

Systematic Review

Percutaneous Lumbar Mechanical Disc Decompression Utilizing Dekompressor®: An Update of Current Evidence

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Background: The primary goal of the surgical treatment of nerve root compression from a disc protrusion continues to be the relief of compression by removing the herniated nuclear material with open discectomy. However, poor results have been reported for contained disc herniations with open surgical interventions. In recent years, a number of minimally invasive nuclear decompression techniques for lumbar disc prolapse, protrusion, and/or herniation have been introduced, including the Dekompressor®. The efficacy of several alternative techniques, including the Dekompressor, automated percutaneous discectomy, and laser discectomy, has been described, but is not convincing. There is a continued paucity of evidence for all decompression techniques.

Objective: The objective of this systematic review is to evaluate and update the literature describing the clinical effectiveness of Dekompressor, a high rotation per minute (RPM) device used in mechanical lumbar disc decompression.

Study Design: A systematic review of the literature focusing on mechanical disc decompression with Dekompressor.

Methods: The available literature on the use of percutaneous disc decompression (PDD) with Dekompressor to manage chronic low back and lower extremity pain was reviewed using the Cochrane Musculoskeletal Review Group criteria for randomized trials and the Newcastle-Ottawa Scale criteria for observational studies.

The level of evidence was classified as good, fair, and limited or poor based on the US Preventive Services Task Force (USPSTF) system for grading the quality of evidence.

Data sources included relevant literature identified through PubMed and EMBASE from 1966 through September 2012, and manual searches of the bibliographies of known primary and review articles.

Outcome Measures: Pain relief was the primary outcome measure. Secondary outcome measures were functional improvement, improvement of psychological status, opioid intake, and return to work.

Short-term effectiveness was defined as one year or less. Long-term effectiveness was defined as greater than one year.

Results: Only 5 studies were considered for inclusion. Of those, only 3 of them met inclusion criteria.

Based on USPSTF criteria, the level of evidence for PDD with Dekompressor is limited.

Limitations: Paucity of high quality literature.

Conclusion: This systematic review found limited evidence for PDD with Dekompressor.

Key words: Intervertebral disc disease, chronic low back pain, mechanical disc decompression, disc protrusion, disc extrusion, radiculitis, Dekompressor.

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Lumbar disc herniation is the most common cause of radiculitis and is generally effectively treated by surgery when refractory to conservative therapies, including interventional techniques. Surgery for lumbar disc herniation can be classified into 2 broad categories: open versus minimally invasive. In 1934, Mixter and Barr were the first authors to treat lumbar disc herniation surgically by performing an open laminectomy and discectomy (1). Lumbar disc surgery remains one of the most commonly performed operations in the United States (2,3). The Spine Patient Outcomes Research Trial (3) demonstrated that, at 4 years, patients who underwent surgery for lumbar disc herniation achieved greater improvement than did patients treated nonoperatively in all primary and secondary outcomes except work status.

Lumbar discectomies are often performed to decompress the nerve root and alleviate radicular pain in cases of failed conservative therapy. The primary goal of surgical treatment is the relief of nerve root compression by removing the herniated nuclear material, and the primary modality of treatment has been open discectomy. However, the specific pathology often determines the most suitable procedure. Extruded and sequestered disc herniations may require more invasive procedures to retrieve the disc material, whereas disc protrusions are potentially more amenable to minimally invasive percutaneous procedures. Multiple alternative techniques to open surgical discectomy have been introduced, including microdiscectomy, chemonucleolysis, automatic or manual percutaneous discectomy, laser discectomy, nucleoplasty, and the Dekompressor® (Stryker Spine, Allendale, NJ), a high RPM device (4-20). In a 1938 editorial, Love (15) described the removal of a protruded intervertebral disc without laminectomy. Hijikata (10,11) described manual percutaneous lumbar discectomy in the 1970s. Subsequently, in 1985, Onik et al (16) described automated percutaneous lumbar discectomy (APLD), a minimally invasive method for mechanically treating contained disc herniations. The Dekompressor system was introduced based on the philosophy of APLD (4,17-20).

The understanding of the causes of low back pain has evolved over the past century in concert with an explosive increase in chronic low back pain, a growing number of modalities available for chronic low back pain diagnosis and management, and escalating costs and their impact on health care resources. (21-70). Absolute indications for surgery include altered bladder function and progressive muscle weakness, but these are rare (71). In the Cochrane Collaboration review,

Gibson and Waddell (71) presented the results from 40 randomized controlled trials (RCTs) and 2 quasi-randomized controlled trials of surgical interventions for lumbar disc prolapse, including 17 new trials since the first issue of the review. This review concluded that the effectiveness of alternative forms of discectomy other than traditional open discectomy is unclear.

The authors stated that there is considerable evidence that surgical discectomy provides effective clinical relief for carefully selected patients with sciatica due to lumbar disc prolapse that fails to resolve with conservative management (71). They noted that, at present, the use of micro- or standard discectomy probably depends more on the training and expertise of the surgeon and the resources available than on scientific evidence of efficacy. In addition, they concluded that, at present, unless or until better scientific evidence is available, multiple minimally invasive decompression techniques should be regarded as investigational.

Even though the specific pathology often determines the most suitable procedure, few studies have attempted to correlate outcomes of microdiscectomy for lumbar disc herniations with the specific type or level of disc herniation (72-84). Less satisfactory outcomes with smaller lumbar disc herniations have been identified, demonstrating that surgical outcomes are better predicted by herniation size and type than by patient age, gender, or workers' compensation status (84). Lumbar disc herniation types have been described based on annular competence and the presence of a sequestered or extruded disc fragment.

Carragee et al (83) reported the outcome of single level lumbar discectomies in 187 consecutive patients with a mean age of 37.5 years. They observed poorer surgical outcomes in patients with massive annular defects and in those with an intact annulus and no identifiable fragment. Dewing et al (82), in an evaluation of 197 consecutive single level lumbar microdiscectomies performed by a single surgeon, demonstrated that patients with sequestered or extruded lumbar disc herniations had significantly better outcomes than did those with contained herniations. Patients are expected to have poorer outcomes and decreased return to duty rates if they have contained disc herniations, have a predominance of back pain, are on restricted duty, and/or are smokers. The authors concluded that, in carefully screened patients, lumbar microdiscectomy for symptomatic disc herniation results in an overall high success rate, patient satisfaction, and return to physically demanding activities.

