Systematic Review

An Updated Review of Automated Percutaneous Mechanical Lumbar Discectomy for the Contained Herniated Lumbar Disc

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Disclaimer: There was no external funding in the preparation of this manuscript. Conflict of interest: None.

Manuscript received: 01-04-2013 Accepted for publication: 02-05-2013

Free full manuscript: www.painphysicianjournal.com

Background: Lumbar disc prolapse, protrusion, and extrusion are the most common causes of nerve root pain and surgical interventions, and yet they account for less than 5% of all low back problems. The typical rationale for traditional surgery is that it is an effort to provide more rapid relief of pain and disability. It should be noted that the majority of patients do recover with conservative management. The primary rationale for any form of surgery for disc prolapse associated with radicular pain is to relieve nerve root irritation or compression due to herniated disc material. The primary modality of treatment continues to be either open or microdiscectomy, although several alternative techniques, including automated percutaneous mechanical lumbar discectomy, have been described. There is, however, a paucity of evidence for all decompression techniques, specifically alternative techniques including automated and laser discectomy.

Study Design: A systematic review of the literature of automated percutaneous mechanical lumbar discectomy for the contained herniated lumbar disc.

Objective: To evaluate and update the effectiveness of automated percutaneous mechanical lumbar discectomy.

Methods: The available literature on automated percutaneous mechanical lumbar discectomy in managing chronic low back and lower extremity pain was reviewed. The quality assessment and clinical relevance criteria utilized were the Cochrane Musculoskeletal Review Group criteria, as utilized for interventional techniques for randomized trials, and the criteria developed by the Newcastle-Ottawa Scale criteria for observational studies.

The level of evidence was classified as good, fair, and limited or poor, based on the quality of evidence scale developed by the U.S. Preventive Services Task Force (USPSTF).

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

Outcome Measures: Pain relief was the primary outcome measure. Other 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, whereas long-term effectiveness was defined as greater than one year.

Results: Nineteen studies were included; none of the randomized trials and 19 observational studies met inclusion criteria for methodological quality assessment. Overall, 5,515 patients were studied with 4,412 patients (80%) showing positive results lasting one year or longer.

Based on USPSTF criteria, the indicated evidence for automated percutaneous mechanical lumbar discectomy is limited for short- and long-term relief.

Limitations: A paucity of randomized controlled trials in the literature describing automated percutaneous mechanical disc decompression.

Conclusion: This systematic review shows limited evidence for automated percutaneous mechanical lumbar discectomy. Automated percutaneous mechanical lumbar discectomy may provide appropriate relief in properly selected patients with contained lumbar disc herniation.

Key words: Intervertebral disc disease, chronic low back pain, mechanical disc decompression, automated percutaneous mechanical lumbar discectomy, internal disc disruption, radiculitis.

Pain Physician 2013; 16:SE151-SE184

Lumbar disc prolapse, protrusion, and herniation are the most common causes of nerve root pain, and yet they account for less than 5% of all low back problems (1-3). Lumbar disc surgery remains one of the most commonly performed operations (4-7). Recent randomized trials demonstrated that surgery provides faster pain relief and perceived recovery in patients with a herniated disc (4,6,7). In addition, in the assessment of surgical versus nonoperative treatment for lumbar disc herniation, in a combined as-treated analysis at 4 years, patients who underwent surgery for a lumbar disc herniation achieved greater improvement than nonoperatively treated patients in all primary and secondary outcomes, except work status (4). The primary goal of surgery is the retrieval of herniated disc fragments and decompression of the nerve root. Since the first report of lumbar disc surgery in 1934, a laminectomy with transdural disc removal by Mixter and Barr (8), various less invasive techniques have been developed. Absolute indications for surgery include altered bladder function and progressive muscle weakness, which are rare (1).

Yasargil, in 1977, was the first to perform the removal of a herniated disc with the use of an operative microscope (9). With the introduction of the microscope, Yasargil and Casper refined the original laminectomy into open microdiscectomy (10,11). The principles of microsurgery for lumbar disc disease evolved in the 1990s with the routine practice of microdiscectomy. Subsequently, this technique has become the most common procedure worldwide. In 1997, Foley and Smith (12) introduced the transmuscular approach of the nonendoscopic discectomy with advanced optics and instruments applied.

Herniated discs are of 2 basic types: contained and non-contained. Contained herniated discs have an intact outer annulus containing displaced disc material. In contrast, non-contained herniated discs have localized displacement of disc material beyond the intervertebral disc space and a breach in the outer annulus (1-3).

Besides the risk of the development of a failed back surgery syndrome, the complication rates of lumbar disc surgery are substantial (13-25). Within 5 years of Mixter and Barr's (8) description of laminectomy in 1939, Love (26) was advocating a much more limited approach using a hemilaminectomy. Due to the radiographic evaluation of the ruptured disc being unreliable; as well as secondary issues related to myelography (27), Semmes (28) advised 2-level explorations using the laminotomy approach as being less morbid than myelography. Smith (29) introduced chemonucleolysis, which was later withdrawn due to devastating complications, leading to the description in the 1970s by Hijikata (30) and Williams (31) of minimally invasive surgical approaches. Following the tendency towards a progressively more discreet approach to the herniated disc, the innovation of a suction-cutting probe placed into the disc space has emerged (27). Onik, a radiologist, recognizing the similarity between vitreous material of the eye and the nucleus of the disc, proposed the use of redesigned ophthalmic equipment for this purpose, now known as Nucleotome (32,33). All minimally invasive treatments for disc protrusion, however, faced fierce opposition from some members of the surgical community, despite enjoying good outcomes and a high level of psychological acceptance by patients and surgeons (34,35). The procedure that finally emerged and was widely accepted was the intervertebral foraminal endoscopic discectomy, in which the herniation could be visualized and manually removed (36-40).

Microdiscectomy continues to be the standard method of treatment due to its simplicity, low rate of complications, and high percentage of satisfactory results (9). Endoscopic transforaminal discectomy appears to be a reliable method, provided the surgeon is expert enough in the technique, which implies a steep learning curve. When these conditions are met, and the operation is performed effectively, with no complications, the results are similar to microdiscectomy (23). Furthermore, in addition to endoscopic discectomy, other procedures of decompression have been described, including automated percutaneous mechanical lumbar discectomy (3), lumbar laser discectomy (25), coblation nucleoplasty (2), and utilization of the mechanical high RPM device, or DeKompressor® (24). Of all these, automated percutaneous mechanical lumbar discectomy is the oldest technique, having been used for approximately 35 years, and can allegedly produce satisfactory results with a small wound and fewer serious complications (2,29-35,41-78). However, debate regarding the indications and effectiveness of automated percutaneous mechanical lumbar discectomy continues (1,2,41,79). In addition, the overall criticism of various diagnostic and therapeutic modalities provided in lumbar disc displacement, and chronic pain in general, continues to escalate (23-25,39,79-129).

Gibson and Waddell (1), in the Cochrane Collaboration review; presented the results from 40 randomized controlled trials (RCTs).This review indicated that the indication for forms of discectomy, other than traditional open discectomy, is unresolved. Trials of percutaneous

discectomy suggest that clinical outcomes following treatment are at best fair and often certainly worse than after microdiscectomy, although the importance of patient selection is acknowledged (1). They also concluded 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 (1). Discectomy provides faster relief from the acute attack of sciatica, although any positive or negative effects on the long-term natural history of the underlying disc disease are unclear. In addition, they noted that the choice of micro- or standard discectomy at present probably depends more on the training and expertise of the surgeon and the resources available than on any scientific evidence of efficacy. However, these authors noted that, at present, unless or until better scientific evidence is available, automated percutaneous mechanical lumbar discectomy should be regarded as a research technique.

In a technology assessment report (41), 4 randomized published studies were included (43-46), all with negative results. Hirsch et al (3), in a systematic review of automated percutaneous lumbar discectomy for the contained herniated lumbar disc, concluded that, based on U.S. Preventive Services Task Force (USPSTF) criteria (130), the evidence for automated percutaneous lumbar discectomy was at Level II-2 for short- and long-term relief.

