Endoscopic Decompression of Spinal Cord for Adults with Sciatica or Low Back Pain (CPT 62380)

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Center for Evidence-based Policy
Oregon Health & Science University
3030 SW Moody, Suite 250
Portland, OR 97201
Phone: 503.494.2182
Fax: 503.494.3807
www.ohsu.edu/policycenter

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Overview

This report reviews the evidence for the effectiveness and safety of endoscopic decompression of the spinal cord, as well as the clinical practice guidelines and payer policies related to this intervention. Compression of the spinal cord or nerve roots can arise from herniation of the intervertebral disc. Individuals with lumbar disc herniation (LDH) may experience low back pain and/or pain or numbness of the lower extremities. Endoscopic decompression is a minimally invasive spine surgery that uses a specialized camera to visualize the associated lumbar intervertebral disc. Throughout this report, endoscopic decompression refers to the use of an endoscope to assist in performing decompression of the spinal cord or nerve roots that lead to symptomatic LDH.

Endoscopic decompression can be performed via different anatomical approaches to access the implicated disc (e.g., transforaminal, dorsal/laminar), be accompanied by the use of a microscope or magnification, and vary by type of tool used to remove the implicated disc. Access to the intervertebral disc is often made percutaneously (percutaneous endoscopic lumbar decompression [PELD]) using a guidewire under fluoroscopic guidance; some procedures utilize sequential tubular retractors that split the muscles and act as a working channel (microendoscopic decompression [MED]).

Key Findings

- A recent Current Procedural Terminology (CPT) code addition (62380) provides a billing code for endoscopic decompression of the spinal cord or nerve roots at the lumbar level.
- The available evidence on endoscopic decompression consists largely of nonrandomized comparative studies and case series conducted outside the U.S. Despite intrinsic biases in favor of endoscopic approaches, the evidence reported similar effects on pain, function, and disability compared to open discectomy or microdiscectomy. Microdiscectomy is the most common approach to surgery for LDH. The available evidence demonstrated a significant decrease in procedure-related blood loss, but any clinical significance of this finding is unclear and is likely to be minimal.
- Evidence on endoscopic decompression for primary symptomatic LDH demonstrates similar function and disability outcomes compared to open discectomy or microdiscectomy.
- A single systematic review with meta-analysis did not observe any significant differences in outcomes for individuals with recurrent LDH who received endoscopic decompression compared to open discectomy. The population of individuals with recurrent LDH included individuals with a return of LDH symptoms following a prior surgery (i.e., open discectomy) for LDH or simply individuals with return of LDH symptoms after a pain-free interval. The analysis combined findings from both percutaneous transforaminal and interlaminar routes to access the disc. Additionally, this study combined two populations: individuals with

previous spine surgery and those with a prior episode of LDH that resolved without surgery, and thus the outcomes for either group alone are unclear.

- The identified studies reported a significant decrease in time away from work for endoscopic recipients compared to open discectomy or microdiscectomy. However, these studies were performed outside of the U.S., limiting the ability to generalize this finding to Medicaid recipients.
- A limited number of clinical practice guidelines have addressed the use of endoscopic decompression to treat LDH. Of the three guidelines identified, all recommended the use of endoscopic decompression for the treatment of sciatica and LDH with radiculopathy. The authors of the 2016 NICE guideline highlighted the need for surgeons to obtain specific training and mentoring in the procedure and recommended that details from any endoscopic discectomy should be recorded in the British Spine Registry.
- Endoscopic decompression is considered experimental and not covered by the private insurers reviewed. Medicare, however, through a national coverage determination (NCD), allows for the use of an endoscope on an individual basis across many settings. PELD with image guidance (e.g., fluoroscopy) is conditionally covered under a 'coverage with evidence development' policy (e.g., when a patient is enrolled in a prospective, randomized clinical trial). Medicaid policies cover endoscopic decompression in six of the nine states reviewed in this report.

Background

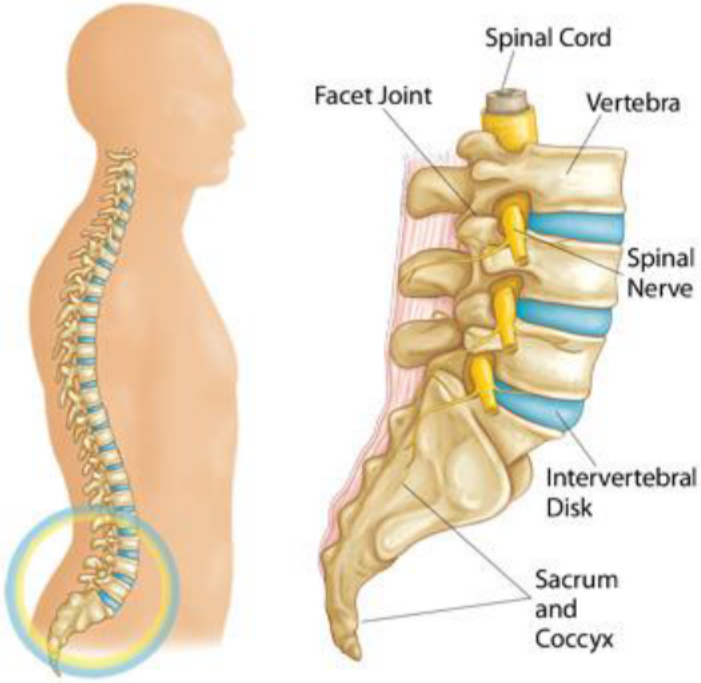
Clinical Overview

- The spine consists of 26 vertebrae that are divided into four regions (number of vertebrae per region): cervical (7), thoracic (12), lumbar (5), sacrum (1), and the coccyx (1).
- Compression of the spinal cord or nerve roots at the lumbar spine may present with low back pain, nerve pain down the legs (e.g., sciatica), or leg weakness. Figures 1 provides a visual aid on basic spine anatomy at the lumbar level.
- When a tear occurs in the outer surface of the intervertebral disc, the disc can apply pressure on the spinal cord or nerve root. This is referred to as a herniated disc. For this report, LDH refers to the symptomatic condition, as opposed to asymptomatic disc herniation incidentally observed on imaging. Figure 2 provides a visual aid on normal and herniated intervertebral discs.
- The majority of cases of symptomatic LDH will improve on their own, regardless of therapy, because the disc decreases in size over time (North American Spine Society, 2012). Patients and providers could agree to try conservative therapies (e.g., nonsteroidal anti-inflammatory drugs, physical therapy). In the event that the patient's symptoms do not improve, typically

within a six- to eight-week timeframe, a surgical option can be considered (North American Spine Society, 2012).

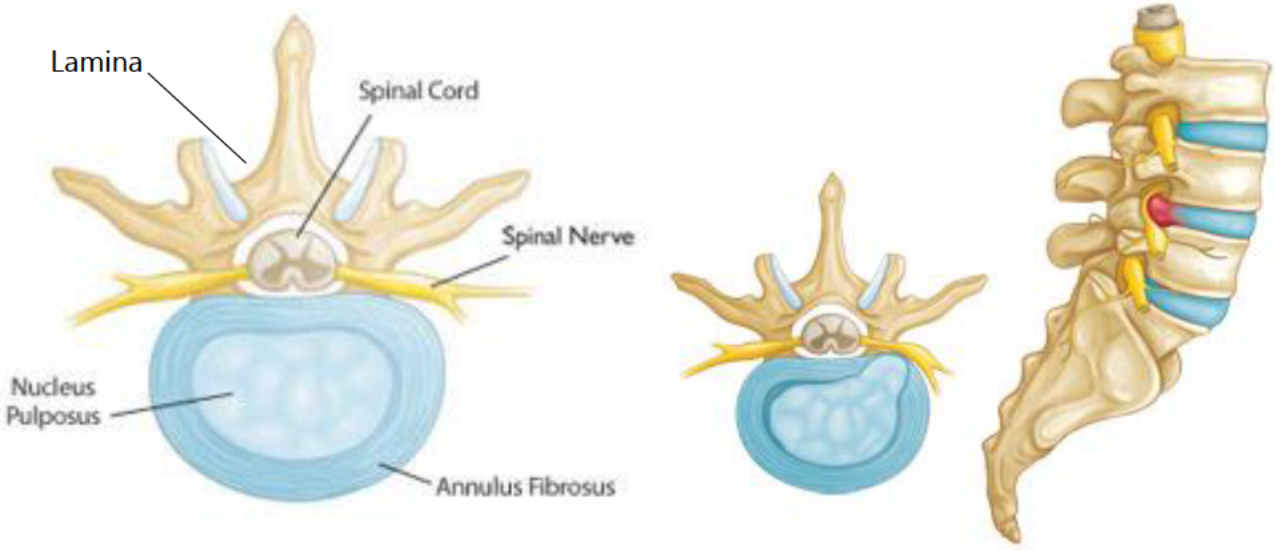
- Surgical options for spinal cord or nerve root decompression vary by their level of invasiveness (e.g., incision size), approach (e.g., route taken to reach the disc), and how the surgeon visualizes the operating field (e.g., unassisted or with the aid of a microscope, endoscope, fluoroscopic guidance, or combination). Decisions on approach vary based on the anatomic considerations of the patient and the disc itself.
- The original surgical approach to address LDH, open discectomy, consists of a large incision on the back with direct visualization and dissection of bony and muscular tissues (including removal of the lamina, a bony covering of the spinal cord). Since it was introduced in the 1970s, microdiscectomy, in which the surgeon uses an operating microscope or magnifying glasses, has been widely adopted and has supplanted open discectomy (Rasouli, Rahimi-Movaghar, Shokraneh, Moradi-Lakeh, & Chou, 2014).
- The use of an endoscope, a flexible camera providing a view of the operating field, can allow the surgeon to use a smaller incision and requires less dissection of muscle tissue. Table 1 provides a high-level overview of surgical approaches for lumbar disc herniation. PELD uses local anesthesia to numb the skin and subcutaneous tissues, avoiding the risks of general anesthesia. As with most new surgical techniques, there is likely to be a learning curve for surgeons who are new to endoscopic decompression (Wang et al., 2013a).
- Although the procedure is typically performed by surgeons, there are reports of interventional pain specialists increasingly using endoscopic decompression as a tool to treat individuals with symptomatic LDH (Epstein, 2016). Some of these procedures also use a laser to destroy the disc, which is outside of the scope of this review (Epstein, 2016).
- The myriad approaches and tools to address LDH are outside the scope of this review, which focuses solely on the evidence, guidelines, and policies related to the use of an endoscope to treat spinal cord or nerve root compression at the lumbar level. Adding complexity to effectiveness comparisons, the use of an endoscope can be combined with a microscope or accompany different approaches to reach the disc, leading to variation in how the muscle is dissected.