An evaluation of magnetic resonance imaging (MRI) accuracy and the detection of lumbar disc containment

by Weiner and Patel (85) found that MRI may inaccurately assess containment status of lumbar disc herniations in 30% of cases. Consequently, the authors concluded that, given the importance of containment with respect to patient selection for indirect discectomy techniques and intradiscal therapies, coupled with prognostic significance, other methods of assessing containment should be employed when alternative interventions are being considered. Thus, discography may be useful in assessing the containment of disc herniation (86,87).

The Dekompressor system is a single-use probe intended for percutaneous discectomies under fluoroscopic imaging. The device removes a predetermined amount of disc material from the herniated disc, reducing pressure in the disc and the surrounding area. Using a cannula placement similar to that used for a standard discography, less pertinent scarring and less postoperative fibrosis may be expected with this device (19). The Dekompressor has been described as a minimally invasive technique with advantages over other techniques (17).

A systematic assessment of the efficacy of percutaneous lumbar disc decompression utilizing Dekompressor demonstrated limited evidence for both short-term and long-term relief (4).

A review of the current literature focusing on percutaneous mechanical disc decompression using the Dekompressor device (88) identified 3 nonrandomized studies and a single case series. All studies were reasonably rigorous in reporting pain relief and the use of analgesics. Data related to physical functioning were scarce. The results suggested that, even though the investigators reported pain relief, there was a lack of rigor with respect to other outcome measures, such as the use of other health care resources and physical functioning.

The objective of this systematic review is to evaluate and update the literature describing the efficacy of percutaneous lumbar mechanical disc decompression using the Dekompressor, a mechanical high revolutions per minute device described in a previous publication (4). The need for frequent updates of systematic reviews has been described elsewhere (89,90).

1.0 METHODS

The methodology utilized in this systematic review was based on the review process derived from evidence-based systematic reviews and meta-analysis of randomized trials and observational studies (27,91-98), including Consolidated Standards of Reporting Trials guidelines for the conduct of randomized trials (36,99-102), Standards for Reporting Observational Studies (66,103), Cochrane

guidelines (27,96,97), Chou and Huffman's guidelines (29), and quality of reporting of meta-analyses (93).

1.1 Criteria for Considering Studies for This Review

1.1.1 Types of Studies

The types of studies considered for inclusion were RCTs, nonrandomized observational studies, and case reports and reviews for adverse effects.

1.1.2 Types of Patients

Patients of interest were adults at least 18 years of age with chronic low back and lower extremity pain for at least 3 months.

Patients must have failed previous conservative therapy prior to starting interventional pain management techniques.

1.1.3 Types of Interventions

The interventions considered for inclusion were PDD with Dekompressor.

1.1.4 Types of Outcome Measures

- ◆ The primary outcome measure was pain relief.
- ◆ The secondary outcome measures were functional improvement; change in psychological status; return to work; reduction or elimination of opioid use, other drugs, or other interventions; and complications.
- ◆ At least 2 of the review authors independently, in an unblinded standardized manner, assessed the outcomes measures. Any disagreements between reviewers were resolved by a third author and consensus.

1.2 Literature Search

Searches were performed from the following sources without language restrictions:

1. PubMed from 1966
www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed
2. EMBASE from 1980
www.embase.com/
3. Cochrane Library
www.thecochranelibrary.com/view/0/index.html
4. U.S. National Guideline Clearinghouse (NGC)
www.guideline.gov/
5. Previous systematic reviews and cross references
6. Clinical Trials
clinicaltrials.gov/

The search period was from 1966 through September 2012.

1.3 Search Strategy

The search strategy emphasized chronic low back and lower extremity pain, disc herniation, and radiculitis treated with PDD with Dekompressor.

Search terms included chronic low back pain, disc herniation, radiculitis, microdiscectomy, percutaneous disc decompression, and percutaneous disc decompression with Dekompressor.

At least 2 of the review authors independently, in an unblinded standardized manner, performed each search. Accuracy was confirmed by a statistician. All searches were combined to obtain a unified search strategy. Any disagreements between reviewers were resolved by a third author and consensus.

1.4 Data Collection and Analysis

The review focused on RCTs, observational studies, and reports of complications. The population of interest was patients suffering with chronic low back and lower extremity pain for at least 3 months. Only PDD with Dekompressor was evaluated. All of the studies providing appropriate management and with outcome evaluations of one month or longer and statistical evaluations were reviewed. Reports without appropriate diagnosis, nonsystematic reviews, book chapters, and case reports were excluded.

1.4.1 Selection of Studies

- ◆ In an unblinded standardized manner, 2 review authors screened the abstracts of all identified studies against the inclusion criteria.
- ◆ All articles with possible relevance were then retrieved in full text for comprehensive assessment of internal validity, quality, and adherence to inclusion criteria.

1.4.2 Inclusion and Exclusion Criteria

The following inclusion and exclusion criteria were used:

1. Are the patients described in sufficient detail to al-

low one to determine whether they are comparable to those who are treated in interventional pain management clinical practices?

- A. Setting – office, hospital, outpatient, inpatient.
 - B. Physician – interventional pain physician, general practice physician, anesthesiologist, physiatrist, neurologist, rheumatologist, orthopedic surgeon, neurosurgeon, etc.
 - C. Patient characteristics - duration of pain.
 - D. Previous noninterventional techniques or surgical intervention.
2. Is the intervention described in sufficient detail to enable one to apply its use to patients in interventional pain management settings?
 - A. Nature of intervention.
 - B. Frequency of intervention.
 - C. Duration of intervention.
 3. Were clinically relevant outcomes measured?
 - A. Proportion of pain relief.
 - B. Disorder/specific disability.
 - C. Functional improvement.
 - D. Allocation of eligible and noneligible patients to return to work.
 - E. Ability to work.

1.4.3 Clinical Relevance

The clinical relevance of the included studies was evaluated according to 5 questions recommended by the Cochrane Back Review Group (Table 1) (95,104). Each question was scored as positive (+) if the answer was “yes,” negative (-) if the answer was “no,” and unclear (?) if data were not available to answer the question.

1.4.4 Methodological Quality or Validity Assessment

Methodological quality assessment was performed by 2 review authors who independently assessed, in an unblinded standardized manner, the internal validity of all the studies. Discrepancies were evaluated by a third reviewer and settled by consensus.