Based on the necessity of updating systematic reviews (131,132), this systematic review is undertaken to update the previous systematic review (3) and also to evaluate the current evidence for automated percutaneous mechanical lumbar discectomy.

1.0 Methods

The methodology utilized in this systematic review followed the review process derived from evidence-based systematic reviews and meta-analysis of randomized trials and observational studies (133-148), Consolidated Standards of Reporting Trials (CONSORT) guidelines for the conduct of randomized trials (139-142), Standards for Reporting Observational Studies (STROBE) (143), Cochrane guidelines (83,136,137), Chou and Huffman's guidelines (85), and quality of reporting of analysis (13).

1.1 Criteria for Considering Studies

1.1.1 Types of Studies

Randomized controlled trials
Non-randomized observational studies
Case reports and reviews for adverse effects

1.1.2 Types of Participants

Participants of interest were adults aged at least 18 years with chronic low back and lower extremity pain of at least 3 months duration.

Participants must have failed previous pharmacotherapy, exercise therapy, injection therapy, etc. prior to automated percutaneous mechanical lumbar discectomy.

1.1.3 Types of Interventions

The intervention was automated percutaneous mechanical lumbar discectomy.

1.1.4 Types of Outcome Measures

- The primary outcome parameter 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 automated percutaneous mechanical lumbar discectomy.

The search terms used were intervertebral disc, degenerative disc disease, disc herniation, disc protrusion, disc extrusion, disc prolapse, disc displacement, auto-

mated percutaneous mechanical lumbar discectomy, percutaneous lumbar discectomy/diskectomy/nucleotomy and mechanical disc decompression.

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 randomized trials, 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 automated percutaneous mechanical lumbar discectomy 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, non-systematic 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 are the inclusion and exclusion criteria:

1. Are the patients described in sufficient detail to allow one to decide 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 physician, anesthesiologist, physiatrist, neurologist, rheumatologist, orthopedic surgeon, neurosurgeon, etc.
   C. Patient characteristics - duration of pain
   D. Non-interventional techniques or surgical intervention in the past
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 non-eligible 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) (144). Each question was scored as positive (+) if the clinical relevance item was met, negative (–) if the item was not met, and unclear (?) if data were not available to answer the question.

1.4.4 Methodological Quality or Validity Assessment

The methodological qualities assessment was performed by 2 review authors who independently assessed, in an unblinded standardized manner, the internal validity of all the studies.

The methodological quality assessment was performed in such a manner as to avoid any discrepancies which, when detected, were evaluated by a third reviewer and settled by consensus.

The quality of each individual article used in this analysis was assessed by the Cochrane review criteria (Table 2) (136) for randomized trials and the Newcastle-

Table 1. *Clinical relevance questions*.

	P (+)	N (-)	U (unclear)
A) Are the patients described in detail so that one can decide whether they are comparable to those who are treated in practice?			
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) Are 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 (144).

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 outcome assessments.	Yes/No/ Unsure

Adapted and modified from Furlan AD, et al. 2009 updated method guidelines for systematic reviews in the Cochrane Back Review Group. *Spine (Phila Pa 1976)* 2009; 34:1929-1941 (136).

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 hernation 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.
Adapted and modified from 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 (145).

Ottawa Scale for observational studies (Tables 3 and 4) (145). For nonrandomized observational studies, the patient population had to have at least 50 total or at least 25 in each group, assuming they were comparison groups. Even though none of these instruments or criteria have been systematically assessed, the advantages and disadvantages of each system were debated.

Each study was evaluated by at least 2 authors for the stated criteria, and any disagreements were discussed with a third reviewer. Authors with a perceived conflict of interest for any manuscript were recused from reviewing the manuscript.

For adverse effects, confounding factors, etc., it was not possible to use quality assessment criteria. Thus,

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 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
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.
Adapted and modified from 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 (145).

these were considered based on interpretations of the published reports and critical analysis of the literature.

Only randomized trials meeting at least 50% of the inclusion criteria were utilized in the analysis. A description, opinion and critical analysis were provided for studies scoring lower than 50%.

Observational studies had to meet a minimum of 7 of the 13 criteria for cohort studies and 5 of 10 for

case-control studies. A description, opinion, and analysis were also provided for studies meeting less than 7 of the criteria.

If the literature search provided at least 5 randomized trials meeting the inclusion criteria and if they were homogenous, a meta-analysis was performed.

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 were available that met the inclusion criteria.

Qualitative (the direction of a treatment effect) and quantitative (the magnitude of a treatment effect) conclusions were evaluated. Random-effects meta-analysis to pool data was also used (146).

1.4.7 Assessment of Outcomes

The minimum amount of change in pain score to be clinically meaningful has been described as a 2-point change on a scale of 0 to 10 (or 20 percentage points), based on findings in commonly utilized trials studying general chronic pain (147), chronic musculoskeletal pain (148), and chronic low back pain (133,135,149,150). However, recent descriptions of clinically meaningful improvement showed either pain relief or functional status as 50% (151-183). Consequently, for this analysis, we utilize clinically meaningful pain relief of at least a 3-point change on an 11-point scale of 0 to 10, or 50% pain relief from the baseline, and functional status improvement of 40% or more as clinically significant.

1.5 Summary Measures

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

1.6 Analysis of Evidence

The analysis of the evidence was performed based on USPSTF criteria as illustrated in Table 5, which have been utilized by multiple authors (85,130,168-181).

The analysis was conducted using 3 levels of evidence: good, fair, and 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 were recused from assessment and analysis.

1.7 Outcome of the Studies

In the randomized trials, a study was judged to be positive if the use of automated percutaneous mechanical lumbar discectomy was clinically relevant and effective, either with a placebo control or active control. This indicates that the difference in the effect for the primary outcome measure is statistically significant on the conventional 5% level. In a negative study, no difference between the study treatments or no improvement from baseline is identified. Furthermore, the outcomes were judged at the reference point, with positive or negative results also reported at 6 months, one year, and later.

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 (85,130).

For observational studies, a study was judged to be positive if the automated percutaneous mechanical lumbar discectomy was effective, with outcomes reported at the reference point with positive or negative results at 6 months, one year, and later. However, observational studies were included in the evidence synthesis only if there were less than 5 randomized trials meeting inclusion criteria for evidence synthesis.

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

2.0 Results

Figure 1 shows a flow diagram of study selection, as recommended by Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (134). There were 106 studies considered for inclusion (27,29-34,43-75,77,78,81,82,182-243). Only studies with one-year follow-up utilizing automated percutaneous mechanical lumbar discectomy were included in the methodological quality assessment.

Table 6 shows the reasons for exclusion of selected studies. Table 7 illustrates the characteristics of studies