Figure 1. Overview of Lumbar Spine Anatomy



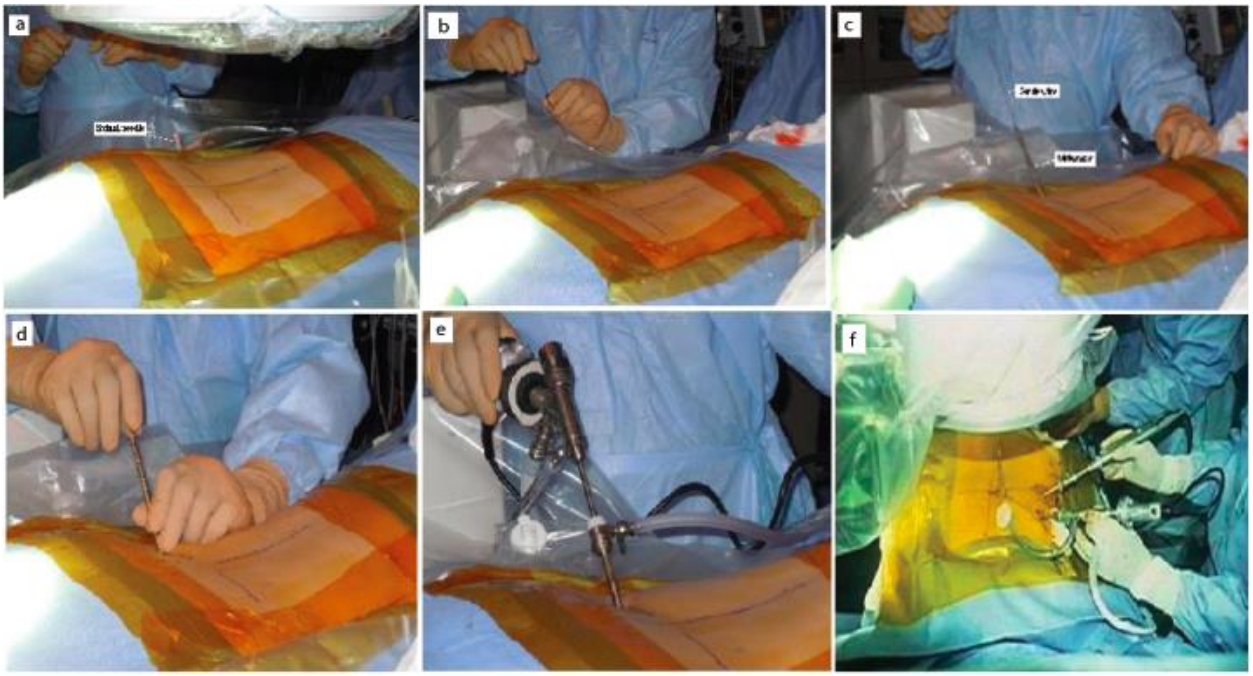
Source: http://orthoinfo.aaos.org/topic.cfm?topic=a00053

Figure 2. Normal (left) and Herniated (right) Intervertebral Discs



Source: http://orthoinfo.aaos.org/topic.cfm?topic=A00534

Figure 3. Percutaneous Endoscopic Decompression



Source: Zahid H. Bajwa, R. Joshua Wootton, Carol A. Warfield: *Principles and Practice of Pain Medicine*, 3rd Edition
www.accessanesthesiology.com

Table 1. Comparison of Surgical Approaches for Lumbar Disc Herniation

Common Surgery Name	Summary (Origin Dates)
Open discectomy	Laminectomy, partial disc removal (1934)
Microdiscectomy	Uses an operating microscope; most common approach for surgical correction of LDH (1970s)
Arthroscopic microdiscectomy	Use of a rigid scope and microscope to visualize the surgical field (1983)
Endoscopic Techniques	
Percutaneous endoscopic lumbar discectomy (PELD)	Uses a guidewire and fluoroscopy to gain access to intervertebral disc and flexible endoscope (subdivided into transforaminal or interlaminar by approach)
Microendoscopic discectomy	Use of an endoscope and microscope and tubular retractors to split muscles (1997)

Source. Adapted from Mu, Wei, and Li (2015); Rasouli et al. (2014).

Prevalence

Low back pain affects approximately 20% to 30% of adults in the U.S., and accounts for over 3% of all emergency department visits (Waterman, Belmont, & Schoenfeld, 2012). Of individuals with low back pain, approximately 3% have lumbar radiculopathy that in 90% of cases is caused by LDH (Rasouli et al., 2014).

PICO

The following PICO guides this evidence review.

Population: Adults with sciatica or low back pain arising from a ruptured, herniated, or bulging disc in the lumbar region, not responding to conservative management

Intervention: Endoscopic decompression of spinal cord or nerve root(s), including laminectomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, one interspace, lumbar (CPT code 62380)

Comparators: Microdiscectomy, open discectomy

Outcomes: Recovery time, change in pain (at least one year from procedure), function, quality of life, proportion of patients needing revision, adverse events (e.g., infection, bleeding, rehospitalization, morbidity, mortality), cost and cost-effectiveness

Key Questions

1. How does endoscopic decompression differ from microdiscectomy and open discectomy?

2. What is the effectiveness of endoscopic decompression in patients with sciatica or low back pain for the above outcomes?

3. What are the harms and adverse events associated with the use of endoscopic decompression?

4. What are the costs and cost-effectiveness of endoscopic decompression compared to standard therapies?

5. What are current clinical practice guidelines on the use of endoscopic decompression of the lumbar spine?

6. What are Medicare, state Medicaid, and private payer coverage criteria for endoscopic decompression of the lumbar spine?

Methods

Center for Evidence-based Policy (Center) researchers searched Center core evidence and guidelines sources and Ovid MEDLINE for systematic reviews (with or without meta-analysis), and technology assessments on the use of endoscopic decompression that were published within the last 10 years and clinical practice guidelines that were published within the last five years. Search dates for individual studies were determined by the last search dates of the included systematic reviews. Center researchers additionally searched the Ovid MEDLINE database for individual studies published between January 1, 2016 to August 9, 2017. Center researchers evaluated the methodological quality of systematic reviews, individual studies, and clinical practice guidelines eligible for this report using the methodology described in detail in Appendix A and quality assessment tools included with the New York State Department of Health dossier process (available on pages 14 to 33 of the *Dossier Submission Form* located on the New York State Department of Health website)[1]. Center researchers also searched Medicare, several state Medicaid programs, and private payers for coverage policies on the use of endoscopic decompression for the treatment of sciatica or low back pain. See Appendix A for a full list of payers searched.

Center researchers excluded systematic reviews if all of the included studies were also summarized by a more comprehensive systematic review, a systematic review of a higher methodological quality, and/or a more recently published systematic review. Patient-important outcomes that have relevance for New York State Department of Health, provided in the PICO section above, were pre-determined in the topic scope development, and studies reporting on

[1] Center researchers did not assess the methodological quality of the included case series. The case series are included to illustrate potential harms. Any reports of efficacy included in the case series are not described in this report.

other outcomes were not included. Excluded outcomes include radiographic outcomes, surgery characteristics (e.g., operative time, incision size), and biological laboratory markers. Case series were included for estimates on harms, not efficacy, if they included findings from 15 or more individuals. This inclusion criteria was based on the study inclusion criteria used by the most comprehensive of the included systematic reviews (Nellensteijn et al., 2010). Given the breadth of available evidence, systematic reviews that were assessed by Center researchers as having poor methodological quality were excluded. Exclusion criteria were selected prior to review of the studies, and study methods were assessed prior to review of outcomes to eliminate bias. See Appendix A for a full description of methods.

Evidence Review

Findings

Center researchers, through a search of core sources and the Ovid MEDLINE database, identified six recent systematic reviews relevant to the effectiveness of endoscopic decompression for LDH that met inclusion criteria (Li et al., 2016b; Li et al., 2016c; Mu et al., 2015; Nellensteijn et al., 2010; Phan et al., 2017; Ruan et al., 2016).

Center researchers identified one cohort study (Yao et al., 2017b) and 36 case series published after the search dates from the most recent systematic reviews identified. Center researchers included the case series for estimates of harms if they included more than 15 individuals.

Center researched identified three clinical guidelines. The current search did not identify any reports on cost or cost-effectiveness. See Appendix B for a full list of included studies.

Figure 3 outlines the number of articles identified by each search and the total number of studies included in this evidence synthesis. The search strategies and list of studies reviewed in full with reasons for exclusion are in Appendices A and B, respectively.