Table 1. *Clinical relevance questions.*

	P (+)	N (-)	U (unclear)
A) Are the patients described in sufficient detail to allow one to determine whether they are comparable to those who are treated in interventional pain management clinical practices?			
B) Are the interventions and treatment settings described in sufficient detail to apply its use in clinical practice?			
C) Were clinically relevant outcomes measured and reported?			
D) Is the size of the effect clinically meaningful?			
E) Do the likely treatment benefits outweigh the potential harms?			

Scoring adapted and modified from Staal JB, et al. Injection therapy for subacute and chronic low back pain. *Cochrane Database Syst Rev* 2008; 3:CD001824 (104).

The quality of each individual article used in this analysis was assessed by Cochrane review criteria (Table 2) (96) for randomized trials and the Newcastle-Ottawa Scale for observational studies (Tables 3 and 4)

Table 2. *Randomized controlled trials quality rating system.*

A	1. Was the method of randomization adequate?	A random (unpredictable) assignment sequence. Examples of adequate methods are coin toss (for studies with 2 groups), rolling a die (for studies with 2 or more groups), drawing of balls of different colors, drawing of ballots with the study group labels from a dark bag, computer-generated random sequence, pre-ordered sealed envelopes, sequentially-ordered vials, telephone call to a central office, and pre-ordered list of treatment assignments. Examples of inadequate methods are: alternation, birth date, social insurance/ security number, date in which they are invited to participate in the study, and hospital registration number.	Yes/No/Unsure
B	2. Was the treatment allocation concealed?	Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.	Yes/No/Unsure
C	Was knowledge of the allocated interventions adequately prevented during the study?		
	3. Was the patient blinded to the intervention?	This item should be scored "yes" if the index and control groups are indistinguishable for the patients or if the success of blinding was tested among the patients and it was successful.	Yes/No/Unsure
	4. Was the care provider blinded to the intervention?	This item should be scored "yes" if the index and control groups are indistinguishable for the care providers or if the success of blinding was tested among the care providers and it was successful.	Yes/No/Unsure
	5. Was the outcome assessor blinded to the intervention?	Adequacy of blinding should be assessed for the primary outcomes. This item should be scored "yes" if the success of blinding was tested among the outcome assessors and it was successful or: -for patient-reported outcomes in which the patient is the outcome assessor (e.g., pain, disability): the blinding procedure is adequate for outcome assessors if participant blinding is scored "yes" -for outcome criteria assessed during scheduled visit and that supposes a contact between participants and outcome assessors (e.g., clinical examination): the blinding procedure is adequate if patients are blinded, and the treatment or adverse effects of the treatment cannot be noticed during clinical examination -for outcome criteria that do not suppose a contact with participants (e.g., radiography, magnetic resonance imaging): the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed when assessing the main outcome -for outcome criteria that are clinical or therapeutic events that will be determined by the interaction between patients and care providers (e.g., co-interventions, hospitalization length, treatment failure), in which the care provider is the outcome assessor: the blinding procedure is adequate for outcome assessors if item "4" (caregivers) is scored "yes" -for outcome criteria that are assessed from data of the medical forms: the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed on the extracted data.	Yes/No/Unsure
D	Were incomplete outcome data adequately addressed?		
	6. Was the drop-out rate described and acceptable?	The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a "yes" is scored. (N.B. these percentages are arbitrary, not supported by literature).	Yes/No/Unsure
	7. Were all randomized participants analyzed in the group to which they were allocated?	All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of non-compliance and co-interventions.	Yes/No/Unsure
E	8. Are reports of the study free of suggestion of selective outcome reporting?	In order to receive a "yes," the review author determines if all the results from all pre-specified outcomes have been adequately reported in the published report of the trial. This information is either obtained by comparing the protocol and the report, or in the absence of the protocol, assessing that the published report includes enough information to make this judgment.	Yes/No/Unsure
F	Other sources of potential bias:		
	9. Were the groups similar at baseline regarding the most important prognostic indicators?	In order to receive a "yes," groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of main outcome measure(s).	Yes/No/Unsure
	10. Were co-interventions avoided or similar?	This item should be scored "yes" if there were no co-interventions or they were similar between the index and control groups.	Yes/No/Unsure
	11. Was the compliance acceptable in all groups?	The reviewer determines if the compliance with the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). For example, physiotherapy treatment is usually administered over several sessions; therefore it is necessary to assess how many sessions each patient attended. For single-session interventions (e.g., surgery), this item is irrelevant.	Yes/No/Unsure
	12. Was the timing of the outcome assessment similar in all groups?	Timing of outcome assessment should be identical for all intervention groups and for all important assessments.	Yes/No/Unsure

Adapted and modified from Furlan AD et al; Editorial Board, Cochrane Back Review Group. 2009 updated method guidelines for systematic reviews in the Cochrane Back Review Group. *Spine (Phila Pa 1976)* 2009; 34:1929-1941 (96).

Table 3. *Newcastle-Ottawa quality assessment scale: Case control studies.*

Selection
1) Is the case definition adequate?
a) yes, with independent validation *
b) yes, e.g. record linkage or based on self reports
c) no description
2) Representativeness of the cases
a) consecutive or obviously representative series of cases *
b) potential for selection biases or not stated
3) Selection of Controls
a) community controls *
b) hospital controls
c) no description
4) Definition of Controls
a) no history of disease (endpoint) *
b) no description of source
Comparability
1) Comparability of cases and controls on the basis of the design or analysis
a) study controls for disc herniation or radiculitis *
b) study controls for any additional factor * (This criteria could be modified to indicate specific control for a second important factor.)
Exposure
1) Ascertainment of exposure
a) secure record (eg surgical records) *
b) structured interview where blind to case/control status *
c) interview not blinded to case/control status
d) written self report or medical record only
e) no description
2) Same method of ascertainment for cases and controls
a) yes *
b) no
3) Non-Response rate
a) same rate for both groups *
b) non respondents described
c) rate different and no designation

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

Wells GA, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. www.ohri.ca/programs/clinical_epidemiology/oxford.asp (105).

(105,106). Nonrandomized observational studies were included if they enrolled a total of at least 50 patients or at least 25 patients in each comparison group. Even though none of these instruments or criteria has been systematically evaluated, the advantages and disadvantages of each system were debated.