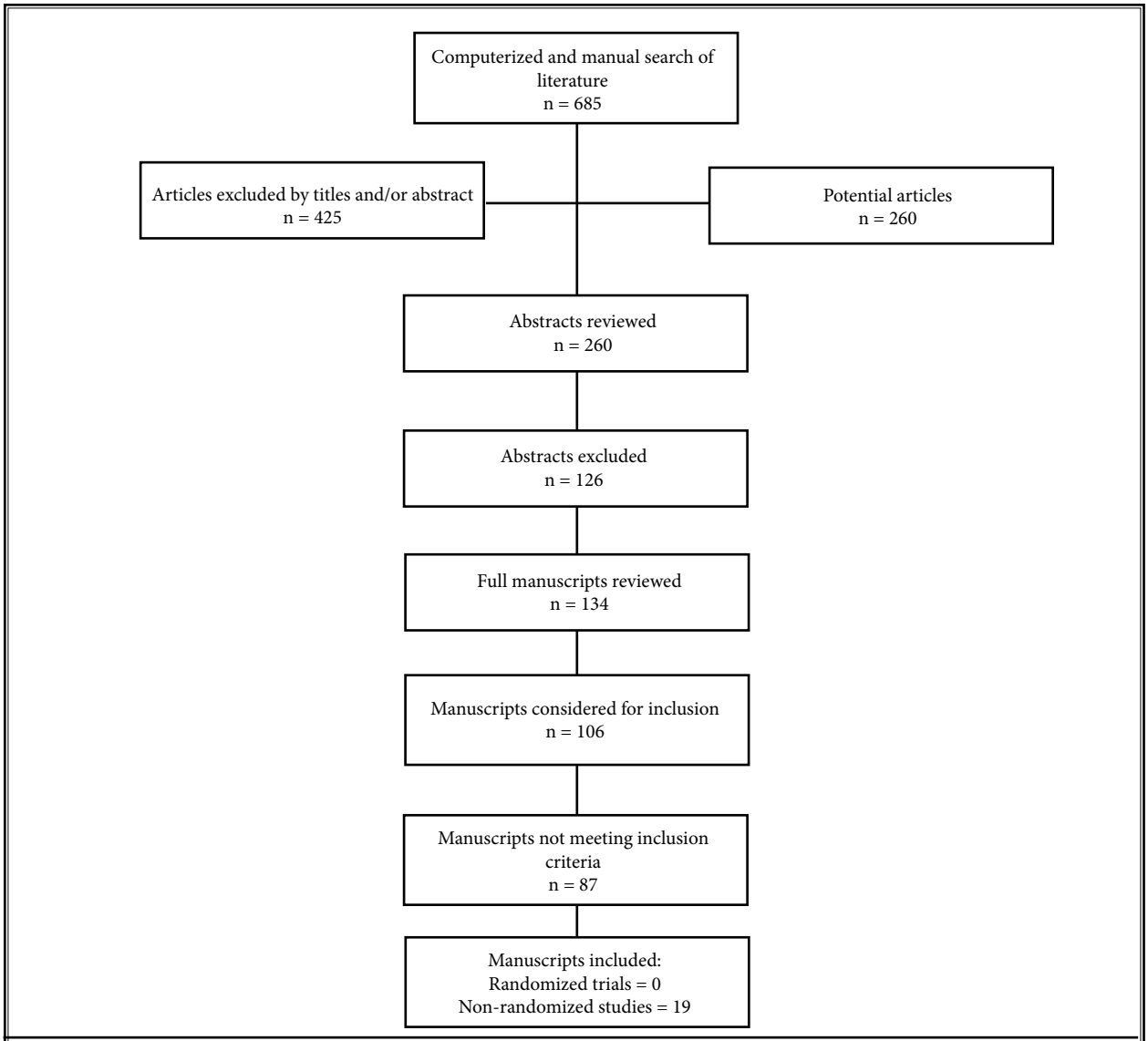

Fig. 1. *The flow diagram illustrating studies evaluating automated percutaneous mechanical lumbar discectomy.*

Table 6. *List of excluded automated percutaneous mechanical lumbar discectomy studies.*

Manuscript Author(s)	Reason For Exclusion
RANDOMIZED	
Haines et al, 2002 (44)	A small study of 27 patients comparing percutaneous discectomy to conventional discectomy with only 6 month follow-up and at 12 month follow-up reduced to 19 patients. The study is excluded due to a very small proportion of the patients selected from a large pool of 5,735 patients screened and 36 enrolled with 8 lost to follow-up at 6 months.
Krugluger & Knafhr, 2000 (46)	This is a randomized study of 22 patients either to chemonucleolysis or automated percutaneous discectomy. Only 10 patients underwent automated percutaneous discectomy. Level of surgeon's experience with techniques is unknown. Patients remained in the hospital for an average of 6 days after the procedure which is unusually high for a percutaneous discectomy which is most often an outpatient procedure. In addition, extremely uncommon technical failure which accounted for 10% of the total failures in automated percutaneous discectomy group in this study. Further, authors acknowledged and attributed failures to central and lateral stenosis, fibrosis, and adhesions with poor selection criteria. In addition, the comparator which was used in this study, chemonucleolysis, is not utilized in the United States. Even through results are considered positive, this study is unreliable. Consequently, it is excluded.
Chatterjee et al, 1995 (45)	Randomized, blinded, controlled trial comparing APLD with microdiscectomy, however, with only 6 month follow-up.
Revel et al, 1993 (43)	A randomized multicenter trial including 69 patients in the automated percutaneous discectomy group and 72 patients in chemonucleolysis group, however, follow-up was limited to only 6 months. This study failed to meet the criteria of one year.
OBSERVATIONAL	
Delgado-Álvarez et al, 2011 (77)	Authors evaluated only 7 patients for post-operative pain relief.
Theron et al, 2007 (194)	6-week follow-up in 44 patients
Lee et al, 2006 (242)	Endoscopic diskectomy < 50 patients
Taşdemiroğlu et al, 2004 (189)	Spondylodiscitis – review of reports of complications
Bonaldi, 2003 (34)	A large retrospective evaluation with 1,047 patients, however, with only 6 months of relief, with improvement in 67.5% of patients.
Ramberg & Sahlstrand, 2001 (67)	< 50 patients (30 patients)
Sahlstrand & Lönntoft, 1999 (190)	< 50 patients (20 patients)
Onik and Helms, 1998 (205)	Review
Du Bois et al, 1998 (209)	Cost effectiveness study
Savitz et al, 1998 (224)	Endoscopic surgery
Mathews et al, 1997 (49)	A prospective evaluation of APLD in 45 patients with a 6 month follow-up
Onik et al, 1997 (213)	Description of controversy
Bernd et al, 1997 (219)	Questionnaires were returned by only 76.4% of the patients who were suitable for evaluation with a mean follow-up of 2.5 years. Overall they reported 60% pain relief and 52% were satisfied with APLD; however, since this was a postal questionnaire with more than 20% lack of return, the study was excluded.
Negri & Belledi, 1996 (73)	Full manuscript not available
Onik, 1996 (192)	APLD in infectious discitis
Fencl & Kozler, 1996 (193)	< 50 patients (45 patients)
Dullerud et al, 1995 (75)	Full manuscript not available
Moon et al, 1995 (185)	Discographic CT evaluation and short-term follow-up
Stevenson et al, 1995 (186)	Cost-effectiveness study with short-term follow-up
Delamarter et al, 1995 (207)	Imaging study in < 50 patients (30 patients)
Mirovsky et al, 1994 (70)	< 50 patients (24 patients)

APLD = Automated Percutaneous Lumbar Discectomy

Table 6 (cont.). *List of excluded automated percutaneous mechanical lumbar discectomy studies*.

Manuscript Author(s)	Reason For Exclusion
Fiume et al, 1994 (74)	Full manuscript not available
Simons et al, 1994 (243)	Short-term follow-up
Shea et al, 1994 (195)	Basic science study
Gill, 1994 (196)	Onset of sciatic after automated percutaneous discectomy
Kotilainen et al, 1994 (226)	In this evaluation only 45 patients were treated by percutaneous nucleotomy.
Yeo & Tay, 1993 (68)	Short-term follow-up and < 50 patients
Kornberg, 1993 (71)	< 50 patients (21 patients)
Gunzburg et al, 1993 (197)	Experimental study
Castro et al, 1992 (187)	A prospective evaluation including 97 patients, however, the follow-up was limited to only 3 to 7 months.
Onik et al, 1992 (188)	Cauda equina syndrome due to Nucleotome probe
Castro et al, 1992 (199)	Study of biomechanics
Gill & Blumenthal, 1991 (58)	Preliminary report of Gill and Blumenthal (54)
Kambin & Schaffer, 1991 (63)	Comment on endoscopic diskectomy
Onik & Helms, 1991 (198)	Review article
Pitto et al, 1990 (66)	Short-term follow-up
Onik et al, 1990 (69)	< 50 patients (4 patients), description of far-lateral disk herniation
Pfeiffer et al, 1990 (184)	Cadaver study
Gill, 1990 (191)	Retroperitoneal bleeding
Kahanovitz et al, 1990 (241)	This was a multicenter analysis of percutaneous discectomy in 38 patients.
Davis & Onik, 1989 (56)	Short-term follow-up
Swiecicki, 1989 (57)	Percutaneous technique, but not APLD
Hammon, 1989 (59)	Presentation at a society meeting
Maroon et al, 1989 (64)	Review
Goldstein et al, 1989 (65)	< 50 patients with short-term follow-up
Hijikata, 1989 (200)	Percutaneous technique, but not APLD
Schreiber et al, 1989 (201)	Percutaneous technique, but not APLD
Kambin & Schaffer, 1989 (202)	Percutaneous technique, but not APLD
Hoppenfeld, 1989 (204)	Percutaneous technique, but not APLD
Gobin et al, 1989 (206)	< 50 patients (39 patients)
Mink, 1989 (215)	Imaging evaluation
Onik et al,1985 (32)	Probe description
Onik et al,1985 (33)	Cadaver study
Onik et al, 1987 (72)	< 50 patients (36 initial report)
Williams, 1978 (31)	Microdiscectomy
Hijikata, 1975 (30)	Described experience of his technique
Smith, 1964 (29)	Chemonucleolysis study

