing pressure within the intervertebral disc and adjacent nerve root. (8) The efficacy of that approach may be limited, however, by reherniation and/or reoperation depending on the amount of annular invasion required. (7) As a result, open surgical disc decompression may be ineffective in some patients (6,7) and is associated with morbidity. (7,9-11)

In contrast, open surgical disc decompression plays a limited role in the management of noncompressive, disc herniations where nonoperative strategies also commonly fail. (12-13) This more common group typically presents with a painful, nonprogressive motor, sensory, and/or reflex change (ie, radicular pattern) on serial neurologic exam. (1,3,5,13) These patients are treated initially with rest, physical therapy, chiropractic, and nonsteroidal anti-inflammatory medications. If symptoms persist, spinal injection therapy may be instrumental in clarifying the diagnosis and potentially treating the root inflammation/radiculitis (as described in the Methods and Discussion sections below), but does not address refractory pain from the inciting disc herniation directly. Thus, the Dekompressor® PLD probe was developed to allow for a quantifiable, selective extraction of herniated nucleus pulposus without annular or nuclear disruption (1,14,15) (Figure 1,b). This report follows up at 1 year the initial 6-month outcomes of the Dekompressor® PLD probe in the initial cohort of 50 patients.

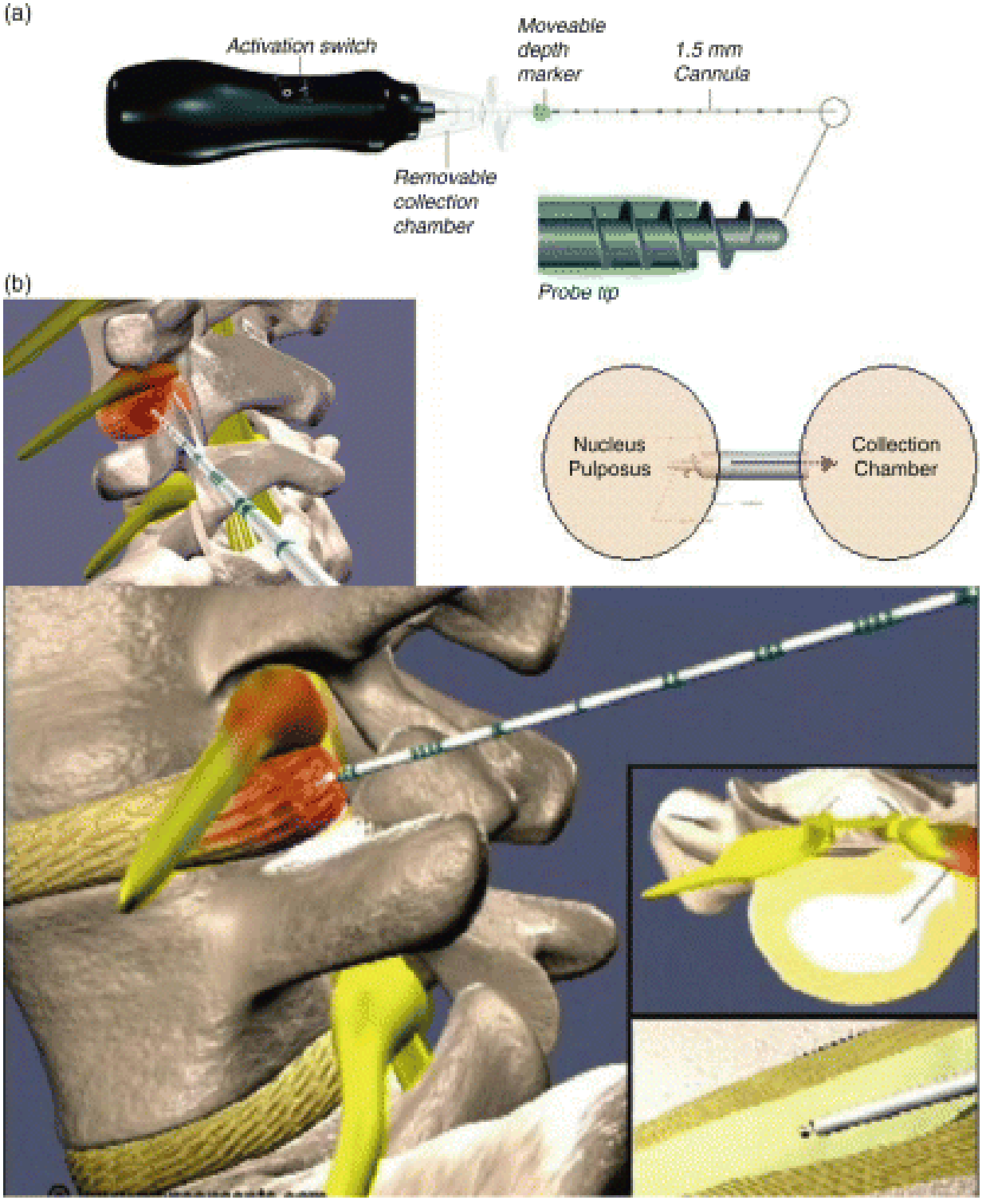

Figure 1. (a) Dekompressor® 1.5-mm (17-gauge) Percutaneous Lumbar Discectomy probe: component parts and posterolateral, extrapedicular cannula disc positioning. (b) Schematic of extraspinal, extrapedicular cannulation within a posterolateral contained disc herniation (auger inset). (Reprinted with permission from Pain Pract. 2004;4:20.)

