IN THE SUPREME COURT OF THE STATE OF NEVADA

ALBERT H. CAPANNA, M.D., Appellant/Cross-Respondent, vs. BEAU R. ORTH, Respondent/Cross-Appellant.	Case No. 69935 District Court Case No. A648041
ALBERT H. CAPANNA, M.D., Appellant, vs. BEAU R. ORTH, Respondent.	Case No. 70227

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APPENDIX TO RESPONDENT/CROSS-APPELLANT'S COMBINED OPENING AND ANSWERING BRIEF

VOL. 3 PART 3

DENNIS M. PRINCE, ESQ.
Nevada Bar No. 5092
KEVIN T. STRONG, ESQ.
Nevada Bar No. 12107
EGLET PRINCE
400 South 7th Street, 4th Floor
Las Vegas, NV 89101
Tel.: 702-450-5400
Email: eservice@egletlaw.com
Attorneys For Respondent/Cross-Appellant, Beau Orth

CHRONOLOGICAL INDEX TO RESPONDENT/CROSS-APPELLANT'S APPENDIX

This defendant reserves the right to incorporate all witnesses, documents and/or exhibits as listed in all other parties' pre-trial disclosures or statements, as currently stated, supplemented or amended in the future.

This defendant, further, preserves the right to object to any and all witnesses offered by any other party, as well as any other objections which are not stated herein, but may, nevertheless, be applicable at the time of trial.

Defendant ALBERT H. CAPANNA, M.D. reserves the right to supplement and/or amend this disclosure as needed during the course of discovery.

Dated: July 22, 2015 LAURIA TOKUNAGA GATES & LINN, LLP

By: /s/ Anthony D. Lauria
Anthony D. Lauria
Nevada Bar No. 4114
Attorneys for Defendant
Albert H. Capanna, M.D.

CERTIFICATE OF SERVICE

Pursuant to N.R.C.P. 5(b), I certify that I am an employee of Lauria Tokunaga Gates & Linn, and that on this 22nd day of July, 2015, I served a true and correct copy of the foregoing **DEFENDANT ALBERT H. CAPANNA, M.D.'S SUPPLEMENT TO NRCP 16.1 EARLY CASE CONFERENCE DISCLOSURE OF WITNESSES AND DOCUMENTS:**

☐ By placing same to be deposited for mailing in the United States Mail, in a sealed envelope upon which first class postage was prepared in Sacramento, California; and/or

X By mandatory electronic service (e-service), proof of e-service attached to any copy filed with the Court; and/or

☐ By facsimile, pursuant to EDCR 7.26 (as amended); and/or

☐ By personal service

as follows:

Dennis M. Prince, Esq
EGLET PRINCE
400 South 7th Street, Box 1, Suite 400
Las Vegas, NV 89101
Tel. 702.450.5400

John T. Keating, Esq.
KEATING LAW GROUP
9130 West Russell Road, Suite 200
Las Vegas, NV 89148
Tel. 702.228.6800

MARISA PEREZ
An employee of Lauria Tokunaga Gates & Linn, LLP

EXHIBIT 23

EXHIBIT 23

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Abstract

Evid Based Spine Care J. 2014 Oct;5(2):77-86. doi: 10.1055/s-0034-1386750.

Microdiscectomy for the treatment of lumbar disc herniation: an evaluation of reoperations and long-term outcomes.

Aichmair A[1], Du JY[1], Shue J[1], Evangelisti G[2], Sama AA[1], Hughes AP[1], Lebl DR[1], Burket JC[3], Cammisa FP[1], Girardi FP[1].

Author information

[1]Department of Orthopaedic Surgery, Spine and Scoliosis Service, Hospital for Special Surgery, Weill Cornell Medical College, New York, New York, United States.
[2]1st Orthopaedic Clinic, Cisanello Hospital, University of Pisa, Pisa, Italy.
[3]Department of Epidemiology and Biostatistics, Hospital for Special Surgery, Weill Cornell Medical College, New York, New York, United States.