APLD = Automated Percutaneous Lumbar Discectomy

Table 7. *Study characteristics of published reports of automated percutaneous mechanical lumbar disc decompression.*

Study/ Methods	Study Characteristics	Participants	Intervention(s)	Outcome(s)	Result(s)	Conclusion(s) Short-term relief ≤one year Long-term relief >one year
Liu et al, 2010 (78)	Retrospective evaluation The study was performed from January 2000 to March 2002 and was published in 2010.	Retrospective evaluation was performed in consecutive patients with lumbar disc herniation treated with percutaneous lumbar discectomy in 104/129 patients or microendoscopic discectomy in 101 patients in a single hospital. 81% in both groups were eligible for analysis.	APLD, microendoscopic discectomy	Oswestry Disability Index, Medical Outcomes Study 36-Item Short-Form Health Survey, pain relief Minimum follow-up 6 months Mean follow-up period of 6.5 years	Successful outcome in percutaneous lumbar discectomy 75.96% versus 84.15% in microendoscopic discectomy The cost and length of hospitalization were higher or longer in microendoscopic discectomy group. Long-term complications were 2.44% in microendoscopic discectomy group and 0% in APLD.	Positive short-term and long-term results.
Degobbis et al, 2005 (62)	Retrospective evaluation	50 patients with disc herniation were assessed.	Automated percutaneous nucleotomy	Pain relief, improvement in function, medication use	76% of the patients reported excellent or good results	Positive short-term and long-term results
Marks, 2000 (48)	Retrospective evaluation	103 patients with low back pain with or without radiation to one or both lower extremities after failure of rigorous trial of conservative care.	APLD	Relief of back and leg pain, further surgical interventions, return to previous employment, physical activity status, medication intake; mean follow-up 30.7 months (6 to 82 months)	63% of the patients showed good to excellent results, whereas, 83% showed fair to excellent results. 17% of the patients showed poor results. 55% of the patients returned to same work and 27% returned to lighter work among the patients on workers' compensation.	Positive short-term and long-term results. The indications were internal disc derangement rather than disc herniation.
Teng et al, 1997 (53)	Prospective, multi-institutional	1,474/1,525 patients were selected with disc herniation.	APLD	Pain relief, functional status improvement, return to work, pain medication intake	Mean follow-up was 18.3 months. Success rate 83% overall at one year. Success rate was 76% in post-surgical patients.	Positive short-term and long-term results in a large multi-institutional study.
Hanaoka et al, 1996 (240)	Retrospective evaluation	63 patients with disc herniation were included. Post operative period ranged from 6 months to 6 years and 11 months with an average of 2 years.	Percutaneous lumbar nucleotomy	Pain relief, return to work, pain medication use, functional status improvement	Successful outcome was seen in 81% or 51 patients were successful.	Positive short-term and long-term results.
Rezaian & Ghista, 1995 (50)	Retrospective evaluation	285 patients were selected for percutaneous discectomy with disc herniation.	APLD	Relief of pain, return to work, need for medication and satisfaction.	Excellent results in 110 patients, good results were present in 141 patients with returning to work one to 6 months after surgery. 28 patients were considered fair returning to modified job. Poor results were present in 6 patients. Overall good to excellent results were present in 251 of 285 patients, and fair results in 10% of the patients.	Positive short-term and long-term results. Positive results, however, there were patients with only 3 months duration of sciatica.

APLD = Automated Percutaneous Lumbar Discectomy

Table 7 (cont.). *Study characteristics of published reports of automated percutaneous mechanical lumbar disc decompression.*

Study/ Methods	Study Characteristics	Participants	Intervention(s)	Outcome(s)	Result(s)	Conclusion(s) Short-term relief ≤one year Long-term relief >one year
Grevitt et al, 1995 (51)	Retrospective evaluation	137 patients were selected with symptomatic lumbar disc prolapse with 115 available for final follow-up interview. Follow-up range was 55 months on average with a range of 44 to 71.	APLD	Pain relief, return to work, pain medication, Oswestry Disability Index	82% of the patients reported fair to excellent results with 30% fair, 52% excellent or good, poor results were reported in 18% of the patients. Mean Oswestry improvement was 28.2%. 76% were in full or part-time employment at final follow-up.	Positive short-term and long-term results with only 17 or 137 patients requiring further surgical intervention.
Shapiro, 1995 (52)	Retrospective evaluation	57 patients with single-level disc prolapse with unilateral sciatica.	APLD	Pain relief, functional status improvement.	At final follow-up, an average of 27 months with mean of 6 to 45 months, 58% reported successful outcome with improved sciatica. Only 5% were totally pain free.	Positive results in a small study with moderate results with removal of 3.5 grams of material.
Gill & Blumenthal, 1993 (54)	Retrospective evaluation	109 patients with disc herniation were evaluated with low back and lower extremity pain.	APLD	Visual analogue scale, Oswestry Disability Questionnaire, physical findings, return to pre-injury function, pain medication intake	Overall success rate 79%. Success rate in private pay patients 85%. Success rate in workers' compensation patients 70%. 79% of the patients reported successful outcome; however, among the patients who were private pay, 93% improved and among the workers' compensation 65% were successful. Overall 70% of patients were able to return to work within 2 weeks.	Positive short-term and long-term results.
Sakou & Masuda, 1993 (203)	Retrospective evaluation	117 patients with lumbar disc herniation were included. Mean duration of pain was 6.1 months.	APLD	Pain relief, functional status with Oswestry, return to work, pain medicine intake	Effectiveness was demonstrated in 80.3% of the patients. The improvement was more marked in patients with protrusion of prolapse type herniations.	Positive results for short-term and long-term, however, authors included patients with acute pain.
Bonaldi et al, 1991 (55)	Retrospective evaluation	234 patients with disc herniation were included in the study.	APLD	Pain relief, functional status improvement, need for pain medication, patient satisfaction.	Overall success rate 75%. Good results obtained from older patients and patients who had previously undergone traditional surgery. 85.7% success rate in patients presenting with back pain only.	Positive short-term and long-term results.
Gill & Blumenthal, 1991 (58)	Retrospective evaluation	62 patients with disc herniation with a follow-up of 2.2 to 4.5 years.	APLD	Pain relief, narcotic medication, return to work, improvement in function, patient satisfaction	79% of the patients reported successful outcome	Positive short-term and long-term improvement

APLD = Automated Percutaneous Lumbar Discectomy

Table 7 (cont.). *Study characteristics of published reports of automated percutaneous mechanical lumbar disc decompression.*