Each study was evaluated against the criteria by at least 2 authors, and any disagreements were discussed

with a third reviewer. Authors with a perceived conflict of interest for any manuscript recused themselves from reviewing the manuscript.

It was not possible to use quality assessment criteria to evaluate reports of adverse effects, confounding factors, etc. Thus, these were considered based on interpretation of the reports published and critical analysis of the literature.

Table 4. *Newcastle-Ottawa quality assessment scale for cohort studies.*

Selection
1) Representativeness of the exposed cohort
a) truly representative of the average _____ (describe) in the community *
b) somewhat representative of the average _____ in the community *
c) selected group of users e.g. nurses, volunteers
d) no description of the derivation of the cohort
2) Selection of the non exposed cohort
a) drawn from the same community as the exposed cohort *
b) drawn from a different source
c) no description of the derivation of the non exposed cohort
3) Ascertainment of exposure
a) secure record (eg surgical records) *
b) structured interview *
c) written self report
d) no description
4) Demonstration that outcome of interest was not present at start of study
a) yes *
b) no
Comparability
1) Comparability of cohorts on the basis of the design or analysis
a) study controls for disc herniation or radiculitis *
b) study controls for any additional factor * (This criteria could be modified to indicate specific control for a second important factor.)
Outcome
1) Assessment of outcome
a) independent blind assessment *
b) record linkage *
c) self report
d) no description
2) Was follow-up long enough for outcomes to occur
a) yes (select an adequate follow up period for outcome of interest) *
b) no
3) Adequacy of follow up of cohorts
a) complete follow up - all subjects accounted for *
b) subjects lost to follow up unlikely to introduce bias - small number lost - > ____ % (select an adequate %) follow up, or description provided of those lost) *
c) follow up rate < ____ % (select an adequate %) and no description of those lost
d) no statement

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability.

Wells GA, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. www.ohri.ca/programs/clinical_epidemiology/oxford.asp (105).

Only the randomized trials meeting at least 50% of the inclusion criteria were included in the analysis. Studies meeting less than 50% of the inclusion criteria were described and discussed.

Observational studies meeting a minimum of 7 of the 13 criteria for cohort studies and 5 of the 10 criteria for case-control studies were included in the analysis. Studies not meeting these minimums were described and discussed.

1.4.5 Data Extraction and Management

Two review authors independently, in an unblinded standardized manner, extracted the data from the included studies. Disagreements were resolved by discussion between the 2 reviewers; if no consensus could be reached, a third author was called in to break the impasse.

1.4.6 Measurement of Treatment Effect in Data Synthesis (Meta-Analysis)

Data were summarized using meta-analysis when at least 5 studies met the inclusion criteria.

Qualitative (the direction of a treatment effect) and quantitative (the magnitude of a treatment effect) conclusions were evaluated. A random-effects meta-analysis to pool data was also used (106).

1.4.7 Clinical Effectiveness

To be considered clinically meaningful, a patient's pain score must have changed by at least 2 points on a scale of 0 to 10 (or 20 percentage points), based on commonly utilized findings in trials studying general chronic pain (107), chronic musculoskeletal pain (108), and chronic low back pain (92,93,109,110). However, recent descriptions of clinically meaningful improvement identified either pain relief or functional status as at least 50% (111-124). Consequently, to determine clinical effectiveness for this analysis, a patient must have experienced 1) at least a 3-point change on an 11-point pain scale (0 to 10), 2) at least 50% pain relief from the baseline, or 3) functional status improvement of at least 40% from the baseline.

1.5 Summary Measures

Summary measures included at least 50% or more pain reduction in at least 40% of the patients, or at least a 3-point decrease in pain scores and a relatively low risk of adverse events, including side effects.

1.6 Analysis of Evidence

The analysis of the evidence was performed based on United States Preventive Services Task Force criteria (125) as illustrated in Table 5, which have been utilized by multiple authors (29,126-143).

The analysis was conducted using 3 levels of evidence: good to fair to limited or poor.

At least 2 of the review authors independently, in an unblinded standardized manner, analyzed the evidence. Any disagreements between reviewers were resolved by a third author and consensus. If there were any conflicts of interest (e.g., authorship), those reviewers recused themselves from the analysis.

1.7 Outcome of the Studies

In the randomized trials, a study was judged to be positive if PDD with Dekompressor was clinically relevant and effective, and the study included a placebo control or active control. A study was judged to be negative if no difference between the study treatments or no improvement from baseline was identified. Further, the outcomes were judged at the reference point, with positive or negative results reported at 6 months, one year, and after one year.

For observational studies, a study was judged to be positive if the percutaneous disc decompression with Dekompressor was effective, with outcomes reported at the reference point with positive or negative results at 6 months, one year, and after one year. However, observational studies were included in the analysis only if there were fewer than 5 randomized trials meeting the inclusion criteria.

Short-term effectiveness was defined as one year or less. Long-term effectiveness was defined as greater than one year.

Table 5. Method for grading the overall strength of the evidence for an intervention.

Grade	Definition
Good	Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least 2 consistent, higher-quality RCTs or studies of diagnostic test accuracy).
Fair	Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least one higher-quality trial or study of diagnostic test accuracy of sufficient sample size; 2 or more higher-quality trials or studies of diagnostic test accuracy with some inconsistency; at least 2 consistent, lower-quality trials or studies of diagnostic test accuracy, or multiple consistent observational studies with no significant methodological flaws).
Limited or Poor	Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

Adapted and modified from methods developed by U.S. Preventive Services Task Force (29,125).

2.0 RESULTS

Figure 1 depicts a flow diagram of the study selection as recommended by Preferred Reporting Items for Systematic Reviews and Meta-Analyses (94). There were 5 studies considered for inclusion (17-19,144,146). Of those, none were randomized. One was retrospective (144) and 4 were prospective evaluations (17-19,145). One study was published as 2 reports (17,18). One study (144) included only 10 patients, thus failing to meet an inclusion criteria. Therefore, 3 studies were available for inclusion (17,19,145).

Table 6 describes the studies considered for inclusion.

2.1 Clinical Relevance

As illustrated in Table 7, all of the 3 studies (n=3) met the criteria for clinical relevance with a score of 5 of 5 (17-19,145).