CLINICAL STUDY

A 12-month prospective, nonrandomized, human clinical study was undertaken. This is a continuation of the previously reported 6-month study with the identical inclusion, exclusion, and outcome assessments re-enumerated below.

Inclusion Criteria

1. Radicular pain associated with contained disc herniation less than or equal to 6 mm.
2. Clinical history and physical exam findings consistent with radiographic findings of disc herniation < 6 mm.
3. Duration of radicular pain greater than 6 months.
4. Failure of conservative therapy including: physical therapy, therapeutic injections, oral analgesics, and anti-inflammatory medications.
5. Good to excellent short-term (<2 weeks) response to fluoroscopically guided transforaminal injection of local anesthetic and corticosteroid at symptomatic level(s) (Figure 2).
6. Confirmatory selective segmental spinal nerve block with 0.5 1.5 cc of anesthetic providing > 80% relief of radicular pain lasting at least the duration of local anesthetic (Figure 2).
7. Preservation of disc height (less than 50% loss).

Exclusion Criteria

1. Progressive neurological deficit.
2. More than two symptomatic disc levels.
3. Previous open surgery at proposed treatment level.
4. Spinal instability.
5. Spinal fracture or tumor.
6. Pain drawing inconsistent with clinical diagnosis.
7. Significant coexisting medical or psychological condition.

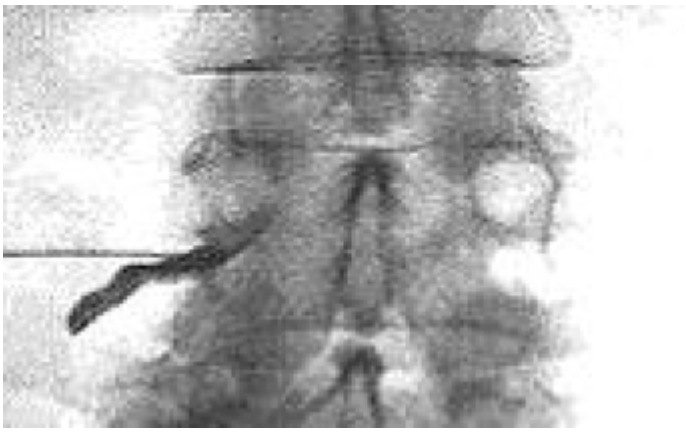

Figure 2. Anteroposterior xeroradiograph of low-volume selective nerve root block. Documentation of foraminal dye (Iohexol 240 m) spread followed by dermatomal local anesthetic phase assessment (1 cc Bupivacaine 0.75%).

