Surgery for symptoms of lumbar radiculopathy

Clinical Expert

Christoph P. Hofstetter

Assistant Professor, Department of Neurological Surgery, University of Washington
Director of Spine Surgery, University of Washington Medical Center
Neurosurgeon, Harborview Medical Center
Applicant Name: Christoph Hofstetter
Address: Campus Box 356470, Room RR744A
1959 NE Pacific Street
University of Washington, Seattle 98195-6470

1. Business Activities
(a) If you or a member of your household was an officer or director of a business during the immediately preceding calendar year and the current year to date, provide the following:

<table>
<thead>
<tr>
<th>Title</th>
<th>Business Name &amp; Address</th>
<th>Business Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
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</tr>
</tbody>
</table>

(b) If you or a member of your household did business under an assumed business name during the immediately preceding calendar year or the current year to date, provide the following information:

<table>
<thead>
<tr>
<th>Business Name</th>
<th>Business Address</th>
<th>Business Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
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</tr>
</tbody>
</table>

2. Honorarium
If you received an honorarium of more than $100 during the immediately preceding calendar year and the current year to date, list all such honoraria:

<table>
<thead>
<tr>
<th>Received From</th>
<th>Organization Address</th>
<th>Service Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>J&amp;J</td>
<td>Raynham, MA</td>
<td>Teaching, Consulting</td>
</tr>
<tr>
<td>Joimax</td>
<td>Irvine, CA</td>
<td>Teaching</td>
</tr>
<tr>
<td>Click here to enter text.</td>
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</tr>
</tbody>
</table>

3. Sources of Income
(a) Identify income source(s) that contributed 10% or more of the combined total gross household income received by you or a member of your household during the immediately preceding calendar year and the current year to date.

<table>
<thead>
<tr>
<th>Source Name &amp; Address</th>
<th>Received By</th>
<th>Source Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>UW</td>
<td>Hofstetter</td>
<td>salary</td>
</tr>
<tr>
<td>Click here to enter text.</td>
<td>Click here to enter text.</td>
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<tr>
<td>Click here to enter text.</td>
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</tr>
</tbody>
</table>
(b) Does any income source listed above relate to, or could it reasonably be expected to relate to, business that has, or may, come before the Committee?

☐ Yes ☒ No

If “yes”, describe:  Click here to enter text.
Click here to enter text.
Click here to enter text.

(c) Does an income source listed above have a legislative or administrative interest in the business of the Committee?

☐ Yes ☒ No

If “yes”, describe:  Click here to enter text.
Click here to enter text.
Click here to enter text.

4. Business Shared With a Lobbyist

If you or a member of your household shared a partnership, joint venture, or similar substantial economic relationship with a paid lobbyist, were employed by, or employed, a paid lobbyist during please list the following:

(Owning stock in a publicly traded company in which the lobbyist also owns stock is not a relationship which requires disclosure.)

<table>
<thead>
<tr>
<th>Lobbyist Name</th>
<th>Business Name</th>
<th>Type Business Shared</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>Click here to enter text.</td>
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<tr>
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<td>Click here to enter text.</td>
</tr>
</tbody>
</table>

Provide the information requested in items 5, 6, and 7 below only if:
(a) Your response involves an individual or business if you or a member of your household did business with, or reasonably could be expected to relate to business that has or may come before the Health Technology Clinical Committee.
(b) The information requested involves an individual or business with a legislative or administrative interest in the Committee.

5. Income of More Than $1,000

List each source (not amounts) of income over $1,000, other than a source listed under question 3 above, which you or a member of your household received during the immediately preceding calendar year and the current year to date:

<table>
<thead>
<tr>
<th>Income Source</th>
<th>Address</th>
<th>Description of Income Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Click here to enter text.</td>
<td>Click here to enter text.</td>
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</tr>
</tbody>
</table>
6. **Business Investments of More Than $1,000**

(Do not list the amount of the investment or include individual items held in a mutual fund or blind trust, a time or demand deposit in a financial institution, shares in a credit union, or the cash surrender value of life insurance.)

If you or a member of your household had a personal, beneficial interest or investment in a business during the immediate preceding calendar year of more than $1,000, list the following:

<table>
<thead>
<tr>
<th>Business Name</th>
<th>Business Address</th>
<th>Description of Business</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
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</tbody>
</table>

7. **Service Fee of More Than $1,000**

(Do not list fees if you are prohibited from doing so by law or professional ethics.)

List each person for whom you performed a service for a fee of more than $1,000 in the immediate preceding calendar year or the current year to date.

<table>
<thead>
<tr>
<th>Name</th>
<th>Description of Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>J&amp;J</td>
<td>Teaching, Consulting</td>
</tr>
<tr>
<td>Joimax</td>
<td>Teaching</td>
</tr>
<tr>
<td>Click here to enter text.</td>
<td>Click here to enter text.</td>
</tr>
</tbody>
</table>

I certify that I have read and understand this Conflict of Interest Form and the information I have provided is true and correct as of this date.

Print Name: Christoph Hofstetter  
Check One: ☒ Committee Member ☐ Subgroup Member ☐ Contractor

Date: 5/7/2018
CURRICULUM VITAE
Christoph, P Hofstetter, M.D., Ph.D.

PERSONAL DATA
Place of Birth: St. Pölten, Austria
Citizenship: Austrian
Date of Birth: 02/27/1977

EDUCATION
09/95 to 01/05 M.D., University of Vienna, Vienna, Austria
09/00 to 05/05 Ph.D., Karolinska Institute, Stockholm, Sweden

POSTGRADUATE TRAINING
07/05 to 06/06 Pre-Residency Fellowship, Mayo Clinic, Rochester, MN
07/05 to 06/06 Internship, Weill Cornell Medical College, New York, NY
07/06 to 06/13 Neurosurgery Residency, Weill Cornell Medical College, New York, NY
07/13 to 06/14 Complex spine fellowship, University of Miami, Miami, FL

FACULTY POSITIONS
09/14-present Assistant Professor, Department of Neurological Surgery, University of Washington, Seattle WA

HOSPITAL APPOINTMENTS
06/14 to 08/14 Locum tenant, San Juan Regional Medical Center, Farmington, NM
06/14-present Director of Spine surgery, University of Washington Medical Center, Department of Neurological Surgery, Seattle, WA
06/14-present Neurosurgeon, Harborview Medical Center, Department of Neurological Surgery Seattle, WA

HONORS
2012 Distinguished Housestaff Award, NewYork-Presbyterian Hospital, NY
2010 Research Fellowship, Neurosurgical Research Educational Fund
2010 Andlinger Residency Exchange Fellowship, Austrian-American Foundation
2006 Chorafas Prize for Best Doctoral Thesis, Karolinska Institute, Sweden
2002 Karolinska Institute Travel Grant, Stockholm, Sweden
2002 Golges Grant, Stockholm, Sweden
2000 Siegfried Ludwig Educational Grant, St. Pölten, Austria
1999 Erasmus Grant, University of Vienna, Vienna, Austria
CURRICULUM VITAE
Christoph, P Hofstetter, M.D., Ph.D.

1995 First Place, Eighth Annual Russian Olympiad, Moscow, Russia

BOARD CERTIFICATION
2017–present American Board of Neurological Surgery

MEDICAL LICENSURE
2014–present Washington (MD60464459)
2014 to 2017 New Mexico (MD2014-0310)
2013 to 2015 Florida (ME116257)
2009 to 2015 New York State (255163)

PROFESSIONAL ORGANIZATIONS
2014–present AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, Member
2014–present North America Spine Society (NASS), Member
2007–present International Society for the Advancement of Spine Surgery (ISASS), Member
2007–present Congress of Neurological Surgeons, Member
2001–present American Association of Neurological Surgeons, Member
2001–present Society for Neuroscience, Member

TEACHING RESPONSIBILITIES
2014–present Teaching residents surgical and medical management of patients with neurosurgical ailments.

Recent CME Courses taught:
04/2018 Instructor: Endoscopic spinal Surgery, Global spine congress, Singapore
04/2018 Course Co-chair: Advanced endoscopic course, Irvin, CA
01/2018 Course Co-chair: Advanced endoscopic course, Irvin, CA
12/2018 Instructor: Surgeon’s Cockpit: Training of MISS AO spine, Davos, Switzerland
10/2017 Endoscopic TLIF Lab course, Boston, MA
10/2017 Endoscopic TLIF Lab course, Boston, MA
09/2017 Advanced Endoscopic spine surgery course, Salzburg, Austria
07/2017 Mazor and O-arm course, California
07/2017 Course Co-chair: Advanced endoscopic course, Irvin, CA
07/2017 Course Co-chair: Advanced endoscopic course, Irvin CA
06/2017 Course Co-chair: Advanced endoscopic spinal Surgery
Axis Research, Irvine, CA
05/2017 Instructor: Endoscopic spinal Surgery, NeuroSpine Symposium, Houston Methodist Hospital, Houston, TX
06/2017 Instructor: Advanced MIS Techniques
Seattle Science Foundation, Seattle, WA
05/2017 Instructor: Endoscopic spinal Surgery
NeuroSpine Symposium, Houston Methodist Hospital, Houston, TX
03/2017 Instructor: Endoscopic spinal Surgery
Surgical Innovations Lab, Weill Cornell Medical Center, New York, NY
2014–present Course chairman and Instructor, Minimally Invasive Spine Surgery Hands-on Course 29th and 30th annual NASS meeting.
07/2016 Instructor: Endoscopic interlaminar spinal Surgery
Surgical Innovations Lab, Las Vegas, NV
05/2016 Instructor: Endoscopic Lumbar spinal Surgery
85th annual AANS meeting, Chicago, IL
2012 – 2013 Instructor, Endoscopic Spine Workshops
Surgical Innovations Lab, Weill Cornell Medical Center, New York, NY
09/2011 Lecturer, Neurosurgery, Spine, and Neurotrauma
Open Medical Institute, Salzburg, Austria
2000 – 2005 Head Teaching Assistant
Department of Anatomy, Karolinska Institute, Stockholm, Sweden
1997 – 1999 Head Teaching Assistant
Department of Anatomy, University of Vienna, Vienna, Austria

List trainees taught during last five years.
Zin Khaing, Ph.D., Rachel Bakemore, Thank Tuong, Selena Muong, Brian Kim, Michael Cruz, Jeffrey Hyde, Dane DeWees, Fatma Inanici, M.D., Zeinab Birjandian, M.D., Anna Marie Yanny, Lynn McGrath, M.D., Ashley Gaing, Kayla Shade, Brian Kim, Aubrey Sonnenfeld, Anna-Sophie Hofer, M.D.
EDITORIAL RESPONSIBILITIES

2015-present  World Neurosurgery, Reviewer
2016-present  International Journal of Spine Surgery, Reviewer

SPECIAL NATIONAL RESPONSIBILITIES

2015-present  NASS, Member of the scientific committee
2016-present  AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, Member of the scientific committee

RESEARCH FUNDING, PAST AND CURRENT

Craig Neilsen Foundation (PI: Hofstetter) 07/31/18 – 07/30/20
Ultrafast contrast-enhanced ultrasound to measure local blood flow after SCI
*The primary goal of this project is to develop ultrafast contrast-enhanced ultrasound to identify tissue in vicinity of a spinal cord lesion at risk for secondary-injury*

WACIC, Washington State Spinal Cord Injury Consortium (PI: Hofstetter) 11/01/17-06/30/19
Contrast enhanced-ultrasound to identify potentially viable tissue within the penumbra of human spinal cord injury
*The primary aim of this project was to collect contrast enhanced-ultrasound data characterizing the potentially salvageable penumbra of traumatic spinal cord injuries.*

WACIC, Washington Spinal Cord Injury Consortium (PI: Moritz) 11/13/17-06/30/19
Transcutaneous spinal stimulation to improve hand & arm function for people with chronic cervical spinal cord injury
*We perform a clinical trial of transcutaneous electrical stimulation in patients with chronic cervical spinal cord injury aiming to improve upper extremity function.*
Role: Co-Investigator

Therapeutic Transcutaneous Spinal Stimulation for Improved Recovery after Cervical Spinal Cord Injury in the Rat
*Development of translational rodent model for transcutaneous to reproduce the extremely favorable results we have seen in our clinical trial with cervical spinal cord stimulation.*
Role: Co-Investigator

University of Washington Royalty Research Fund (PI: Hofstetter) 6/1/2016 – 5/31/2017
Ultrasound-based assessment of spinal perfusion following traumatic spinal cord injury
*The primary aim of this project is to determine the contribution of elevated intraspinal pressure towards hypoperfusion of the acutely injured spinal cord*
University of Washington Royalty Research Fund (PI: Hofstetter) 6/1/2016 – 5/31/2017
Ultrasound-based assessment of spinal perfusion following traumatic spinal cord injury
*The primary aim of this project is to determine the contribution of elevated intraspinal pressure towards hypoperfusion of the acutely injured spinal cord.*

University of Washington Institute of Translational Health Sciences (PI: Hofstetter) 6/1/2016 – 5/31/2017
Immunomodulatory 3D scaffold to promote neuronal regeneration after spinal cord injury
*The primary aim of this project is to develop novel scaffolds alter the phenotypes of local macrophages and hereby reduce local scar formation and promote tissue regeneration.*

University of Washington Institute of Translational Health Sciences (PI: Perlmutter) 6/1/2015 - 5/31/2016
Role: Co-investigator
*An NHP Model for Cervical Myelopathy and Therapeutic Use of Electrical Stimulation.*
The primary aim of this project is to establish a primate model of cervical myelopathy using a chronic compression device.

BIBLIOGRAPHY

PEER REVIEWED JOURNAL ARTICLES


50. Åberg E, Hofstetter CP, Olson L, Brene S. Moderate ethanol consumption in adult mice increases hippocampal cell proliferation and neurogenesis in adult mouse. International J of Neuropsychopharmacology 2005; 8: 1-11.


**BOOK CHAPTERS**


**PUBLISHED BOOKS, VIDEOS, SOFTWARE**


**OTHER PUBLICATIONS**


**MANUSCRIPTS SUBMITTED**


**ABSTRACTS**

1. Clinical outcomes Following MIS vs. Endoscopic Laminectomy; 34th annual AANS/CNS Spine Section Meeting; Orlando, FL March 2018.

3. Contrast-enhanced ultrasound to visualize and quantify local blood flow and perfusion after traumatic spinal cord injury; 34th annual AANS/CNS Spine Section Meeting; Orlando, FL March 2018.

4. Transcutaneous electrical spinal stimulation: Preliminary clinical results and novel translational model; ISNR annual meeting, Asilomar, CA; December 2017

5. Contrast-enhanced ultrasound to visualize and quantify local blood flow and perfusion after traumatic spinal cord injury; ISNR annual meeting, Asilomar, CA; December 2017

6. Contrast-enhanced ultrasound to visualize and quantify local blood perfusion after traumatic spinal cord injury; 47th annual Society for Neuroscience conference, Washington, DC; November 2017


8. Biomimetic injectable 3D hydrogels with aligned topography for neural tissue engineering 45th annual Society for Neuroscience conference, Chicago, IL; October 2015.

9. Minimally invasive foraminotomy through tubular retractors via a contralateral approach in patients with unilateral radiculopathy; 30th annual AANS/CNS Spine Section Meeting; Orlando, FL March 2014.

10. Unilateral tubular approach for bilateral laminectomy: Effect on ipsilateral and contralateral buttock and leg pain; 30th annual AANS/CNS Spine Section Meeting, Orlando, FL; March 2014.

11. Impact of cage height, width and positioning on clinical and radiographic outcome of extreme lateral interbody fusion; 29th annual AANS/CNS Spine Section Meeting, Phoenix, AZ; March 2013.

12. Midterm experience with expandable PEEK spacers for interbody fusion for Degenerative Lumbar Disease; 29th annual AANS/CNS Spine Section Meeting, Phoenix, AZ; March 2013.

13. Volumetric classification for giant pituitary macroadenomas predicts outcome and morbidity of endoscopic endonasal transsphenoidal surgery; NASBS, Scottsdale, AZ; February 2011.


25. Spontaneous recovery of the sensory system after spinal cord injury; a functional MRI study; 32nd Annual meeting, Society for Neuroscience, Orlando, FL; November 2002.