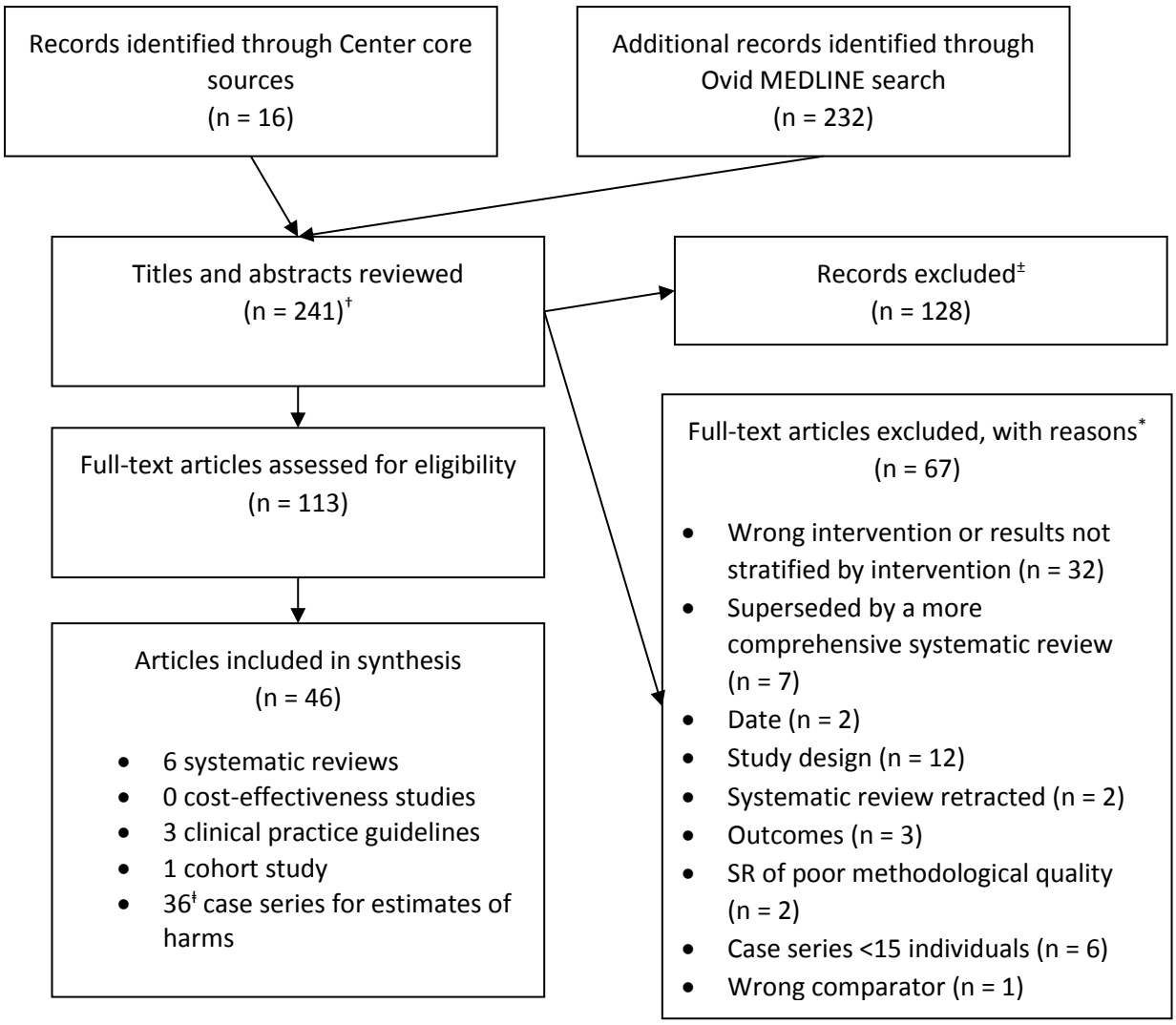
Overview of Evidence Sources

Center researchers summarized the evidence as reported by the included systematic reviews. Center researchers did not review the methodological quality of eligible individual studies within the systematic reviews unless necessary for clarification of information reported in the systematic review. There was substantial overlap in study inclusion across the systematic reviews and meta-analyses. In total, 69 individual studies (15 randomized controlled trials [RCTs] and 54 observational studies) were identified across the six included systematic reviews. Of the RCTs, 10 of the 15 were included in at least two systematic reviews; five RCTs were in only one systematic review because of inclusion criteria differences, publication timing, or language [i.e., Chinese]).

Pain was commonly assessed using the visual analogue scale (VAS). Patient satisfaction and quality of life were assessed using either the MacNab (or modified MacNab) criteria or Oswestry Disability Index (ODI). Details of the assessment tools are provided in Appendix D.

Table 2, evidence in primary symptomatic LDH, and Table 3, evidence on recurrent symptomatic LDH, provide an overview of findings from the included systematic reviews and individual studies.

Figure 3. Search Results



† Some duplication of articles between Center core source search results and Ovid MEDLINE search results.

± Articles were excluded if they did not meet predetermined inclusion criteria (e.g., PICO, study design, English language, publication date) as described in Appendix A.

ǂ Individual studies consisted of case series of greater than 15 individuals and were included for harms.

* Exclusion rationale provided in Appendix B.

Systematic Reviews with Meta-analysis

Li et al. (2016b)

Li et al. (2016b) conducted a good methodological quality systematic review with meta-analysis on the use of PELD compared to open discectomy or open microdiscectomy for adults with LDH with a minimum of six months of follow-up. The authors conducted an extensive literature search for studies published between 1973 and September 2015. The authors identified seven studies (four RCTs, three retrospective comparative studies) that reported on operation time, blood loss, length of hospital stay, VAS, MacNab criteria, mean disability period, complications, recurrence, and reoperation (Li et al., 2016b).

Li et al. (2016c)

Li et al. (2016c) conducted a fair methodological quality systematic review on the use of PELD compared to open discectomy or microdiscectomy for adults with recurrent LDH. The authors conducted an extensive literature search for studies published between 2002 and July 2015. The authors identified eight studies for inclusion (one prospective RCT, two retrospective controlled studies, two prospective cohort studies, three observational retrospective studies) that reported on leg pain, back pain, disability, global perceived effect (MacNab criteria score), complications, recurrence rate, and reoperation rate (Li et al., 2016c). The authors conducted meta-analyses on the three "controlled" studies, which on review by Center researchers consisted of one RCT and two nonrandomized comparative studies.

Mu et al. (2015)

Mu et al. (2015) conducted a fair methodological quality systematic review with meta-analysis on the use of microendoscopic discectomy compared to open discectomy for adults with LDH. The authors conducted an extensive literature search for RCTs published through June 2015. The authors identified nine RCTs that reported on operation time, blood loss, size of incision, length of hospital stay, time to return to work, disability, pain, patient satisfaction, and adverse events (Mu et al., 2015). The authors' fluency allowed this review to include two studies written in Chinese.

Phan et al. (2017)

Phan et al. (2017) conducted a fair methodological quality systematic review with meta-analysis comparing endoscopic approaches (i.e., PELD, microendoscopic discectomy) to open discectomy or microdiscectomy in adults with LDH. The authors conducted a comprehensive literature search for comparative studies published from database inception[2] to February 2016. However, not all studies made a comparison to open discectomy or microdiscectomy, and in the largest

[2] Inception dates vary across databases. For example, the inception date for Ovid MEDLINE is 1946 (Ovid, 2017) and for PsychINFO it is 1597, although comprehensive coverage starts in the 1880s (American Psycological Association, 2017).

included study the non-endoscopic procedure was not described by the original authors. Some of the included studies compared different endoscopic approaches. Using a comprehensive search strategy, the authors identified 23 comparative studies, three of which made comparisons between endoscopic approaches (Phan et al., 2017). Phan et al. (2017) reported on pain, disability, patient satisfaction, operation duration, hospital length of stay, blood loss, complications, recurrence rate, reoperation rate, and adverse events.

Ruan et al. (2016)

Ruan et al. (2016) conducted a fair methodological quality systematic review with meta-analysis comparing PELD to microdiscectomy in adults with LDH. The authors conducted a comprehensive literature search and included randomized and observational studies published from inception[3] through March 2016. Using a comprehensive search strategy, the authors identified seven studies meeting inclusion criteria (i.e., two RCTs and five retrospective cohort studies) (Ruan et al., 2016). The authors reported on pain, function, complications, length of hospital stay, operation time, and reoperation rate (Ruan et al., 2016).

Systematic Reviews

Nellensteijn et al. (2010)

Nellensteijn et al. (2010) conducted a fair methodological quality systematic review comparing transforaminal endoscopic decompression to open discectomy or microdiscectomy for adults with LDH or lumbar spinal stenosis. The authors conducted an extensive search of the literature published from 1973 to May 2008. The authors identified 39 studies: 31 case series (with n >15 and over six weeks of follow-up), seven cohort studies, and one RCT. Although the authors referred to several of the cohort studies as "retrospective controlled studies," this is not in keeping with standard terminology. The authors recalculated outcome measures across all studies to address several outcomes incorrectly handled by the original study authors: loss to follow-up, dropouts, and failed surgery attempts.

Individual Studies

Yao et al. (2017b)

Yao et al. (2017b) conducted a fair methodological quality retrospective cohort study comparing repeat PELD to microendoscopic discectomy or minimally invasive transforaminal lumbar interbody fusion (a non-endoscopic fusion procedure using a microscope) for individuals with recurrent LDH after an original PELD procedure in a single center in China. The cohort consisted of 74 individuals who experienced recurrent LDH after PELD (defined as at least one month pain free and imaging consistent with LDH). Participants were given the option of the three

[3] Inception dates vary across databases. For example, the inception date for Ovid MEDLINE is 1946 (Ovid, 2017)and for PsychINFO it is 1597, although comprehensive coverage starts in the 1880s (American Psycological Association, 2017).

aforementioned surgeries under the guidance of surgeons. The authors reported on pain, disability, and function at 12 months.

Center researchers identified 36 case series published since the search dates of the most recent systematic reviews that are included in this report. Because case series are non-comparative, these studies are included for estimates of harms only and formal quality assessment was not done. There was significant heterogeneity across the included case series in terms of the type of endoscopic decompressive procedure, study location, patient demographics, and outcomes reported.

Quality and Limitations

Center researchers rated one of the systematic reviews as having good methodological quality (Li et al., 2016b), and five as having fair methodological quality (Li et al., 2016c; Mu et al., 2015; Nellensteijn et al., 2010; Phan et al., 2017; Ruan et al., 2016). The single identified retrospective cohort study (Yao et al., 2017b) was rated as having fair methodological quality. Center researchers did not assess the methodological quality of the included case series. Center researchers assessed the methodological quality of included systematic reviews and meta-analyses and not the individual studies within them. The included systematic reviews all used rigorous search strategies, provided clear inclusion criteria, and used a system to quality-assess the eligible studies in their reviews.

Given the variety of approaches to researching interventions for LDH through surgical approaches, the published literature in this field includes many non-comparative studies and historical cohort comparisons. The included fair methodological systematic reviews often combined estimates of efficacy from studies using similar but not identical surgical approaches with varying follow-up periods, which led to a downgrading of their methodological quality. The eligible studies included in the systematic reviews were quality-assessed by the respective review authors. Generally, the authors of the systematic reviews noted that the eligible studies were at high risk of bias. References to study quality of the individual studies in the systematic reviews are taken directly from the systematic reviews, and are not assessments made by Center researchers. Of the 15 RCTs identified across systematic reviews, 10 were included across multiple reviews, but all 15 were not included in a single systematic review. The high overlap across systematic reviews means that future research could change the estimates reported in this review.

Summary of the Evidence

The evidence is summarized in the tables below by comparator and then by outcomes of effectiveness and harms. Table 2 includes the evidence identified for individuals with primary symptomatic LDH. Table 3 includes evidence for individuals with recurrent symptomatic LDH. Assessment of methodological quality of the overall systematic review by Center researchers is

provided in the left-hand column. Individual study quality of included studies within the systematic review is taken directly from the review authors and is not the Center's original assessment of the work.

Table 2. Overview of Included Studies for Primary Symptomatic Lumbar Disc Herniation

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
Systematic Review with Meta-analysis			
Li et al. (2016b) Search Dates 1973 to September 2015 Eligible Study Designs Randomized and nonrandomized controlled studies Methodological Quality of the SR (assessed by Center researchers) Good	k = 7 (4 RCTs, 3 retrospective studies) total n = 1,301 adults (298 from RCTs) *Methodological quality of included studies (assessed by the SR authors)* RCTs: 2 at high risk of bias; 2 at low risk Retrospective: 1 at high risk of bias; 2 at low risk	Comparators PELD vs. open discectomy or microdiscectomy Outcomes *Function (MacNab score at final follow-up)* Mean difference 1.04 (95% CI, 0.72 to 1.50; p = .91) *Leg pain (VAS score at final follow-up)* Mean difference -0.23 (95% CI, -0.53 to 0.07; p = .14) *Median blood loss (from 2 RCTs)* Mean difference -64.88 mL (95% CI, -114.51 to -15.25; p < .0001) *Recovery time (based on time to return to work)* Mean difference -34.34 days (95% CI, -53.90 to -14.77; p = .0002)	The quality assessment scoring tool used by the authors created a cumulative score. Only one RCT used an adequate randomization and concealment approach. None were blinded or performed an intention to treat analysis. Final follow-up was not consistent across all studies and ranged from 6 to 38 months after surgery. The authors combined estimates from randomized and nonrandomized studies in meta-analysis, which is not usual practice. Use of return to work as an estimate of recovery time presumes entire cohort was employed prior to surgery, but baseline employment status was not provided.