OUTCOME ASSESSMENT

Previously reported outcome measures were selected to evaluate the clinical utility of this method:

1. Visual Analog Scale (VAS) 10 cm scale upon which patient marked current level of radicular pain between 0 and 10. Significant efforts were made to standardize the presentation and questioning. Ten (10) was defined consistently as "The worst pain imaginable."
2. Analgesic use, defined as transition between one of three categories:
   (a) long acting analgesics;
   (b) short acting analgesics;
   (c) no prescription medication.
3. Self-reported, individual functional improvement in one or more clearly and prospectively defined activities of daily living not possible prior to treatment.
4. Overall satisfaction, defined as positive answer to:
   (a) patient would undergo the same procedure for the same result;
   (b) patient would recommend the procedure to a family member;
   (c) patient felt that his/her expectations were met.

An independent evaluator performed data collection and statistical analysis at initial evaluation and 1-year postprocedure.

MATERIALS AND METHODS

The procedure using the Dekompressor® was standardized prior to the initial patient evaluation. (16) This evaluation and assessment parallels the previously reported 6-month methodology.1
First, a detailed physical exam was performed to assess for lumbar radicular involvement. As described above, any patient with an evolving neurological deficit (myelopathy, worsening sensory, paresis, reflex change, or bowel/bladder functional loss) was deemed to likely have a compressive herniation and was referred for spinal surgery evaluation and was not included in this cohort. Record review (minimum 1 year) was then performed on included patients to confirm a lack of sustained response to medical management (physical therapy, oral analgesic/anti-inflammatory medication, and/or corticosteroid at the root/epidural level). An imaging study (eg, magnetic resonance imaging [MRI]) was then assessed specifically for a lumbosacral disc(s) herniation or other structural explanation for the radicular findings. If a contained herniation was confirmed at one of more potentially correlatable levels to the clinical presentation, then a low-volume, transforaminal, selective nerve root block was performed (Figure 2). If the radicular pain was relieved during the local anesthetic phase (>80% relief in the specific dermatome blocked), yet recurred without a longer-term corticosteroid response, then percutaneous decompression was considered.1 Great care was taken to correlate the unilateral or bilateral radicular/dermatomal presentation with the anesthetic phase (given the central disc position and crossover/bilateral innervation at each level).
Prior to percutaneous decompression, informed consent was obtained with full disclosure. Cannulation was technically specific for the herniation location (posterolateral vs. posterolateral-central) (Figure 3 a,b).