Abstract

Design Retrospective case series. Objective The objective of this study was to assess the reoperation rate after **microdiscectomy** for the treatment of lumbar disc herniation (LDH) in patients with ≥ 5-year follow-up and identify demographic, perioperative, and outcome-related differences between patients with and without a reoperation. Methods The medical records, operative reports, and office notes of patients who had undergone **microdiscectomy** at a single institution between March 1994 and December 2007 were reviewed and **long-term** follow-up was assessed via a telephone questionnaire. Results Forty patients (M:24, F:16) with an average age at surgery of 39.9 ± 12.5 years (range: 18-80) underwent **microdiscectomy** at the levels L5-S1 (n = 28, 70%), L4-L5 (n = 9, 22.5%), L3-L4 (n = 2, 5.0%), and L1-L2 (n = 1, 2.5%). After an average of 40.4 ± 40.1 months (range: 1-128), 25% of patients (10/40) required further spine surgery related to the initial **microdiscectomy**. At an average postoperative follow-up of 11.1 ± 4.0 years (range: 5-19), additional symptoms apart from back and leg pain were reported more frequently by patients who underwent a reoperation (p = 0.005). Patient satisfaction was significantly higher in patients who did not undergo a reoperation (p = 0.041). For the Oswestry disability index, pain intensity (p = 0.036), and pain-related sleep disturbances (p = 0.006) were reported to be more severe in the reoperation group. Conclusions **Microdiscectomy** for the treatment of LDH results in a favorable **long-term** outcome in the majority of cases. The reoperation rate was higher in our series than reported in previous investigations with shorter follow-up. Although there were no statistically significant pre-/perioperative differences between patients with and without reoperation, our findings suggest a difference in self-reported **long-term** outcome measures.

KEYWORDS: ODI; Oswestry disability index; limited discectomy; **long-term** outcome; lumbar disc herniation; **microdiscectomy**; reoperation

PMID: 25278881 [PubMed] PMCID: PMC4174230 [Available on 2015-10-01]

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Abstract

Full text links

Wolters Kluwer

J Spinal Disord Tech. 2014 Feb;27(1):E8-E13. doi: 10.1097/BSD.0b013e31828da8f1.

Limited microdiscectomy for lumbar disk herniation: a retrospective long-term outcome analysis.

Soliman J[1], Harvey A, Howes G, Seibly J, Dossey J, Nardone E.

Author information

[1]*Department of Neurosurgery, Advocate BroMenn Medical Center, Normal †Central Illinois Neuro Health Science, Bloomington ‡Department of Mathematics, Illinois State University Normal, Normal, IL.

Abstract

OBJECTIVE AND SUMMARY OF BACKGROUND DATA: Surgical treatment of lumbar disk herniation is traditionally accomplished by removal of the extruded fragment as well as an aggressive decompression of the disk space. This retrospective study evaluates the **long-term** results of limited discectomy, otherwise known as fragmentectomy, for lumbar disk herniation using a minimally invasive technique. Although there are ample studies in literature regarding short-**term** outcome after limited **microdiscectomy**, there is a paucity of literature for **long-term outcomes** after fragmentectomy. We present **long-term outcomes** averaging 7 years after limited discectomy.

STUDY DESIGN AND METHODS: A total of 152 patients were operated on between January 1, 2001 and June 30, 2003 for single-level herniated lumbar disks. All patients had microsurgical fragmentectomy performed through a small skin incision off the midline using a tubeless retraction system. Fifty-four patients participated in the study, whereas 98 patients were lost to **long-term** follow-up. **Long-term** outcome was assessed by telephone survey or mail-in survey using the Oswestry Low Back Pain Disability Index and a patient outcome survey. After Institutional Review Board approval and patient consent, all 54 patients had a thorough chart review for evaluation of further lumbar surgeries. The mean **long-term** follow-up was 86.2 months (range, 72-104 mo) or about 7.2 years.

RESULTS: Forty-eight of the 54 patients (88.9%) reported an excellent (26 patients) or good (22 patients) **long-term** outcome with surgery. **Long-term** back and leg pain improvement was seen in 44 of 49 (89.8%) and 44 of 50 (88.0%) patients reporting back or leg pain, respectively. The mean Oswestry Disability Index for **long-term** follow-up was 8.89, indicating minimal disability. Same-level recurrences requiring reoperation were seen in 6 of the 54 patients who participated (11.1%) within the average 86.2-month follow-up. Four of 34 (11.85%) known contained herniations and 2 of 20 (10.0%) known extruded herniations presented for same-level surgical recurrence. All recurrences were successfully treated with reexploration and fragmentectomy. Two patients from the recurrence group and 1 from the original 54 progressed to need an arthrodesis at the initial operated level (5.6%). One patient in the same-level recurrence group and 2 patients from the original 54 developed an operative herniated disk at an adjacent level (5.6%).