INVITED LECTURES

12/2017 My path to MIS Endoscopy; Expanding the armamentarium of the complex spine surgeon; 11th New York City Minimally Invasive Spine, Spinal Endoscopy, Robotics & Navigation Symposium, Weill Cornell Medical Center, New York, NY

12/2017 Over the top MIS decompression with and without MIS transforaminal lumbar interbody fusion – Step – by – Step technique, AO spine Surgeon’s Cockpit, Davos, Switzerland

10/2017 Interlaminar lumbar stenosis decompression: Can it replace traditional laminectomy? 32nd Annual Meeting, NASS, Orlando, FL

10/2017 Lumbar Decompression and Discectomy: Microscope versus Endoscope; 32nd Annual Meeting, NASS, Orlando, FL

06/2017 Endoscopic Discectomy and Fusion using IntraLIF; Seattle Science Foundation, Seattle, WA

04/2017 How to Adopt Endoscopy: Training for Team & Fellows; 85th Annual Meeting, AANS, Los Angeles, CA

04/2017 The interlaminar endoscopic approach – advancing MIS; ISASS – 17th Annual Conference, Boca Raton, FL

10/2016 Pushing the Limits of Decompression with Endoscopic Spinal Surgery; Minimally Invasive Procedures to Minimize Exposure and Dissection; 31st Annual Meeting, NASS, Boston, MA

10/2016 Endoscopic Approaches to the Cervical and Lumbar spine; Minimally Invasive Lumbar Fusion Surgeries; 2017 CNSCN2016, Xi An, China

06/2016 Better Spinal Decompression Surgery using Next Generation Minimally Invasive Spine Surgery; 2016 Annual Meeting, WSANS, Cle Elum, WA
Interlaminar Endoscopic approach; 84th Annual Meeting, AANS, Chicago, IL

Explorative Meta-analysis on Dose-related Efficacy and Morbidity of Bone Morphogenetic Protein in Spinal Arthrodesis Surgery; 32nd Annual Meeting, AANS/CNS Spine Section, Orlando, FL

Early Experience with Endoscopic Revision of Lumbar Arthrodesis Constructs; 32nd Annual Meeting, AANS/CNS Spine Section, Orlando, FL

Characterization Intraspinal Pressure Following Traumatic Rodent Spinal Cord Injury; 32nd Annual Meeting, AANS/CNS Spine Section, Orlando, FL

Epidural stimulation for chronic cervical spinal cord injury; SCI Forum, UW, Seattle, WA

Pain Management following Discharge from Spine Surgery; 30th Annual Meeting, NASS, Chicago, IL.

Minimally invasive TLIF; 30th Annual Meeting, NASS, Chicago, IL.

Advances in Minimally Invasive Spine Surgery; UW CME course, Missoula, MT

Extreme Lateral Interbody fusion for Unilateral Symptomatic Vertical Foraminal Stenosis; Annual Meeting, ISASS, Miami, FL

Endoscopic Lumbar Foraminoplasty: A Cadaveric Study; Annual Meeting, ISASS, Miami, FL

Endoscopic foraminal decompression; Annual Meeting of the AANS/CNS Spine section, Orlando, FL

Optimizing indirect foraminal decompression by Extreme Lateral Interbody Fusion; Annual Meeting, Florida Neurosurgical Society, Palm Beach, FL

Minimally invasive laminectomy through tubular retractors for lumbar spinal stenosis in patients with and without pre-operative spondylolisthesis: clinical outcome and re-operation rate; 29th Annual Meeting, AANS/CNS Spine Section, Phoenix, AZ

PP2A activity protects hypoxic tumor stem cells from apoptosis; Grand Rounds, Vienna, Austria

MRI-based imaging techniques: From the lab bench to neurosurgical practice; Nobel Conference, Stockholm, Sweden

Directed differentiation of adult neural stem cells reduces side effects of stem cell based spinal cord injury treatment; 34th Annual Meeting, Society for Neuroscience, San Diego, CA

Marrow stromal cell transplantation in spinal cord injury; Grand Rounds, Dept. of Neurosurgery, Medical College of Wisconsin, Milwaukee, WI

Cell transplantation therapy in spinal cord injury; 13th NECTAR meeting, Amsterdam, Belgium

Novel methods and repair strategies in spinal cord injury, Department of Neuroscience, Uppsala University, Uppsala, Sweden
Agency medical director comments

Surgery for lumbar radiculopathy

Gary Franklin, MD, MPH
Medical Director, Department of Labor and Industries
Research Professor, University of Washington
Co-chair, WA Agency Medical Director’s Group
May 18, 2018

State Agency

- Main concern over minimally invasive surgery (MID/S)
  - 9 procedures, 14 RCTs, most low-very low quality
  - Can’t lump these together in a grade analysis
- Data on open procedures solid enough to cover with conditions
- Repeat surgery-only covered in limited circumstances
Background

- The most common etiology of lumbar radiculopathy is nerve root compression caused by a **disc herniation** or **spinal stenosis**, which is, narrowing of the lateral recess, or the neural foramen due to degenerative arthritis affecting the spine
- Severity of lumbar radiculopathy
  - Pure sensory/painful radicular pattern - radicular pain and a segmental pattern of sensory dysfunction but no other neurologic deficits
  - Mild motor deficit pattern - radicular pain, sensory dysfunction, and mild nonprogressive segmental motor weakness and/or reflex change
  - Severe motor deficit pattern - radicular pain and sensory dysfunction with severe or worsening motor deficits
- For this report, NOT dealing with central stenosis/cauda equina compression

The procedures

- The purpose of surgery for symptomatic lumbar radiculopathy is to relieve symptoms by decompressing the affected nerve
- A variety of discectomy techniques are available:
  - The open discectomy (OD) is performed with a standard surgical incision, often with the aid of eyepiece (loupe) magnification. It frequently involves a laminectomy
  - Microdiscectomy (MD) involves a smaller incision in the back, with visualization through an operating microscope, followed by a hemilaminectomy and removal of the disc fragment compressing the affected nerve or nerves.
  - Minimally invasive techniques (MID/S):
    - Nine different techniques, 14 RCTs
    - Direct visualization rarely used
    - Indirect visualization, via microscope/camera or loupe magnification
Federal oversight of medical interventions

<table>
<thead>
<tr>
<th></th>
<th>Drugs</th>
<th>Medical devices</th>
<th>Surgical procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required for FDA</td>
<td>2 prospective, placebo</td>
<td>“Substantial equivalence”</td>
<td>No approval</td>
</tr>
<tr>
<td>approval</td>
<td>controlled RCTs</td>
<td>to pre-existing device</td>
<td>requirements</td>
</tr>
<tr>
<td>Study outcomes</td>
<td>Disease-related</td>
<td>Engineering</td>
<td>None</td>
</tr>
<tr>
<td>endpoints</td>
<td>endpoints</td>
<td>performance only</td>
<td></td>
</tr>
<tr>
<td>Published studies</td>
<td>Common</td>
<td>Uncommon</td>
<td>Not considered</td>
</tr>
<tr>
<td>with patient-</td>
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<td></td>
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<tr>
<td>orientated endpoints</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Patient population</td>
<td>Narrowly defined set</td>
<td>Varies widely (e.g.,</td>
<td>Not considered</td>
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<tr>
<td></td>
<td>of conditions (e.g.,</td>
<td>implantable</td>
<td></td>
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<td></td>
<td>depression, dementia)</td>
<td>defibrillators, laproscopes)</td>
<td></td>
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<tr>
<td>Post-marketing</td>
<td>Sporadic, sometimes</td>
<td>Rare, usually low quality</td>
<td>None</td>
</tr>
<tr>
<td>evaluation?</td>
<td>high quality</td>
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Most new MID are approved based on 510k equivalence - no study required

EG., Disc-FX system-approved 12/28/2005

“We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.”
Agency medical director concern level
MID/S vs. OD/MD

- Safety = Medium
- Efficacy = Medium-High
- Cost = High

Current state agency policy

<table>
<thead>
<tr>
<th>Description</th>
<th>Medicaid</th>
<th>PEBB/UMP</th>
<th>LNI</th>
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<tbody>
<tr>
<td>OD/MD (Laminectomy, laminotomy, discectomy, foraminotomy)</td>
<td>PA</td>
<td>PA</td>
<td>PA</td>
</tr>
<tr>
<td>MID/S (Endoscopic decompression procedures CPT 62380)</td>
<td>PA</td>
<td>PA</td>
<td>PA</td>
</tr>
<tr>
<td>MID/S (Percutaneous decompression procedures under indirect image guidance e.g., fluoroscopic, CT CPT 0275T)</td>
<td>NC</td>
<td>C</td>
<td>NC</td>
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</tbody>
</table>

C: Covered
NC: Not covered
PA: Prior authorization required
### Utilization: Surgical decompression procedures – Medicaid

<table>
<thead>
<tr>
<th>Medicaid MCO</th>
<th>2015</th>
<th>2016</th>
<th>2017*</th>
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</thead>
<tbody>
<tr>
<td>Unique Patients w/Diagnosis of Radiculopathy</td>
<td>320</td>
<td>352</td>
<td>256</td>
</tr>
<tr>
<td>Total Treatments w/Diagnosis of Radiculopathy</td>
<td>351</td>
<td>394</td>
<td>242</td>
</tr>
<tr>
<td>Treatments w/o Diagnosis</td>
<td>476</td>
<td>501</td>
<td>378</td>
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<tr>
<td>Total Dollars Paid by Treatments w/Diagnosis</td>
<td>$1,835,396</td>
<td>$1,779,602</td>
<td>$1,311,784</td>
</tr>
<tr>
<td>Average Paid Dollars/Patient w/Diagnosis</td>
<td>$5,754</td>
<td>$6,425</td>
<td>$3,780</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Medicaid HCA</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
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</thead>
<tbody>
<tr>
<td>Unique Patients w/Diagnosis</td>
<td>25</td>
<td>29</td>
<td>3</td>
</tr>
<tr>
<td>Total Treatments w/Diagnosis</td>
<td>25</td>
<td>28</td>
<td>3</td>
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<tr>
<td>Treatments w/o Diagnosis</td>
<td>42</td>
<td>37</td>
<td>6</td>
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<tr>
<td>Total Dollars Paid by Treatments w/Diagnosis</td>
<td>$110,476</td>
<td>$88,391</td>
<td>$24,329</td>
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<tr>
<td>Average Paid Dollars/Patient w/Diagnosis</td>
<td>$4,419</td>
<td>$3,048</td>
<td>$8,110</td>
</tr>
</tbody>
</table>

### Utilization: Surgical decompression procedures

L&I, PEBB/UMP and PEBB/Medicare

<table>
<thead>
<tr>
<th>L&amp;I</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
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<tbody>
<tr>
<td>Unique Patients</td>
<td>223</td>
<td>231</td>
<td>213</td>
</tr>
<tr>
<td>Total Treatments with Diagnosis of Radiculopathy</td>
<td>229</td>
<td>240</td>
<td>216</td>
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<tr>
<td>Treatments w/o Diagnosis</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total Dollars Allowed by Treatments w/Diagnosis</td>
<td>$2,657,263</td>
<td>$3,333,749</td>
<td>$3,243,177</td>
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<tr>
<td>Average Dollars Allowed/Patient w/Diagnosis</td>
<td>$11,916</td>
<td>$14,431.81</td>
<td>$15,226.18</td>
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</table>

<table>
<thead>
<tr>
<th>PEBB/UMP</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unique Patients w/Diagnosis</td>
<td>76</td>
<td>91</td>
<td>79</td>
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<tr>
<td>Total Treatments w/Diagnosis</td>
<td>79</td>
<td>96</td>
<td>83</td>
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<tr>
<td>Treatments w/o Diagnosis</td>
<td>192</td>
<td>185</td>
<td>142</td>
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<tr>
<td>Total Dollars Paid by Treatments w/Diagnosis</td>
<td>$675,955</td>
<td>$943,363</td>
<td>$785,274</td>
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<tr>
<td>Average Paid Dollars/Patient w/Diagnosis</td>
<td>$8,894</td>
<td>$10,367</td>
<td>$9,940</td>
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<table>
<thead>
<tr>
<th>PEBB/Medicare</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
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<tbody>
<tr>
<td>Unique Patients w/Diagnosis</td>
<td>73</td>
<td>39</td>
<td>39</td>
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<tr>
<td>Total Treatments w/Diagnosis</td>
<td>82</td>
<td>42</td>
<td>41</td>
</tr>
<tr>
<td>Treatments w/o Diagnosis</td>
<td>144</td>
<td>111</td>
<td>101</td>
</tr>
<tr>
<td>Total Dollars Paid by Treatments w/Diagnosis</td>
<td>$52,834</td>
<td>$35,125</td>
<td>$33,866</td>
</tr>
<tr>
<td>Average Paid Dollars/Patient w/Diagnosis</td>
<td>$724</td>
<td>$901</td>
<td>$868</td>
</tr>
</tbody>
</table>
Effectiveness – open surgical procedures (OD)

- 7 RCTs compared surgery to conservative management (probably most valid comparator)
  - Pain: surgery reduces pain more than conservative care for the short term (up to 26 weeks), but no difference in the long run (1-8 years)
  - Function: surgery improves function more than conservative care for the short term (up to 26 weeks), but no difference in the long run (1-8 years)
  - QoL, neurologic symptoms and return to work: either similar or improved by about the same amount.
- Quality of evidence – very low or low

Effectiveness – open “micro” procedures (MD)

- Compared to standard procedures
  - Pain reduction: similar for both the short term (6 weeks) and the long term (26 weeks - 2 years)
  - Function improvement: similar (26 weeks – 2 years)
  - QoL: Similar (26 weeks – 2 years)
  - Return to work: similar duration of postoperative work disability (10.4 weeks for “micro” vs. 10.1 weeks for standard.
- Quality of evidence – very low or low
Effectiveness – minimally invasive procedures (MID/S)

- Compared to standard procedures
  - Pain reduction, function improvement, QoL and neurologic symptoms improvement: similar for either the short term (up to 26 weeks) or the long term (1-2 years)
  - Return to work: reduces the duration of postoperative disability by 4-15 weeks (quality of the evidence is very low)

- Quality of evidence – very low, low or moderate
- These procedures are all quite different - cannot lump them

Minimally invasive procedures (MID/S): Examples of troubles

Ref 36-Chatterjee et al, Spine 1995; 20: 734-38

- Automated percutaneous lumbar discectomy (APLD) vs. microdiscectomy (MD) for small contained discs (no clinical criteria)
- Randomized, independent assessment of outcome-Macnab outcome classification
- APLD-9/31 (29%) satisfactory outcome (MID/S)
- Micro-32/40 (80%) satisfactory outcome (MD)
- 20/22 APLD with unsatisfactory outcome opted for another surgery
- Trial stopped early due to poor outcomes
- UK = Public funded, well designed trial

- Percutaneous laser disc decompression (MID/S) vs. microdiscectomy (MD)
- RCT with non-inferiority design, no blinding
  - N=115 with sciatica and disc herniation
- Public funding-Healthcare Insurance Board
  - Netherlands academic institutions
- Outcomes: Roland-Morris (primary) and VAS
  - Roland-Morris non-inferior at 8 and 52 weeks
- Speedier recovery in conventional surgery
- Reoperations percutaneous (38%) vs. conventional (16%)

Cochrane review (2014): Minimally invasive (MID/S) vs. micro/open discectomy (OD/MD)

- Cochrane Database system Rev 2014
  - *Not included in RTI-UNC report
- Eleven studies; 7/11 had high risk of bias
- MID/S: Higher risk of re-hospitalization due to recurrent disc herniation, increased dural tears and slightly worse pain outcomes
5-year follow-up of the best MID/S study (Arts, JAMA)
*Not included in RTI-UNC report
- Tubular discectomy (MID/S) vs. conventional microdiscectomy (MD)
- No clinically significant differences in main clinical outcomes (RMDQ-Sciatica, VAS) at any point during 5 yrs f/u (63%)-mean functional outcome difference of 0.9 favoring conventional microdiscectomy NS
- Reop rate 18% tubular discectomy vs. 13% microdiscectomy (p=0.29)
  - Total reops 39 Tubular vs. 23 Micro (p=0.10)
  - 6 patients in tubular group ended up with instrumented fusion vs. none in conventional microdiscectomy (p=0.03)

Overdevest GM et al. J Neurol Neurosurg Psychiatry 2017; 88: 1008-16.