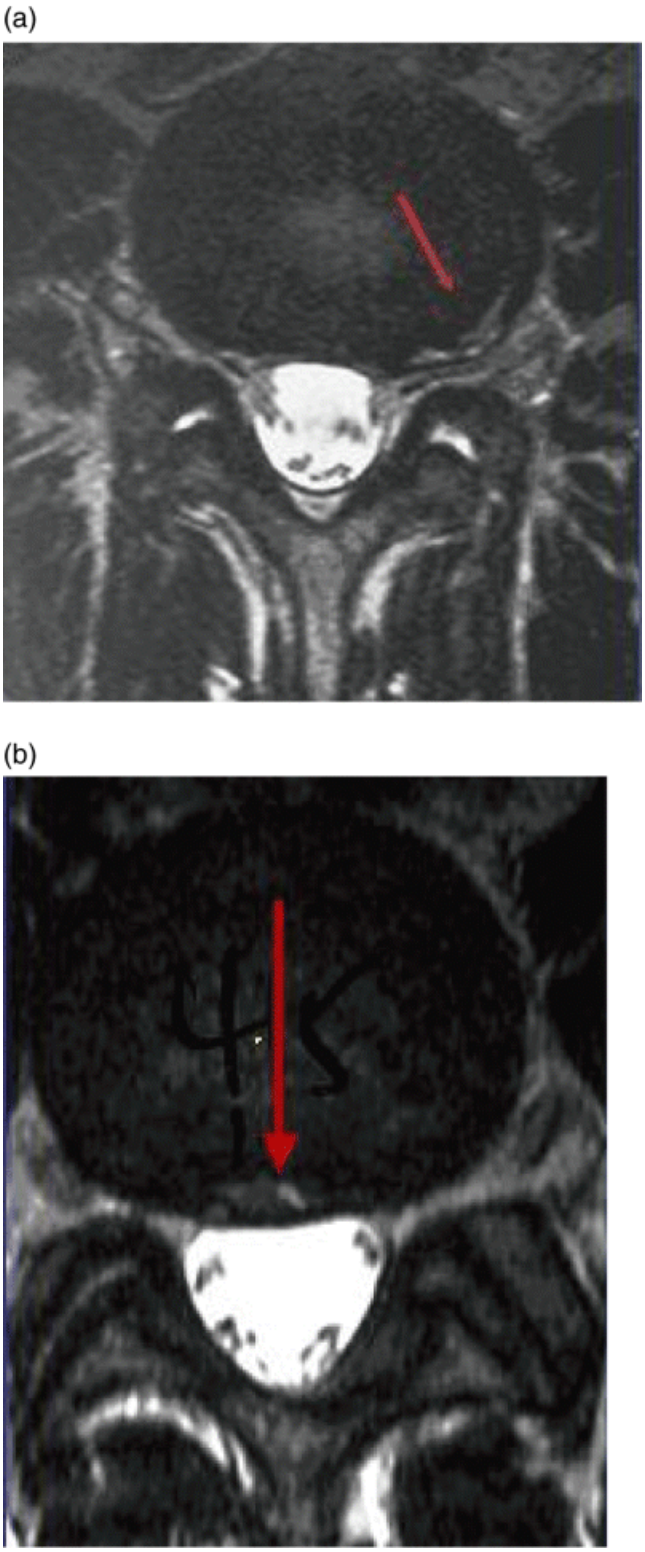

Figure 3. Coronal view of (a) posterolateral and (b) paracentral L4/5 contained disc herniation, see arrows. (Reprinted with permission from Pain Pract. 2004;4:22.)

Monitored anesthesia care was used with the patient remaining awake and interactive throughout the procedure. Disc access was gained with a posterolateral, extrapedicular approach on the symptomatic side using the 1.5 mm (17G) Dekompressor® cannula with stylet (Figures 1,4a,c). This approach is similar to that used for standard lumbar discography.

Once the cannula was placed, intranuclear contrast (0.5−1 cc of Iohexol 300M with 2 mg/cc cefazolin) was injected to visualize the posterolateral nuclear/annular boundary (Figure 4b). A depth stop was then positioned on the cannula to mark the ventral annular/nuclear boundary. (1)