Study/ Methods	Study Characteristics	Participants	Intervention(s)	Outcome(s)	Result(s)	Conclusion(s) Short-term relief ≤one year Long-term relief >one year
Davis et al, 1991 (61)	Prospective evaluation with a follow-up of 2 years	518 consecutive patients with disc herniation, sciatica and failure of conservative management with physical therapy, bedrest and drug treatment.	APLD	Pain relief, return to work, improvement in functional status, intake of pain medication	85% of the patients reported successful outcome. 87% of non-compensated patients were successful 74% of compensation patients were successful 70% were able to return to work within 2 weeks	Positive short-term and long-term results.
Onik et al, 1990 (47)	A prospective multi-institutional study	327 patients with sciatica, after failure of at least 6 weeks of conservative therapy, and were candidates for open surgical discectomy.	APLD	Improvement in radicular pain, discontinuation of narcotic analgesics, improvement in functional status and patient satisfaction.	Of the 327 patients who were followed for one-year or longer within the protocol, the success rate was 75.2% (n = 246)	Positive short-term and long-term results.
Mooney, 1989 (27)	Retrospective evaluation	64 patients with disc herniation.	APLD	Pain relief, medication intake, return to work, return to preinjury status, patient satisfaction	Success rate 75%	Positive short-term and long-term relief.
Davis & Onik, 1989 (56)	Prospective evaluation	200 patients with disc herniation were studied. These patients were considered surgical candidates for microdiscectomy or laminectomy.	APLD	Pain relief, improvement in function, need for pain medication, return to preinjury status and work.	77.5% of the patients reported good pain relief. 70% of patients were able to return to work within 2 weeks. APLD averaged less than half of the cost of microdiscectomy or laminectomy in 1988.	Positive short-term and long-term results.
Swiecicki, 1989 (57)	Retrospective evaluation with follow-up from 8 to 20 months	300 patients with 100 patients in each subgroup were treated with percutaneous lumbar discectomy, laminotomy or chemonucleolysis.	APLD and chemonucleolysis	Pain relief, return to work, return to preinjury status, patient satisfaction.	84% of APLD patients were successful 79% of patients were successful for laminotomy 58% of chemonucleolysis patients were successful	Successful short-term and long-term outcome comparing laminotomy and chemonucleolysis with superior results with APLD.
Maroon & Allen, 1989 (60)	Retrospective multi-institutional study with participation of 35 U.S. surgeons	1,054 patients were recruited from multiple centers with symptomatic contained herniated nucleus pulposus after failure of conservative management.	APLD	Pain relief, return to work	82.9% of the patients reported successful outcome. Average amount of nucleus material removed was 2.4 grams with the lowest being one and highest being 8 grams.	Positive short-term and long-term results.
Morris, 1988 (210)	Retrospective multi-institutional study	479 patients with disc herniation diagnosed by computed tomography scanning were included.	APLD	Pain relief, functional status improvement, narcotic use, satisfaction of patient and surgeon	73.5% of the patients reported successful outcome.	Positive short-term and long-term outcome.

APLD = Automated Percutaneous Lumbar Discectomy

considered for inclusion. Only studies with at least one-year follow-up were considered for inclusion. There were no randomized trials meeting the inclusion criteria as all of them were of a short-term nature with follow-up of less than 6 months. There were 19 observational studies (27,47,48,50-58,60-62,78,203,210,240).

2.1 Clinical Relevance

Of the 19 studies assessed for clinical relevance, all met the criteria, with a score of 3 of 5 or greater (27,47,48,50-58,60-62,78,203,210,240). Table 8 illustrates assessment of clinical relevance.

2.2 Methodological Quality Assessment

There were no randomized trials meeting the inclusion criteria.

A methodological quality assessment of the observational studies meeting inclusion criteria was carried out utilizing the Newcastle-Ottawa Scales as illustrated in Tables 9 and 10. Studies scoring 67% or higher were considered high quality, studies scoring 50% or higher were considered moderate quality, and studies scoring less than 50% were considered low quality and were excluded.

There were 19 non-randomized or observational studies, including case reports, evaluating the long-term effectiveness of automated percutaneous mechanical lumbar discectomy with follow-up of 12 months or longer (27,47,48,50-62,78,203,210,240). All were considered to be of moderate quality.

2.3 Meta-Analysis

There were no randomized trials meeting the inclusion criteria, thus no metaanalysis was feasible.

2.4 Analysis of Evidence

Based on the USPSTF criteria, the evidence is considered at 3 levels – good, fair, and limited or poor. Table

Table 8. *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
Liu et al, 2010 (78)	+	+	+	+	+	5/5
Degobbis et al, 2005 (62)	+	+	+	+	+	5/5
Marks, 2000 (48)	+	+	+	+	+	5/5
Hanaoka et al, 1996 (240)	+	+	+	+	+	5/5
Teng et al, 1997 (53)	+	+	+	+	+	5/5
Rezaian & Ghista, 1995 (50)	+	+	+	+	+	5/5
Grevitt et al, 1995 (51)	+	+	+	+	+	5/5
Shapiro, 1995 (52)	+	+	+	+	+	5/5
Gill & Blumenthal, 1993 (54)	+	+	+	+	+	5/5
Sakou & Masuda, 1993 (203)	+	+	+	+	+	5/5
Bonaldi et al, 1991 (55)	+	+	+	+	+	5/5
Gill & Blumenthal, 1991 (58)	+	+	+	+	+	5/5
Davis et al, 1991 (61)	+	+	+	+	+	5/5
Onik et al, 1990 (47)	+	+	+	+	+	5/5
Mooney, 1989 (27)	+	+	+	+	+	5/5
Davis & Onik, 1989 (56)	+	+	+	+	+	5/5
Swiecicki, 1989 (57)	+	+	+	+	+	5/5
Maroon & Allen, 1989 (60)	+	+	+	+	+	5/5
Morris, 1988 (210)	+	+	+	+	+	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 (144).

Table 9. *Newcastle-Ottawa quality assessment scale: Case control studies.*

	Liu et al, 2010 (78)	Swiecicki, 1989 (57)
Selection		
1) Is the case definition adequate?		
a) yes, with independent validation *		
b) yes, e.g. record linkage or based on self reports	X	X
c) no description		
2) Representativeness of the cases		
a) consecutive or obviously representative series of cases *		X
b) potential for selection biases or not stated	X	
3) Selection of Controls		
a) community controls *	X	X
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 *	X	X
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	X	X
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	X	X
a) yes *		
b) no		
3) Non-Response rate		
a) same rate for both groups	X	X
b) non respondents described		
c) rate different and no designation		
SCORE	7/13	7/13

11 illustrates the results of 19 observational studies of the effectiveness of automated percutaneous mechanical lumbar discectomy in managing disc herniation or radiculitis.

Due to the lack of randomized trials, the evidence is limited for automated percutaneous mechanical lumbar discectomy.

3.0 Complications

Percutaneous discectomy is associated with multiple complications and side effects; such as those associated with intradiscal procedures with a large cannula (244,245). These complications associated with any intradiscal procedures include hematoma, infection, either superficial or associated with abscess, allergic

Table 10. *Newcastle-Ottawa quality assessment scale for cohort studies.*

	Degobbis et al, 2005 (62)	Marks, 2000 (48)	Hanaoka et al, 1996 (240)	Teng et al, 1997 (53)	Rezaian & Ghista, 1995 (50)	Grevitt et al, 1995 (51)	Shapiro, 1995 (52)	Gill & Blumenthal, 1993 (54)	Sakou & Masuda, 1993 (203)
Selection									
1) Representativeness of the exposed cohort									
a) truly representative of the average _____ (describe) in the community *	X	X	X	X	X	X	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	X	X	X	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) *									
b) structured interview *	X	X	X	X	X	X	X	X	X
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 *	X	X	X	X	X	X	X	X	X
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	X	X	X	X	X	X
c) self report									

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
Source: Wells GA, Shea B, O'Connell D, Peterson J, Welch V, Losos M, Tugwell P. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. www.ohri.ca/programs/clinical_epidemiology/oxford.asp (145).

Table 10 (cont.). *Newcastle-Ottawa quality assessment scale for cohort studies.*

	Degobbis et al, 2005 (62)	Marks, 2000 (48)	Hanaoka et al, 1996 (240)	Teng et al, 1997 (53)	Rezaian & Ghista, 1995 (50)	Grevitt et al, 1995 (51)	Shapiro, 1995 (52)	Gill & Blumenthal, 1993 (54)	Sakou & Masuda, 1993 (203)
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	X	X	X	X	X	X
b) no									
3) Adequacy of follow up of cohorts									
a) complete follow up - all subjects accounted for *	X	X	X	X	X		X	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	7/12	7/12	7/12	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 two stars can be given for Comparability
Source: Wells GA, Shea B, O'Connell D, Peterson J, Welch V, Losos M, Tugwell P. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. www.ohri.ca/programs/clinical_epidemiology/oxford.asp (145).

reaction to radiographic contrast or antibiotic, bleeding, direct needle trauma to a spinal nerve with transient or persistent paresthesia ,and spondylodiscitis (7,8,24,25,34,41,46,47,53,55,60,78,246-249).