RTW outcomes with MID/S

Ref 26-Thome, 2005-sequestrectomy vs. microdiscectomy; COI not reported
- N=84; outcome 4-6 mos and 12-18 mos; No clinical criteria for entry
- Prolo score-combination of pain interference and capacity for RTW-1 (poor) 5(excellent) x2=total score 2-10-N/S difference at 4-6 months; and SF-36 physical function-N/S

Ref 41-Hermantin, 1999-video assisted arthroscopic microdiscectomy (O/P) vs. open discectomy (hospitalized); stated COI
- Study conducted in surgeon's office N=60; litigation and workers’ comp cases excluded
- Outcomes all patient self-report
- Mean duration of time lost from work or until resumption of normal activities 49 days vs. 27 days; no tests of significance done
- Overall outcomes excellent in both groups (93-97%)
Ref 29: Ruetten et al, 2008

- German study, no COI
- N=200, randomized to endoscopic (MID/S) vs. conventional microsurgical discectomy (MD)
- Outcomes from patient instruments (VAS, NASS, Oswestry)
  - Exam at baseline (day 1) and at 3, 6, 12, and 24 months. Outcome examiners not involved in surgery but can’t tell if blinded.
- 3 reops, 3 fusions not included in f/u
- Reop rates N/S (6.6% End vs. 5.7% micro)
  - 2 Endo patients had 2nd reop
- Mean post-op work disability less in endo group (25 days) vs. micro group (49 days, p<0.01)
  - Can’t tell what proportion of patients had pre-op OR post-op disability-no methods presented

Ref 32: Mayer, 1993

- N = 40; “preliminary results”; RCT; COI not available
- Endoscopic microdiscectomy vs. microsurgical discectomy
- 2-year f/u
- Equivalent clinical outcomes
- 95% of endo vs. 72.2% of micro had returned to previous occupation
  - No methods available
  - Not primary outcome
Effectiveness – repeat surgery

- Almost nothing on this

Worse surgical outcomes in workers compensation*

Association between compensation status and unsatisfactory outcome

<table>
<thead>
<tr>
<th>Procedure</th>
<th># Studies</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shoulder acromioplasty</td>
<td>13</td>
<td>4.48 (2.71-7.40)</td>
</tr>
<tr>
<td>Lumbar spine fusion</td>
<td>19</td>
<td>4.33 (2.81-6.62)</td>
</tr>
<tr>
<td><strong>Lumbar spine discectomy</strong></td>
<td><strong>24</strong></td>
<td><strong>4.77 (3.51-6.50)</strong></td>
</tr>
<tr>
<td>Carpal tunnel decompression</td>
<td>10</td>
<td>4.24 (2.43-7.40)</td>
</tr>
</tbody>
</table>

Safety – Surgery

- Surgical morbidity (SPORT trial)
  - Dural tear or spinal fluid leaks – 4.0%
  - Superficial postoperative wound infection – 1.6%
  - Vascular injury – 0.4%
  - Other intraoperative complications – 0.81%
  - Other unspecified postoperative complications (microdiscectomy) – 3.6%

- Reoperation rate (0% - 10%)
- Compared to nonsurgical interventions
  - All-cause mortality: no difference
  - Persistent opioid use: no difference
- Post-laminectomy syndrome, failed back surgery syndrome: epidural scarring of unknown prevalence

Reoperations

Martin et al (Spine Journal 2012; 12: 89-97) population-based study using WA state hospital discharge data

- Hospital reoperation rates:
  - 90 days - 1.9% (1.1-3.4%)
  - 1 yr - 6.4% (2.8-12.5%)
  - 4 yrs - 13.8% (8.1-24.5%)

- Variation of reop rates was greater for surgeons than across hospitals
Safety – Minimally invasive vs. standard surgery

- Questions about higher re-op rates in MID/S
- Quality of evidence: very low or low

Cost-effectiveness

- Surgery may be cost-effective depending on a decision-makers' willingness to pay threshold
- The evidence on cost-effectiveness for MID/S compared to standard approaches (OD/MD) is inconclusive and methodologically inconsistent
- Microdiscectomy (MD) and discectomy (OD) are comparable with respect to efficacy and safety, but microdiscectomy costs may be higher
  - Patient presentation may influence surgical decision
Sample private payers’ policies
(From the evidence report)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medicare</th>
<th>Premera</th>
<th>Regence</th>
<th>Cigna</th>
<th>United</th>
<th>Aetna</th>
<th>Humana</th>
<th>Kaiser</th>
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</thead>
<tbody>
<tr>
<td>OD/MD (Laminectomy, laminotomy, discectomy, foraminotomy)</td>
<td>—</td>
<td>✔️</td>
<td>—</td>
<td>—</td>
<td>✔️</td>
<td>✔️</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>MID/S Automated percutaneous lumbar disc decompression</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>MID/S (Percutaneous) endoscopic discectomy</td>
<td>—</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>MID/S (Percutaneous) laser discectomy</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>MID/S Percutaneous nucleoplasty with coablation technology</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>—</td>
<td>—</td>
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</tbody>
</table>

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Spine SCOAP outcomes after spine surgery

- N=1965 spine surgery candidates with baseline and at least one follow up interview; 80.6% with elective fusion
- Overall 306/528 (58%) improved in Oswestry by at least 15/100 points at 12 months among those with moderate/severe symptoms
- Odds of functional improvement if:
  - Workers comp 0.20 p<.001
  - Current smoker 0.43 p<.01
- Odds of NRS back pain improvement if:
  - Rx opiate use 0.65 p<.65
State agency recommendation

- OD/MD (Lumbar laminectomy, laminotomy, discectomy, foraminotomy) are covered with conditions
  - Adult patients with lumbar radiculopathy with subjective and objective neurologic findings that are corroborated with an advanced imaging test (CT scan, MRI or myelogram)
  - Failure to improve with minimal four weeks of non-surgical care
    - Unless progressive motor weakness is present

- MID/S (APLD, Percutaneous laser, endoscopic, nucleoplasty, etc)- Not covered
  - Concern on higher cost, low quality data and substantial questions about greater re-operation rate

State agency recommendation

- Re-operation - covered with conditions
  - Only for recurrent symptoms that occur after a period of clinically meaningful improvement in pain and function lasting at least 6 months, and clear cut evidence of a recurrent disc herniation
  - If a recurrent or residual HNP, seen on a postoperative MRI, is equal in size or larger than the original HNP, earlier surgical intervention may be required (6 weeks as opposed to 6 months would be reasonable)
  - Absence of co-morbidities that could explain lack of improvement, such as smokers, opioids, workers compensation
Spine SCOAP outcomes after spine surgery

- N=1965 spine surgery candidates with baseline and at least one follow up interview; 80.6% with elective fusion
- Overall 306/528 (58%) improved in Oswestry by at least 15/100 points at 12 months among those with moderate/severe symptoms
- Odds of functional improvement if:
  - Workers comp 0.20 p<.001
  - Current smoker 0.43 p<.01
- Odds of NRS back pain improvement if:
  - Rx opiate use 0.65 p<.65

Questions?

More Information:
Gary Franklin, MD, MPH
fral235@lni.wa.gov
www.hca.wa.gov/about-hca/health-technology-assessment
/surgery-for-symptomatic-lumbar-radiculopathy
CURRICULUM VITAE
Christoph, P Hofstetter, M.D., Ph.D.

PERSONAL DATA
Place of Birth: St. Pölten, Austria
Citizenship: Austrian
Date of Birth: 02/27/1977

EDUCATION
09/95 to 01/05 M.D., University of Vienna, Vienna, Austria
09/00 to 05/05 Ph.D., Karolinska Institute, Stockholm, Sweden

POSTGRADUATE TRAINING
07/05 to 06/06 Pre-Residency Fellowship, Mayo Clinic, Rochester, MN
07/05 to 06/06 Internship, Weill Cornell Medical College, New York, NY
07/06 to 06/13 Neurosurgery Residency, Weill Cornell Medical College, New York, NY
07/13 to 06/14 Complex spine fellowship, University of Miami, Miami, FL

FACULTY POSITIONS
09/14-present Assistant Professor, Department of Neurological Surgery, University of Washington, Seattle WA

HOSPITAL APPOINTMENTS
06/14 to 08/14 Locum tenant, San Juan Regional Medical Center, Farmington, NM
06/14-present Director of Spine surgery, University of Washington Medical Center, Department of Neurological Surgery, Seattle, WA
06/14-present Neurosurgeon, Harborview Medical Center, Department of Neurological Surgery Seattle, WA

HONORS
2012 Distinguished Housestaff Award, New York-Presbyterian Hospital, NY
2010 Research Fellowship, Neurosurgical Research Educational Fund
2010 Andlinger Residency Exchange Fellowship, Austrian-American Foundation
2006 Chorafas Prize for Best Doctoral Thesis, Karolinska Institute, Sweden
2002 Karolinska Institute Travel Grant, Stockholm, Sweden
2002 Golges Grant, Stockholm, Sweden
2000 Siegfried Ludwig Educational Grant, St. Pölten, Austria
1999 Erasmus Grant, University of Vienna, Vienna, Austria
CURRICULUM VITAE
Christoph, P Hofstetter, M.D., Ph.D.

1995 First Place, Eighth Annual Russian Olympiad, Moscow, Russia

BOARD CERTIFICATION
2017-present American Board of Neurological Surgery

MEDICAL LICENSURE
2014-present Washington (MD60464459)
2014 to 2017 New Mexico (MD2014-0310)
2013 to 2015 Florida (ME116257)
2009 to 2015 New York State (255163)

PROFESSIONAL ORGANIZATIONS
2014–present AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, Member
2014–present North America Spine Society (NASS), Member
2007–present International Society for the Advancement of Spine Surgery (ISASS), Member
2007–present Congress of Neurological Surgeons, Member
2001–present American Association of Neurological Surgeons, Member
2001–present Society for Neuroscience, Member

TEACHING RESPONSIBILITIES
2014-present Teaching residents surgical and medical management of patients with neurosurgical ailments.

Recent CME Courses taught:
04/2018 Instructor: Endoscopic spinal Surgery, Global spine congress, Singapore
04/2018 Course Co-chair: Advanced endoscopic course, Irvin, CA
01/2018 Course Co-chair: Advanced endoscopic course, Irvin, CA
12/2018 Instructor: Surgeon’s Cockpit: Training of MISS AO spine, Davos, Switzerland
10/2017 Endoscopic TLIF Lab course, Boston, MA
10/2017 Endoscopic TLIF Lab course, Boston, MA
09/2017 Advanced Endoscopic spine surgery course, Salzburg, Austria
07/2017 Mazor and O-arm course, California
07/2017 Course Co-chair: Advanced endoscopic course, Irvin, CA
07/2017 Course Co-chair: Advanced endoscopic course, Irvin CA
06/2017 Course Co-chair: Advanced endoscopic spinal Surgery
Axis Research, Irvine, CA
05/2017 Instructor: Endoscopic spinal Surgery, NeuroSpine Symposium, Houston Methodist Hospital, Houston, TX
06/2017 Instructor: Advanced MIS Techniques
Seattle Science Foundation, Seattle, WA
05/2017 Instructor: Endoscopic spinal Surgery
NeuroSpine Symposium, Houston Methodist Hospital, Houston, TX
03/2017 Instructor: Endoscopic spinal Surgery
Surgical Innovations Lab, Weill Cornell Medical Center, New York, NY
2014–present Course chairman and Instructor, Minimally Invasive Spine Surgery Hands-on Course 29th and 30th annual NASS meeting.
07/2016 Instructor: Endoscopic interlaminar spinal Surgery
Surgical Innovations Lab, Las Vegas, NV
05/2016 Instructor: Endoscopic Lumbar spinal Surgery
85th annual AANS meeting, Chicago, IL
2012 – 2013 Instructor, Endoscopic Spine Workshops
Surgical Innovations Lab, Weill Cornell Medical Center, New York, NY
09/2011 Lecturer, Neurosurgery, Spine, and Neurotrauma
Open Medical Institute, Salzburg, Austria
2000 – 2005 Head Teaching Assistant
Department of Anatomy, Karolinska Institute, Stockholm, Sweden
1997 – 1999 Head Teaching Assistant
Department of Anatomy, University of Vienna, Vienna, Austria

List trainees taught during last five years.
Zin Khaing, Ph.D., Rachel Bakemore, Thank Tuong, Selena Muong, Brian Kim, Michael Cruz, Jeffrey Hyde, Dane DeWees, Fatma Inanici, M.D., Zeinab Birjandian, M.D., Anna Marie Yanny, Lynn McGrath, M.D., Ashley Gaing, Kayla Shade, Brian Kim, Aubrey Sonnenfeld, Anna-Sophie Hofer, M.D.
EDITORIAL RESPONSIBILITIES

2015-present World Neurosurgery, Reviewer
2016-present International Journal of Spine Surgery, Reviewer

SPECIAL NATIONAL RESPONSIBILITIES

2015-present NASS, Member of the scientific committee
2016-present AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, Member of the scientific committee

RESEARCH FUNDING, PAST AND CURRENT

Craig Neilsen Foundation (PI: Hofstetter) 07/31/18 – 07/30/20
Ultrafast contrast-enhanced ultrasound to measure local blood flow after SCI
The primary goal of this project is to develop ultrafast contrast-enhanced ultrasound to identify tissue in vicinity of a spinal cord lesion at risk for secondary-injury

WACIC, Washington State Spinal Cord Injury Consortium (PI: Hofstetter) 11/01/17-06/30/19
Contrast enhanced-ultrasound to identify potentially viable tissue within the penumbra of human spinal cord injury
The primary aim of this project was to collect contrast enhanced-ultrasound data characterizing the potentially salvageable penumbra of traumatic spinal cord injuries.

WACIC, Washington Spinal Cord Injury Consortium (PI: Moritz) 11/13/17-06/30/19
Transcutaneous spinal stimulation to improve hand & arm function for people with chronic cervical spinal cord injury
We perform a clinical trial of transcutaneous electrical stimulation in patients with chronic cervical spinal cord injury aiming to improve upper extremity function.
Role: Co-Investigator

Therapeutic Transcutaneous Spinal Stimulation for Improved Recovery after Cervical Spinal Cord Injury in the Rat
Development of translational rodent model for transcutaneous to reproduce the extremely favorable results we have seen in our clinical trial with cervical spinal cord stimulation.
Role: Co-Investigator

University of Washington Royalty Research Fund (PI: Hofstetter) 6/1/2016 – 5/31/2017
Ultrasound-based assessment of spinal perfusion following traumatic spinal cord injury
The primary aim of this project is to determine the contribution of elevated intraspinal pressure towards hypoperfusion of the acutely injured spinal cord
University of Washington Royalty Research Fund (PI: Hofstetter) 6/1/2016 – 5/31/2017
Ultrasound-based assessment of spinal perfusion following traumatic spinal cord injury
*The primary aim of this project is to determine the contribution of elevated intraspinal pressure towards hypoperfusion of the acutely injured spinal cord.*

University of Washington Institute of Translational Health Sciences (PI: Hofstetter) 6/1/2016 – 5/31/2017
Immuno-modulatory 3D scaffold to promote neuronal regeneration after spinal cord injury
*The primary aim of this project is to develop novel scaffolds alter the phenotypes of local macrophages and hereby reduce local scar formation and promote tissue regeneration.*

University of Washington Institute of Translational Health Sciences (PI: Perlmutter) 6/1/2015 - 5/31/2016
Role: Co-investigator
*An NHP Model for Cervical Myelopathy and Therapeutic Use of Electrical Stimulation.*
The primary aim of this project is to establish a primate model of cervical myelopathy using a chronic compression device.

BIBLIOGRAPHY

PEER REVIEWED JOURNAL ARTICLES


50. Åberg E, Hofstetter CP, Olson L, Brene S. Moderate ethanol consumption in adult mice increases hippocampal cell proliferation and neurogenesis in adult mouse. International J of Neuropsychopharmacology 2005; 8: 1-11.


BOOK CHAPTERS


PUBLISHED BOOKS, VIDEOS, SOFTWARE


OTHER PUBLICATIONS


MANUSCRIPTS SUBMITTED


ABSTRACTS
1. Clinical outcomes Following MIS vs. Endoscopic Laminectomy; 34th annual AANS/CNS Spine Section Meeting; Orlando, FL March 2018.