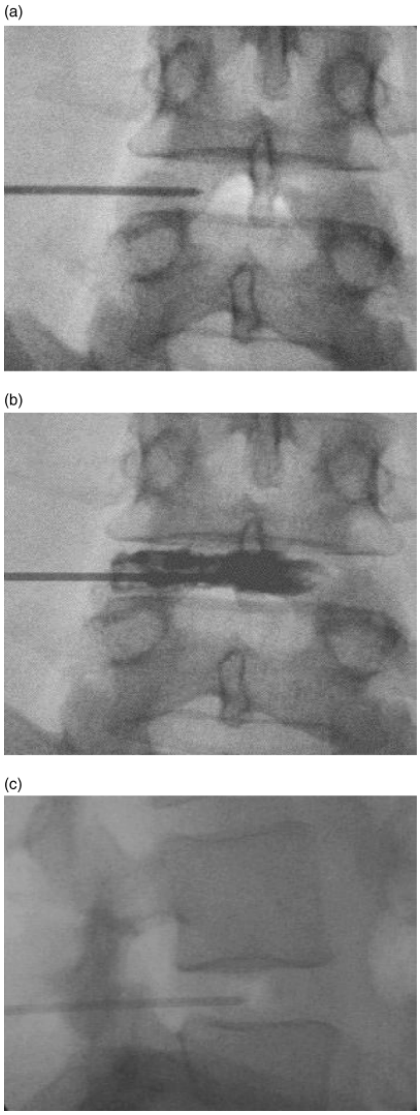

Figure 4. (a) Anteroposterior xeroradiograph of left posterolateral extrapedicular insertion of 17G Dekompressor® cannula at L4/5. (b) Anteroposterior xeroradiographic view of posterolateral-central nuclear Iohexol filling of left L4/5 symptomatic contained herniation. (c) Lateral xeroradiography of central nuclear 17-gauge Dekompressor® cannula at L4/5 (positioned via a left posterolateral approach).

The probe (titanium auger) was then introduced through the cannula. This auger is connected to a disposable rotational motor, which mechanically aspirates nucleus along this element toward the proximal chamber (1) (Figure 1a,b). Each herniation was decompressed for an average of 3 minutes (0.75 to 2 cc of disc material removed with a mean of 1.25 cc).

Objective confirmation of disc material was achieved visually, quantitatively, or at pathologic section (Figure 5).

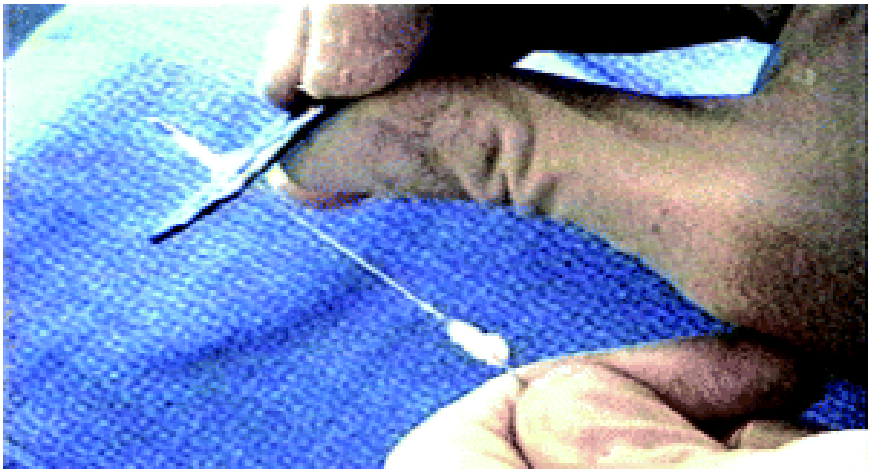

Figure 5. Disc material removed intraoperatively by Dekompressor® 1.5-mm PLD probe. This is objectively confirmed (and quantified) at operation, yet may also be sent for pathological qualitative analysis and quantification. (Reprinted with permission from Pain Pract. 2004;4:22.)

RESULTS

Percutaneous decompression/discectomy was evaluated in 42 patients (54 levels) at 1 year. Eight patients from the original cohort of 50 were lost to follow-up. An average reduction in preoperative pain score (VAS) of 5.13 (64.77%, $P < 0.001$) was reported with 78.6% of patients reducing their analgesic intake and 90.5% improving their postdecompression functional status. Overall satisfaction with therapy was 88.1%. There were no procedure-related complications (Table 1).

Table 1. Twelve Month Pre- and Post-VAS, Functional Rating, Medication Reduction, and Patient Satisfaction Scores after Dekompressor®

Patient	Pre-VAS	12-month VAS	Levels	Satisfaction	Red Analgesics	Age	Gender	Improved Function
1	8	2	1	Y	Y	23	M	Y
2	8	6	1	N	N	61	M	N
3	6	LTF						
4	6	0	2	Y	Y	41	F	Y
5	6	LTF						
6	9.5	3	1	Y	Y	26	M	Y