CONCLUSIONS: Our **long-term** outcome study shows that a minimally invasive approach to **microdiscectomy** with removal of the fragment only is an effective way to treat lumbar disk herniation. The rate of recurrence in our **long-term** study seems slightly higher compared with previously published studies, which generally had shorter follow-up periods. **Long-term** patient **outcomes** for back and leg pain were also very low. No appreciable difference in operative reherniation could be found with patients who had contained verses extruded fragments. It is difficult to predict from this study whether a simple fragmentectomy was the cause of the progression to further surgeries or whether this was the natural progression of a degenerative spine. Further prospective trials are necessary to fully understand the factors associated with limited **microdiscectomy**.

PMID: 23563332 [PubMed - indexed for MEDLINE]

MeSH Terms

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EXHIBIT 25

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Abstract

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Wolters Kluwer

Neurosurgery. 2009 Feb;64(2):338-44; discussion 344-5. doi: 10.1227/01.NEU.0000337574.58662...

Recurrent disc herniation and long-term back pain after primary lumbar discectomy: review of outcomes reported for limited versus aggressive disc removal.

McGirt MJ[1], Ambrossi GL, Datoo G, Sciubba DM, Witham TF, Wolinsky JP, Gokaslan ZL, Bydon A.

Author information

[1]Department of Neurosurgery, The Johns Hopkins Spinal Column Biomechanics and Surgical **Outcomes** Laboratory, The Johns Hopkins Hospital, Baltimore, Maryland 21287, USA.

Abstract

OBJECTIVE: It remains unknown whether aggressive disc removal with curettage or limited removal of disc fragment alone with little disc invasion provides a better outcome for the treatment of lumbar disc herniation with radiculopathy. We reviewed the literature to determine whether **outcomes** reported after limited discectomy (LD) differed from those reported after aggressive discectomy (AD) with regard to **long-term** back pain or recurrent disc herniation.

METHODS: A systematic MEDLINE search was performed to identify all studies published between 1980 and 2007 reporting **outcomes** after AD or LD for a herniated lumbar disc with radiculopathy. The incidence of short- and **long-term** recurrent back or leg pain and recurrent disc herniation was assessed from each reported LD or AD cohort and the cumulative incidence compared.

RESULTS: Fifty-four studies (60 discectomy cohorts) met the inclusion criteria, reporting the **outcomes** of 13 359 patients after lumbar discectomy (LD, 6135 patients; AD, 7224 patients). The reported incidence of short-**term** recurrent back or leg pain was similar after LD (mean, 14.5%; range, 7-16%) and AD (mean, 14.1%; range, 6-43%) ($P < 0.01$). However, more than 2 years after surgery, the reported incidence of recurrent back or leg pain was 2.5-fold less after LD (mean, 11.6%; range, 7-16%) compared with AD (mean, 27.8%; range, 19-37%) ($P < 0.0001$). The reported incidence of recurrent disc herniation after LD (mean, 7%; range, 2-18%) was greater than that reported after AD (mean, 3.5%; range, 0-9.5%) ($P < 0.0001$).

CONCLUSION: Review of the literature demonstrates a greater reported incidence of **long-term** recurrent back and leg pain after AD but a greater reported incidence of recurrent disc herniation after LD. Prospective, randomized trials are needed to firmly assess this possible difference.

PMID: 19190461 [PubMed - indexed for MEDLINE]

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EXHIBIT 26

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Abstract

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J Neurosurg Spine. 2010 Feb;12(2):178-82. doi: 10.3171/2009.9.SPINE09410.

Long-term back pain after a single-level discectomy for radiculopathy: incidence and health care cost analysis.

Parker SL[1], Xu R, McGirt MJ, Witham TF, Long DM, Bydon A.

Author information

[1]The Johns Hopkins Spinal Column Biomechanics and Surgical Outcomes Laboratory, The Johns Hopkins University School of Medicine, Baltimore, Maryland, USA.

Abstract

OBJECT: The most common spinal procedure performed in the US is lumbar discectomy for disc herniation. Longterm disc degeneration and height loss occur in many patients after lumbar discectomy. The incidence of mechanical back pain following discectomy varies widely in the literature, and its associated health care costs are unknown. The authors set out to determine the incidence of and the health care costs associated with mechanical back pain attributed to segmental degeneration or instability at the level of a prior discectomy performed at their institution.