3. Contrast-enhanced ultrasound to visualize and quantify local blood flow and perfusion after traumatic spinal cord injury; 34th annual AANS/CNS Spine Section Meeting; Orlando, FL March 2018.

4. Transcutaneous electrical spinal stimulation: Preliminary clinical results and novel translational model; ISNR annual meeting, Asilomar, CA; December 2017

5. Contrast-enhanced ultrasound to visualize and quantify local blood flow and perfusion after traumatic spinal cord injury; ISNR annual meeting, Asilomar, CA; December 2017

6. Contrast-enhanced ultrasound to visualize and quantify local blood perfusion after traumatic spinal cord injury; 47th annual Society for Neuroscience Conference, Washington, DC; November 2017


8. Biomimetic injectable 3D hydrogels with aligned topography for neural tissue engineering 45th annual Society for Neuroscience conference, Chicago, IL; October 2015.

9. Minimally invasive foraminotomy through tubular retractors via a contralateral approach in patients with unilateral radiculopathy; 30th annual AANS/CNS Spine Section Meeting; Orlando, FL March 2014.

10. Unilateral tubular approach for bilateral laminectomy: Effect on ipsilateral and contralateral buttock and leg pain; 30th annual AANS/CNS Spine Section Meeting, Orlando, FL; March 2014.

11. Impact of cage height, width and positioning on clinical and radiographic outcome of extreme lateral interbody fusion; 29th annual AANS/CNS Spine Section Meeting, Phoenix, AZ; March 2013.

12. Midterm experience with expandable PEEK spacers for interbody fusion for Degenerative Lumbar Disease; 29th annual AANS/CNS Spine Section Meeting, Phoenix, AZ; March 2013.

13. Volumetric classification for giant pituitary macroadenomas predicts outcome and morbidity of endoscopic endonasal transsphenoidal surgery; NASBS, Scottsdale, AZ; February 2011.


25. Spontaneous recovery of the sensory system after spinal cord injury; a functional MRI study; 32th Annual meeting, Society for Neuroscience, Orlando, FL; November 2002.


INVITED LECTURES

12/2017 My path to MIS Endoscopy; Expanding the armamentarium of the complex spine surgeon; 11th New York City Minimally Invasive Spine, Spinal Endoscopy, Robotics & Navigation Symposium, Weill Cornell Medical Center, New York, NY

12/2017 Over the top MIS decompression with and without MIS transforaminal lumbar interbody fusion – Step – by – Step technique, AO spine Surgeon’s Cockpit, Davos, Switzerland

10/2017 Interlaminar lumbar stenosis decompression: Can it replace traditional laminectomy? 32nd Annual Meeting, NASS, Orlando, FL

10/2017 Lumbar Decompression and Discectomy: Microscope versus Endoscope; 32nd Annual Meeting, NASS, Orlando, FL

06/2017 Endoscopic Discectomy and Fusion using IntraLIF; Seattle Science Foundation, Seattle, WA

04/2017 How to Adopt Endoscopy: Training for Team & Fellows; 85th Annual Meeting, AANS, Los Angeles, CA

04/2017 The interlaminar endoscopic approach – advancing MIS; ISASS – 17th Annual Conference, Boca Raton, FL

10/2016 Pushing the Limits of Decompression with Endoscopic Spinal Surgery; Minimally Invasive Procedures to Minimize Exposure and Dissection; 31st Annual Meeting, NASS, Boston, MA

10/2016 Endoscopic Approaches to the Cervical and Lumbar spine; Minimally Invasive Lumbar Fusion Surgeries; 2017 CNSCN2016, Xi An, China

06/2016 Better Spinal Decompression Surgery using Next Generation Minimally Invasive Spine Surgery; 2016 Annual Meeting, WSANS, Cle Elum, WA
05/ 2016  Interlaminar Endoscopic approach; 84th Annual Meeting, AANS, Chicago, IL
03/2016  Explorative Meta-analysis on Dose-related Efficacy and Morbidity of Bone Morphogenetic Protein in Spinal Arthrodesis Surgery; 32nd Annual Meeting, AANS/CNS Spine Section, Orlando, FL
03/2016  Early Experience with Endoscopic Revision of Lumbar Arthrodesis Constructs; 32nd Annual Meeting, AANS/CNS Spine Section, Orlando, FL
03/2016  Characterization Intraspinal Pressure Following Traumatic Rodent Spinal Cord Injury; 32nd Annual Meeting, AANS/CNS Spine Section, Orlando, FL
01/2016  Epidural stimulation for chronic cervical spinal cord injury; SCI Forum, UW, Seattle, WA
10/2015  Characterization of intraspinal pressure following traumatic rodent spinal cord injury; 45th Annual Meeting, Society for Neuroscience, Chicago, IL.
10/2015  Pain Management following Discharge from Spine Surgery; 30th Annual Meeting, NASS, Chicago, IL.
10/2015  Minimally invasive TLIF; 30th Annual Meeting, NASS, Chicago, IL.
09/2015  Advances in Minimally Invasive Spine Surgery; UW CME course, Missoula, MT
04/2014  Extreme Lateral Interbody fusion for Unilateral Symptomatic Vertical Foraminal Stenosis; Annual Meeting, ISASS, Miami, FL
05 2014  Endoscopic Lumbar Foraminoplasty: A Cadaveric Study; Annual Meeting, ISASS, Miami, FL
032014  Endoscopic foraminal decompression; Annual Meeting of the AANS/CNS Spine section, Orlando, FL
09/2013  Optimizing indirect foraminal decompression by Extreme Lateral Interbody Fusion; Annual Meeting, Florida Neurosurgical Society, Palm Beach, FL
03/2013  Minimally invasive laminectomy through tubular retractors for lumbar spinal stenosis in patients with and without pre-operative spondylolisthesis: clinical outcome and re-operation rate; 29th Annual Meeting, AANS/CNS Spine Section, Phoenix, AZ
12/2010  PP2A activity protects hypoxic tumor stem cells from apoptosis; Grand Rounds, Vienna, Austria
05/2007  MRI-based imaging techniques: From the lab bench to neurosurgical practice; Nobel Conference, Stockholm, Sweden
10/2004  Directed differentiation of adult neural stem cells reduces side effects of stem cell based spinal cord injury treatment; 34th Annual Meeting, Society for Neuroscience, San Diego, CA
01/2003  Marrow stromal cell transplantation in spinal cord injury; Grand Rounds, Dept. of Neurosurgery, Medical College of Wisconsin, Milwaukee, WI
12/2002  Cell transplantation therapy in spinal cord injury; 13th NECTAR meeting, Amsterdam, Belgium
05/2002  Novel methods and repair strategies in spinal cord injury, Department of Neuroscience, Uppsala University, Uppsala, Sweden
**Order of Scheduled Presentations:**

**Surgery for symptoms of lumbar radiculopathy**

<table>
<thead>
<tr>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Jean-Christophe Leveque, MD</td>
</tr>
</tbody>
</table>
Disclosure

Any unmarked topic will be considered a “Yes”

<table>
<thead>
<tr>
<th>Potential Conflict Type</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Salary or payments such as consulting fees or honoraria in excess of $10,000.</td>
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</tr>
<tr>
<td>2. Equity interests such as stocks, stock options or other ownership interests.</td>
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</tr>
<tr>
<td>3. Status or position as an officer, board member, trustee, owner.</td>
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<td>X</td>
</tr>
<tr>
<td>4. Loan or intellectual property rights.</td>
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<td>X</td>
</tr>
<tr>
<td>5. Research funding.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>6. Any other relationship, including travel arrangements.</td>
<td></td>
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</tr>
</tbody>
</table>

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

Nuvasive: speaker/trainer for surgical skills, receive honoraria for this activity

IIMAC: Washington State L&I Committee, serve as member

Research Funding: Virginia Mason Research Funding (Wilske) for opioid research 2018-2019

<table>
<thead>
<tr>
<th>Potential Conflict Type</th>
<th>Yes</th>
<th>No</th>
</tr>
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<tbody>
<tr>
<td>7. Representation: if representing a person or organization, include the name and filling sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

If yes to #7, provide name and funding Sources:

Washington State Association of Neurological Surgeons: President, funding from member dues, industry funding of didactic sessions throughout the year, including annual meeting

*If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may attach additional sheets explaining why you believe that you should not be excluded.*

I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

[Signature]

4/26/18

Jean-Christophe Leveque

Print Name

So we may contact you regarding your presentation, please provide the following:

Email Address: jc.leveque@virginiamason.org

Phone Number: [Redacted]
Washington State HTA Program
Draft Evidence Report: Surgery for Symptomatic Lumbar Radiculopathy

Response

American Association of Neurological Surgeons
Congress of Neurological Surgeons
AANS/CNS Section on Disorders of the Spine and Peripheral Nerves
International Society for the Advancement of Spine Surgery
North American Spine Society
Washington State Association of Neurological Surgeons

Cited Literature Does Not Warrant a Policy Change

• We do not believe that there is a substantial change in evidence on this topic
• We do not support a change to the current coverage policy
• Have issue with some of the specific elements of the report
Limitations of Studies from Outside the United States

- Majority of studies in HTA were non-U.S. studies
  - Example 1: 18 of 22 RCTs for efficacy question 1 were non-U.S.
  - Example 2: 4 of 6 studies for cost-effectiveness analysis were non-U.S.
- Non-U.S. studies evaluate impact in other health care systems with different socioeconomics and demographics
- Vulnerable to error when applied to U.S.
- Limiting the analysis to the studies from U.S. alone would have been more appropriate

Conclusion on Long-term Outcomes is Inaccurate

- Draft evidence report concludes that compared to non-surgical tx, surgery reduces pain and improves function up to 26 weeks of follow-up but the “difference does not persist at 1 year or longer.”
- There is substantial high-quality literature that directly contradicts this statement
- One example is SPORT trial:
  - Intent-to-treat analysis: improvement in sciatica bothersomeness index and self-rated improvement at 1 yr and 4 yrs in favor of surgery (despite high crossover)
  - As-treated analysis (to address issues with crossover): in favor of surgery for all primary and secondary outcome measures (exception: work status) at every time point, including the latest f/u time point of 4 years. F/u study demonstrated persistence at 8 yrs
  - Also demonstrated benefit to patients who crossed over to surgery; subset of patients would not have achieved or maintained the beneficial outcome without surgical intervention
Minimally Invasive Surgery

- Outcomes for minimally invasive approaches were comparable to more traditional open discectomy and microdiscectomy in the draft evidence report
- Minimally invasive techniques may have distinct patient advantages, and choice based on patient factors, as most surgeons are adept at both
- We support the continued use of minimally invasive approaches for appropriately selected patients

Inherent Limitations to Meta-analysis

- A primary concern of this study design relates to patient heterogeneity
  - patients from different studies often represent distinct patient populations
  - grouping of these patients together often inappropriate
- Significant bias introduced when defining inclusion/exclusion criteria
  - Arbitrarily including RCTs from abroad and excluding important U.S.-based observational studies—do not agree with many of these assumptions
Conclusion

- Surgery remains a cornerstone treatment option for patients with lumbar radiculopathy when considering both therapeutic value and cost-effectiveness
- Cited literature does not warrant a policy change

References

Overview of presentation

- Background
- Methods
  - Strength of evidence grading
- Results
  - Primary research synthesis
  - Clinical practice guideline synthesis
- Discussion
  - Summary of evidence
  - Limitations
  - Payor coverage policies
Lumbar Radiculopathy/Sciatica

A *clinical* syndrome characterized by radiating leg pain, with or without motor weakness, and sensory disturbances in a myotomal or dermatomal distribution.

Results from spinal nerve root compression
- Disc herniation
- Spondylosis
- Various other pathological processes

Treatment objective is symptom relief through nonsurgical management of symptoms, surgical intervention to address the underlying causative mechanism, or both.

Image obtained from [http://www.neuroanatomy.wisc.edu/SClinic/Radiculo/Radiculopathy.htm#sciatic](http://www.neuroanatomy.wisc.edu/SClinic/Radiculo/Radiculopathy.htm#sciatic)
Epidemiology

- Prevalence estimates vary
  - Lifetime 3% to 43%
  - Period (1 year) 2.2% to 34%
  - Point 1.6% to 13.4%

- Risk factors:
  - Prior history of trauma
  - Prolonged driving
  - Pregnancy
  - Job requiring manual labor
  - Prior history of axial low back pain

Technology Description

- Standard, open procedures including microsurgical approaches
  - Disc removal procedures
    - Examples: Discectomy and microdiscectomy
  - Decompressive procedures
    - Examples: Laminectomy, laminotomy, foraminotomy

- Minimally-invasive surgeries (MIS)
  - Use direct (endoscopic) or indirect visualization (percutaneous)
  - Use various approaches for disc removal, destruction, and decompression
    - Mechanical (manual or automated)
    - Laser-assisted techniques
    - Radiofrequency thermal ablation
    - Coblation (plasma)
Regulatory Status

U.S. Food and Drug Administration (FDA) clears surgical instruments and devices used, typically through the 510(k) process.

- “aspiration of disc material during percutaneous discectomies”
- “cutting, grinding and aspirating intervertebral disc material during discectomy”
- “ablation and coagulation of intervertebral disc material during discectomy” or “coagulation and decompression of disc material”

- Arthroscopes, endoscopes, and related accessories
- Laser instruments are cleared for incision, excision, resection, ablation, vaporization, and coagulation of tissue during surgical procedures

Policy Context for Washington

<table>
<thead>
<tr>
<th>Area of concern</th>
<th>Level of concern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety</td>
<td>Medium</td>
</tr>
<tr>
<td>Efficacy</td>
<td>Medium</td>
</tr>
<tr>
<td>Cost</td>
<td>High</td>
</tr>
</tbody>
</table>
Methods

1. Primary Research Synthesis
2. Synthesis of Relevant Clinical Practice Guidelines

Analytic Framework

- Pain
- Neurological symptoms
- Health-related quality of life
- Physical, psychological, and social functioning
- Return to work
- Reoperations for relapse/
- recurrent symptoms
- $/quality-adjusted life year gained
- $/disability-adjusted life year gained

Subpopulations: Recurrent surgery or on disability

Adults with symptomatic lumbar radiculopathy → Surgical interventions to reduce pain, symptoms, and improve function

EQ1, efficacy question 1
EQ2, efficacy question 2
CQ1, cost question 1
SQ1, safety question 1

• Surgery-related morbidity and mortality
• Reoperations for complications
• Persistent opioid use

Figure 1
# Study Selection for Primary Research Review

<table>
<thead>
<tr>
<th>Population</th>
<th>Age $\geq$ 18, symptomatic lumbar radiculopathy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>Surgical interventions primarily for the treatment of radiculopathy. Includes “micro” approaches and minimally-invasive surgical procedures</td>
</tr>
<tr>
<td>Comparator</td>
<td>Placebo or no treatment comparators Active comparators: nonsurgical (e.g., physical therapy, pharmacologic treatment) or surgery</td>
</tr>
<tr>
<td>Outcomes</td>
<td>EQ1, EQ2: Pain, function/disability, quality of life, neurologic symptoms, return to work SQ1: Mortality, surgical morbidity, reoperations, persistent opioid use CQ1: Cost, cost per QALY, cost per DALY</td>
</tr>
<tr>
<td>Study Design</td>
<td>EQ1, EQ2, and SQ1: randomized clinical trial, controlled clinical trials (for all comparisons except surgery vs surgery) CQ1: costs, cost-effectiveness analysis, cost-benefit analysis, cost-utility analysis</td>
</tr>
<tr>
<td>Setting</td>
<td>Inpatient or outpatient settings in countries categorized as “very high” on United Nations Human Development Index</td>
</tr>
</tbody>
</table>

## What is Excluded from this HTA:

- **Populations:** cauda equina syndrome, neurogenic claudication or symptoms related primarily to central spinal stenosis, spondylolisthesis, nonradicular leg or low back pain

- **Interventions or Comparators:**
  - Spinal fusion, arthroplasty, artificial disc replacement, interspinous process decompression, minimally-invasive procedures designed for treating discogenic low back pain
  - Chemonucleolysis or biologic (e.g., stem cells, mesenchymal cells) agents.