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
		Complication RR 0.76 (95% CI, 0.40 to 1.43; p = .39) *Reoperation* RR 1.40 (95% CI, 0.90 to 2.16; p = .13)	
Mu et al. (2015) Search Dates Published through June 2015, no lower end date reported Eligible Study Designs RCTs Methodological Quality of the SR (assessed by Center researchers) Fair	k = 9 RCTs total n = 774 adults *Methodological quality of included studies (assessed by the SR authors)*: 2 studies at low risk of bias, remaining at high risk of bias	Comparators Microendoscopic vs. open discectomy Outcomes *Recovery time (return to work)* Standardized mean difference -4.58 days (95% CI, -9.16 to -0.02; p = .05) *Blood loss* Standardized mean difference -1.26 mL (95% CI, -3.57 to -1.79; p < .00001) *Total complications* Mean difference 1.33 (95%, CI 0.92 to 1.91; p = .13) *Dural leak* Mean difference 1.27 (95% CI, 0.69 to 2.33; p = .44)	Included studies published in English or Chinese. The authors reported on the number of "effective cases," but it is unclear how the term was defined and what outcomes were used to calculate the effective case rate. Because of this lack of detail, efficacy outcomes from this systematic review are not included in this report. Use of return to work as an estimate of recovery time presumes entire cohort was employed prior to surgery, but baseline employment status was not provided.

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
Phan et al. (2017) Search Dates Inception to February 2016 Eligible Study Designs Observational and RCTs Methodological Quality of the SR (assessed by Center researchers) Fair	k = 23 (10 RCTs) total n = 28,487 *Methodological quality of included studies (assessed by the SR authors)*: Authors assessed individual quality, but did not provide a summary statement and omitted components of the quality-scoring tool; leading to concern about potential high risk of bias in the included studies	Comparators Endoscopic (PELD or microendoscopic) vs. open discectomy Outcomes *Blood loss (5 studies)* Mean difference -4.79 mL (95% CI, -6.52 to -3.07; p < .00001) *Patient satisfaction (6 studies)* OR 2.03 (95% CI, 1.08 to 3.81; p = .03) *Leg pain postoperative (VAS) (7 studies)* Mean difference -0.04 (95% CI, -0.37 to 0.30; p = .84) *Function (ODI) (4 studies)* Mean difference -1.88 (95% CI, -4.06 to 0.29; p = .09) *Total complications* Mean difference 0.77 (95% CI, 0.45 to 1.31; p = .33)	Not all identified studies included in this study used open discectomy as a common comparator. Not all identified studies provided details on surgical approaches. Final follow-up was not consistent across all studies and ranged from 6 to 36 months after surgery. The use of an odds ratio may overestimate the relative risk. Center researchers calculated a relative risk using the provided data for patient satisfaction and found RR 1.07 (95% CI, 1.01 to 1.14). The largest study (n = 26,612) did not provide details on surgical approaches nor length of follow-up. The approach for PELD (transforaminal or interlaminar) was not clear across all included study descriptions. Only 2 studies occurred in the U.S., limiting generalizability to the U.S. Medicaid population.

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
			Significant heterogeneity noted in the majority of meta-analyses, with the exception of patient satisfaction. Length of follow-up varied across all included studies, and the authors did not address how this was handled in their analyses.
Ruan et al. (2016) Search Dates Inception to March 2016 Eligible Study Designs Observational and RCTs Methodological Quality of the SR (assessed by Center researchers) Fair	k = 7 (2 RCTs) total n = 1,389 *Methodological quality of included studies (assessed by the SR authors)*: 2 studies of high quality, 4 of good quality, 1 of low quality	Comparators PELD vs. microdiscectomy Outcomes *Postoperative back pain (VAS) (4 studies)* Weighted mean difference -0.56 (95% CI, -1.43 to 0.31; p = .21) *Postoperative function (ODI) (4 studies)* Weighted mean difference -0.98 (95% CI, -4.96 to 3.00; p = .63) *Reoperation (7 studies)* OR 1.44 (95% CI, 0.94 to 2.20; p = .09) *Complications (5 studies)* OR 1.79 (95% CI, 0.95 to 3.37; p = .07)	All of the included studies occurred outside the U.S., limiting generalizability to the Medicaid population. None of the included studies blinded participants or staff to treatment received, thus increasing bias. Outcome assessors not blinded to treatment, also increasing bias. Final follow-up was not consistent across all studies and ranged from 13 to 34 months after surgery. Significant heterogeneity noted in all meta-analyses, with exception of complication and reoperation estimates. The use of an odds ratio overestimates the relative risk in data from studies in which the outcome is not "rare."

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
			Center researchers used the data provided by the study authors to calculate relative risk for the outcomes of reoperation and complications: *Reoperation* RR 2.01 (95% CI, 1.10 to 3.66) *Complications* RR 1.33 (95% CI, 0.90 to 1.97)
Systematic Reviews (without meta-analysis)			
Nellensteijn et al. (2010) Search Dates 1973 to May 2008 Eligible Study Designs Comparative cohorts, RCTs, case series (if n > 15 and >6 week follow-up) Methodological Quality of the SR (assessed by Center researchers) Fair	k = 39 (1 RCT, 7 cohorts, 31 case series) total n = 8,296 (60 from 1 RCT) *Methodological quality of included studies (assessed by the SR authors)*: All at high risk of bias except a single RCT (low risk)	Comparators Transforaminal endoscopic surgery vs. microdiscectomy Outcomes *(no statistical analysis on any comparison)* *Leg pain reduction (VAS)* 89% vs. 87% *Back pain reduction (VAS)* 42% vs. -8.3% *Functional change (MacNab or ODI)* 84% satisfactory (range, 70 to 97%) vs. 78% satisfactory (range, 65 to 93%)	Included studies with lumbar disc herniation or lumbar spinal stenosis. Specifically excludes microendoscopic discectomy as is not a transforaminal approach. The authors recalculated outcomes to incorporate dropouts, loss to follow-up, failed operations. Of the 8 comparative studies, 4 were reported to be randomized, but the authors stated that the method was adequate in only one study. Final follow-up was not consistent across all studies, ranged from 6 weeks to 36 months after surgery, and was not consistent for all outcomes within the same study.

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
		Reoperation 6.8% (range, 3.3 to 15%) vs. 4.7% (range, 0 to 11.5%) *Complications* 1.5% (range, 0 to 6.7%) vs. 1.0% (range, 0 to 12%)	The authors found heterogeneity across all studies in regard to population, indication for surgery, surgical techniques, and follow-up. The authors inappropriately identified non-comparative case reports as cohort studies. "We conclude the current evidence on the effectiveness of transforaminal endoscopic surgery is poor and does not provide valid information to either support or refute using this type of surgery in patients with symptomatic lumbar disc herniations" (Nellensteijn et al., 2010, p. 199).

Abbreviations. CI: confidence interval; mL: milliliter; ODI: Oswestry Disability Index; PELD: percutaneous endoscopic lumbar discectomy; OR: odds ratio; RCT: randomized controlled trial; RR: relative risk; VAS: visual analogue scale. Note. a indicates assessed by systematic review authors.

Table 3. Overview of Included Studies for Symptomatic Recurrent Lumbar Disc Herniation

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
Systematic Reviews with Meta-analysis			
Li et al. (2016c) Search Dates 2002 to July 2015 Eligible Study Designs Randomized and observational studies Methodological Quality of the SR (assessed by Center researchers) Fair	k = 8 (1 RCT) total n = 579 *Meta-analysis limited to k = 3 "controlled" studies, (n = 197)* *Methodological quality of included studies (assessed by the SR authors)*: 6 at low risk of bias, 2 at high risk of bias	Comparators PELD vs. microdiscectomy Outcomes *Blood loss* Mean difference -161.73 mL (95% CI, -418.46 to 95.01) *Back pain (VAS)* Mean difference -0.28 (95% CI, -3.90 to 3.33) *Leg pain (VAS)* Mean difference 2.03 (95% CI, -1.38 to 5.44) *Disability (ODI)* Mean difference -3.62 (95% CI, -13.93 to 6.70) *Recurrence* RR 0.53 (95% CI, 0.13 to 2.22) *Total complications* RR 0.24 (95% CI, 0.06 to 1.30)	Eligible studies included individuals with prior surgery and those with a prior episode of pain from LDH not requiring surgery. The authors assessed two "controlled" studies as having low risk of bias despite absence of randomization, allocation concealment, and blinding; leading to concern about high risk of bias. Reported estimates in this table arise from the authors' meta-analysis of 3 "controlled" studies. The authors combined estimates from randomized and nonrandomized studies in meta-analysis, which is not usual practice. Timing of final follow-up was not reported by all included studies.

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
			The authors found significant heterogeneity for all estimates from meta-analysis, with the exception of disability, complications, and recurrence estimates.
Observational Studies			
Yao et al. (2017b) Location China Follow-up 12 months Methodological Quality Fair	n = 74 adults with recurrent LDH after PELD	Comparators MIS-TLIF vs. microendoscopic discectomy vs. PELD Outcomes *Blood loss* 146.54 mL, not measured for MED or PELD *Complications* 1/26 vs. 2/20 vs. 4/28 (no statistically significant difference between groups) *Re-recurrence* 0/26 vs. 3/20 vs. 7/28 (p = 0.026) *VAS (back) at 12 months* 3.92 vs. 3.94 vs. 3.00 (statistically significant improvement for MIS-TLIF compared to PELD, additional detail not provided)	Retrospective nested cohort from a registry in China. Unclear decision process for choice of surgical approach. Small sample sizes and setting limit generalizability to U.S. population. MIS-TLIF is a non-endoscopic technique using a microscope for visualization for spinal fusion, not decompression. Authors noted statistically significant differences between groups but did not provide confidence intervals or exact p-values for all outcomes.

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
		VAS (leg) at 12 months No statistically significant difference between groups *Disability (ODI)* No statistically significant difference between groups *Function (SF-12)* No statistically significant difference between groups	

Abbreviations. CI: confidence interval; MIS-TLIF: minimally invasive transforaminal lumbar interbody fusion; ODI: Oswestry Disability Index; PELD: percutaneous endoscopic lumbar discectomy; RCT: randomized controlled trial. Note. a indicates assessed by systematic review authors.