METHODS: The authors retrospectively reviewed the data for 111 patients who underwent primary, single-level lumbar hemilaminotomy and discectomy for radiculopathy. All diagnostic modalities, conservative therapies, and operative treatments used for the management of postdisectomy back pain were recorded. Institutional billing and accounting records were reviewed to determine the billed costs of all diagnostic and therapeutic measures.

RESULTS: At a mean follow-up of 37.3 months after primary discectomy, 75 patients (68%) experienced minimal to no back pain, 26 (23%) had moderate back pain requiring conservative treatment only, and 10 (9%) suffered severe back pain that required a subsequent fusion surgery at the site of the primary discectomy. The mean cost per patient for conservative treatment alone was $4696. The mean cost per patient for operative treatment was $42,554. The estimated cost of treatment for mechanical back pain associated with postoperative same-level degeneration or instability was $493,383 per 100 cases of first-time, single-level lumbar discectomy ($4934 per primary discectomy).

CONCLUSIONS: Postoperative mechanical back pain associated with same-level degeneration is not uncommon in patients undergoing single-level lumbar discectomy and is associated with substantial health care costs.

PMID: 20121353 [PubMed - indexed for MEDLINE]

MeSH Terms

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EXHIBIT 27

EXHIBIT 27

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Abstract

Evid Based Spine Care J. 2014 Oct;5(2):77-86. doi: 10.1055/s-0034-1386750.

Microdiscectomy for the treatment of lumbar disc herniation: an evaluation of reoperations and long-term outcomes.

Aichmair A[1], Du JY[1], Shue J[1], Evangelisti G[2], Sama AA[1], Hughes AP[1], Lebl DR[1], Burket JC[3], Cammisa FP[1], Girardi FP[1].

Author information

[1]Department of Orthopaedic Surgery, Spine and Scoliosis Service, Hospital for Special Surgery, Weill Cornell Medical College, New York, New York, United States.
[2]1st Orthopaedic Clinic, Cisanello Hospital, University of Pisa, Pisa, Italy.
[3]Department of Epidemiology and Biostatistics, Hospital for Special Surgery, Weill Cornell Medical College, New York, New York, United States.

Abstract

Design Retrospective case series. Objective The objective of this study was to assess the reoperation rate after **microdiscectomy** for the treatment of **lumbar** disc herniation (LDH) in patients with ≥ 5-year follow-up and identify demographic, perioperative, and outcome-related differences between patients with and without a reoperation. Methods The medical records, operative reports, and office notes of patients who had undergone **microdiscectomy** at a single institution between March 1994 and December 2007 were reviewed and **long-term** follow-up was assessed via a telephone questionnaire. Results Forty patients (M:24, F:16) with an average age at surgery of 39.9 ± 12.5 years (range: 18-80) underwent **microdiscectomy** at the levels L5-S1 (n = 28, 70%), L4-L5 (n = 9, 22.5%), L3-L4 (n = 2, 5.0%), and L1-L2 (n = 1, 2.5%). After an average of 40.4 ± 40.1 months (range: 1-128), 25% of patients (10/40) required further spine surgery related to the initial **microdiscectomy**. At an average postoperative follow-up of 11.1 ± 4.0 years (range: 5-19), additional symptoms apart from back and leg pain were reported more frequently by patients who underwent a reoperation (p = 0.005). Patient satisfaction was significantly higher in patients who did not undergo a reoperation (p = 0.041). For the Oswestry disability index, pain intensity (p = 0.036), and pain-related sleep disturbances (p = 0.006) were reported to be more severe in the reoperation group. Conclusions **Microdiscectomy** for the treatment of LDH results in a favorable **long-term** outcome in the majority of cases. The reoperation rate was higher in our series than reported in previous investigations with shorter follow-up. Although there were no statistically significant pre-/perioperative differences between patients with and without reoperation, our findings suggest a difference in self-reported **long-term** outcome measures.

KEYWORDS: ODI; Oswestry disability index; limited discectomy; **long-term** outcome; **lumbar** disc

herniation; **microdiscectomy**; reoperation

PMID: 25278881 [PubMed] PMCID: PMC4174230 [Available on 2015-10-01]

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EXHIBIT 28

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Abstract

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Spine J. 2006 Jul-Aug;6(4):380-4.

Mid- to long-term outcome of disc excision in adolescent disc herniation.

Smorgick Y[1], Floman Y, Millgram MA, Anekstein Y, Pekarsky I, Mirovsky Y.