2.2 Methodological Quality Assessment

A methodological quality assessment of the observational studies meeting the inclusion criteria was carried out utilizing the Newcastle-Ottawa Scale, as illustrated in Table 8. For cohort studies, scoring 67% or higher were considered high quality, studies scoring 50% to 66% were considered moderate quality, and studies scoring less than 50% were considered low quality and were excluded.

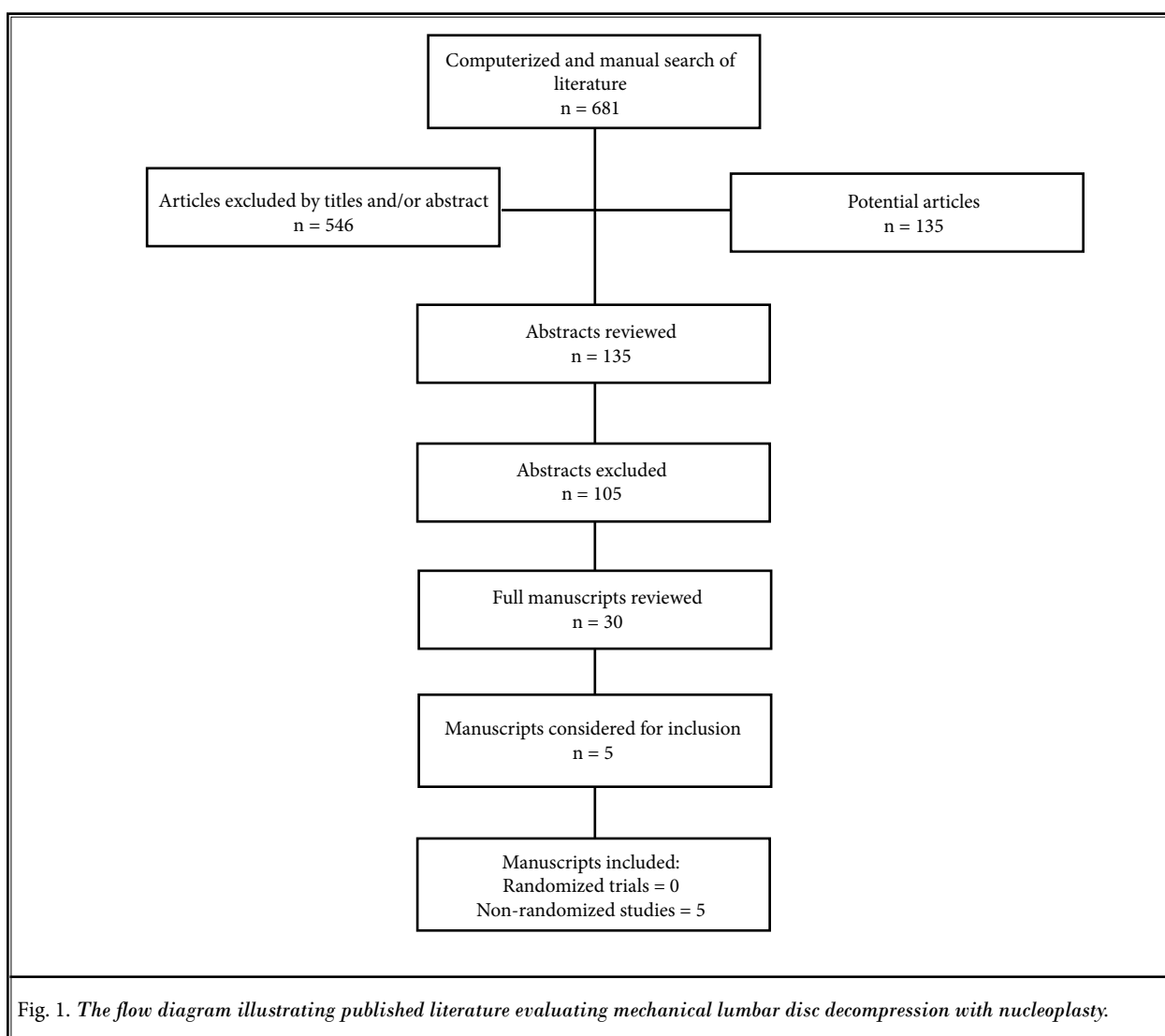


Fig. 1. The flow diagram illustrating published literature evaluating mechanical lumbar disc decompression with nucleoplasty.

Table 6. Study characteristics of published reports of mechanical lumbar disc decompression with Dekompressor.

Study/Methods	Study Characteristics	Participants	Intervention(s)	Outcome(s)	Result(s)	Conclusion(s) Short term relief ≤12 mos. Long-term relief >12 mos.
Alo et al, 2004, 2005 (17,18)	Prospective	50 patients with radicular pain of greater than 6 months with disc herniation of less than 6 mm after having failed conservative care, including positive response to spinal nerve block were included.	Percutaneous disc decompression with Dekompressor	Pain relief and follow-up at 6 months and 12 months with mean pain scores and proportion of patients with response	16% were lost to follow-up. Mean reduction of pain was 65%. Over two-thirds of the patients achieved at least 50% relief of pain at 12 months, with 14% achieving complete relief, and a further 8% achieving greater than 80% pain reduction, while 58% of patients maintained VAS scores of less than 4 at 12 months.	Positive short-term and long-term relief
Lierz et al, 2009 (19)	Prospective	64 patients with radicular pain of greater than 6 months with disc herniation of less than 6 mm after having failed conservative care and positive response to transforaminal epidural injection were studied.	Percutaneous disc decompression	Follow-up at 6 months and 12 months with mean pain scores and proportion of patients with response	Significant proportion of patients with improvement of pain, function and opioid use.	Positive short-term and long-term relief
Amoretti et al, 2006 (145)	Prospective	50 patients were studied with radicular pain of unclear duration or at least 3 weeks with preserved disc height and failure to respond to conservative care.	Percutaneous disc decompression	Pain relief at 6 months	Very good pain relief was reported with greater than 75% reduction of pain in a significant proportion of patients.	Positive short-term and long-term relief

Table 7. Clinical relevance of included studies.

Manuscript Author(s)	A) Patient description	B) Description of interventions and treatment settings	C) Clinically relevant outcomes	D) Clinical importance	E) Benefits versus potential harms	Total Criteria Met
Alo et al, 2004, 2005 (17,18)	+	+	+	+	+	5/5
Lierz et al, 2009 (19)	+	+	+	+	+	5/5
Amoretti et al, 2006 (145)	+	+	+	+	+	5/5

+ = positive; - = negative; U = unclear

Scoring adapted from Staal JB, et al. Injection therapy for subacute and chronic low-back pain. Cochrane Database Syst Rev 2008; 3:CD001824 (104).