- **Study Designs:**
  - Observational studies
  - “as treated” or “per protocol” analyses from RCTs
**Outcome Measurement and Interpretation**

- Varied across studies; for synthesis we defined the following:
  - **Short-term**: 4 weeks up to 12 weeks
  - **Medium-term**: 12 weeks up to 52 weeks*
  - **Long-term**: 52 weeks or longer

  *In actuality no studies reported outcomes between 26 and 52 weeks, so empirically outcomes reported as medium term represent those measured between 12 and 26 weeks.

- We concluded between-group differences if:
  - Magnitude of difference were above the minimally important difference (MID) threshold, AND
  - Estimates of the difference were precise enough to exclude a null effect (i.e., statistical significance)

**Risk of Bias**

- Risk of bias (study quality) is assessed at the individual study level
  - Cochrane Risk of Bias version 2.0 instrument
    - High risk of bias
    - Some concerns for bias
    - Low risk of bias
  - Quality of Health Economic Studies instrument
    - Good
    - Fair
    - Poor
Strength of the Evidence - Modified GRADE approach

- **Strength of evidence (SOE/certainty) ratings**
  - ○○○○○ INSUFFICIENT
  - ☐○○○○ VERY LOW
  - ☐☐○○○ LOW
  - ☐☐☐○○ MODERATE
  - ☐☐☐☐○ HIGH

- **Domains assessed:**
  - Risk of bias
  - Inconsistency
  - Indirectness
  - Imprecision
  - Reporting bias

- Bodies of RCT evidence start at **HIGH** SOE based on study design

- Downgrade based on domain assessment
  - No concerns
  - Serious concerns (↓ one level)
  - Very serious concerns (↓ two levels)

---

### Results

1. Primary Research Synthesis
2. Synthesis of Relevant Clinical Practice Guidelines
Search Results

- Primary Research Synthesis:
  - Titles/Abstracts screened: **1,861**
  - Full text articles screened: **223**
  - Full text studies included: **25** (from 39 articles)
    - EQ1/EQ2/SQ1: **24 RCTs**
    - CQ1: **7 studies**

- Clinical Practice Guidelines: **14**

Organizing Comparisons

- EQ1, SQ1, CQ1
  - Surgery vs. Nonsurgical Interventions
    - Surgery vs. Surgery
      - Minimally-invasive Surgery vs. Standard Surgery
      - Microdiscectomy vs. Discectomy

- EQ2, SQ1
  - Repeat surgery vs. comparator
    - Minimally-invasive repeat surgery vs. nonsurgical intervention
    - Minimally-invasive repeat surgery vs. standard repeat surgery
**EQ1 - Study Characteristics (Efficacy)**

<table>
<thead>
<tr>
<th>Surgical Intervention</th>
<th>Comparator</th>
<th>Population/Setting/Risk of Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Efficacy</strong> RCTs (k=7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microdiscectomy</td>
<td>• Spinal manipulation (McMorland 2010(^{29}))</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Physiotherapy (Osterman 2003(^{29}))</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Epidural steroid injection</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Conservative management</td>
<td></td>
</tr>
<tr>
<td>● Percutaneous disc decompression with coblation technology (Gerszten 2003(^{31}))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>● Percutaneous disc decompression (Erginousakis 2011(^{37}))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>● Discectomy (Weber 1983(^{26}))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>● Discectomy/microdiscectomy (Weinstein 2006 [SPORT](^{22}))</td>
<td></td>
<td></td>
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<tr>
<td>● Microdiscectomy (Peul 2007(^{32}))</td>
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</tbody>
</table>

**Patients:** diagnosis confirmed with imaging, failed 6 to 12 weeks conservative treatment, no immediate indications for surgery, mean duration of symptoms 8 to 52 weeks

**Countries:** U.S. (2), Canada (1), Greece (1), Finland (1), Netherlands (1), Norway (1)

**Risk of Bias:** high (5), some concerns (1), some/high (1)

---

**EQ1 - Surgery vs. Nonsurgical Interventions (Pain)**

**VAS 100 Leg Pain**

(Scale 0 to 100, higher is worse pain, MID 7 to 11)

- **Short- and medium-term:** ▲▲□ □ LOW Favors surgery
- **Long-term:** ▲▲▲▲ VERY LOW No difference

- Pain improves in both groups
  - Improves by 41 to 57 for surgery, 20 to 36.5 for comparator
  - **Pain improves 6 to 26 points more with surgery** through 26 weeks (k=3, \(^{22,33,41}\) N=429)
  - Within-group improvements persist, **no between-group differences** through 52 weeks to 5 years (k=2, \(^{22,33}\) N=339)

---

**VAS 100 Back Pain**

- **Short- and medium-term:** ▲▲□ □ LOW Favors surgery
- **Long-term:** ▲▲▲▲ VERY LOW No difference

- Similar treatment effect to VAS 100 Leg Pain, but baseline scores start lower.
**EQ1 - Surgery vs. Nonsurgical Interventions (Pain con’t)**

### SF-36 Bodily Pain (0 to 100, lower is worse pain, MID 3 to 4)

<table>
<thead>
<tr>
<th>Short- and medium-term:</th>
<th>Long-term:</th>
</tr>
</thead>
<tbody>
<tr>
<td>○○○○ INSUFFICIENT</td>
<td>○○○○ VERY LOW</td>
</tr>
<tr>
<td>Mixed findings</td>
<td>No difference</td>
</tr>
</tbody>
</table>

- Pain improves in both groups
  - Improves by 14.1 to 40.9 for surgery, 17.3 to 30.5 for comparator
- **Between-group differences mixed** through 26 weeks (k=4, 22, 23, 32, 41, N=914)
- Within-group improvements persist, no between-group differences through 52 weeks to 8 years (k=2, 22, 32, N=784)

**Sciatica Index** (0 to 24, higher is worse pain, MID 2.4)

<table>
<thead>
<tr>
<th>Short- and medium-term:</th>
<th>Long-term:</th>
</tr>
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<tbody>
<tr>
<td>○○○○ LOW</td>
<td>○○○○ VERY LOW</td>
</tr>
<tr>
<td>Favors surgery</td>
<td>No difference</td>
</tr>
</tbody>
</table>

- Pain improves in both groups on both subscales
  - Improves by 9.0 to 10.7 for surgery, 6.8 to 6.9 for comparator
- Pain improves **2.1 to 4.0 points more with surgery** through 26 weeks (k=2 22, 32, N=784)
- Within-group improvements persist, no between-group differences through 52 weeks to 8 years (k=2, 22, 32, N=784)

### Oswestry Disability Index** (0 to 100, higher scores worse function, MID 8 to 11)

<table>
<thead>
<tr>
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<th>Long-term:</th>
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<tbody>
<tr>
<td>○○○○ VERY LOW</td>
<td>○○○○ VERY LOW</td>
</tr>
<tr>
<td>Favors surgery</td>
<td>No difference</td>
</tr>
</tbody>
</table>

- Function improves in both groups
  - Improves by 12 to 26 for surgery, 5 to 21.3 for comparator
- Function improves **4.7 to 10 points more with surgery** through 26 weeks (k=3, 22, 33, 41, N=647)
- Within-group improvements persists, no between-group differences through 52 weeks to 8 years (k=2, 22, 33, N=557)

**Roland-Morris Disability Ques.** (0 to 24, higher scores worse function, MID 2 to 5)

<table>
<thead>
<tr>
<th>Short- and medium-term:</th>
<th>Long-term:</th>
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<tbody>
<tr>
<td>○○○○ INSUFFICIENT</td>
<td>○○○○ INSUFFICIENT</td>
</tr>
<tr>
<td>Mixed findings</td>
<td>Single study</td>
</tr>
</tbody>
</table>

- Function improves in both groups
  - Improves by 0.7 to 10.4 in surgery, 2.5 to 7.1 for comparator
- **Between-group differences mixed** through 26 weeks (k=2, 23, 32, N=323)
- Within-group improvement persists, no between-group differences through 5 years (k=1, 32, N=283)
## EQ1 - Surgery vs. Nonsurgical Interventions (Function con’t)

### SF-36 Physical Functioning

(0 to 100, lower is worse function, MID 3 to 4)

<table>
<thead>
<tr>
<th>Short- and medium-term:</th>
<th>Long-term:</th>
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</thead>
<tbody>
<tr>
<td>○○○○ INSUFFICIENT Mixed findings</td>
<td>囍 ○○○ VERY LOW No difference</td>
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</tbody>
</table>

- Function improves in both groups
  - Improves by 8.6 to 37.3 for surgery, 7.4 to 27.3 for comparator
- **Between-group differences mixed** through 26 weeks (k=3, 22,23,32 N=647)
- Within-group improvements persist, **no between-group differences** through 52 weeks to 8 years (k=2, 22,32 N=784)

### EQ1 - Surgery vs. Nonsurgical Interventions (Other Efficacy Outcomes)

#### Quality of Life

<table>
<thead>
<tr>
<th>Short- and medium-term:</th>
<th>Long-term:</th>
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<tbody>
<tr>
<td>⊖ ○○○ VERY LOW No difference</td>
<td>○○○○ INSUFFICIENT Single study</td>
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</table>

- Cumulative total SF-36, 15D
- Improves in both groups, **no between-group differences**
  - Short- to medium-term (k=2, 23,33 N=96)
  - Long-term (k=1, 33 N=56)

#### Neurological Symptoms

<table>
<thead>
<tr>
<th>Short- and medium-term:</th>
<th>Long-term:</th>
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<tbody>
<tr>
<td>⊖ ○○○ VERY LOW No difference</td>
<td>○○○○ INSUFFICIENT Single study</td>
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</tbody>
</table>

- Improves in both groups, **no between-group differences** (k=2, 33,41 N=146)

#### Return to Work

<table>
<thead>
<tr>
<th>Short- and medium-term:</th>
<th>Long-term:</th>
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<tbody>
<tr>
<td>⊖ ○○○ VERY LOW No difference</td>
<td>○○○○ INSUFFICIENT Single study</td>
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</table>

- Variation in and poor validity of measures used
  - **No between-group differences** (k=5, 22,26,33,37,41 N=835)

#### Measures of Global Recovery

<table>
<thead>
<tr>
<th>Short- and medium-term:</th>
<th>Long-term:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>○○○○ INSUFFICIENT Single study</td>
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</tbody>
</table>

- Heterogenous measures, but generally mirror pain and function measures (k=4, 22,26,32,33 N=966)
**SQ1 - Surgery vs. Nonsurgical Interventions**

### Mortality

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Evidence</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>📄褥褥褥褥LOW</td>
<td>No surgery-related deaths (k=5, 22,23,32,33,41 N=970)</td>
<td>All-cause mortality rare, <em>no between-group differences</em> through 26 weeks to 10 years (k=3, 22,26,41 N=717)</td>
<td></td>
</tr>
</tbody>
</table>

### Surgical Morbidity

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Evidence</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>📄褥褥褥褥LOW</td>
<td>Infrequent, dural tears most commonly reported adverse event (k=6, 22,23,32,33,37,41 N=555)</td>
<td></td>
<td></td>
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</tbody>
</table>

### Reoperations

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Evidence</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>📄褥褥褥褥VERY LOW</td>
<td>Variably measured and reported, most were for recurrent symptoms</td>
<td>Incidence 0% to 10% through 1 to 5 years (k=5, 22,23,32,33,37 N=466)</td>
<td></td>
</tr>
</tbody>
</table>

### Persistent Opioid Use

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Evidence</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>📄褥褥褥褥INSUFFICIENT</td>
<td>No between-group differences through 26 weeks (k=1, 41 N=90)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**CQ1 - Surgery vs. Nonsurgical Interventions (Study Characteristics)**

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Related RCT (Year)</th>
<th>Country</th>
<th>Quality-Time Horizon</th>
<th>Surgical Intervention (N randomized)</th>
<th>Comparator (N randomized)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malter (1996) 44</td>
<td>U.S. Cost Data</td>
<td>Fair- 10 years</td>
<td></td>
<td>Discectomy (NA)</td>
<td>Nonsurgical management (NA)</td>
</tr>
</tbody>
</table>

---

25 Table 26, 31, 36, 41  
Pages in Report: 74-75, 77-79, 83-84, 89

26 Table 44  
Pages in Report: 91-93
CQ1 - Surgery vs. Nonsurgical Interventions (Findings)

Cost-effectiveness

![Very Low]

- All studies (k=34,49,50) reported higher QALYs but similar or higher costs for surgery compared to nonsurgical interventions.
- The mean cost per QALY gained from the payor perspective ranged from $51,156 to $83,322 in 2010 U.S. dollars.

EQ1 - Study Characteristics (Comparative Effectiveness)

<table>
<thead>
<tr>
<th>Surgical Intervention</th>
<th>Comparator</th>
<th>Population/Setting/Risk of Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microdiscectomy</td>
<td>Patients: diagnosis confirmed with imaging, failed some amount of conservative therapy in most studies, must have met specific anatomical criteria depending on procedure, mean duration of symptoms 8 to 30 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Countries: US (2), Germany (5), Netherlands (2), UK (1), Japan (1), Italy (1), Denmark (1), Sweden (1), Taiwan (1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Risk of Bias: high (5), some concerns (9), low (1)</td>
<td></td>
</tr>
<tr>
<td>Tubular discectomy</td>
<td>Microdiscectomy</td>
<td>Patients: diagnosis confirmed with imaging, failed some amount of conservative therapy in most studies, must have met specific anatomical criteria depending on procedure, mean duration of symptoms 8 to 30 weeks</td>
</tr>
<tr>
<td>Trocar discectomy</td>
<td>Countries: US (2), Germany (5), Netherlands (2), UK (1), Japan (1), Italy (1), Denmark (1), Sweden (1), Taiwan (1)</td>
<td></td>
</tr>
<tr>
<td>Automated percutaneous lumbar discectomy</td>
<td>Risk of Bias: high (5), some concerns (9), low (1)</td>
<td></td>
</tr>
<tr>
<td>Percutaneous endoscopic discectomy</td>
<td>Countries: US (2), Germany (5), Netherlands (2), UK (1), Japan (1), Italy (1), Denmark (1), Sweden (1), Taiwan (1)</td>
<td></td>
</tr>
<tr>
<td>Endoscopic discectomy</td>
<td>Risk of Bias: high (5), some concerns (9), low (1)</td>
<td></td>
</tr>
<tr>
<td>Microendoscopic discectomy</td>
<td>Countries: US (2), Germany (5), Netherlands (2), UK (1), Japan (1), Italy (1), Denmark (1), Sweden (1), Taiwan (1)</td>
<td></td>
</tr>
<tr>
<td>Percutaneous laser disc decompression</td>
<td>Risk of Bias: high (5), some concerns (9), low (1)</td>
<td></td>
</tr>
<tr>
<td>Microscopically assisted percutaneous nucleotomy</td>
<td>Countries: US (2), Germany (5), Netherlands (2), UK (1), Japan (1), Italy (1), Denmark (1), Sweden (1), Taiwan (1)</td>
<td></td>
</tr>
<tr>
<td>Automated percutaneous discectomy/endoscopic percutaneous discectomy</td>
<td>Countries: US (2), Germany (5), Netherlands (2), UK (1), Japan (1), Italy (1), Denmark (1), Sweden (1), Taiwan (1)</td>
<td></td>
</tr>
<tr>
<td>Video-assisted arthroscopic microdiscectomy</td>
<td>Risk of Bias: high (5), some concerns (9), low (1)</td>
<td></td>
</tr>
<tr>
<td>Microendoscopic discectomy</td>
<td>Countries: US (2), Germany (5), Netherlands (2), UK (1), Japan (1), Italy (1), Denmark (1), Sweden (1), Taiwan (1)</td>
<td></td>
</tr>
<tr>
<td>Microdiscectomy (Henriksen 1996, Teli 2010, Tullberg 1993)</td>
<td>Countries: US (2), Germany (5), Netherlands (2), UK (1), Japan (1), Italy (1), Denmark (1), Sweden (1), Taiwan (1)</td>
<td></td>
</tr>
</tbody>
</table>
**EQ1 - MIS vs. Standard Surgery (Pain)**

**VAS Leg Pain** (Scale 0 to 100, higher is worse pain, MID 7 to 11)

- Pain improves in both groups
  - Improves by 42.5 to 69 for MIS, 29.8 to 62 for standard surgery
- **No between-group differences** at any time point (k=5, \(^{28,29,31,39,40}\), N=869)
  - 12 to 26 weeks pooled AMD 0.3 (95% CI, -2.2 to 2.9; N=640)
  - 2 years pooled AMD -0.1 (95% CI, -2.7 to 2.4; k=4; N=640; \(I^2=0\%\))