7	7	4	2	Y	Y	49	M	Y
8	7	0	1	Y	Y	42	F	Y
9	8	LTF						
10	8	1	2	Y	N	44	M	Y
11	4	0	1	Y	Y	53	F	Y
12	8	0	2	Y	Y	48	F	Y
13	8	LTF						
14	6	1	2	Y	Y	41	F	Y
15	7	LTF						
16	6	3	2	Y	Y	53	M	Y
17	8	0	2	Y	Y	52	F	Y
18	7.5	3	2	Y	Y	55	F	Y
19	6	LTF						
20	7	4	1	Y	Y	40	M	Y
21	8	8	1	N	Y	46	M	Y
22	7	3	2	Y	Y	60	M	Y
23	9	5	2	N	N	40	M	N
24	8	8	1	N	N	59	F	N
25	9	2	1	Y	Y	54	M	Y
26	7	1	1	Y	Y	42	M	Y
27	6	4	1	Y	Y	36	F	Y
28	9	0	1	Y	Y	20	F	Y
29	8	1	2	Y	Y	43	F	Y
30	7	2	1	Y	N	52	F	Y
31	9	3	1	Y	Y	45	F	Y
32	8	4	1	Y	Y	52	F	Y
33	9	4	1	Y	Y	37	F	Y
34	9.5	4	1	Y	Y	55	F	Y
35	7	2	1	Y	N	68	F	Y
36	9	2	1	Y	Y	30	M	Y
37	9	3	1	Y	Y	52	F	Y
38	9	5	1	Y	N	59	F	Y
39	8	3	1	Y	Y	46	F	Y
40	9	5	1	N	N	47	M	N
41	9	LTF						
42	9	2	1	Y	Y	65	F	Y
43	8	3	1	Y	Y	52	F	Y
44	8	3	1	Y	Y	52	F	Y
45	9	LTF						

46	9	0	2	Y	Y	49	F	Y
47	8	3	1	Y	Y	56	F	Y
48	9	4	1	Y	Y	52	F	Y
49	9	3	1	Y	Y	43	M	Y
50	8	3	1	Y	N	56	M	Y
	7.92	2.79	54	88.10%	78.60%	47.52	16M/26F	90.50%
	SD 1.2	SD 1.8		37Y/5N	33Y/9N			38Y/4N
Average decrease in VAS 5.13 (range 0 to 9).								
LTF, lost to follow-up.								

DISCUSSION

Discogenic leg pain is a primary cause of health care expenditure in the U.S.A., afflicting nearly 10 million people at an estimated cost of over $20 billion. (1,2) This pain is often due to herniation of the intervertebral disc (3-5) and clinically characterized as compressive or noncompressive. (3)

Historically, compressive herniations have been treated with open surgical discectomy/decompression when a progressive motor, sensory, and/or reflex change (ie, radiculopathic pattern) is noted on serial neurologic exam. (6,7) In that setting, surgical disc decompression has produced clinical improvement by reducing pressure within the intervertebral disc and adjacent nerve root. (8) The efficacy of that approach may be limited, however, by reherniation and/or reoperation depending on the amount of annular invasion required. (7) As a result, open surgical disc decompression may be ineffective in some patients (6,7) and is associated with morbidity. (7,9-11)

Specifically, Stolke, Sollman, and Siefert reported a complication rate of 13% with one death, three nerve root injuries, and a 1% discitis rate. (1,9) Ramirez and Thisted reviewed 28,000 discectomy procedures with 1 in 64 patients having a major complication, 1 in 335 having a neurological complication, nearly 1 in 500 having a cardiovascular complication, and 1 in 1700 dying from the procedure. (1,10,11)

In contrast, open surgical disc decompression plays a limited role in the management of noncompressive, contains disc herniations where nonoperative strategies also commonly fail. (12,13) This more common group (described here) typically presents with a painful, nonprogressive motor, sensory, and/or reflex change (ie, radicular pattern) on serial neurologic exam. Symptoms may be treated initially with rest, physical therapy, chiropractic, and nonsteroidal anti-inflammatory medications, but often remain refractory. (17) When symptoms persist, selective diagnostic spinal injections can be instrumental in clarifying the pain source, as well as potentially treating the root inflammation/radiculitis. In this vein, strict attention must be paid when analyzing the immediate postblock dermatomal anesthetic phase (hours) vs. longer-term (days to weeks) inflammatory corticosteroid phase response. For example, if a patient was able to correlate the short-term anesthetic phase with their painful dermatome, but saw no longer-term relief (greater than 2 weeks) from the corticosteroid, they might be considered for percutaneous decompression. However, if the patient saw sustained benefit from the corticosteroid (in addition to anesthetic phase confirmation of