2.3 Meta-Analysis

No randomized trials were available. Consequently, no meta-analysis was feasible.

2.4 Analysis of Evidence

Because there were only 3 prospective studies evaluating the effectiveness of Dekompressor (17-19,145), with one duplicate publication (17), the evidence for PDD with Dekompressor is limited.

3.0 COMPLICATIONS

The complications of percutaneous disc decompression (PDD) with Dekompressor are similar to complications occurring for other PDD modalities involving the passage of an instrument into the disc and include hematoma; abscess; allergic reaction to radiographic contrast medium or antibiotic; direct needle trauma to the spinal nerve; transient or persistent paresthesia;

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Table 8. *Methodological quality assessment of cohort studies utilizing Newcastle-Ottawa quality assessment scale.*

	Alo et al (17,18)	Lierz et al (19)	Amoretti et al (145)
Selection			
1) Representativeness of the exposed cohort			
a) truly representative of the average _____ (describe) in the community *	X	X	X
b) somewhat representative of the average pain patients in the community*			
c) selected group of users e.g. nurses, volunteers			
d) no description of the derivation of the cohort			
2) Selection of the non exposed cohort			
a) drawn from the same community as the exposed cohort *	X	X	X
b) drawn from a different source			
c) no description of the derivation of the non exposed cohort			
3) Ascertainment of exposure			
a) secure record (eg surgical records) *	X	X	X
b) structured interview v			
c) written self report			
d) no description			
4) Demonstration that outcome of interest was not present at start of study			
a) yes *	X	X	X
b) no			
Comparability			
1) Comparability of cohorts on the basis of the design or analysis			
a) study controls for disc hernation or radiculitis *			
b) study controls for any additional factor * (This criteria could be modified to indicate specific control for a second important factor.)			
Outcome (Exposure)			
1) Assessment of outcome			
a) independent blind assessment *			
b) record linkage *	X	X	X
c) self report			
d) no description			
2) Was follow-up long enough for outcomes to occur			
a) yes (select an adequate follow up period for outcome of interest) *	X	X	X
b) no			
3) Adequacy of follow up of cohorts			
a) complete follow up - all subjects accounted for *		X	X
b) subjects lost to follow up unlikely to introduce bias - small number lost - > ____ % (select an adequate %) follow up, or description provided of those lost) *	X		
c) follow up rate < ____ % (select an adequate %) and no description of those lost			
d) no statement			
SCORE	7/12	7/12	7/12

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of 2 stars can be given for Comparability

Wells GA, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. www.ohri.ca/programs/clinical_epidemiology/oxford.asp (105).

and spondylodiscitis (72,146-158).

One critical failure of the Dekompressor probe was reported while performing a discectomy at the L4/5 level on a 54-year-old patient (146). When the probe was removed after operating the instrument for one to 2 minutes, 4 inches of the tip broke off and remained embedded in the patient. The tip was removed surgically, and the patient recovered without any major complication. Similar instances have been previously reported by 2 other authors. One was thought to be caused by a bent cannula, which may have contributed to tip breakage.

4.0 Discussion

This systematic review of 3 relatively small observational studies of PDD with Dekompressor identified limited evidence to support efficacy in terms of either short-term or long-term pain relief. These findings suggest that PDD with Dekompressor is inferior to nucleoplasty, APLD, and laser discectomy (74-76), which have been assessed in multiple studies (74-76,157-192).

The Dekompressor is significantly different from these other modalities in that it removes a predetermined amount of disc material from the herniated disc, reducing pressure in the disc and the surrounding area. Less perineural scarring and postoperative fibrosis may be expected using a cannula placement similar to that used for a standard discography. However, epidural fibrosis may also develop with minimally invasive techniques (156). One of the major advantages of the new Dekompressor system is reported to be the cannula's small diameter, minimizing the risk of injury during disc insertion (19). Proponents of Dekompressor claim that, unlike other available systems, the device removes material from the disc in a fashion that can be quantified and examined histologically. However, except for the cannula size, Dekompressor is not significantly different from APLD, which is performed with a pneumatically driven, suction-cutting probe in a cannula with a 2.8 mm outer diameter. In both techniques, the disc is removed to decompress the nerve roots this can be examined externally; however, there are currently no specific recommendations for either technique. The proponents of Dekompressor claim that, because of the fast and gentle procedure, it is possible to treat multiple levels of the lumbar spine concurrently, specifically under computed tomography (CT) control (19). However, it is also clear that patients undergoing treatment at multiple levels experience relatively less benefit with respect to a number of outcome parameters (19). Con-

sequently, as is the case with other procedures, appropriate patient selection is crucial. For example, the best results may be obtained when the disc herniation is contained and is limited to a single level.

In a systematic review comparing surgery to conservative management of sciatica due to a herniated lumbar disc (31), Jacobs et al demonstrated that there was no significant difference between the two. However, the Spine Patient Outcomes Research Trial (SPORT) study found significant improvement with surgical intervention when compared to conservative management. In contrast to PDD, clinical outcomes after microdiscectomy for disc herniation and recurrent disc herniation have been very favorable (193-197).

A systematic review of the literature focusing on transforaminal endoscopic surgery for symptomatic lumbar disc herniation included one RCT, 7 nonrandomized controlled trials, and multiple observational studies (7,194,197-215). Overall, these studies found microdiscectomy to be superior to transforaminal endoscopic surgery. However, some of the studies reported superior or equal improvement with endoscopic discectomy.

In this evaluation, only one systematic review (4) and one comprehensive review (88) were assessed. The total number of studies evaluated was 3, compared to 2 in previous systematic evaluations (18,19,145). There has been only one new study since the previously published evaluation. The available literature on Dekompressor illustrates the common shortcomings of observational studies of interventions. Even though Dekompressor may be considered a new intervention modality, the early studies were published approximately 8 years ago. Consequently, one would expect that the technique's continued use would be supported by more recent, high quality evaluations. Even though all the studies are of moderate quality, they lack scientific rigor because of their observational, albeit prospective, design. Further, these studies do not include sufficiently large numbers of patients.