**SF-36 Bodily Pain** (0 to 100, lower is worse pain, MID 3 to 4)

- Short-term: \(\Theta\Theta\Theta\Theta\) LOW
  - No difference
- Medium- and long-term: \(\Theta\Theta\Theta\Theta\Theta\) VERY LOW
  - No difference

- Pain improves in both groups
  - Improves by 6.7 to 46.5 for MIS, 5.9 to 51.1 for standard surgery
- **No between-group differences**
  - Short-term (k=2, \(^{39,40}\), N=443), medium- to long-term (k=4, \(^{28,30,39,40}\), N=587)
  - Pooled AMD at 12 to 26 weeks:
    - -3.0 (95% CI, -12.8 to 6.8; k=3, \(^{28,39,40}\), N= 500, \(I^2=75.4\%\))

**Sciatica Index** (0 to 24, higher is worse pain, MID 2.4)

- Moderate
  - No difference

- Pain improves in both groups on both subscales
  - Improves by 4 to 8.5 for MIS, 3.2 to 8.7 for standard surgery
- Within-group improvements persist; **no between-group differences** through 2 years (k=2, \(^{39,40}\), N=443)
**EQ1 - MIS vs. Standard Surgery (Function)**

**Oswestry Disability Index** (0 to 100, higher scores worse function, MID 8 to 11)

- **Medium- and long-term:** VERY LOW
  - No difference
  - Function improves in both groups
  - Improves by 28 to 53 for MIS, 29 to 47 for standard surgery
  - **No between-group differences** through 12 weeks to 2.8 years (k=4, N=502)

**Roland-Morris Disability Ques.** (0 to 24, higher scores worse function, MID 2 to 5)

- **Short-term:** LOW
  - No difference
- **Medium- and long-term:** VERY LOW
  - No difference
  - Function improves in both groups
  - Improves by 4.9 to 9.7 for MIS, 2.3 to 10.6 for standard surgery
  - **Few between-group differences**
  - Short-term (k=2, N=443)
  - Medium- to long-term (k=3, N=477)

**SF-36 Physical Functioning** (0 to 100, lower is worse function, MID 3 to 4)

- **Short-term:** INSUFFICIENT
  - Mixed findings
- **Medium-term:** VERY LOW
  - No difference
- **Long-term:** INSUFFICIENT
  - Mixed findings
  - Function improves in both groups
  - Improves by 27.2 to 41.8 for MIS, 2.6 to 51.9 for standard surgery
  - **No between-group differences**
  - Medium-term (k=4, N=561)
  - Between-group differences mixed
  - Short-term (k=2, N=443)
  - Long-term (k=4, N=587)
# EQ1 - MIS vs. Standard Surgery (Other efficacy outcomes)

## Quality of Life
- **SF-36 Mental and Physical Component Scores**
  - Improves in both groups, **no between-group differences** (k=3, N=286)
- **No difference**

## Neurological Symptoms
- **Improves in both groups; no between-group differences** (k=6, N=544)
- **No difference**

## Return to Work
- **Favors MIS**
  - Variation and validity of measures used
  - Mean duration of post-operative work disability is **lower by 3.4 to 15.2 weeks for MIS** (k=6, N=555)
- **No difference**

## Measures of Global Recovery
- **Heterogenous measures, but generally no between-group differences** (k=10, N=840)

---

# SQ1 - MIS vs. Standard Surgery

## Mortality
- **No studies reported any surgery-related deaths** (k=5, N=463)
- **All-cause mortality rare, no between-group differences** through 2 years (k=2, N=528)

## Surgical Morbidity
- **Heterogenous measures and reporting** (k=10, N=1,151)
  - **Between group-differences similar** for nearly all adverse events reported, dural tears most commonly reported adverse event

## Persistent Opioid Use
- **No between-group differences through 26 weeks** (k=1, N=60)

---

*Table 16, 19, 21*
**SQ1 - MIS vs. Standard Surgery (con’t)**

**Reoperations**

- Variously measured and ascertained, most were for recurrent symptoms
- Incidence ranged between 2% to 64.5% (k=10, N=1,200)

### Table 37, Figure G-6

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Length of Followup</th>
<th>Minimally-Invasive Surgery</th>
<th>N Reoperation/Total N</th>
<th>Standard Surgery</th>
<th>N Reoperation/Total N</th>
<th>Risk Difference [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arts (2009)</td>
<td>5y</td>
<td>Tubular discectomy</td>
<td>30/166</td>
<td>Microdiscectomy</td>
<td>21/159</td>
<td>0.05 [0.03, 0.13]</td>
</tr>
<tr>
<td>Brouwer (2015)</td>
<td>52w</td>
<td>Percutaneous laser disc decompression</td>
<td>24/55</td>
<td>Microdiscectomy</td>
<td>9/57</td>
<td>0.28 [0.12, 0.44]</td>
</tr>
<tr>
<td>Chatterjee (1995)</td>
<td>26w</td>
<td>Automated percutaneous lumbar discectomy</td>
<td>20/11</td>
<td>Microdiscectomy</td>
<td>1/40</td>
<td>-0.62 [0.44, 0.80]</td>
</tr>
<tr>
<td>Franke (2009)</td>
<td>52w</td>
<td>Microscopically-assisted percutaneous nucleotomy</td>
<td>252</td>
<td>Microdiscectomy</td>
<td>5/48</td>
<td>-0.07 [0.03, 0.17]</td>
</tr>
<tr>
<td>Herrmann (1999)</td>
<td>2y</td>
<td>Video-assisted endoscopic discectomy</td>
<td>130</td>
<td>Discectomy</td>
<td>2/50</td>
<td>-0.03 [0.14, 0.00]</td>
</tr>
<tr>
<td>Mayer (1993)</td>
<td>2y</td>
<td>Percutaneous endoscopic discectomy</td>
<td>320</td>
<td>Microdiscectomy</td>
<td>1/20</td>
<td>0.10 [0.08, 0.26]</td>
</tr>
<tr>
<td>Rutsen (2008)</td>
<td>2y</td>
<td>Endoscopic discectomy</td>
<td>791</td>
<td>Microdiscectomy</td>
<td>10/87</td>
<td>-0.04 [0.12, 0.05]</td>
</tr>
<tr>
<td>Ryang (2008)</td>
<td>1.3y</td>
<td>Minimal access endoscopic discectomy</td>
<td>203</td>
<td>Microdiscectomy</td>
<td>4/30</td>
<td>-0.07 [0.02, 0.17]</td>
</tr>
<tr>
<td>Teli (2010)</td>
<td>2y</td>
<td>Microendoscopic discectomy</td>
<td>870</td>
<td>Microdiscectomy</td>
<td>3/72</td>
<td>0.07 [0.02, 0.10]</td>
</tr>
<tr>
<td>Thome (2005)</td>
<td>1.5y</td>
<td>Laminectomy</td>
<td>242</td>
<td>Microdiscectomy</td>
<td>4/42</td>
<td>-0.05 [0.10, 0.06]</td>
</tr>
</tbody>
</table>

RE Model for All Studies (Q = 54.51, df = 9, p = 0.001, I² = 85.1%): RR 1.37 (95% CI, 0.74 to 2.52)

Without Chatterjee:
RD: 0.02 (95% CI, -0.04 to 0.08)
RR: 1.17 (95% CI, 0.70 to 1.97)

---

**CQ1 - MIS vs. Standard Surgery (Study Characteristics)**

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Country</th>
<th>Quality-Time Horizon</th>
<th>Surgical Intervention (N randomized)</th>
<th>Comparator (N randomized)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Van den Akker (2011)</td>
<td>Netherlands</td>
<td>Good-52 weeks</td>
<td>Tubular discectomy (167)</td>
<td>Microdiscectomy (161)</td>
</tr>
<tr>
<td>Arts (2009)</td>
<td>Netherlands</td>
<td>Good-52 weeks</td>
<td>Microdiscectomy (161)</td>
<td>Microdiscectomy (161)</td>
</tr>
<tr>
<td>Van den Akker (2017)</td>
<td>Netherlands</td>
<td>Good-52 weeks</td>
<td>Percutaneous laser disc compression (57)</td>
<td>Discectomy, with laminotomy as needed (58)</td>
</tr>
<tr>
<td>Chatterjee (1995)</td>
<td>Italy</td>
<td>NA</td>
<td>Microendoscopic discectomy (70)</td>
<td>Microdiscectomy (72)</td>
</tr>
<tr>
<td>Teli (2010)</td>
<td>Italy</td>
<td>NA</td>
<td>Microendoscopic discectomy (70)</td>
<td>Microdiscectomy (72)</td>
</tr>
</tbody>
</table>

Table 44

Pages in Report: 91-93
CQ1 - MIS vs. Standard Surgery (Findings)

Cost-effectiveness

- Inconsistent findings across studies
  - One study\(^{21}\) reported higher costs and lower effectiveness (MIS is dominated)
  - One study\(^{22}\) reported lower costs and lower effectiveness for MIS (calculated cost per QALY $97,424).
  - One study\(^{23}\) reported an additional cost of $3,573 per successful outcome at 26 weeks
  - One study\(^{29}\) reported a $722 (95% CI, $551 to $892) higher surgical cost

Note: all values converted to 2010 U.S. Dollars

Table 46
Pages in Report: 95-97

EQ1 - Microdiscectomy vs. Discectomy (Efficacy Outcomes)

VAS Leg or Back Pain (0 to 100, higher is worse pain, MID 7 to 11)

- Pain improves in both groups
  - No between-group differences through 6 weeks (k=1,\(^{35}\) N=80)
  - No between-group differences through 2 years (k=2,\(^{27,29}\) N=202)

Oswestry Disability Index (0 to 100, higher is worse function, MID 8 to 11)

- No between-group differences from 26 weeks through 2 years (k=1,\(^{29}\) N=142)

Table 11 and 14
Pages in Report: 43-44, 56
## EQ1 - Microdiscectomy vs. Discectomy (Efficacy Outcomes con’t)

### Quality of Life (SF-36 Mental and Physical Component Scores)

<table>
<thead>
<tr>
<th>Category</th>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single study</td>
<td>INSUFFICIENT</td>
<td>No between-group differences from 26 weeks through 2 years (k=1, N=142)</td>
</tr>
</tbody>
</table>

### Return to Work

<table>
<thead>
<tr>
<th>Category</th>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single study</td>
<td>INSUFFICIENT</td>
<td>Similar duration of postoperative disability (10.4 vs. 10.1 weeks) (k=1, N=60)</td>
</tr>
</tbody>
</table>

---

## SQ1 - Microdiscectomy vs. Discectomy

### Mortality

<table>
<thead>
<tr>
<th>Category</th>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single study</td>
<td>INSUFFICIENT</td>
<td>No surgery-related deaths (k=1, N=142)</td>
</tr>
</tbody>
</table>

### Surgical Morbidity

<table>
<thead>
<tr>
<th>Category</th>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>No difference</td>
<td>VERY LOW</td>
<td>Infrequent, no between-group differences (k=3, N=282)</td>
</tr>
</tbody>
</table>

### Reoperations

<table>
<thead>
<tr>
<th>Category</th>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>No difference</td>
<td>VERY LOW</td>
<td>Incidence 3.3 to 4%, no between-group differences (k=2, N=202)</td>
</tr>
</tbody>
</table>

---

Table 17 and 22, Pages in Report: 59, 65-66

Table 28, 33, 38, Pages in Report: 76, 80-81, 87
## EQ 2 - Repeat Surgery for Recurrence (Efficacy and Safety)

### Repeat lumbosacral decompression vs. spinal cord stimulation (k=1, \( N=50 \))

<table>
<thead>
<tr>
<th>Insufficient</th>
<th>Single study</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pain, QOL or neurologic outcomes reported, function/disability and return to work similar differences.</td>
<td></td>
</tr>
<tr>
<td>Reoperations: 0 vs. 3</td>
<td></td>
</tr>
<tr>
<td>Stable or decreased opioid use: 58% vs. 87%, ( P=0.025 )</td>
<td></td>
</tr>
</tbody>
</table>

### Revision endoscopic discectomy vs. revision microdiscectomy (k=1, \( N=100 \))

<table>
<thead>
<tr>
<th>Insufficient</th>
<th>Single study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Similar improvements in pain, function/disability, and neurologic symptoms</td>
<td></td>
</tr>
<tr>
<td>Fewer surgical complications: 6% vs. 21%, ( P&lt; 0.05 )</td>
<td></td>
</tr>
<tr>
<td>Shorter return to work: 4 weeks vs. 7 weeks, ( P&lt;0.01 )</td>
<td></td>
</tr>
<tr>
<td>Reoperations: 2 vs. 3</td>
<td></td>
</tr>
</tbody>
</table>

---

### Clinical Practice Guideline Synthesis

- 14 CPGs or “interventional procedure guidance” documents
  - National Institute for Health and Care Excellence (UK) 2016
  - North American Spine Society 2012
  - American Pain Society 2009
  - American Society of Interventional Pain Physicians 2013
  - American College of Occupational and Environmental Medicine 2016
  - NICE interventional guidance (UK) (9 separate documents)
## Clinical Practice Guideline Synthesis

<table>
<thead>
<tr>
<th>Organization</th>
<th>Year</th>
<th>Recommendation</th>
<th>Evidence Base/ Strength of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Institute for Health and Care Excellence (U.K.) (6 out of 7)</td>
<td>2016</td>
<td>Consider spinal decompression for sciatica (includes laminectomy, foraminotomy, and/or discectomy) when nonsurgical treatment has not improved pain or function and their radiological findings are consistent with sciatica symptoms.</td>
<td>9 RCTs, 4 cohort studies (only evaluated surgery vs. conservative treatment)</td>
</tr>
</tbody>
</table>

### Clinical Practice Guideline Synthesis (con’t)

<table>
<thead>
<tr>
<th>Organization</th>
<th>Year</th>
<th>Recommendation</th>
<th>Recommendation Rating/ Evidence Base</th>
</tr>
</thead>
<tbody>
<tr>
<td>North American Spine Society (5 out of 7)</td>
<td>2012</td>
<td>For patients whose symptoms are severe enough to warrant surgery: -discectomy is suggested to provide more effective symptom relief than medical/interventional care -surgical intervention prior to 6 months is suggested, earlier surgery is associated with faster recovery Surgical decompression provides better medium-term (1y to 4y) symptom relief compared with medical/interventional care</td>
<td>Grade: B (3 RCT, 2 PCS) Grade: B (4 unclear study designs) Grade: B (3 RCT, 1 PCS)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Surgical decompression provides long-term (greater than four years) symptom relief</td>
<td>Level IV (1 RCS, 5 CS)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Performance of sequestrectomy or aggressive discectomy is recommended for decompression</td>
<td>Grade: B (1 RCT, 1 PCS)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Endoscopic and automated percutaneous discectomy may be considered</td>
<td>Grade: C (5 RCTs, 4 RCS, 4 PCS)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Automated percutaneous lumbar discectomy (APLD) may achieve equivalent results to open discectomy in a select group of patients</td>
<td>Grade C: (3 RCTs)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tubular discectomy, use of fusion, surgical approach for lateral herniation, medial facetectomy, fusion for specific populations</td>
<td>Insufficient</td>
</tr>
</tbody>
</table>

**Abbreviations:** RCT = randomized controlled trial; RCS = retrospective cohort study; PCS = prospective cohort study; CS = case series
### Clinical Practice Guideline Synthesis (con’t)

<table>
<thead>
<tr>
<th>Organization</th>
<th>Year</th>
<th>Recommendation</th>
<th>Evidence Base/ Strength of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Pain Society (5 out of 7)</td>
<td>2009</td>
<td>Open discectomy or microdiscectomy for radiculopathy with prolapsed disc.</td>
<td>4 RCTs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Insufficient evidence for determining superiority of open vs. micro approaches.</td>
<td>Level B/Good</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Insufficient evidence to evaluate alternative surgical methods, including laser- or endoscopic-assisted techniques.</td>
<td>Moderate net benefit for short-term outcomes (up to 12 weeks) only</td>
</tr>
</tbody>
</table>

**Discussion**

---

Table 48

Pages in Report: 98-107

---

Pages in Report: 107-126
Grade: Insufficient

Very low certainty

Low certainty

Moderate certainty

High certainty

Timing of Follow-up:
- Short- and medium-term (6 to 26 weeks)
- Long-term (52 weeks or longer)
- Short- or medium-, and long-term