Effectiveness Outcome #1: Recovery Time or Return to Work

Systematic Reviews

Primary LDH

Two systematic reviews with meta-analyses reported on time to return to work for endoscopic decompression compared to open discectomy or microdiscectomy (Li et al., 2016b; Mu et al., 2015). The reported mean difference in time until return to work was shorter for endoscopic recipients in both reviews, but the estimates were imprecise and varied by a factor of more than six between the systematic reviews. Reported estimates ranged from 4.58 days sooner (95% CI, 9.16 sooner to 0.02 sooner) (Mu et al., 2015) to 34.34 days sooner (95% CI, 53.90 sooner to 14.74 sooner) (Li et al., 2016b).

Recurrent LDH

Center researchers did not identify any studies that reported on this outcome for individuals with recurrent LDH.

Individual studies

Center researchers did not identify any individual studies that reported on this outcome.

Effectiveness Outcome #2: Disability or Function (at ≥1 year)

Systematic Reviews

Primary LDH

Four systematic reviews, three with meta-analysis, found no significant differences in disability or function at one year post-surgery for endoscopic recipients compared to open discectomy or microdiscectomy (Li et al., 2016b; Nellensteijn et al., 2010; Phan et al., 2017; Ruan et al., 2016).

Recurrent LDH

A single systematic review reported no significant differences in disability for individuals with recurrent LDH (Li et al., 2016c).

Individual studies

Recurrent LDH

A single cohort study observed no statistically significant difference in disability or function at one year post-surgery for individuals with recurrent LDH (Yao et al., 2017b).

Effectiveness Outcome #3: Pain or Symptom Severity (at ≥ 1 year)

Systematic Reviews

Primary LDH

Three systematic reviews with meta-analysis found no significant differences in leg or back pain scores at follow-up. The assessment of low back or leg pain was assessed using the VAS across the systematic reviews (Li et al., 2016b; Phan et al., 2017; Ruan et al., 2016). The timing of the

assessment of pain severity at follow-up was not consistently reported in all the included reviews. In their older systematic review, Nellensteijn et al. (2010) reported differing estimates for leg and back pain. Reduction in leg pain was similar for endoscopic and microdiscectomy recipients (89% vs. 87%), and back pain reduction was observed for endoscopic recipients, but not those undergoing microdiscectomy (42% vs. -8.3%) (Nellensteijn et al., 2010). The absence of formal statistical analysis limits the ability to interpret the significance of these estimates.

Recurrent LDH

A single systematic review reported no significant differences in pain or symptom severity for individuals with recurrent LDH (Li et al., 2016c).

Individual studies

Recurrent LDH

A single cohort study observed statistically significant differences between PELD and translaminar interbody fusion for low back pain at one year (Yao et al., 2017b). The difference was statistically significant, but very small (Yao et al., 2017b). A beneficial clinical effect is unlikely because there was no difference in disability or function.

Effectiveness Outcome #4: Recurrence of Symptoms or Need for Reoperation

Systematic Reviews

Primary LDH

Three systematic reviews, two with meta-analysis, found no significant differences in reoperation or recurrence of symptoms for endoscopic recipients compared to open discectomy or microdiscectomy recipients (Li et al., 2016b; Nellensteijn et al., 2010; Ruan et al., 2016).

Recurrent LDH

A single systematic review reported no significant differences in recurrence for individuals with recurrent LDH (Li et al., 2016c).

Individual studies

Recurrent LDH

A single cohort study observed greater rates of re-recurrence of symptoms for individuals with a history of LDH and PELD (Yao et al., 2017b). Rates of recurrence were greater for PELD recipients than for those who underwent microendoscopic discectomy or translaminar interbody fusion (Yao et al., 2017b).

Effectiveness Outcome #5: Patient Satisfaction

Systematic Reviews

Primary LDH

One systematic review with meta-analysis found greater patient satisfaction for recipients of endoscopic decompression compared to open discectomy or microdiscectomy; odds ratio (OR), 2.03 (95% CI, 1.08 to 3.81) (Phan et al., 2017). The study authors did not describe the specific tool or tools used to assess patient satisfaction. Follow-up periods ranged widely across the eligible studies, from less than six months to more than three years, and the authors pooled all estimates of patient satisfaction into this analysis.

The use of an odds ratio for this estimate, which combines data from prospective and retrospective studies, could overestimate the relative risk (RR). Center researchers used the data provided by the study authors and observed no difference between groups (RR 1.07, 95% CI, 1.01 to 1.14).

Recurrent LDH

Center researchers did not identify any studies that reported on this outcome for this population.

Individual studies

Center researchers did not identify any individual studies that reported on this outcome.

Harms Outcome #1: Perioperative Blood Loss

Systematic Reviews

Primary LDH

Three systematic reviews with meta-analysis observed consistently less blood loss for recipients of endoscopic decompression (Li et al., 2016b; Mu et al., 2015; Phan et al., 2017). In their review of PELD compared to open discectomy or microdiscectomy, Li et al. (2016b) observed 64.88 mL less bleeding for endoscopic recipients (95% CI, 114.51 mL less to 15.25 mL less). The clinical significance of this volume difference is not clear because none of the included systematic reviews provided outcomes on blood transfusions or other clinical effects of this blood loss.

The remaining two systematic reviews evaluated blood loss for microendoscopic discectomy and all endoscopic decompression techniques respectively (Mu et al., 2015; Phan et al., 2017). The observed differences, although statistically significantly different, are very small (less than a teaspoon) and unlikely to have a clinical effect (-1.26 mL to -4.79 mL; 95% CI, ranging from -6.52 mL to -1.79 mL).

Recurrent LDH

A single systematic review reported no significant differences in blood loss for individuals with recurrent LDH (Li et al., 2016c).

Individual studies

Recurrent LDH

A single cohort study observed less bleeding from endoscopic approaches compared to translaminar interbody fusion for individuals with recurrent LDH (Yao et al., 2017b).

Harms Outcome #2: Complications

Systematic Reviews

Primary LDH

Five systematic reviews, four with meta-analysis, reported no significant differences in rates of complications for endoscopic decompression recipients compared to open discectomy or microdiscectomy recipients (Li et al., 2016b; Mu et al., 2015; Nellensteijn et al., 2010; Phan et al., 2017; Ruan et al., 2016).

Recurrent LDH

A single systematic review reported no significant differences in complications for individuals with recurrent LDH (Li et al., 2016c).

Individual Studies

Recurrent LDH

A single cohort study observed similar rates of complications for individuals with recurrent LDH (Yao et al., 2017b).

Center researchers identified 36 case series (total n = 13,640) that reported on adverse events from the use of endoscopic decompression surgery for LDH. There was significant heterogeneity in the type of endoscopic decompression surgery, patient demographics, and location across the case series. Nerve damage or root injury, dural tears, and infection incidence were the most commonly reported adverse events across the case series. Three of the case series reported that there were no complications and did not report on specific adverse events (Kang, Li, Cheng, & Liu, 2017; Lee, Kim, Jang, & Jang, 2016b; Yokosuka et al., 2016). Table 4 provides a high-level summary of the types of adverse events reported, the number of included case series that reported on each outcome, and the reported incidence ranges.

Table 4. Incidence of Adverse Events in Included Case Series

Outcome	# of Case Series Reporting Outcome	Incidence Ranges
Infection	19	0 to 1.3%
Dural tear	14	0 to 12.0%
Nerve damage or root injury	14	0 to 9.7%
Fragment retention or incomplete decompression	9	0.9 to 11.1%
Hemorrhage	8	0% (0 to 68 mL blood loss reported)
Dysesthesia	8	0.7 to 4.5%
Decrease in motor function or strength	7	0 to 47.6%
Cerebrospinal fluid leak	6	None
Hematoma (symptomatic)	6	0.1 to 2.2%
Thrombosis	5	0 to 4.8%
Bladder and bowel disturbance (transient)	2	0.6 to 2.4%
Discitis	2	0 to 1.8%
Paralysis	2	1.0 to 1.2%
Death	1	0%
Headache	1	1.72%
Severe sensory radiculopathy	1	1.3%

Costs or Cost-effectiveness

The current search strategy did not identify any estimates of cost or cost-effectiveness for endoscopic decompression.

Clinical Practice Guidelines

Center researchers identified three clinical practice guidelines that address the use of endoscopic decompression surgery for the treatment of LDH. One of the guidelines was rated as having poor methodological quality (North American Spine Society, 2012), and two of the guidelines were rated as having fair methodological quality (National Institute for the Health and Care Excellence [NICE], 2016a; NICE, 2016b). Table 5 provides a summary of recommendations across the included guidelines. The strength of underlying evidence noted in the table for guideline recommendations is an assessment by the guideline authors and not Center researchers.

The guidelines from NICE and the North American Spine Society concur with their recommendations for the use of endoscopic lumbar discectomy for the treatment of sciatica and LDH, respectively. The NICE guidelines, based on a comprehensive literature review and guideline development process, recommend that surgeons need specific training and mentoring to adequately perform the procedure and recommend reporting all outcomes to the British Spine Registry (NICE, 2016a; NICE, 2016b). The North American Spine Society (2012) suggests that the use of endoscopic percutaneous decompression can be useful for reducing early postoperative disability and opioid use in carefully selected patients who have LDH with radiculopathy. Although this guideline provides an overview of the guideline development process used by the North American Spine Society, it does not provide any details of the underlying evidence review (e.g., search strategy, evidence review methods).

Table 5. Summary of Clinical Practice Guidelines' Recommendations for Endoscopic Decompression

Citation, Methodological Quality‡	Recommendation (Evidence Rating)*
National Institute for Health and Care Excellence (2016b) Fair	"Current evidence on the safety and efficacy of percutaneous interlaminar endoscopic lumbar discectomy for sciatica is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. 1.2 Percutaneous interlaminar endoscopic lumbar discectomy for sciatica is a procedure that needs particular experience. Surgeons should acquire the necessary expertise through specific training and mentoring. It should only be done by surgeons who do the procedure regularly. 1.3 Details about all patients having percutaneous interlaminar endoscopic lumbar discectomy for sciatica should be entered onto the British Spine Registry."
National Institute for Health and Care Excellence (2016a) Fair	"1.1 Current evidence on the safety and efficacy of percutaneous transforaminal endoscopic lumbar discectomy for sciatica is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. 1.2 Percutaneous transforaminal endoscopic lumbar discectomy for sciatica is a procedure that needs particular experience. Surgeons should acquire the necessary expertise through

Citation, Methodological Quality‡	Recommendation (Evidence Rating)*
	specific training and mentoring. It should only be done by surgeons who do the procedure regularly. 1.3 Details about all patients having percutaneous transforaminal endoscopic lumbar discectomy for sciatica should be entered onto the British Spine Registry."
North American Spine Society (2012) Poor	"Endoscopic percutaneous discectomy may be considered for the treatment of lumbar disc herniation with radiculopathy. Grade of Recommendation: C (poor-quality evidence [Level IV or V studies] for or against recommending intervention)" (North American Spine Society, 2012, p. 40). "Endoscopic percutaneous discectomy is suggested for carefully selected patients to reduce early postoperative disability and reduce opioid use compared with open discectomy in the treatment of patients with lumbar disc herniation with radiculopathy. Grade of Recommendation: B (fair evidence [Level II or III studies with consistent findings] for or against recommending intervention)" (North American Spine Society, 2012, p. 41).