Alo et al (17,18) published 2 papers based on a single randomized prospective clinical trial evaluating the efficacy of treating disc herniations treated with the Dekompressor in an initial cohort of 50 consecutive patients with chronic radicular pain. Data were collected at 6-month follow-up.

Inclusion criteria were radicular pain with contained herniation ≤ 6 mm, correlating history and physical findings, pain for > 6 months, failure of conservative therapies, good to excellent short-term relief (< 2 weeks) after a fluoroscopically guided transforaminal

injection, confirmatory selective segmental spinal nerve block with 0.5–1.5 mL of anesthetic providing > 80% relief lasting at least the duration of the local anesthetic, and preservation of disc height (< 50% loss). Patients with progressive neurological deficits, more than 2 symptomatic levels, previous open surgery at the proposed treatment level, spine instability, fracture or tumor, and significant coexisting medical or psychological condition were excluded.

The authors assessed the patients' outcomes using the visual analog scale (VAS) for pain, analgesic usage, self-reported functional improvement, and overall satisfaction. The findings may have been more objective if the assessment had included some form of functional improvement measure. After 6 months, 74% of the patients reported reducing their analgesic intake, 90% reported improvement in functional status, and 80% reported overall satisfaction with the therapy. At the one-year follow-up, results were published for 42 patients (54 treatment levels). The authors noted a 65% average reduction in the preoperative VAS pain score, as well as a 79% reduction in analgesic intake. Functional improvement was observed in 91% of the patients.

Lierz et al (19) evaluated percutaneous lumbar discectomy at 76 lumbar levels in 64 patients using the Dekompressor system under CT guidance. Follow-up data at 12 months were obtained for all patients. The average reported pain level, as measured by VAS, was 7.3 at baseline and 2.1 at 12 months. Before the procedure, 61 patients (95%) regularly used opioid or nonopioid analgesics; after one year, 51 patients (80%) were able to reduce analgesic use. None of the patients reported procedure-related complications. The authors concluded that, when standardized patient selection criteria are used, treating patients with radicular pain associated with contained disc herniation using Dekompressor can be a safe and efficient procedure.

Amoretti et al (145) published results of a clinical follow-up of 50 patients treated by percutaneous lumbar discectomy using Dekompressor. Although not a blinded and randomized study, the data collection methodology was considered good and was based on clearly defined inclusion and exclusion criteria. Patients were included if they presented with "lumbar sciatica of disco-lumbar origin" secondary to a herniated disc documented by an MRI. Patients had undergone medical therapies such as "CT-guided infiltration" (presumably a corticosteroid injection). There was no change in disc height and the discs were satisfactorily hydrated,

as documented by a T2 signal on MRI. Patients were excluded if they presented with extruded herniations and inconsistency between MRI and clinical findings. Other exclusion criteria included infection and coagulopathy, as well as pro-operative treatment with morphine and anti-inflammatory drugs.

Using Dekompressor under CT or fluoroscopic guidance, the authors performed disc decompression primarily on L4-5 and L5-S1 discs, as well as on some L3-4 discs. Eleven patients did not respond satisfactorily to the treatment, but 39 patients were either able to suspend or reduce their medications (n=31 and n=8 respectively). Pain reduction was reported to stabilize after about 7 days in most patients. Of the patients who responded favorably, 36 out of 50 experienced > 70% relief. More importantly, the authors noted > 70% improvement in 79% of patients with posterolateral hernias, as compared to only 50% of patients with posteromedial hernias. However, this study failed to meet inclusion criteria, as the follow-up was limited to only 6 months.

Overall, these studies suggest that Dekompressor treatment improves pain and function and also reduces health care utilization, as described in Table 6. However, no validated instruments were used to arrive at those conclusions. Proponents state that these studies consistently demonstrate that significant numbers of patients achieve marked improvements that are sustained for 6 or 12 months, without significant decay in the response. However, there are multiple flaws in this analysis. Only one study reported complete relief in 14% of patients (17,18). Other studies reported only the proportion of patients reporting significant pain relief, without corroboration by outcome measures (88). Because of their observational nature, the studies also lack a control group and randomization, and are potentially biased by the investigators. Consequently, the true effectiveness of Dekompressor may be less than reported and also raises questions. Although the study by Alo et al (17,18) rigorously reported pain-related data, it was sponsored by the device manufacturer and involved the inventor of the device, again raising questions about potential bias (88).

In spite of the limited evidence, the Dekompressor is appealing because of its simplicity, relative safety, and the fact that it destroys minimal tissue, which suggests that disc height is maintained, or decreases more slowly, thus allowing the body time to adapt. The Dekompressor may be considered prior to open discectomy for patients with leg pain and a contained disc herniation.

Considering the multiple challenges related to surgical interventions and the other treatment modalities (e.g., interventional techniques and other conservative modalities) which these patients have basically failed prior to considering Dekompressor, they have no other option except for high-dose opioid therapy. Consequently, PDD by any of the modalities may still be an attractive option for patients with persistent pain (35-37,50-52,54-58).

The limitations of this systematic review include a lack of literature and lack of wide application of Dekompressor. This systematic review includes only limited evidence due to a lack of randomized trials which, along with a lack of placebo-controlled trials is often an issue for all interventional pain management. There is significant misunderstanding about the difference between active-controlled trials and placebo-controlled trials. At best, only active-controlled trials can be used to assess interventional pain management techniques. Consequently, this misunderstanding continues to persist in interventional pain management, with resultant inappropriate determination of evidence. As an example, in interventional pain management settings, many studies described as placebo-controlled are truly active-controlled or sham-controlled, since they utilize local anesthetic injection that produces a facet joint nerve block (216-218). However, as the literature demonstrates, a facet joint nerve block can provide prolonged relief averaging 13 to 16 weeks (111,112,117). It changes the assessment dynamics when clinical effectiveness is determined based on the differences between 2 groups of patients, rather than the differences between baseline and follow-up in the same patient. Thus, all of these studies could be construed as active-controlled trials, even though sham treatment was utilized. Similarly, multiple evaluations of epidural treatment have utilized local anesthetic and have been called placebo studies. Technically, these are sham-controlled. It is not always feasible to perform the best outcome studies with placebo control in an interventional setting, since it is extremely difficult to design a proper placebo in interventional pain management. In the absence of these studies, many methodologists and third party payers continue to deny payments for effective therapies.