Note: Pattern-filled outcomes indicate that multiple measures within the outcome were reported but graded as having different levels of certainty; or that certainty was different at different follow-up times.
Limitations of the Evidence Base

- Nearly half of included studies were high risk of bias (poor quality).
- Studies underpowered for many outcomes of interest.
- Variation in diagnosis and severity/duration of symptoms at entry.
- Limited number of studies for any single MIS procedure.
- Variation in type, timing, and completeness in reporting outcomes.
- Applicability of older studies and RCTs to community practice.
- Limited number of U.S. cost studies.
- Limitations in AGREE guideline appraisal instrument.
Payer Coverage Policies

- **CMS**
  - No national coverage determination related to standard or microsurgical procedures
  - Non-coverage for thermal intradiscal procedures, which includes percutaneous disc decompression

- Private payers with policies cover decompressive procedures including microsurgical approaches for disc herniation with radicular symptoms.
  - Specific criteria vary by payer but often include a failed trial of conservative management for 6 to 12 weeks.
  - Most payers require imaging confirmation of nerve root compression.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medicare</th>
<th>Premera</th>
<th>Regence</th>
<th>Cigna</th>
<th>United</th>
<th>Aetna</th>
<th>Humana</th>
<th>Kaiser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laminectomy, laminotomy, discectomy, foraminotomy</td>
<td>❌</td>
<td>✔️</td>
<td>❌</td>
<td>❌</td>
<td>✔️</td>
<td>✔️</td>
<td>❌</td>
<td>❌</td>
</tr>
<tr>
<td>Automated percutaneous lumbar disc decompression</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>✔️</td>
<td>❌</td>
<td>❌</td>
</tr>
<tr>
<td>(Percutaneous) endoscopic discectomy</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
</tr>
<tr>
<td>(Percutaneous) laser discectomy</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
</tr>
<tr>
<td>Percutaneous nucleoplasty with coblation</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
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</tr>
</tbody>
</table>

Table 49 and 50

Pages in Report: 118-124

Limitations of this Health Technology Assessment

- **Scope**
  - English-language articles only
  - Only included efficacy outcomes reported at 4 weeks or later
  - Excluded observational studies and ‘as-treated’ analyses from RCTs

- **Process**
  - Search limited to 3 databases
  - Hand-searches for studies published prior to 2007
  - Single reviewer for title/abstract screening

- **Analysis**
  - Grouping of MIS procedures
    - Endoscopic procedures
    - Percutaneous procedures
    - Others: tubular or trocar discectomy, sequestrectomy
## Conclusions

- **Surgery** reduces pain more compared to nonsurgical interventions at follow-up through 26 weeks, but these findings did not persist at one year or longer. No differences in function/disability (long-term), quality of life (short-medium term), neurologic symptoms, or return to work; but evidence insufficient for quality of life (long-term), function/disability (short-medium term), and persistent opioid use.

- Minimally-invasive surgery is comparable to microdiscectomy or discectomy for nearly all efficacy and safety outcomes, but evidence is insufficient for reoperations and persistent opioid use.

- Microdiscectomy and discectomy are comparable with respect to pain, surgical morbidity, and reoperations; evidence is insufficient for all other efficacy and safety outcomes.

- The evidence is insufficient for repeat surgery among individuals with recurrent radiculopathy.

## Additional Details
### Included Studies- Surgery vs. Nonsurgical Interventions (EQ1)

<table>
<thead>
<tr>
<th>Citation</th>
<th>Reference</th>
</tr>
</thead>
</table>

53

### Included Studies- MIS vs. Standard Surgery (EQ1)

<table>
<thead>
<tr>
<th>Citation</th>
<th>Reference</th>
</tr>
</thead>
</table>
# Included Studies - Microdiscectomy vs. Discectomy (EQ1)

<table>
<thead>
<tr>
<th>Citation</th>
<th>Reference</th>
</tr>
</thead>
</table>

# Included Studies - Repeat Surgery (EQ2)

<table>
<thead>
<tr>
<th>Citation</th>
<th>Reference</th>
</tr>
</thead>
</table>
Search Strategy and Selection Process

- **Data Sources**
  - Hand search: 40 existing systematic reviews, reference lists of pertinent articles
  - Websites: Government (FDA, NICE), Payors, Professional Societies

- **Selection Process**
  - English-language only
  - Title and abstracts: single reviewer screened conducted after substantial interrater reliability established on initial set of 50 titles/abstracts
  - Full text: dual independent review with one team member and the lead investigator

Data Abstraction and Analysis

- **Abstraction**
  - One person abstracted data into structured template, reviewed by lead investigator for accuracy

- **Risk of bias**
  - Two independent assessments using ROB 2.0, QHES, and AGREE-II instruments

- **Qualitative synthesis**
  - By outcome and comparison (for primary research studies)
  - Tabular summary (for guideline synthesis)

- **Quantitative synthesis**
  - 3 or more studies with same outcome measure and compatible reporting

- Used a modified GRADE approach for assessing strength of evidence

---

ROB 2.0 = Cochrane risk of bias for trials; QHES = Quality of Health Economic Studies; AGREE-II = Appraisal of Guidelines for Research & Evaluation II
### SOE interpretation

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td><strong>We are very confident that the estimate of effect lies close to the true effect for this outcome.</strong> The body of evidence has few or no deficiencies. We believe that the findings are stable, that is, another study would not change the conclusions.</td>
</tr>
<tr>
<td>Moderate</td>
<td><strong>We are moderately confident that the estimate of effect lies close to the true effect for this outcome.</strong> The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.</td>
</tr>
<tr>
<td>Low</td>
<td><strong>We have limited confidence that the estimate of effect lies close to the true effect for this outcome.</strong> The body of evidence has major or numerous deficiencies (or both). We believe that additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.</td>
</tr>
<tr>
<td>Very Low</td>
<td><strong>We have very limited confidence that the estimate of effect lies close to the true effect for this outcome.</strong> The body of evidence has numerous major deficiencies. We believe that substantial additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.</td>
</tr>
<tr>
<td>Insufficient</td>
<td><strong>We have no evidence, we are unable to estimate an effect, or we have no confidence in the estimate of effect for this outcome.</strong> No evidence is available or the body of evidence has unacceptable deficiencies, precluding reaching a conclusion.</td>
</tr>
</tbody>
</table>

### Main Efficacy Outcomes Reported

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Score Range</th>
<th>Interpretation of Between-Group Treatment Effect</th>
<th>Minimally Important Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS 100 mm Pain, leg, back or general</td>
<td>0 to 100</td>
<td><strong>Negative</strong> mean difference favors intervention group</td>
<td>7 to 11 points</td>
</tr>
<tr>
<td>SF-36 Bodily Pain</td>
<td>0 to 100</td>
<td><strong>Positive</strong> mean difference favors intervention group</td>
<td>3 to 4 points</td>
</tr>
<tr>
<td>SF-36 Physical Functioning</td>
<td>(norm-based: mean 50, SD (10))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roland Morris Disability</td>
<td>1 to 24</td>
<td><strong>Negative</strong> mean difference favors intervention group</td>
<td>2 to 5 points</td>
</tr>
<tr>
<td>Oswestry Disability</td>
<td>0 to 100</td>
<td><strong>Negative</strong> mean difference favors intervention group</td>
<td>8 to 11 points</td>
</tr>
<tr>
<td>Sciatica Index-Bothersomeness and Frequency</td>
<td>0 to 24</td>
<td><strong>Negative</strong> mean difference favors intervention group</td>
<td>None established, 10% relative difference is 2.4 points</td>
</tr>
</tbody>
</table>
## Abbreviations

- **AMD** absolute mean difference
- **CI** confidence interval
- **CS** case series
- **DALY** disability adjusted life year
- **k** number of studies
- **N** number of participants
- **MID** minimally important difference
- **MIS** minimally-invasive surgery
- **NR** not reported
- **NS** not significant
- **PCS** prospective cohort study
- **QALY** quality-adjusted life year
- **ROB** risk of bias
- **RCS** retrospective cohort study
- **RCT** randomized controlled trial
- **RD** risk difference
- **RR** relative risk
- **SF-36** short-form 36 survey
- **SD** standard deviation
- **SOE** strength of evidence
- **VAS** visual analog scale
FINAL Key Questions and Background

Surgery for Symptomatic Lumbar Radiculopathy

Background
Radiculopathy is a clinical syndrome characterized by pain, motor weakness, and sensory disturbances in a myotomal or dermatomal distribution. When radicular symptoms are in the low back and legs, this condition is referred to as lumbar radiculopathy or sciatica. Nerve root compression is a common cause of radiculopathy and various pathological processes may be responsible, but most often it results from disc herniation or spondylosis (i.e., degenerative joint and disc disease). Both processes can cause stenosis of the lateral recesses or neural foramina and resulting spinal nerve root compression. Degenerative changes can also produce spondylolisthesis, central spinal canal stenosis, and facet joint hypertrophy, which may be associated with nonradicular low back pain. Less common etiologies of radiculopathy include infection, inflammation, neoplasm, vascular disease, and congenital abnormalities. Radiculopathy is a clinical diagnosis because spinal nerve root compression identified with imaging may not always be symptomatic. Thus, correlation of symptoms and physical exam with imaging is usually used to diagnose radiculopathy, with electromyography reserved for selected patients. The lifetime prevalence of lumbar radiculopathy is 3 to 5%.

Lumbar radiculopathy is a heterogenous condition that may present acutely (as in the case of an acute disc herniation with chemical radiculitis) or more insidiously (as in the case of spondylosis). Further, radiculopathy may present only with pain or with varying degrees of sensory disturbance or motor weakness. The objective of treatment for radiculopathy is symptom relief. If pain or neurologic symptoms are severe or nonresponsive to conservative measures, then surgical treatment of the underlying causative mechanism may be warranted.

Policy Context
Numerous surgical and nonsurgical approaches to the management of lumbar radiculopathy have been studied and are routinely used within current clinical practice. In addition to standard open surgical techniques (e.g., discectomy with laminotomy or laminectomy as needed), minimally invasive surgical techniques that use percutaneous or endoscopic approaches are also available. This health technology assessment (HTA) will review the efficacy, safety, and cost-effectiveness of surgical interventions to treat symptomatic lumbar radiculopathy in adults to assist the State of Washington’s Health Technology Clinical Committee in determining coverage for selected surgical interventions.

Scope
The proposed research questions, analytic framework, and key study selection criteria are listed in this section.
Efficacy Question 1 (EQ1). In adults with symptomatic lumbar radiculopathy, what is the effectiveness and comparative effectiveness of surgical interventions?

Efficacy Question 2 (EQ2). In adults with symptomatic lumbar radiculopathy, does effectiveness or comparative effectiveness of surgical interventions vary for patients who are not employed because of disability or patients who are undergoing recurrent surgery for relapse?

Safety Question 1 (SQ1). In adults with symptomatic lumbar radiculopathy, what are the adverse events associated with surgical interventions?

Cost Question 1 (CQ1). In adults with symptomatic lumbar radiculopathy, what is the cost-effectiveness of surgical interventions?

Figure 1 depicts the framework of the proposed HTA.

**Figure. Analytic Framework Depicting Scope of Proposed Health Technology Assessment**

**Population:** Adults (18 years and over) with symptomatic lumbar radiculopathy are included; adults with cauda equina syndrome, neurogenic claudication, spondylolisthesis, cervical or thoracic symptoms, traumatic or congenital structural abnormalities, or radiculopathy not related to lumbar disc herniation or spondylosis are excluded.

**Intervention:** The following open surgical interventions are included:

- Discectomy
- Laminectomy, laminotomy
- Foraminotomy
- Nucleotomy
- Sequestrectomy
“Micro” approaches to the above open procedures, which may involve smaller incisions, smaller areas of dissection, and use of a microscope or loupe magnification are also eligible. Minimally invasive surgical procedures including percutaneous or endoscopic approaches to the above interventions are also eligible.

The following interventions are excluded as they are primarily designed to treat neurogenic claudication because of central spinal stenosis, spinal instability, or nonradicular low back pain.

- Spinal fusion
- Arthroplasty
- Artificial disc replacement
- Interspinous process decompression
- Minimally invasive surgical procedures designed primarily to treat discogenic low back pain or lumbar spinal stenosis

Chemonucleolysis with chymopapain is also excluded because it is a rarely used treatment for lumbar disc herniation and related radiculopathy in current practice.

**Comparator:** Placebo or no treatment comparators (sham surgery, expectant management); active treatment comparators including nonsurgical management (e.g., physical therapy, chiropractic treatment, epidural injection, medication) or surgical interventions listed above as eligible interventions. Studies without a comparator group, or studies that use active treatment interventions that are listed as ineligible interventions will be excluded.

**Outcomes**

**Efficacy:** Pain, neurologic symptoms, health-related quality of life, physical, psychological, and social functioning, return to work, reoperations for relapse; measures of pain, quality of life, and function must be measured using valid and reliable instruments or scales. Only outcomes reported at 4 weeks post-op or later will be included as differences in efficacy before 4 weeks may not be clinically relevant.

**Safety:** Surgery-related morbidity including venous thromboembolism, paralysis, new onset neurologic symptoms, dural tear, epidural hematoma, surgical mortality, reoperations for complications, persistent opioid use

**Cost/Cost-Effectiveness:** cost per quality-adjusted life years gained, cost per disability-adjusted life years gained

**Setting:** Inpatient or outpatient settings in countries categorized as “very high” on United National Human Development Index

**Time Period:** No restriction on included studies; however, search strategy will use existing systematic reviews to identify potentially relevant studies published prior to 2007.
Other Criteria

Only studies published in English will be included.

For all efficacy and safety research questions, only controlled clinical trials, randomized clinical trials, and systematic reviews of controlled or randomized clinical trials will be included. For active treatment comparisons, only randomized clinical trials or systematic reviews of randomized clinical trials will be included. For cost-effectiveness research question, we will include cost-effectiveness, cost-utility, or cost-benefit analyses performed from payor or societal perspectives.

Studies will be included regardless of risk of bias, however; we will only include studies with a high risk of bias rating in quantitative analysis if fewer than 3 studies are available.

References


Public comment and response

See Draft Key Questions: Public Comment & Response document published separately.
HTCC Coverage and Reimbursement Determination
Analytic Tool

HTA’s goal is to achieve better health care outcomes for enrollees and beneficiaries of state programs by paying for proven health technologies that work.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:
1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

**Principle One: Determinations are evidence-based**

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective\(^1\) as expressed by the following standards\(^2\):

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

**Principle Two: Determinations result in health benefit**

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms\(^3\):

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.

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\(^1\) Based on Legislative mandate: See RCW 70.14.100(2).

\(^2\) The principles and standards are based on USPSTF Principles at:  http://www.ahrr.gov/clinic/ajpmsuppl/harris3.htm

\(^3\) The principles and standards are based on USPSTF Principles at:  http://www.ahrr.gov/clinic/ajpmsuppl/harris3.htm
In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.

The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. **Availability of evidence:**
   Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. ** Sufficiency of the evidence:**
   Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence using characteristics such as:
   - Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
   - The amount of evidence (sparse to many number of evidence or events or individuals studied);
   - Consistency of evidence (results vary or largely similar);
   - Recency (timeliness of information);
   - Directness of evidence (link between technology and outcome);
   - Relevance of evidence (applicability to agency program and clients);
   - Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

<table>
<thead>
<tr>
<th>Not Confident</th>
<th>Confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.</td>
<td>Very certain of evidentiary support. Further information is unlikely to change confidence</td>
</tr>
</tbody>
</table>

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4 Based on GRADE recommendation: [http://www.gradeworkinggroup.org/FAQ/index.htm](http://www.gradeworkinggroup.org/FAQ/index.htm)
3. Factors for Consideration - Importance

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology’s safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

Clinical committee findings and decisions

Efficacy considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests’ accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?
Health Technology Evidence Identification

Safety
- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost impact
- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall
- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next step: Cover or no cover
If not covered, or covered unconditionally, the chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next step: Cover with conditions
If covered with conditions, the committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence statement
   - What issues need to be addressed and evidence statement

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.
Clinical committee evidence votes

First voting question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Discussion document: What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

<table>
<thead>
<tr>
<th>Safety outcomes</th>
<th>Importance of outcome</th>
<th>Safety evidence/ confidence in evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical morbidity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reoperations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Persistent opioid use</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Efficacy –effectiveness outcomes</th>
<th>Importance of outcome</th>
<th>Efficacy / Effectiveness evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Function/ disability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality of life</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurological symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Return to work</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cost outcomes</th>
<th>Importance of outcome</th>
<th>Cost evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost effectiveness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct costs</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Special population / Considerations outcomes</th>
<th>Importance of outcome</th>
<th>Special populations/ Considerations evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employment status</td>
<td></td>
<td></td>
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</tbody>
</table>
**Health Technology Evidence Identification**

**For safety:**
Is there sufficient evidence that the technology is safe for the indications considered?

<table>
<thead>
<tr>
<th>Unproven (no)</th>
<th>Less (yes)</th>
<th>Equivalent (yes)</th>
<th>More in some (yes)</th>
<th>More in all (yes)</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

**For efficacy/effectiveness:**
Is there sufficient evidence that the technology has a meaningful impact on patients and patient care?