*Note. ǂDetermined by Center researchers. *Determined by guideline authors.*

Payer Policies

Center researchers searched for policies on the coverage of CPT code 62380 (endoscopic decompression of neural elements and/or excision of herniated intervertebral discs) from Aetna, Anthem, Blue Shield of Northeastern New York, Capital District Physicians' Health Plan, Centers for Medicare and Medicaid Services (CMS), Cigna, Emblem Health, Empire Blue Cross Blue Shield (BCBS), Excellus BCBS, Tufts Health Plan, UnitedHealthcare, and nine state Medicaid programs (CA, FL, MA, NJ, NY, OR, PA, TX, WA).

Endoscopic decompression for disc herniation (CPT code 62380) is addressed by two national coverage determinations (NCDs) from CMS. The first NCD (100.2) is a broad coverage policy pertaining to all endoscopic procedures. It allows coverage of endoscopic procedures when "reasonable and necessary for the individual patient" (CMS, n.d.). The second NCD (150.13) addresses percutaneous image-guided lumbar decompression through a coverage with evidence development policy. Percutaneous image-guided lumbar decompression is covered when a patient is enrolled in a prospective RCT (CMS, 2016). The NCD outlines clinical trial criteria that must be met for coverage of the procedure (CMS, 2016). Outside the context of a clinical trial, the NCD states that coverage for "endoscopic assisted laminotomy/laminectomy,

which requires open and direct visualization" is at the discretion of the contractor (CMS, 2016). Center researchers did not identify any local coverage decisions (for which contractors would specify coverage criteria).

Center researchers identified nine private payer coverage policies pertaining to endoscopic decompression procedures. None of the identified policies provide coverage for any type of endoscopic decompression procedure, and many of the payers stated that endoscopic decompression procedures are considered experimental and investigational, and thus not medically necessary. No coverage criteria was identified from the Capital District Physicians' Health Plan.

Six of the nine state Medicaid programs cover CPT code 62380. Only Oregon Medicaid addresses endoscopic procedures in a provider manual and includes all endoscopic procedures (including CPT 62380) as part of the global surgical payment. The other five state Medicaid agencies (FL, MA, NJ, TX, WA) list CPT 62380 with an assigned rate in their respective current fee schedules, but do not provide any coverage criteria. No coverage criteria on CPT 62380 was identified in the provider manuals searched for the California, New York, and Pennsylvania Medicaid programs, nor was CPT 62380 listed in the respective fee schedules. Table 6 provides a comparison of identified coverage criteria across all payers searched.

Table 6. Endoscopic Decompression (CPT 62380) Coverage Policies

Payer	Indication Requirements
Medicare	
NCD 100.2 (*effective date not posted*)	"Endoscopic procedures are covered when reasonable and necessary for the individual patient" (CMS, n.d.).
NCD 150.13 (*effective 12/7/2016*)	"[Percutaneous image-guided lumbar decompression] for [lumbar spine stenosis] may only be covered under the context of a clinical trial." "Endoscopically assisted laminotomy/laminectomy, which requires open and direct visualization, as well as other open lumbar decompression procedures for LSS are not within the scope of this NCD and coverage is at contractor discretion" (CMS, 2016). Reimbursement: *62380 is contractor priced, and not priced at the national or the New York localities rates.*
Private Payers	
Aetna (*last review 12/2016*)	"Considered experimental and investigational: • Endoscopic disc decompression, ablation, or annular modulation using the DiscFX system • Endoscopic laser foraminoplasty, endoscopic foraminotomy, laminotomy, and rhizotomy

Payer	Indication Requirements
	• Endoscopic transforaminal discectomy • Far lateral microendoscopic discectomy for extra-foraminal lumbar disc herniations or other indications • Microendoscopic discectomy procedure for decompression of lumbar spine stenosis, lumbar disc herniation, or other indications • Percutaneous endoscopic discectomy with or without laser [...] Reimbursement Note: Use of a microscope or endoscope is considered an integral part of the spinal surgery and not separately reimbursable" (Aetna, 2016).
Anthem (*last review 8/2016*)	"Percutaneous or endoscopic spinal surgical techniques are considered investigational and not medically necessary" (Anthem, 2017).
Blue Shield of Northeastern New York (*last reviewed 7/2016*)	"Endoscopic discectomy is considered investigational as a technique of intervertebral disc decompression in patients with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine" (Blue Shield of Northeastern New York, 2016).
Capital District Physicians' Health Plan	*No policy identified.*
Cigna (*last reviewed 6/2017*)	"A percutaneous or endoscopic laminectomy or disc decompression procedure, including but not limited to any of the following, is considered experimental, investigational or unproven: [...] endoscopic anterior spinal surgery/Yeung endoscopic spinal system (YESS)/percutaneous endoscopic discectomy (PELD)/arthroscopic microdiscectomy, selective endoscopic discectomy (SED) (CPT code 62287), endoscopic disc decompression (CPT code 62380)" (Cigna, 2017).
Emblem Health (*effective 1/2017*)	CPT 62380 is not covered (EmblemHealth, 2017).
Empire BCBS (*last reviewed 8/2016*)	"Percutaneous or endoscopic spinal surgical techniques are considered investigational and not medically necessary" (Empire BCBS, 2017).
Excellus BCBS (*last reviewed 1/2017*)	"Endoscopic discectomy techniques, including endoscopic discectomy, endoscopic microdiscectomy, and percutaneous endoscopic discectomy have not been medically proven to be effective and are considered investigational as a technique of intervertebral disc decompression in patients with disc herniation of the cervical, thoracic or lumbar spine" (Excellus BCBS, 2017).
Tufts Health Plan (*last reviewed 3/2017*)	CPT code 62380 is considered investigational and not covered (Tufts Health Plan, 2017).
UnitedHealthcare (*effective 1/2017*)	"Percutaneous discectomy and decompression procedures are unproven and not medically necessary for treating discogenic pain. Percutaneous discectomy and

Payer	Indication Requirements
	decompression procedures include, but are not limited to, the following procedures: [...] percutaneous endoscopic discectomy with or without laser (PELD), Yeung endoscopic spinal surgery (YESS) (arthroscopic microdiscectomy or percutaneous endoscopic discectomy)" (UnitedHealthcare, 2017).
State Medicaid	
California *(effective 7/15/2017)*	*No coverage criteria identified.* Reimbursement: *62380 not listed*
Florida *(effective 1/1/2017)*	CPT 62380 is a covered service. Reimbursement: $567.91
Massachusetts *(effective 1/1/2017)*	CPT 62380 is a covered service. Reimbursement: *Pricing based on individual consideration*
New Jersey *(effective 1/1/2017)*	CPT 62380 is a covered service. Reimbursement: $687.02 (specialist); $583.97 (non-specialist)
New York *(effective 3/23/2017)*	*No coverage criteria identified.* Reimbursement: *62380 not listed*
Oregon *(effective 5/25/2017)*	Endoscopy included in global surgical payment. Reimbursement: *62380 not listed*
Pennsylvania *(6/28/2017)*	*No coverage criteria identified.* Reimbursement: *62380 not listed*
Texas *(effective 1/1/2017)*	CPT 62380 is a covered service. Reimbursement: $463.11 (0 to 20 years); $441.05 (21+ years)
Washington *(effective 7/1/2017)*	CPT 62380 is a covered service. Reimbursement: *Pricing based by report*

Abbreviations. BCBS: Blue Cross Blue Shield; CPT: Current Procedural Terminology.

Discussion

A recent CPT code addition (62380) provides a billing code for endoscopic decompression of the spinal cord or nerve roots at the lumbar level. Endoscopic approaches include percutaneous and microendoscopic techniques, which vary by anatomical approach and by the other tools used to perform the discectomy or decompression. The available evidence on endoscopic decompression is largely from nonrandomized, non-comparative studies at risk of bias. Despite the inherent biases of the body of evidence that would favor endoscopic decompression, endoscopic decompression performs similarly to open discectomy or microdiscectomy in terms of changes in symptom severity, function, disability, and complications. Statistically significant differences in blood loss are small and likely not clinically relevant.

All of the guidelines identified recommend the use of endoscopic decompression for the treatment of sciatica or LDH with radiculopathy, however, the guideline authors cautioned that surgeons need mentorship and training to successfully perform this procedure and that

additional research is needed to fully establish clinical efficacy. Payer policies for endoscopic decompression are not consistent. Private payers consider the procedure experimental and do not cover it, but six of the nine Medicaid agencies reviewed for this report allow coverage. Medicare does not have a policy specific to this code, but allows for the use of an endoscope across many procedures at the physician's discretion if medically indicated. Percutaneous imaging-guided procedures are covered by Medicare under coverage with evidence development.

Strength of Evidence

The Center uses the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) Working Group approach to enhance consistency in grading the strength of evidence. RCTs are initially categorized as having high strength of evidence and observational studies are categorized as having low strength of evidence. The strength rating is downgraded based on limitations including inconsistency of results, uncertainty of directness of measurement or population, imprecise or sparse data, and high probability of reporting bias. The grade is increased from low for evidence from observational studies if there is a strong association,[4] a very strong association,[5] or a dose-response gradient. The grade is also increased if all plausible confounders would have reduced the effect (Schünemann, Brozek, Guyatt, & Oxman, 2014). Table 7 provides an overview of the strength of evidence by outcome and associated rationale for the strength of evidence rating.

Table 7. Strength of Evidence for Endoscopic Decompression Effectiveness, Harms, and Costs

Outcome	Strength of Evidence Assessment	Rationale
Effectiveness		
Recovery time	Moderate	SRs observed shorter time away from work for endoscopic recipients. • Downgraded for risk of bias
Function, Disability, Pain Severity	Moderate	SRs observed similar function, disability, and pain severity for endoscopic recipients. • Downgraded for risk of bias
Quality of Life	*The current search did not identify any findings on this outcome*	
Revision of Reoperation	Moderate	SRs observed similar rates of need for revision or reoperation for endoscopic recipients.

[4] Significant relative risk of >2 or <0.5 with no plausible confounders in 2 or more observational studies.
[5] Significant relative risk of >5 or <0.2 based on direct evidence with no major threats to validity.

Outcome	Strength of Evidence Assessment	Rationale
		• Downgraded for inconsistency
Harms		
Blood loss	Moderate	SRs observed less bleeding for endoscopic recipients, but the estimates differed across included SRs. • Downgraded for inconsistency
Complications	Low	SRs observed similar rates of complications for endoscopic recipients, but the data are largely from nonrandomized, non-comparative case series. • Downgraded two levels for risk of bias
Costs		
The current search did not identify any estimates on costs.		

Abbreviations. SR: systematic review.