Author information

[1]Department of Orthopedic Surgery, Assaf Harofeh Medical Center, Zerifin, 70300, Israel. Noam.Yossi@Yahoo.com

Abstract

BACKGROUND CONTEXT: Adolescent disc herniation and its surgical treatment have been the subjects of many published clinical series. The majority of these series were heterogeneous; the number of adolescent patients (12-17 years) as opposed to young adults (18-20 years) was generally small and the length of follow-up varied greatly. Although the short-term outcome of disc excision in adolescents was mostly favorable, their long-term outcome is unknown.

OBJECTIVES: To evaluate the mid- and long-term results of discectomy in patients younger than 17 years of age.

STUDY DESIGN: Retrospective examination of a series of adolescent patients under the age of 17 years who underwent surgery for lumbar intervertebral disc herniation.

PATIENT SAMPLE: The medical records of 26 patients (15 males, 11 females, 12-17 years old [average 14.6]) who were operated for lumbar intervertebral disc herniation in three spine centers between 1984 and 2002 were reviewed. These subjects represented the total number of patients meeting the criteria of adolescents undergoing discectomy for lumbar disc herniation in these institutions during the study period. All patients were located and contacted by an independent observer not involved in the care of these patients. Low back pain associated with leg pain was the main clinical symptom in 20 patients (77%), leg pain in 4 (15%), and back pain in 2 (8%). They all underwent posterior disc excision: 23 (88%) patients had one level discectomy, and 3 (12%) had simultaneous discectomy at two levels. The L4-L5 interspace was involved 19 times, and the L5-S1 interspace 10 times. Slipped vertebral apophysis was diagnosed in 4 patients (15%). Twelve of the 26 patients (46%) had a first-degree relative with a history of lumbar disc herniation.

OUTCOME MEASURES: Telephone interviews provided follow-up data for 26 patients. Results were classified as excellent, good, moderate, or poor according to current symptom status, the need for additional surgery, the Oswestry Disability Index, and back and leg pain scores.

RESULTS: The average time from surgery to follow-up was 8.9 years (range 3-21 years). At follow-up, the clinical results were excellent in 13 patients (50%), good in 4 (15%), moderate in 8 (31%), and poor in 1 (4%). Four subjects (15%) underwent a subsequent disc excision in the lumbar region, and one of them later underwent fusion.

CONCLUSIONS: Discectomy provides satisfactory clinical results in young patients with disc herniation. The rate of reintervention (15%) is comparable to that in adults, indicating that discectomy for young patients should be approached similarly to that in adults.

PMID: 16825042 [PubMed - indexed for MEDLINE]

Publication Types, MeSH Terms

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EXHIBIT 29

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PubMed

Abstract

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Wolters Kluwer

Spine (Phila Pa 1976). 2008 Jan 1;33(1):33-8. doi: 10.1097/BRS.0b013e31815e3a42.

The outcomes of lumbar microdiscectomy in a young, active population: correlation by herniation type and level.

Dewing CB[1], Provencher MT, Riffenburgh RH, Kerr S, Manos RE.

Author information

[1]Department of Orthopaedic Surgery, San Diego, CA 92134-1112, USA.

Abstract

STUDY DESIGN: Prospective longitudinal clinical study.

OBJECTIVE: The purpose of our article was to investigate the clinical outcomes with type and level of disc herniation in a young, active population undergoing lumbar microdiscectomy.

SUMMARY OF BACKGROUND DATA: There are few reported outcomes studies on the relationship between disc herniation level, type of disc herniation, and surgical outcomes of lumbar microdiscectomy in a young, active population.

METHODS: One hundred ninety-seven (197) consecutive single-level lumbar microdiscectomies performed by a single surgeon were prospectively followed over a 3-year period. All patients had failed a period of nonoperative care including physical therapy and/or transforaminal epidural steroid injections. One hundred eighty-three patients (139 males, 44 females) with a mean age of 27.0 years (range 19-46 years) were prospectively followed for a mean of 26 months (range, 12-38 months). Outcomes were assessed using Visual Analog Scale (VAS), Oswestry disability index, patient satisfaction, return to military duty, and need for additional surgery. The type of disc herniation (contained, extruded, or sequestered) and the lumbar level of herniation were also recorded.