their painful dermatome), they might not require further therapy given their improved symptoms. Although less sensitive than emerging techniques currently being applied by two of the authors (KMA and REW Appendix A), this approach provided a useful clinical framework for correlating whether a specific root was being affected by the herniation (anesthetic phase) and whether or not percutaneous decompression was warranted (sustained recurrent symptoms within 2 weeks of selective blockade). The current and newer techniques promise to further clarify multidermatomal unilateral and bilateral cross-innervation presentations. Thus, once the root(s)/level(s) were symptomatically confirmed, the Dekompressor® PLD probe was applied to extract the specific contained herniated nucleus pulposus in question (Figure 3a,b).

In the current case series, percutaneous discectomy with Dekompressor® resulted in significant improvement in functionality, pain scores (VAS), and patient satisfaction in carefully selected patients with radicular pain at 1 year. These results show a sustained response to therapy when compared with the previously reported 6-month data in this same group. (1) Furthermore, these results were achieved with small volumes of disc removal (mean 1.25 cc) objectively in all patients within an average of 3 minutes (Figure 5). Also, follow-up MRI at 1 year has demonstrated sustained postoperative reductions in treated contained herniations without accelerated disc degeneration, auger fragmentation, or tissue injury (Figure 6a,b). Furthermore, these same studies demonstrated no annular or internal nuclear disruption, validating preclinical bench and animal testing. (14,15) Specifically, the lack of post-Dekompressor® accelerated disc degeneration after selective small-volume extractions may be significant for maintained efficacy. (18,19)

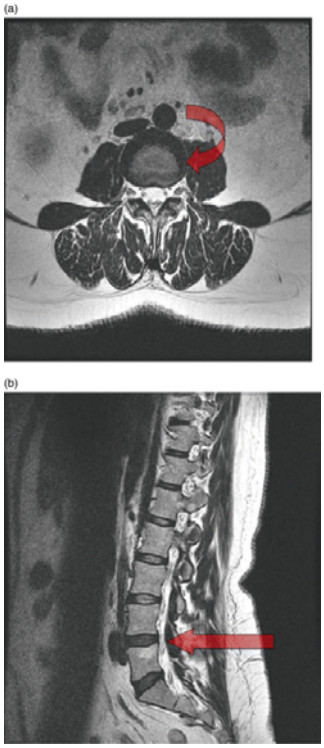

Figure 6. (a) Coronal and (b) Saggital MRI 1 year post decompression of patient 3(a) noting resolution of posterolateral L4/5 contained herniation. Patient resolved their back and leg pain. Note reduction of contained herniation arrows.

As previously reported, quantitative and qualitative analysis of the disc sample aspirate has been clinically useful. (1) First, it provided objective evidence that disc was removed, the cellular character of that material, and provided a qualitative and quantitative measure. Second, this cellular analysis confirmed a lack of tissue injury on all samples, validating preclinical laboratory testing. (14,15) Third, the sample size has been a clinical reference when staging residual herniation treatment (ie, when correlating to what degree the original herniation had been reduced by the initial decompression). Finally, it has provided both photographic (intraoperative) and written evidence (the pathology report) of quantifiable disc removal; the evolving standard for hospitals, patients, insurance precertification, and third party payers. (1) In the future, disc samples may also provide further diagnostic or therapeutic analysis of the internal disc architecture (biochemical study of radiculitis; confirmation and staging of progressive or evolving degenerative disc disease, bacterial discitis diagnosis and treatment, etc.); aiding diagnosis and treatment of painful discogenic conditions. (10)

This report is a follow-up to the initial 6-month study, and purposefully follows the original clinical format. Like its predecessor, it specifically lacks a control group, randomization, and assesses discogenic leg pain without an evaluation of low back pain efficacy. Furthermore, discogenic leg pain was purposefully correlated between clinical exam, imaging study, and response to the local anesthetic phase dermatomaly of low-volume selective nerve root blockade. No previously operated (open) disc level was included. Finally, all patients were given ample time to fail more conservative medical management (at least 6 months of rest, physical therapy, medication use, and lack of sustained response to epidural and/or selective root block corticosteroid).