It has been widely reported by Cochrane reviewers and others that placebo effect studies are susceptible to response bias and to other types of biases. Hróbjartsson et al (219) reviewed the pervasive and complex connection between the placebo effect and bias. Ever since the concept of the placebo was brought to the attention of the medical community by Beecher (220) in

his classic 1955 JAMA article, "The Powerful Placebo," in which he presented a review of assorted placebo-control trials, and argued that the substantial improvement in the condition of patients receiving placebo was caused by the placebo intervention. Nevertheless, Beecher's analysis committed the very fallacy that underlies the need for controlled trials. The observed response to placebo in randomized trials does not itself provide any reliable, unbiased, evidence of a placebo effect—an outcome caused by receiving a sham treatment disguised to be indistinguishable from an active medical intervention. Further, unbiased assessment of the placebo effect requires comparison of placebo interventions with a suitable control group in order to distinguish an effect of the placebo intervention from confounding factors, for example the natural history of the condition under investigation or regression to the mean (221). Even though Beecher's approach was clearly recognized as flawed in the late 1990's (222), by that time the notion of 'powerful placebo' became deeply rooted. Meanwhile methodologists haven't started anchoring to every study results of the natural history of the condition under investigation or regression to the mean. However, Krogsbøll et al (223) in reference to spontaneous improvement in randomized clinical trials and metaanalysis of 3-armed trials comparing no treatment, placebo, and active intervention, dispelled these myths. They showed that the conditions that had most pronounced spontaneous improvement were nausea 45%, smoking 40%, depression 35%, phobia 34%, and acute pain 25%. They also showed that overall, across all conditions and interventions there was a statistically significant change from baseline in all 3 arms. However, for chronic pain no treatment contributed to very small improvement and placebo response was also less than 30%, whereas active treatment showed effect of 60%. Assessment of standardized mean difference for changes from baseline group by acute or chronic conditions showed no change in the no treatment group. Consequently, authors concluded that spontaneous improvement and effect of placebo contributed importantly to the observed treatment effect in actively treated patients, but the relative importance of these factors differed according to clinical condition and intervention. Further, in 2001, in sharp contrast, the power of placebo was challenged by a systematic review published in the New England Journal of Medicine (224). This review identified 114 randomized clinical trials including placebo and no treatment groups, and reported no evidence of overall effects of placebo for objective and binary

outcomes and a small, and doubtfully clinically relevant, effect for continuous subjective outcomes, such as pain. These findings are clearly incompatible with Beecher's classic position and present methodologists view of spontaneous improvement of the disorder or disease. While some academic commentators either pointed out that worthwhile effects could still exist in some settings (225), or saw the review as a necessary scientific correction to set the bar differently for claims concerning placebo (226), some media commentators interpreted the result as demonstrating the placebo effect to be a myth (227). Even though the review, which was updated in 2004, showed similar findings (228), the latest update from 2010 reported more multifaceted results (229). The recent systematic review showed that large analgesic effects of placebo interventions were found in several well conducted trials and a considerable variation in effect could in part be explained by differences in trial design; for example, the placebo effect was larger when the intervention was a device compared with a pill. Overall popular fascination with the placebo effect, specifically methodologists who do not like any type of interventions in medicine, fueled fascination with the placebo effect with unrealistic assessments of its therapeutic effects to rule out any treatment successes. On the same token, some have suggested the therapeutic potential of placebos (230). However, all the metaanalysis (226,228,229) involving progressively larger number of studies and subjects, performed for Cochrane review, challenges the belief that in general that the placebo is powerful. Consequently, estimating the size of the effect of placebo is not only subject to considerable uncertainty, but seems to be almost impossible. Hróbjartsson et al (219) in their methodological analysis and discussion of placebo effect studies and their susceptibility to response bias and to other types of biases, showed that the difference between placebo and no-treatment remains an approximately and fairly crude reflection of the true effect of placebo intervention. They showed that a main problem is response bias in trials with outcomes that are based on patients' reports. Other biases involve differential co-intervention and patient drop-outs, publication bias, and outcome reporting bias, however, they have ignored the bias of the methodologists and improper analysis, and lack of consideration of injection of an inactive solution into active structure. Consequently, the extrapolation of results to clinical settings are challenging because of a lack of clear identification of the causal factors in many clinical trials, and the non-clinical settings and short du-

ration of most laboratory experiments. They (219) concluded that creative experimental efforts are needed to assess rigorously the clinical significance of placebo interventions and investigate the component elements that may contribute to therapeutic benefit.

It is quite evident that placebo solutions, such as sodium chloride, injected into painful structures have been reported to result in significant activity or even pain relief, not only for spinal pain, but also for other chronic pain conditions (231-237). Further, placebo and nocebo effects have been misunderstood, and decisions to consider all local anesthetic injections as placebo reveal a lack of understanding about the basis for placebo and nocebo (238-256). Neural blockade has been shown to result in long-term pain relief by interrupting the nociceptive input, disrupting the reflex arc of afferent pain fibers, inhibiting a topic discharge from damaged nerves, and possibly reversing central sensitization (257,258). Similarly, corticosteroids may also inhibit the synthesis or release of a number of proinflammatory mediators and cause a reversible local anesthetic effect (258-263). Local anesthetics can provide short- to long-term symptomatic relief through their mitigating effects on excessive nociceptive processing, reducing the release of neurotransmitters implicated in pain, increasing blood flow to ischemic nerve tissue, and causing phenotypic changes (263-277). Further, a prolonged effect for local anesthetics has been demonstrated in multiple studies evaluating epidural injections and facet blocks (115,118,119,121,124,125,278-280). In fact, many physicians use so-called impure placebos (272), also considered to be off-label, without documented evidence. The present literature in interventional pain management illustrates various drawbacks in applying placebo-controlled, sham-controlled, and active-controlled trials to intradiscal procedures.

5.0 CONCLUSION

This systematic review of PDD with Dekompressor included 3 studies and found limited evidence of effectiveness. The procedure may be recommended for patients with persistent pain after the failure of other interventional techniques when microdiscectomy is not indicated.

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Conflict of Interest:

Dr. Calodney is a consultant for Stryker, Inc., Medtronic, Inc., and Nimbus Concepts

Dr. Helm is a clinical investigator with Epimed and receives research support from Cephalon/Teva, AstraZeneca, and Purdue Pharma, LP. He has attended an advisory group meeting for Activas.

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