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Appendix A. Methods

Search Strategies

Evidence

A full search of the Center's core clinical evidence primary sources was conducted to identify systematic reviews, meta-analyses, and technology assessments using the search terms *endoscop* and (spin* or decompression or disk or disc or hernia or sacral or spondylodiscitis or chondrosis) and (back or lumbar or sciatica), endoscopic, endoscopy, back, spine, disc, spinal,* and *decompression*. Searches of core sources were limited to citations published after 2006. Center researchers also searched the Ovid MEDLINE database for relevant systematic reviews and meta-analyses, technology assessments, and cost-effectiveness studies published after 2006. To ensure that the most recent data were included, Center researchers also searched Ovid MEDLINE from 2016 to August 9, 2017, for individual studies on the use of endoscopic decompression that were published after the search dates of the most recent included systematic reviews.

The following core sources were searched:

Agency for Healthcare Research and Quality (AHRQ)

BMJ – Clinical Evidence

Cochrane Library (Wiley Interscience)

National Institute for Health and Care Excellence (NICE)

PubMed Health

Tufts Cost-Effectiveness Analysis Registry

Veterans Administration Evidence-based Synthesis Program (ESP)

Washington State Health Technology Assessment Program

Clinical Practice Guidelines

Center researchers conducted a full search of Center clinical practice guidelines primary sources to identify clinical practice guidelines using the terms *endoscop* and (spin* or decompression or disk or disc or hernia or sacral or spondylodiscitis or chondrosis) and (back or lumbar or sciatica), endoscopic, endoscopy, back, spine, disc, spinal,* and *decompression*. Searches were limited to citations published within the last five years. Center researchers included guidelines from governmental bodies and professional associations; guidelines from single clinical institutions (e.g., a single hospital or clinic) were not included.

The guideline sources included the following:

Australian Government National Health and Medical Research Council (NHMRC)

National Guidelines Clearinghouse

National Institute for Health and Care Excellence (NICE)

New Zealand Guidelines Group

Scottish Intercollegiate Guidelines Network (SIGN)

Veterans Administration/Department of Defense (VA/DOD)

World Health Organization (WHO)

Center researchers searched Google 10 pages deep using the terms *(guideline or position or practice) AND lumbar AND endoscopic AND discectomy*.

Coverage Policies

Center researchers searched for policies on the coverage of endoscopic decompression for the treatment of sciatica or low back pain from Aetna, Anthem, Blue Shield of Northeastern New York, Capital District Physicians' Health Plan, Centers for Medicare and Medicaid Services, Cigna, Emblem Health, Empire BCBS, Excellus BCBS, Tufts Health Plan, UnitedHealthcare, and nine state Medicaid programs (CA, FL, MA, NJ, NY, OR, PA, TX, WA).

Ovid MEDLINE

The Ovid MEDLINE search strategy was developed for broad inclusion of relevant systematic reviews and individual studies. Individual studies published after the search dates of the included systematic review or studies that were eligible and not included in the systematic review were included to update the existing systematic review.

Database: Ovid MEDLINE <1946 to July Week 4 2017>, Ovid MEDLINE In-Process & Other Non-Indexed Citations <August 08, 2017>
Search Strategy:

1 Intervertebral Disc Degeneration/
2 Intervertebral Disc Displacement/
3 dis?opath$.tw,ot.
4 spondylodiscitis.tw,ot.
5 (spondylochondrosis or chondrosis).tw,ot.
6 (hernia$ or perfora$ or ruptur$ or degenerat$ or displac$ or prolaps$ or protru$ or avuls$ or compress$ or extru$).tw,ot.
7 1 or 2 or 3 or 4 or 5 or 6
8 Lumbar Vertebrae/
9 Lumbosacral Region/
10 8 or 9
11 Intervertebral Disc/
12 (intervertebral or intradiscal or intradiskal).tw,ot.

13 11 or 12
14 10 and 13
15 (lumb$ adj (disc$ or disk$)).tw,ot.
16 14 or 15
17 exp surgical procedures, minimally invasive/
18 (microdis?ectom$ or nucleotom$ or nucleoplast$ or annuloplasty or (microscop$ adj dis?oto$)).tw,ot.
19 ((mini$ adj3 invas$) or mini?invas$).tw,ot.
20 automated percutaneous discectomy.tw,ot.
21 laser.tw,ot.
22 ((percutaneous or transforaminal) adj (microendoscop$ or endoscop$ or dis?oscop$ or arthroscopy$)).tw,ot.
23 transmuscular tubular.tw,ot.
24 17 or 18 or 19 or 20 or 21 or 22 or 23
25 7 and 16 and 24
26 (animals not (humans and animals)).sh.
27 25 not 26
28 limit 27 to english language
29 limit 28 to yr="2007 -Current"
30 remove duplicates from 29
31 (systematic review$ or (meta adj analys$) or meta?analys$).tw.
32 30 and 31
33 limit 32 to (meta analysis or systematic reviews or technical report)
34 32 or 33
35 from 34 keep 1-41
36 (econom$ or cost or (cost adj effectiv$)).tw,ot.
37 Cost-Benefit Analysis/
38 36 or 37
39 30 and 38
40 limit 30 to yr="2015 -Current"
41 40 not (35 or 39)
42 remove duplicates from 53

Study Inclusion/Exclusion Criteria

Two Center researchers independently reviewed the results from the Center core sources and Ovid MEDLINE database searches at each stage of review (e.g., title and abstract, full text). Any study that was identified by at least one researcher as potentially meeting inclusion criteria was advanced to the next review level. All excluded studies were determined by two Center researchers as not meeting the predetermined inclusion criteria. Any disagreement between

study reviewers regarding the inclusion of a study was arbitrated by a third Center researcher. Center researchers excluded studies that were not systematic reviews, meta-analyses, technology assessments, or individual studies (as applicable by topic); that were published before 2007; were published in a language other than English; or did not meet the specific inclusion/exclusion criteria outlined below.

Inclusion Criteria

Population: Adults with sciatica or low back pain arising from a ruptured, herniated, or bulging disc in the lumbar region, not responding to conservative management

Intervention: Endoscopic decompression of spinal cord or nerve root(s), including laminectomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, one interspace, lumbar (CPT code 62380)

Comparators: Microdiscectomy, open discectomy

Outcomes: Recovery time, change in pain (at least one year from procedure), function, quality of life, proportion of patients needing revision, adverse events (e.g., infection, bleeding, rehospitalization, morbidity, mortality), cost and cost-effectiveness

Exclusion Criteria

Study exclusion criteria included the following:

- Comments, letters, editorials, case reports
- Case series with a sample size <15 individuals
- Case series that did not report adverse events
- Studies reporting radiographic outcomes, surgery characteristics (e.g., operative time, incision size), or biological laboratory markers
- Systematic reviews that were assessed by Center researchers as having poor methodological quality
- Duplicate information from a research study published in more than one source (only the highest quality, most recent publication with outcomes of interest was included)
- Systematic reviews that included only studies summarized by more comprehensive, higher-quality, and/or more recently published systematic reviews
- Studies identified that were included in a summarized systematic review or technology assessment

Quality Assessment

Center researchers assessed the methodological quality of the included studies using standard instruments developed and adapted by the Center that are modifications of the systems in use by the Campbell Collaboration, Cochrane, the Preferred Reporting Items for Systematic Reviews

and Meta-analyses (PRISMA), the National Institute for Health and Care Excellence (NICE), and the Scottish Intercollegiate Guidelines Network (SIGN) (Campbell Collaboration, 2015; Moher, Liberati, Tetzlaff, & Altman, 2009; National Institute for Health and Care Excellence, 2014; Scottish Intercollegiate Guidelines Network, 2015). Two Center researchers independently rated all studies. In cases where there was not agreement about the quality of a study, consensus was reached through discussion.

Each rater assigned the study a rating of good, fair, or poor, based on its adherence to recommended methods and potential for biases. In brief, good-quality systematic reviews include a clearly focused question, a literature search sufficiently rigorous to identify all relevant studies, criteria used to select studies for inclusion (e.g., RCTs) and assess study quality, and assessments of heterogeneity to determine whether a meta-analysis would be appropriate. Good-quality RCTs include a clear description of the population, setting, intervention, and comparison groups; a random and concealed allocation of patients to study groups; low dropout rates; and intention-to-treat analyses. Good-quality systematic reviews and RCTs also have low potential for bias from conflicts of interest and funding source(s). Fair-quality systematic reviews and RCTs have incomplete information about methods that might mask important limitations. Poor-quality systematic reviews and RCTs have clear flaws that could introduce significant bias.

Appendix B. Articles Selected for Full-Text Review Inclusion/Exclusion Rationale

Citation	Inclusion/Exclusion Rationale
Ahn, Jang, and Kim (2016)	Exclude: Sample size <15
Albayrak, Ozturk, Ayden, and Ucler (2016)	Exclude: Intervention (results not stratified by intervention)
Bohl et al. (2016)	Exclude: Intervention (results not stratified by intervention)
Chang et al. (2014)	Exclude: Intervention (results not stratified by intervention)
Choi, Choi, Jung, Lee, and Kim (2016a)	Include for harms
Choi et al. (2016b)	Exclude: Study design (narrative review)
Choi et al. (2013)	Include for harms
Choi, Lee, Shim, Shin, and Park (2017)	Include for harms
Choi et al. (2015)	Include for harms
Chou, Atlas, Stanos, and Rosenquist (2009a)	Exclude: Intervention (results not stratified by intervention)
Chou et al. (2009b)	Exclude: Superseded by more comprehensive SRs
Cong, Zhu, and Tu (2016)	Exclude: Superseded by more comprehensive SRs
Dasenbrock et al. (2012)	Exclude: Intervention (results not stratified by intervention)
Dereymaeker et al. (2016)	Exclude: Intervention (facet joint quandrantectomy)
Devkota, Lohani, and Joshi (2009)	Exclude: Date (published outside of included date range for individual studies)
Dower, Chatterji, Swart, and Winder (2016)	Exclude: Intervention (results not stratified by intervention)
Drazin et al. (2016)	Exclude: Intervention (results not stratified by intervention)
Du et al. (2016)	Exclude: Sample size <15
Eun, Eum, Lee, and Sabal (2017)	Exclude: Study design (case series, does not report harms)
Eun, Lee, and Sabal (2016)	Exclude: Study design (case series, does not report harms)
Gadjradj, van Tulder, Dirven, Peul, and Sanjay Harhangi (2016)	Include for harms
Gibson, Cowie, and Iprenburg (2012)	Exclude: Superseded by more comprehensive SRs
Gibson and Waddell (2007)	Exclude: Superseded by more comprehensive SRs
Golovac (2010)	Exclude: Study design (narrative review)
Gotecha et al. (2016)	Include for harms
Gu, Cui, Shao, Ye, and Gu (2017)	Include for harms
Guan et al. (2016)	Exclude: Sample size <15