Nerve injury can occur from several sources including direct root injury during needle insertion or from the decompression process if improperly performed. This should be avoidable by ensuring that the patient is responsive during the entire procedure and carefully assessing for radicular/paresthesia complaints throughout. Infection risk can be lowered by the use of a meticulous sterile technique and intravenous or intradiscal antibiotics. Other complications include damage to the adjacent endplate, the development of spinal instability, and/or the potential for disc space collapse with associated progressive degenerative changes. Other complications include cauda equina syndrome.

Even though the majority of the studies included in this evaluation have not reported major complications, some studies have reported complications. Krugluger et al (46) reported that 2 patients required open surgery, that one experienced nerve root irritation at 4 weeks, and that there was one technical complication from a broken probe. Onik et al (47) reported that out of 506 patients undergoing procedures in a multi-institutional study, there was only one complication, which was a case of discitis and was successfully treated with antibiotics. Maroon and Allen (60) in a retrospective evaluation of 1,054 automated percutaneous lumbar discectomy cases reported 3 complications with a 0.002% rate. Bonaldi et al (55) reported only one complication (discitis which cleared without clinical or radiological sequelae) in 234 cases yielding a rate of 0.26%. Teng et al (53), in their report of automated percutaneous lumbar discectomy of a prospective multi-institutional study including 1,825 patients, reported a 0.06% incidence of discitis, the only complication reported. Bonaldi (34) reported a complication rate of less than 1% in 1,047 patients in his 14-year experience with 2 cases of discitis, or 0.17%.

4.0 Discussion

This systematic review evaluating the role of disc decompression with automated percutaneous mechanical lumbar discectomy did not identify any randomized trials meeting the inclusion criteria with follow-up of at least one year. Based on the available observational studies, the evidence for automated percutaneous mechanical lumbar discectomy, though extensive with 19 studies (27,47,48,50-58,60-

Table 11. *Summary results of eligible studies of automated percutaneous mechanical lumbar discectomy.*

Study	Methodological Quality Scoring	Number of Participants	Significant Pain Relief	Results
			> 12 mos.	Long-term > 12 mos.
Liu et al, 2010 (78)	7/13	104 APLD 101 MED	76%	P
Degobbis et al, 2005 (62)	7/12	50	76%	P
Marks, 2000 (48)	7/12	103	63%	P
Hanaoka et al, 1996 (240)	7/12	63	81%	P
Teng et al, 1997 (53)	7/12	1,474	83%	P
Rezaian & Ghista, 1995 (50)	7/12	285	88%	P
Grevitt et al, 1995 (51)	7/12	115	45%	P
Shapiro, 1995 (52)	7/12	57	58%	P
Gill & Blumenthal, 1993 (54)	7/12	109	79%	P
Sakou & Masuda, 1993 (203)	7/12	117	80%	P
Bonaldi et al, 1991 (55)	7/12	234	75%	P
Gill & Blumenthal, 1991 (58)	7/12	62	79%	P
Davis et al, 1991 (61)	7/12	518	85%	P
Onik et al, 1990 (47)	7/12	506	75%	P
Mooney, 1989 (27)	7/12	64	75%	P
Davis & Onik, 1989 (56)	7/12	200	78%	P
Swiecicki, 1989 (57)	7/13	100 patients each = 3 groups	84%	P
Maroon & Allen, 1989 (60)	7/12	1054	85%	P
Morris, 1988 (210)	7/12	479	74%	P
TOTAL	7/12	5,515	80%	P

APLD = Automated Percutaneous Lumbar Discectomy; MED = Microendoscopic Discectomy; P = positive

62,78,203,210,240) involving 5,515 patients with at least one year follow-up, is limited. Hirsch et al (3), in a previous systematic review evaluating the role of automated percutaneous lumbar discectomy assessed the evidence based on the Agency for Healthcare Research and Quality (AHRQ) of Level II-2 for short- and long-term relief. However, in this evaluation, they also included one randomized trial performed by Revel et al (43). Furthermore, Diagnostic and Therapeutic Technology Assessment (DATTA) published in JAMA in 1989 (250) concluded that percutaneous discectomy, particularly the automated procedure, using Onik Nucleotome, is a promising treatment for herniated lumbar discs wherein the nuclear bulge is contained by the nucleus. They concluded that further studies were needed to establish the safety and effectiveness of this procedure for this particular indication. The majority of DATTA panelists concluded that when a herniated lumbar disc has nuclear material outside the annulus but still contiguous with the nucleus, either the risk/benefit ratio was unfavorable or evidence was insufficient for a definitive decision regarding the application of percutaneous discectomy. One year after the analysis, in 1991, the same organization, DATTA (251), after reconsideration, concluded that automated percutaneous lumbar discectomy was a safe procedure when used for patients with protruding lumbar discs who had failed conservative therapy. However, there was no consensus on the effectiveness of automated percutaneous lumbar discectomy for this indication, as the majority of the responses fell in either the promising or investigational category. A consensus of the panelists, however, determined that automated percutaneous lumbar discectomy was an inappropriate treatment in terms of both safety and effectiveness for a lumbar disc in which the nuclear material protruded outside the annulus without any free sequestered fragment, an opinion similar to the previous one (250). Since then, no diagnostic or therapeutic technology assessments have been published.

Automated percutaneous mechanical lumbar discectomy is performed with a pneumatically driven, suction-cutting probe placed through a cannula that has a 2.8 mm outer diameter. Most of the disc removal occurs one cm anterior to the herniation, removing approximately one to 3 grams of disc material with the intent of reducing intradiscal pressure and decompressing nerve roots (32-34,198,207,220). In 1990, Onik and Helms (198) outlined various aspects of percutaneous lumbar discectomy, including patient selection. At that time, they described that more than 3,000 physicians had been trained to perform the procedure, and that over 40,000 cases had been completed worldwide.

Gibson and Waddell (1) concluded that clinical outcomes following automated percutaneous lumbar discectomy are at best fair and certainly worse than after microdiscectomy. They also emphasized the importance of patient selection. Four randomized trials met the inclusion criteria. Two trials (43,46) compared automated percutaneous lumbar discectomy and chemonucleolysis, whereas 2 other trials (44,45) compared automated percutaneous lumbar discectomy with microdiscectomy. Revel et al (43) in a randomized trial, demonstrated the inferiority of automated percutaneous lumbar discectomy compared to chemonucleolysis, although multiple deficiencies have been pointed out with this trial. A study by Krugluger and Knahr (46) showed similar improvement in both groups. However, the number of subjects was too small.

Lühmann et al (234) performed a systematic review of minimally invasive surgical procedures for the treatment of lumbar disc herniation. The results showed that the evidence base to assess safety, efficacy, and effectiveness of minimally invasive lumbar disc surgery procedures was rather limited. In reference to automated percutaneous lumbar discectomy, they found 2 RCTs, one case series and 2 economic analyses. They concluded that among all minimally invasive procedures, chemonucleolysis was the only one for which the efficacy may be judged on the basis of results from high quality randomized controlled trials. They described that the only RCT comparing the results of automated percutaneous lumbar discectomy to those of microdiscectomy showed clearly superior results of microdiscectomy (45). This study was excluded from the present systematic review as it failed to meet the inclusion criteria. They also concluded that the results of the economic analyses evaluating various types of minimally invasive lumbar disc decompressions were compromised by conceptual and methodological problems, and of no value for decision-making in the context of the German health care system, which may also be applied to other health care systems.