<table>
<thead>
<tr>
<th>Unproven (no)</th>
<th>Less (yes)</th>
<th>Equivalent (yes)</th>
<th>More in some (yes)</th>
<th>More in all (yes)</th>
</tr>
</thead>
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</table>

**For cost outcomes/cost-effectiveness:**
Is there sufficient evidence that the technology is cost-effective for the indications considered?

<table>
<thead>
<tr>
<th>Unproven (no)</th>
<th>Less (yes)</th>
<th>Equivalent (yes)</th>
<th>More in some (yes)</th>
<th>More in all (yes)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>
Discussion
Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote
Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____ Not covered  _____ Covered unconditionally  _____ Covered under certain conditions

Discussion item
Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Next step: proposed findings and decision and public comment
At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?
2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: final determination
Following review of the proposed findings and decision document and public comments:

Final vote
Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome chair will lead discussion to determine next steps.
**Medicare coverage and guidelines**  
[From page 118 of the Final Evidence Report]

The Centers for Medicare and Medicaid Services (CMS) does not have a national coverage determination related to open standard or microsurgical decompressive procedures (i.e., discectomy, microdiscectomy, foraminotomy, laminectomy/otomy).

[Guidelines from Pages 99-106 of the Final Evidence Report]

<table>
<thead>
<tr>
<th>Organization</th>
<th>Guideline Title (Year)</th>
<th>Guideline Qualitya</th>
<th>Recommendationb</th>
<th>Evidence Base</th>
<th>Rating/Strength of Evidence Narrative Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Institute for Health and Care Excellence (United Kingdom)</td>
<td>Low back pain and sciatica in over 16s: assessment and management-Invasive treatments (2016)</td>
<td>Quality Rating: 6 out of 7</td>
<td>Consider spinal decompression for sciatica (includes laminectomy, foraminotomy, and/or discectomy) when nonsurgical treatment has not improved pain or function and their radiological findings are consistent with sciatica symptoms.</td>
<td>9 RCTs comparing surgery to nonsurgical treatment including epidural steroids, analgesics and anti-inflammatory medication, physical therapyc</td>
<td>Low or very low for nearly all comparisons and outcomesd</td>
</tr>
<tr>
<td>North American Spine Society</td>
<td>Clinical Guidelines for Diagnosis and Treatment of Lumbar Disc Herniation with Radiculopathy (2012)e</td>
<td>Quality Rating: 5 out of 7</td>
<td>Discectomy is suggested to provide more effective symptom relief than medical/interventional care for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgical intervention. In patients with less severe symptoms, surgery or medical/interventional care appear to be effective for both short- and long-term relief.</td>
<td>3 RCTs 2 prospective comparative cohort studies</td>
<td>Grade: Bf</td>
</tr>
<tr>
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<td>Surgical intervention prior to 6 months is suggested in patients with symptomatic lumbar disc herniation whose symptoms are severe enough to warrant surgery. Earlier surgery (within 6 months to 1 year) is associated with faster recovery and improved long-term outcomes.</td>
<td>4 studies (unclear study design)</td>
<td>Grade: Bf</td>
</tr>
<tr>
<td></td>
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<td>The performance of surgical decompression is suggested to provide better medium-term (1 to 4 years) symptom relief as compared with medical/interventional management of patients with radiculopathy from lumbar disc herniation whose symptoms are severe enough to warrant surgery.</td>
<td>3 RCTs 1 prospective comparative cohort study</td>
<td>Grade: Bf</td>
</tr>
<tr>
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<td>Surgical decompression provides long-term (greater than four years) symptom relief for patients with radiculopathy from lumbar disc herniation whose symptoms warrant surgery. It should be noted that a substantial portion (23-28%) of patients will have chronic back or leg pain.</td>
<td>1 retrospective comparative cohort study 5 retrospective case series</td>
<td>f Evidence: IVg</td>
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<tr>
<td>North American Spine Society</td>
<td></td>
<td>When surgery is indicated, performance of sequestrectomy or aggressive discectomy is recommended for decompression in patients with lumbar disc herniation with radiculopathy since there is no difference in rates of reherniation.</td>
<td>1 RCT 1 prospective comparative cohort study</td>
<td>Grade: B&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>North American Spine Society</td>
<td></td>
<td>Use of an operative microscope is suggested to obtain comparable outcomes to open discectomy for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.</td>
<td>2 RCTs</td>
<td>Grade: B&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>North American Spine Society</td>
<td></td>
<td>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.</td>
<td>3 RCTs</td>
<td>Grade: B&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>North American Spine Society</td>
<td></td>
<td>Endoscopic percutaneous discectomy may be considered for the treatment of lumbar disc herniation with radiculopathy.</td>
<td>3 RCTs 4 retrospective case series</td>
<td>Grade: C&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>North American Spine Society</td>
<td></td>
<td>Automated percutaneous discectomy may be considered for the treatment of lumbar disc herniation with radiculopathy.</td>
<td>2 RCTs 4 prospective case series</td>
<td>Grade: C&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>North American Spine Society</td>
<td></td>
<td>In a select group of patients automated percutaneous lumbar discectomy (APLD) may achieve equivalent results to open discectomy, however, this equivalence is not felt to be generalizable to all patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.</td>
<td>3 RCTs</td>
<td>Level of Evidence: II/III&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>North American Spine Society</td>
<td></td>
<td>There is insufficient evidence to make a recommendation for or against the following: Urgent surgery for patients with motor deficits Use of spinal manipulation as an alternative to discectomy The specific surgical approach for far lateral disc herniation Use of tubular discectomy compared with open discectomy Use of medial facetectomy with discectomy Use of fusion for specific patient populations with lumbar disc herniation and radiculopathy</td>
<td>--</td>
<td>Grade: I&lt;sup&gt;a&lt;/sup&gt;</td>
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(continued)
Table 48. Clinical practice guidelines related to lumbar radiculopathy or herniated intervertebral lumbar disc (continued)

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<tr>
<th>Organization</th>
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<tr>
<td>North American Spine Society</td>
<td>Use of percutaneous electrothermal disc decompression Use of intradiscal high-pressure saline injection Use of automated percutaneous discectomy compared with open discectomy Use of plasma disc decompression/nucleoplasty Use of plasma disc decompression as compared with transforaminal epidural steroid injections in patients with lumbar disc herniation who have previously failed transforaminal epidural steroid injection therapy</td>
<td>4 RCTs comparing surgery to conservative management</td>
<td>Level B/Goodf Moderate net benefit for short-term outcomes (up to 12w) only</td>
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<tr>
<td></td>
<td>Quality Rating: 5 out of 7</td>
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<tr>
<td>American Pain Society</td>
<td>Open discectomy or microdiscectomy for radiculopathy with prolapsed disc.</td>
<td>15 observational studies for laser-assisted PLDD 1 SR of 3 observational studies PLDD with DeKompressor. 1 RCT and 14 observational studies for nucleoplasty.</td>
<td>The evidence is limited for APLD, FLDD, and percutaneous disc decompression with DeKompressor. The evidence is limited to fair for mechanical lumbar disc decompression with nucleoplasty.</td>
<td>(continued)</td>
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<td></td>
<td>Quality Rating: 4 out of 7</td>
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(continued)
### Table 48. Clinical practice guidelines related to lumbar radiculopathy or herniated intervertebral lumbar disc (continued)

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<tr>
<th>Organization</th>
<th>Guideline Title (Year)</th>
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<th>Rating/Strength of Evidence</th>
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<tr>
<td>American College of Occupational and Environmental Medicine</td>
<td>Low back disorders. In occupational medicine practice guidelines: evaluation and management of common health problems and functional recovery in workers (2016)¹⁴</td>
<td>Quality Rating: Unknown³</td>
<td>Patients with evidence of specific nerve root compromise confirmed by appropriate imaging studies may be expected to potentially benefit from surgery. Quality evidence indicates that patient outcomes are not adversely affected by delaying nonemergent surgery for weeks or a few months and continued conservative care is encouraged in patients with stable or improving deficits who desire to avoid surgery. However, patients with either moderate to severe neurological deficits that are not improving or trending to improvement at 4 to 6 weeks may benefit from earlier surgical intervention. Those with progressive neurological deficit(s) are believed to have indications for immediate surgery. Those with severe deficits that do not rapidly improve are also candidates for earlier testing and referrals.</td>
<td>Unknown³</td>
<td>Unknown³</td>
<td></td>
</tr>
<tr>
<td>National Institute for Health and Care Excellence (United Kingdom)</td>
<td>Percutaneous transforaminal endoscopic lumbar discectomy for sciatica: Interventional procedures guidance [IPG 556] (2016)¹⁵</td>
<td>Quality Rating: 2 out of 7</td>
<td>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. Percutaneous transforaminal 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.</td>
<td>1 SR of observational studies 1 retrospective comparative cohort study 2 prospective case series 5 retrospective case series</td>
<td>None provided</td>
<td></td>
</tr>
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<td>Organization</td>
<td>Guideline Title (Year)</td>
<td>Guideline Quality</td>
<td>Recommendation</td>
<td>Evidence Base</td>
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<tr>
<td>National Institute for Health and Care Excellence (United Kingdom)</td>
<td>Percutaneous interlaminar endoscopic lumbar discectomy for sciatica: Interventional procedures guidance[IPG555] (2016)</td>
<td>59</td>
<td>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. 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.</td>
<td>2 RCTs, 2 retrospective comparative cohort studies, 4 retrospective case series</td>
<td>None provided</td>
<td></td>
</tr>
<tr>
<td>National Institute for Health and Care Excellence (United Kingdom)</td>
<td>Percutaneous coblation of the intervertebral disc for low back pain and sciatica Interventional procedures guidance[IPG543] (2016)</td>
<td>60</td>
<td>Current evidence on percutaneous coblation of the intervertebral disc for low back pain and sciatica raises no major safety concerns. The evidence on efficacy is adequate and includes large numbers of patients with appropriate follow-up periods. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit. As part of the consent process, patients should be informed that there is a range of treatment options available to them and that further procedures may be needed.</td>
<td>1 SR, 2 RCTs, 1 case series</td>
<td>None provided</td>
<td></td>
</tr>
<tr>
<td>National Institute for Health and Care Excellence (United Kingdom)</td>
<td>Percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica Interventional procedures guidance[IPG544] (2016)</td>
<td>61</td>
<td>Current evidence on percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica raises no major safety concerns. The evidence on efficacy is inconsistent and of poor quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.</td>
<td>1 SR, 1 RCT, 1 Cohort study</td>
<td>None provided</td>
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Table 48. Clinical practice guidelines related to lumbar radiculopathy or herniated intervertebral lumbar disc (continued)

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<tr>
<td>National Institute for Health and Care Excellence (United Kingdom)</td>
<td>Percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain. Interventional procedures guidance[IPG545] (2016)</td>
<td>Current evidence on percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain raises no major safety concerns. The evidence on its efficacy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.</td>
<td>1 RCT 1 nonrandomized CT 2 case series</td>
<td>None provided</td>
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<tr>
<td>Quality Rating: 2 out of 7</td>
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<tr>
<td>National Institute for Health and Care Excellence (United Kingdom)</td>
<td>Epiduroscopic lumbar discectomy through the sacral hiatus for sciatica Interventional procedures guidance[IPG570] (2016)</td>
<td>Current evidence on the safety and efficacy of epiduroscopic lumbar discectomy through the sacral hiatus for sciatica is limited in quantity and quality. Therefore, this procedure should only be used in the context of research.</td>
<td>1 Cohort study</td>
<td>None provided</td>
<td></td>
</tr>
<tr>
<td>Quality Rating: 2 out of 7</td>
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<tr>
<td>National Institute for Health and Care Excellence (United Kingdom)</td>
<td>Percutaneous intradiscal laser ablation in the lumbar spine. Interventional procedures guidance[IPG357] (2010)</td>
<td>Current evidence on the safety and efficacy of percutaneous intradiscal laser ablation in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. Patients selected for the procedure should be limited to those with severe pain refractory to conservative treatment, in whom imaging studies show bulging of an intact disc, and who do not have neurological deficit requiring surgical decompression.</td>
<td>1 RCT 2 Cohort studies 2 Case series</td>
<td>None provided</td>
<td></td>
</tr>
<tr>
<td>Quality Rating: 2 out of 7</td>
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Table 48. Clinical practice guidelines related to lumbar radiculopathy or herniated intervertebral lumbar disc (continued)

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<tr>
<td>National Institute for Health and Care Excellence (United Kingdom)</td>
<td>Automated percutaneous mechanical lumbar discectomy: Interventional procedures guidance<a href="2005">IPG141</a></td>
<td>Current evidence suggests that there are no major safety concerns associated with automated percutaneous mechanical lumbar discectomy. There is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, but evidence from small randomized controlled trials shows conflicting results. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and for audit or research. Clinicians wishing to undertake automated percutaneous mechanical lumbar discectomy should take the following actions: Inform the clinical governance leads in their Trusts. Ensure that patients understand the uncertainty about the procedure’s efficacy and provide them with clear written information. In addition, use of the Institute’s information for the public is recommended. Audit and review clinical outcomes of all patients having automated mechanical percutaneous lumbar discectomy.</td>
<td>3 RCTs 5 case series</td>
<td>None provided</td>
<td></td>
</tr>
<tr>
<td>National Institute for Health and Care Excellence (United Kingdom)</td>
<td>Endoscopic laser foraminoplasty. Interventional procedures guidance<a href="2003">IPG31</a></td>
<td>Current evidence of the safety and efficacy of endoscopic laser foraminoplasty does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake endoscopic laser foraminoplasty should inform the clinical governance leads in their Trusts. They should ensure that patients offered the procedure understand the uncertainty about its safety and efficacy and should provide them with clear written information. Use of the Institute’s information for the public is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Further research into safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.</td>
<td>3 Cohort studies 2 Case series</td>
<td>None provided</td>
<td></td>
</tr>
</tbody>
</table>

a We assessed the quality of guideline using the Appraisal of Guidelines For Research & Evaluation II (AGREE II) Instrument, version 2017. The lowest quality score possible is 1, the highest possible quality score is 7.

b Only recommendations from the guideline pertinent to surgical interventions for lumbar radiculopathy are summarized.

c One included trial was for treatment of sciatica with spinal stenosis, the rest were for treatment of lumbar radiculopathy

d Based on GRADE.

e Level 1=high quality RCTs or SRs of RCTs; Level II=lesser quality RCTs, prospective comparative studies, SRs that include Level II studies; Level III=Case control or retrospective cohort studies, SRs of Level III studies, Level 4=case series; Level 5= Expert Opinion, Grade A=Good evidence (Level 1 studies with consistent findings); Grade B=Fair evidence (Level II or III studies with consistent findings), Grade C=Poor evidence (Level IV or V studies); Grade I=insufficient or conflicting evidence not allowing a recommendation

f One included trial was for treatment of sciatica with spinal stenosis, the rest were for treatment of lumbar radiculopathy

g The complete guideline is not publicly accessible; thus, a full quality appraisal and summary of the evidence base and strength of evidence ratings were not possible.

Abbreviations: RCT = randomized controlled trial; SR = systematic review; CT = controlled trial; w = week(s); y = year(s); APLD = automated percutaneous lumbar decompression; PLDD = percutaneous lumbar disc decomposition.