Citation	Inclusion/Exclusion Rationale
Guan, Zhao, Gu, Zhang, and He (2017)	Exclude: Sample size <15
Guarnieri et al. (2009)	Exclude: Study design (narrative review)
Hahne, Ford, and McMeeken (2010)	Exclude: Intervention (i.e., advice, stabilization exercises, manipulation, traction, laser, ultrasound)
Heo et al. (2017)	Include for harms
Hou et al. (2015)	Include for harms
Jacobs et al. (2013)	Exclude: Superseded by more comprehensive SRs
Jha, Syed, Catalino, and Sandhu (2017)	Exclude: Intervention (does not evaluate endoscopic procedure)
Ji, Shao, Wang, and Liu (2014)	Exclude: SR retracted
Ji, Shao, Wang, and Liu (2017)	Exclude: SR retracted
Jiang et al. (2015)	Exclude: Intervention (results not stratified by intervention)
Jordan, Konstantinou, and O'Dowd (2009)	Exclude: Superseded by more comprehensive SRs
Jordan, Konstantinou, and O'Dowd (2011)	Exclude: Intervention (did not use endoscopic procedure)
Joswig, Richter, Haile, Hildebrandt, and Fournier (2016)	Include for harms
Kamper et al. (2014)	Exclude: Intervention (results not stratified by intervention)
Kamson, Trescot, Sampson, and Zhang (2017)	Include for harms
Kang et al. (2017)	Include for harms
Kapetanakis et al. (2016)	Exclude: Study design (case series, does not report harms)
Kelekis and Filippiadis (2015)	Exclude: Study design (narrative review)
Kim, Chung, and Woo (2016)	Include for harms
Kim et al. (2015a)	Exclude: Sample size <15
Kim et al. (2015b)	Exclude: Study design (case series, does not report harms)
Klemencsics et al. (2016)	Exclude: Intervention (results not stratified by intervention)
Kogias, Franco Jimenez, Klingler, and Hubbe (2015)	Exclude: Poor methodological quality
Kong et al. (2016)	Include for harms
Krzok, Telfeian, Wagner, and Iprenburg (2016)	Include for harms
Lee, Yoon, Ha, and Kang (2016a)	Include for harms

Citation	Inclusion/Exclusion Rationale
Lee, Kim, and Ryu (2017)	Exclude: Intervention (PELD combined with percutaneous epidural neuroplasty)
Lee et al. (2016b)	Include for harms
Lee, Liu, and Fessler (2011)	Exclude: Intervention (results not stratified by intervention)
Lewis et al. (2011)	Exclude: Outcomes (not stratified by intervention)
Li et al. (2016a)	Include for harms
Li et al. (2016b)	Include
Li et al. (2016c)	Include
Li, Hou, Shang, Song, and Zhao (2015a)	Include for harms
Li, Hou, Shang, Song, and Zhao (2015b)	Include for harms
Liao (2014)	Exclude: Poor methodological quality
Lv et al. (2017)	Exclude: Intervention (results not stratified by intervention)
Mahesha (2017)	Include for harms
Manchikanti et al. (2009a)	Exclude: Intervention (does not evaluate endoscopic decompression)
Manchikanti, Derby, Benyamin, Helm, and Hirsch (2009b)	Exclude: Intervention (decompression combined with nucleoplasty)
Manchikanti et al. (2013)	Exclude: Intervention (Dekompressor)
McClelland and Goldstein (2017)	Exclude: Intervention (results not stratified by intervention)
Moliterno et al. (2010)	Exclude: Date (published outside of included date range for individual studies)
Mori et al. (2016)	Exclude: Study design (case series, did not report harms)
Mu et al. (2015)	Include
NICE (2016a)	Include
NICE (2016b)	Include
Nellensteijn et al. (2010)	Include
North American Spine Society (2012)	Include
North American Spine Society (2014b)	Exclude: Intervention (recommendations not specific to endoscopic decompression)
North American Spine Society (2014a)	Exclude: Intervention (recommendations not specific to endoscopic decompression)

Citation	Inclusion/Exclusion Rationale
Ong, Chua, and Vissers (2016)	Exclude: Intervention (endoscopic decompression included as a comparator to automatic percutaneous lumbar discectomy, not reviewed as standalone procedure)
Pan, Ha, Yi, and Cao (2016)	Exclude: Intervention (TESSYS technique)
Passacantilli et al. (2016)	Include for harms
Payer (2011)	Exclude: Intervention (results not stratified by intervention)
Phan et al. (2017)	Include
Quirno, Vira, and Errico (2016)	Exclude: Study design (narrative review)
Ruan et al. (2016)	Include
Sanusi, Davis, Nicassio, and Malik (2015)	Included for harms
Schroeder, Dettori, Brodt, and Kaplan (2012)	Exclude: Intervention (did not evaluate endoscopic decompression)
Sclafani et al. (2015)	Included for harms
Singh et al. (2009)	Exclude: Intervention (Dekompressor)
Siu and Lin (2016)	Exclude: Intervention (does not evaluate endoscopic decompression)
Smith, Masters, Jensen, Khan, and Sprowson (2013)	Exclude: Superseded by more comprehensive SR
Soman, Modi, and Chokshi (2017)	Included for harms
Tabaraee, Ahn, Bohl, Phillips, and Singh (2015)	Exclude: Intervention (microdiscectomy)
Tonosu et al. (2016)	Included for harms
Turk, Kara, Biliciler, and Karasoy (2015)	Included for harms
van den Akker et al. (2011)	Exclude: Intervention (does not evaluation endoscopic decompression)
Wang et al. (2017a)	Exclude: Study design (case report)
Wang et al. (2013b)	Included for harms
Wang, Zhou, Li, Liu, and Xiang (2015a)	Included for harms
Wang et al. (2015b)	Included for harms
Wang et al. (2014)	Exclude: Intervention (results not stratified by intervention)
Wang et al. (2016)	Included for harms
Wang et al. (2017b)	Included for harms
Wu et al. (2016a)	Included for harms

Citation	Inclusion/Exclusion Rationale
Wu, Liao, and Xia (2017)	Exclude: Outcome (radiation exposure to the surgeon)
Wu, Fan, Gu, Guan, and He (2016b)	Included for harms
Xin et al. (2017)	Exclude: Sample size <15
Xu et al. (2016)	Exclude: Intervention (intervertebral fusion)
Xu, Jia, Liu, and Fu (2015)	Exclude: Study design (case series, does not report harms)
Yao et al. (2017a)	Include for harms
Yao et al. (2017b)	Include
Yao et al. (2017c)	Exclude: Comparator (minimally invasive transforaminal lumbar interbody fusion)
Yokosuka et al. (2016)	Included for harms

Abbreviations. PELD: percutaneous endoscopic lumbar discectomy; SR: systematic review.

Appendix C. List of Trials Registered on Clinicaltrials.gov

Trial Name ClinicalTrials.gov Identifier	Status	Notes
Percutaneous Transforaminal Endoscopic Discectomy vs. Open Microdiscectomy for Lumbar Disc Herniation (PTED-study) NCT02602093	Recruiting	Procedure: Transforaminal endoscopic discectomy Procedure: Open microdiscectomy Completion Date: December 2019
Full Endoscopic vs. Open Discectomy for the Treatment of Symptomatic Lumbar Herniated Disc NCT02441959	Recruiting	Procedure: Lumbar discectomy open Procedure: Lumbar discectomy endoscopic Completion Date: July 2017
Percutaneous Transforaminal Endoscopic Discectomy vs. Microendoscopic Discectomy for Treatment of Lumbar Disc Herniation NCT01997086	Active, not recruiting	Procedure: Percutaneous transforaminal endoscopic discectomy Procedure: Microendoscopic discectomy Completion Date: August 2023
Microendoscopic Discectomy vs. Transforaminal Endoscopic Lumbar Discectomy vs. Open Discectomy NCT02358291	Unknown*	Procedure: Open discectomy Procedure: Microendoscopic discectomy Procedure: Transforaminal endoscopic lumbar discectomy Completion Date: March 2017
Comparison Between Conventional vs. Endoscopic Lumbar Discectomy NCT03137485	Not yet recruiting	Procedure: Conventional lumbar discectomy Procedure: Endoscopic lumbar discectomy Device: Easy Go system endoscopy Completion Date: March 2018
Trial to Show Non-inferiority/Superiority of an Endoscopic Transforaminal Discectomy to Standard Microdiscectomy (TESCORT) NCT01622413	Not yet recruiting	Procedure: Joimax TESSYS Procedure: Microdiscectomy Completion Date: September 2018
EuroPainClinics Study V (Prospective Observational Study (EPCSV) NCT02742311	Recruiting	Procedure: Endoscopic discectomy Completion Date: January 2019

*Note: *As stated on clinicaltrials.gov. The trial record in clinicaltrials.gov has not been updated recently.*

Appendix D. Assessment Tools from Clinical Studies

MacNab and Modified MacNab Assessment of Patient Satisfaction

The MacNab and modified MacNab assessment of patient satisfaction were developed to assess patient satisfaction, typically after surgery.

MacNab Criteria

Grade	Description
Excellent	No pain, full activity with work
Good	Occasional pain, not interfering with work
Fair	Pain occasionally, interfering with work
Poor	Persistent pain, frequently interfering with work

Source. Adapted from (Rajasekaran, Subbiah, & Shetty, 2011).

Modified MacNab Criteria

Degree of Recovery	Clinical Status
Excellent	Free of pain, no restriction of mobility, able to return to normal work and activities
Good	Occasional non-radicular pain, relief of presenting symptoms, able to return to modified work
Fair	Some improved functional capacity, still handicapped and/or unemployed
Poor	Continued objective symptoms of root involvement, additional operative intervention needed at operative level irrespective of repeat or length of postoperative period

Source. Adapted from (Azzazi, 2016).

Oswestry Disability Index

The Oswestry Disability Index, also known as the Oswestry Low Back Pain Disability Questionnaire, is commonly used to evaluate interventions for spinal disorders (Fairbank & Pynsent, 2000). The questionnaire includes sections on pain intensity, personal care (e.g., washing, dressing), lifting, walking, sitting, standing, sleeping, sex life, social life, and travelling (Fairbank & Pynsent, 2000).

Visual Analog Scale

The VAS for pain uses a one dimensional measurement for pain intensity (Hawker, Mian, Kendzerska, & French, 2011). The pain VAS typically uses a 10 cm line (100 mm) that is marked on each end with a symptom extreme (e.g., no pain, worst pain imaginable) (Hawker et al., 2011). Scores range from 0 mm (no pain) to 100 mm (worst pain imaginable) (Hawker et al., 2011). Suggested cutoffs for pain VAS scores include no pain (0 to 4 mm), mild pain (5 to 44 mm), moderate pain (45 to 74 mm), and severe pain (75 to 100 mm) (Hawker et al., 2011).

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