Until recently, however, the systematic reviews for surgical interventions based on the results of Spine Patient Outcomes Research Trial (SPORT) studies have not been very positive (1,3,4,6,85,229,252).

In fact, in a study by Carragee et al (222), the authors reported that patients in the fragment-fissure group ,those with a disc fragment and a small annular defect, had the best overall outcomes and the lowest rates of reherniation (1%) and reoperation (1%). Patients in the fragment-contained group had a 10% rate of reherniation and a 5% rate of reoperation. Moreover, patients in the fragment-defect group, who had extruded fragments and massive posterior annular loss, had a 27% rate of reherniation and a 21% rate of reoperation. Finally, patients in the no fragment-contained group did very poorly, with 38% having recurrent or persistent sciatica. The standard outcome scores in this group showed the least improvement compared with those in the other groups ($P < 0.001$). Thus, it is postulated that for patients with contained disc herniation, percutaneous mechanical disc decompression with automated percutaneous lumbar discectomy may be the best choice.

Similarly, Dewing et al (220), in an evaluation of the outcomes of lumbar microdiscectomy showed that patients with sequestered or extruded lumbar disc herniations had significantly better outcomes than did those with contained herniations. Contained discs were associated with the poorest outcomes, significantly worse than either extruded or sequestered disc types.

Automated percutaneous mechanical lumbar discectomy is considered safer than microdiscectomy since it utilizes the Nucleotome probe as the primary instrument for decompression, limiting the amount of times that the physician needs to enter the disc space for removal of nucleus pulposus. In contrast, microdiscectomy uses manual instruments that may need to reenter the disc several times.

The effectiveness of automated percutaneous mechanical lumbar discectomy appears to compare favorably with the results of chymopapain injection and open discectomy, even though it is very difficult to draw conclusions, as these assumptions have not been proven in randomized trials. Furthermore, if optimistic success rates reported for microdiscectomy are considered, the difference in efficacy between open discectomy and automated percutaneous mechanical lumbar

discectomy appears to be only 10% to 15%. Gibson and Waddell (1) concluded that, despite the critical importance of knowing whether surgery is beneficial for disc prolapse, overall, surgical discectomy for carefully selected patients with sciatica due to a prolapsed lumbar disc appears to provide faster relief from an acute attack than does non-surgical management. However, positive or negative effects on the lifetime natural history of the underlying disc disease remain unclear. They also concluded that microdiscectomy gives broadly comparable results to standard discectomy. Considering the benign nature of the procedure and cost, it appears that automated percutaneous lumbar discectomy is recommended in a select group of patients meeting the inclusion criteria.

Even though numerous studies are available, none of the randomized trials met the inclusion criteria. Among the many observational studies, 19 met the inclusion criteria. There have not been many recent studies. One study was published in 2010, although the data were collected from 2000 to 2002 (78). The 4 randomized trials conducted included multiple flaws. The 1995 controlled clinical trial by Chatterjee et al (45) comparing automated percutaneous lumbar discectomy and microdiscectomy in the treatment of contained lumbar disc herniation has been met with both criticism and skepticism. This was because the results showed an unreasonably low success rate with automated percutaneous lumbar discectomy (29%), which may be even less than with placebo, along with poor patient selection. This is an active-control trial comparing 2 modalities of treatment with no control group. Chatterjee et al (45) have been criticized for poor selection criteria and for not describing the response in patients with broad based disc protrusions which they described as only a very small percentage of patients with lumbar disc herniation.

The study performed by Haines et al (44) entitled "Discectomy Strategies for Lumbar Disc Herniation: Results of the LAPDOG Trial" also has been criticized. The general purpose of the study was to invalidate automated percutaneous lumbar discectomy but no such proof was offered. The study was terminated before it accumulated enough data to reach statistically relevant conclusions. The authors were unable to recruit the targeted number of patients. From a potential pool of almost 6,000 patients screened, only 36 patients were included in the study. In addition, the fact that 25% of treated patients were lost to follow-up, even before 6-month data could be collected, raised questions regarding to the quality and validity of the study. Finally, almost 40% of the automated percutaneous lumbar discectomy patients were involved in litigation, which has been described as a complicating factor.

The third study by Revel et al (43) compared automated percutaneous lumbar discectomy with chemonucleolysis. They included 141 patients, of which 69 were treated with automated percutaneous lumbar discectomy. The success rate was 43%; significantly lower than the majority of observational studies. The sample size in this evaluation required 80 patients in each group. This requirement was not met. The follow-up was described as one year, even though it was only 6 months. Selection criteria may have also been inappropriate. The requirement of a contained, non-extruded disc for inclusion is not specified in the study protocol. At discography, 39% of the tested discs showed epidural leakage. The protocol allowed for a migration of up to 5 mm beyond the disc space, and the publication lists 71% of automated percutaneous lumbar discectomy patients in this category. Thus, it appears that 29% of patients had migration beyond 5 mm of the disc space. A major concern is that some of these cases had large extrusions of free fragments as indicated by bilateral lower extremity pain in 8% of patients, large volume herniations in 14%, and the inclusion of patients with a positive crossed straight leg raising test. Furthermore, neither the protocol nor the publication specifies the exclusion of discs with diffuse annular bulging, for which automated percutaneous lumbar discectomy is not effective and is therefore contraindicated. The results show that at the time of discography there was a 16% incidence of severely degenerated discs and a 9% incidence of marked disc space narrowing, with a description of 2 cases as technical failures after it was impossible to introduce the probe into the disc space. An additional criticism has been that there was no requirement that leg pain be greater than back pain for inclusion, even though the publication insists that only sciatica patients were included in the study. Apparently the study shows that 21% of patients had severe back pain, with no available correlation to leg pain. Due to the multiple abnormalities discussed here, the Revel et al study may not be applicable to clinical settings. Since we were able to find only 6-month follow-up results, the study was excluded.

Krugluger & Knafhr (46) also performed a small assessment comparing automated percutaneous lumbar discectomy with chemonucleolysis. In this study, the level of the surgeon's experience has been questioned.

In addition, there were extremely uncommon technical failures, which occur in an estimated 0.005% of cases overall, but account for 10% of the total failures in the automated percutaneous lumbar discectomy group in this study. Furthermore, the authors also acknowledged a 7% to 20% occurrence in post-operative syndromes from open surgery, and attributed failures to central and lateral stenosis, fibrosis, and adhesions. Additionally, for some unknown reasons, hospitals stays of patients averaged 6 days after the procedure, which is most often an outpatient procedure. This is a randomized study of 22 patients either to chemonucleolysis or automated percutaneous discectomy. Only 10 patients underwent automated percutaneous discectomy. Even though results are considered positive, this study is unreliable. Consequently, it is excluded.

Among the 19 observational studies, none of them provided recent data. The recently published 2010 assessment was from data collected from 2000 to 2002 (78). Overall, there were only 3 studies meeting the inclusion criteria since 1997, with one in 2000 (48), one in 2005 (62), and one in 2010 (78), all with positive short- and long-term results. Marks (48), in 2000, published a study on the role of automated percutaneous lumbar discectomy in internal disc derangement rather than disc herniation, with positive results. Internal disc derangement is not an indication even discussed. Thus, it appears there were only 2 studies after 2000 with a total of 179 patients, both showing positive results (62,78). Onik et al (47) in a multi-institutional study to assess automated percutaneous discectomy in the treatment of lumbar disc herniation from 1984 through 1987, included 506 automated percutaneous lumbar discectomies by 18 different surgeons. Of the 327 patients who were followed for one year or longer within the protocol, the success rate was 75.2%. The authors emphasized that automated percutaneous lumbar discectomy is not appropriate for all patients with a herniated disc and should be used only for those patients with a contained disc herniation, that is, with the annulus and/or posterior longitudinal ligaments still intact and without evidence of migration from the disc space. They also showed that nearly 70% of patients in whom the treatment failed and who subsequently had surgery had unrecognized sequestration of free disc fragments. Maroon and Allen (60), in a large study of 1,054 patients undergoing automated percutaneous lumbar discectomy procedures from January 1987 to February 1988 at 35 U.S. hospital facilities reported a 82.9% successful result, both by the treating physician and by the patient. They showed no significant correlation between the disc level and success; however, the primary cause of failure was the preoperative non-discernible presence of free disc fragments. They removed an average of 2.5 grams of nucleus pulposus material from the disc ranging from one gram to 8 grams with no correlation with the outcomes. Teng et al (53) reported the results of 1,582 automated percutaneous lumbar discectomy procedures in a prospective study in 10 independent hospitals from 1992 to 1994, with a success rate of 83% at one year. They also reported good results in post-surgical patients. They reported multiple contraindications including extrusion/sequestration type of herniation, long-term duration of the symptoms, old age, calcification of longitudinal ligaments, and previous surgical discectomy. In contrast to the common philosophy, they reported that patients who had only low back pain with little or no leg pain had significantly better results than those with classic sciatica.