CONCLUSION

This multicenter study obtained safe and effective disc removal and pain relief with the Dekompressor® PLD probe at 1 year. (1) These results sustain the initially reported 6-month reductions in VAS score, functional improvement, medication reduction, and patient satisfaction. Percutaneous disc decompression/discectomy can be successfully integrated into a long-term conservative treatment program for chronic discogenic leg pain. (16,20)

ACKNOWLEDGEMENTS

Stryker Instruments, Kalamazoo, Michigan, provided financial support. Authors REW and SAB have a product development financial interest.

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APPENDIX A

Emerging spinal diagnostic localization and neuromodulatory innervation monitoring techniques: approaches that compliment and/or further clarify/objectify current VAS and localization anesthetic/corticosteroid phase assessments.

1. Pre- and postanesthetic phase dermatomal assessments with real-time cortical electroencephalogram (EEG) (BIS®) monitoring to standardize reporting without intravenous sedation collateral effects (somatic and sympathetic blockade all levels).
2. Intraoperative selective stimulation cannula(e) placements to perform direct intraoperative stimulation/localization testing of the dermatome(s) of interest during spinal (root), or peripheral nerve blockade (also measured at confirmed presedation equivalent EEG cortical functional [BIS®] levels). Maybe via cannulae, catheters selectively, transforaminally, anterograde, retrograde, etc.
3. Pre-, intraoperative, "durational," and/or postoperative sensory conduction threshold/neural conduction velocity/somatosensory evoked potential/electromyographic analyses of spinal diagnostic and/or therapeutic

neuromodulatory modalities (radiofrequency, neuromostimulation, neurochemical, etc.).

4. Functional analysis ("change in delta monitoring"), pre- and postdiagnostic blockade as well as pre-, post-, and/or "durational assessments" of therapeutic modalities (radiofrequency, neuromostimulation, neurochemical, etc.).
5. Combined pre-, post-, and "durational" assessments of functional (physical therapeutic, "change in delta monitors"), and neural (neural conduction threshold, neural conduction velocity [NCV], electromyography [EMG], somato sensory evoked potential [SSEP], etc.) with neurostimulation/neuromodulation therapies.
6. Pre-, post-, and "durational assessments" of site-specific neurostimulation modalities. Examples: Disability and Midas Scores for C1-2-3, V1, or superficial temporal cranial neuralgias (peripheral nerve stimulator [PNS]); vibroproprioceptive peripheral analysis (spinal cord stimulator [SCS], selective nerve root stimulator [SNRS], and PNS); chemical samplings (cerebrospinal fluid [CSF], ventricular, blood) for intrathecal efficacy; cystometrographic analysis and programming for SNRS at the sacral level (urge incontinence, urgency-frequency, pelvic floor dysfunction, pelvic pain, sexual dysfunction, neurogenic bladder, spinal cord injury); transvaginal EMG monitoring for pelvic pain and floor dysfunction (SNRS); coronary sinus lactate sampling for SCS anginal monitoring; transcutaneous oxygen monitoring for peripheral vascular disease (PVD) (SCS, SNRS, PNS).
7. Intradiscal annular and nuclear stimulation with and without provocative discography and/or anesthetic challenge.
8. Intrajoint/capsular/median branch/rami stimulation for concordant localization of atlantooccipital (AO)/atlan to axial (AA)/facet/sacroiliac (SI) joint analysis.

From: Alò K, Timons R, Wright R. *Clinical Perspectives in Pain Management: Objectifying and Clarifying the Evolving Interventional Landscape* (manuscript in preparation).