Davis et al (61) reported on the results of 518 patients with automated percutaneous lumbar discectomy performed on an outpatient basis, with an 85% success rate. Their results also showed that in 427 non-compensation cases, there was an 87% success rate with a 13% failure rate; whereas in 91 compensation patients, the success rate was 74%. Of the 79 patients considered failures, 33 were found to have extruded disc fragments outside interspace. Subsequent microdiscectomy produced successful results. Five patients also had spinal stenosis sufficient to prevent pain relief from the percutaneous discectomy, and later surgery was successfully performed. Davis et al (61) reported a 70% return to work rate in less than 2 weeks for compensation patients.

Bonaldi et al (55) evaluated 234 patients treated by percutaneous discectomy showing an overall success rate of about 75% with follow-up between 11 months and 3 years. They also reported that in a subgroup of 112 of these patients who were continuously followed the clinical results remained consistently good even 24 months after surgery. They also reported a good success rate even in patients with only low back pain.

Liu et al (78) in the most recently published evaluation, studied 104 patients with percutaneous lumbar discectomy and 82 patients with microendoscopic discectomy between 200 and 2002 in a comparative evaluation. Utilizing appropriate outcome parameters, they reported a success rate of 75.96% in the percutaneous lumbar discectomy group and 84.15% in the microendoscopic discectomy group with excellent or good

results, respectively. The costs for percutaneous discectomy were lower and there were no long-term complications, whereas with microendoscopic discectomy 2 patients or 2.44% reported complications. The authors concluded that both percutaneous lumbar discectomy and microendoscopic discectomy show an acceptable long-term efficacy for treatment of lumbar disc herniation. However, while long-term satisfaction was slightly lower in the percutaneous lumbar discectomy patients, complications, hospitalization duration, and costs in the percutaneous lumbar discectomy group were lower.

Overall, in the 19 observational studies meeting inclusion criteria, a total of 5,515 patients underwent automated percutaneous lumbar discectomy with 4,412 of them judged to have positive results ranging from 45% to 88%. The limitations of this systematic review include scant literature, specifically in terms of randomized trials, meeting the inclusion criteria. It appears that there are plenty of observational studies, even though none of them are recent. Consequently, all of the evidence is dependent on observational studies. Due to the strict inclusion criteria, multiple studies, both randomized and observational, were excluded from this systematic review even though they have been included in other systematic reviews. Conducting randomized trials specifically placebo controlled trials is a difficult issue in interventional pain management. Due to a lack of understanding, methodologists and experts tend to focus only on randomized trials and also misinterpret the evidence from the study design and placebo control. The majority of studies which have been considered as placebo controlled in interventional pain management settings, for example as facet joint studies, have included local anesthetic injection after needle positioning, providing in essence a facet joint nerve block (117,178,180,253-256). However, the literature has repeatedly shown that a facet joint nerve block can provide prolonged relief, of on average 13 to 16 weeks (160-162,178,180,257,258). Consequently, these studies could be construed as active control trials even though sham treatment was utilized. Similar misunderstandings have developed with placebo controlled trials of vertebroplasty (259-265) and epidural treatments with local anesthetic.

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 (266) reviewed the pervasive and complex connection between the placebo effect and bias. The concept of the placebo was brought to the attention of the medical community by Beecher (267) 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. Furthermore, unbiased assessment of the placebo effect requires the 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 (268). Even though Beecher's approach was clearly recognized as flawed by the late 1990's (269), by that time the notion of a "powerful placebo" had already become deeply rooted. Meanwhile methodologists haven't started anchoring the natural history of the condition under investigation or regression to the mean to every study. However, Krogsbøll et al (270) 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 the 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. For chronic pain, however, no treatment contributed to very small improvement, and placebo response was also less than 30%, whereas active treatment showed a positive effect of 60%. An assessment of standardized mean difference for changes from baseline group by acute or chronic conditions showed no change in the no treatment group. Consequently, the authors concluded that spontaneous improvement and the effect of placebo contributed importantly to the observed treatment effect in actively treated patients, but that the relative importance of these factors differed according to clinical condition and intervention. Furthermore, in 2001, in sharp contrast, the power of placebo was challenged by a systematic review published in the New England Journal of Medicine (271). This review identified 114 randomized clinical trials including placebo and no

treatment groups, and reported no evidence of the 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 a methodologist's 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 (272), or saw the review as a necessary scientific correction to set the bar differently for claims concerning placebo (273), some media commentators interpreted the result as demonstrating the placebo effect to be a myth (274). Even though the review, which was updated in 2004, showed similar findings (275), the latest update from 2010 reported more multifaceted results (276). The recent systematic review showed that large analgesic effects of placebo interventions were found in several well conducted trials and that a considerable variation in effect could in part be explained by differences in trial design. For example, the effect of the placebo was larger when the intervention was a device versus a pill placebo. 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 effects . On the same token, some have acknowledged the therapeutic potential of placebos (277). However, all the metaanalyses (273,275,276) involving progressively larger number of studies and subjects, performed for the Cochrane review, challenge the general belief 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 (266) 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 significant 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, general disregard to the bias of the methodologists and improper analysis, and a lack of consideration for the injection of an inactive solution into active structure. Consequently, the extrapolation of results to clinical settings are challenging due to a failure to clearly identity the causal factors in many clinical trials, as well as the non-clinical settings and the short duration of most laboratory experiments. They (266) concluded that creative experimental efforts are needed to rigorously assess the clinical significance of placebo interventions and investigate the component elements that may contribute to the therapeutic benefit.

Placebo solutions, such as local anesthetic when 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 conditions (278-290). In addition, decisions to consider all local anesthetic injections as placebo, failure to understand study design, or lack of understanding about the scientific basis for study design and placebo and nocebo results in inappropriate results and consequently denial of many interventions (281,283,291-305).

5.0 Conclusion

This systematic review shows limited evidence for automated percutaneous mechanical lumbar discectomy. However, automated percutaneous mechanical lumbar discectomy may provide appropriate relief in properly selected patients with contained disc herniation. Automated percutaneous mechanical lumbar discectomy is a safe procedure with minimal complications.

Acknowledgments

The authors wish to thank Vidyasagar Pampati, MSc, for statistical assistance; Sekar Edem for assistance in the search of the literature; Alvaro F. Gómez, MA, and Laurie Swick, BS for manuscript review; and Tonie M. Hatton and Diane E. Neihoff, transcriptionists, for their assistance in preparation of this manuscript. We would like to thank the editorial board of *Pain Physician* for review and criticism in improving the manuscript.

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Conflict of Interest:

Dr. Falco is a consultant for St. Jude Medical Inc. and Joimax Inc.

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.

Dr. Benyamin is a consultant with Bioness and Nevro; serves on the advisory boards of Vertos Medical and Nuvo Pharma; teaches/lectures for Vertos Medical, Boston Scientific, Neurotherm, and Bioness; and receives research/grants from Alfred Mann Foundation, Teknon Foundation, Spinal Restoration, Inc., Bioness, Boston Scientific, Vertos Medical, Medtronic, Kimberly Clarke, Epimed, BioDelivery Sciences International, Inc., Theravance, Mundipharma Research, Cephalon/Teva, AstraZeneca, and Purdue Pharma, LP.

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