RESULTS: At final follow-up, 84% (154 of 183) of patients had returned to unrestricted military duty; 16% (29) had been medically discharged. The mean decrease in VAS leg pain score was 4.7 points (from mean preoperative 7.2 to mean postoperative 2.5); 80% (146) reported a decrease of greater than 2 points. The mean Oswestry index improved from 53.6 before surgery to 21.2 at final follow-up. Overall, 85% (156) were satisfied with their surgery. Six patients had recurrent herniations (3%) with 4 of the 6 undergoing additional surgery. Patients with preoperative VAS scores consistent with a preponderance of radicular leg pain versus back pain demonstrated better surgical outcomes in all categories ($P < 0.001$) When classified by disc herniation type, sequestered discs at all levels demonstrated better Oswestry and VAS scores versus extruded or contained disc herniations. ($P < 0.001$) Disc herniations at the L5-S1 level had significantly greater improvements in both mean VAS leg and Oswestry outcome scores than disc herniations at the L4-L5 level. ($P < 0.001$) Preexisting restricted duty status at time of first surgical consultation was associated with poorer outcomes. Smokers had a significantly lower return to full active military duty (P = 0.037).

CONCLUSION: Microdiscectomy for symptomatic lumbar disc herniations in young, active patients with a preponderance of leg pain who have failed nonoperative treatment demonstrated a high success rate based on validated outcome measures, patient satisfaction, and return to active duty. Patients with disc herniations at the L5-S1 level had significantly better outcomes than did those at the L4-L5 level. Patients with sequestered or extruded lumbar disc herniations had significantly better outcomes than did those contained herniations. Patients with contained disc herniations, a predominance of back pain, on restricted duty and smoking should be counseled before surgery of the potential for less satisfaction, poorer outcomes scores, and decreased return to duty rates.

PMID: 18165746 [PubMed - indexed for MEDLINE]

Publication Types, MeSH Terms

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EXHIBIT 30

EXHIBIT 30

Eur Spine J (2014) 23:1021–1043
DOI 10.1007/s00586-013-3161-2

REVIEW ARTICLE

Minimally invasive surgery for lumbar disc herniation: a systematic review and meta-analysis

Steven J. Kamper · Raymond W. J. G. Ostelo · Sidney M. Rubinstein · Jorm M. Nellensteijn · Wilco C. Peul · Mark P. Arts · Maurits W. van Tulder

Received: 2 September 2013 / Revised: 28 December 2013 / Accepted: 29 December 2013 / Published online: 18 January 2014

Abstract
Purpose Assessing the benefits of surgical treatments for sciatica is critical for clinical and policy decision-making. To compare minimally invasive (MI) and conventional microdiscectomy (MD) for patients with sciatica due to lumbar disc herniation.
Methods A systematic review and meta-analysis of controlled clinical trials including patients with sciatica due to lumbar disc herniation. Conventional microdiscectomy was compared separately with: (1) Interlaminar MI discectomy (ILMI vs. MD); (2) Transforaminal MI discectomy (TFMI vs. MD). Outcomes: Back pain, leg pain, function, improvement, work status, operative time, blood loss, length of hospital stay, complications, reoperations, analgesics and cost outcomes were extracted and risk of bias assessed. Pooled effect estimates were calculated using random effect meta-analysis.
Results Twenty-nine studies, 16 RCTs and 13 non-randomised studies ($n = 4{,}472$), were included. Clinical outcomes were not different between the surgery types. There is low quality evidence that ILMI takes 11 min longer, results in 52 ml less blood loss and reduces mean length of hospital stay by 1.5 days. There were no differences in complications or reoperations. The main limitations were high risk of bias, low number of studies and small sample sizes comparing TF with MD.
Conclusions There is moderate to low quality evidence of no differences in clinical outcomes between MI surgery and conventional microdiscectomy for patients with sciatica due to lumbar disc herniation. Studies comparing transforaminal MI with conventional surgery with sufficient sample size and methodological robustness are lacking.

Keywords Lumbar disc · Herniation · Minimally invasive surgery · Sciatica · Systematic review

S. J. Kamper (✉) · R. W. J. G. Ostelo · M. W. van Tulder
Department of Epidemiology and Biostatistics,
VU University Medical Centre, The EMGO+ Institute
for Health and Care Research, Vander Boechorststraat 7,
1081 BT Amsterdam, The Netherlands
e-mail: skamper@george.org.au

S. J. Kamper
The George Institute for Global Health, University of Sydney,
Sydney, Australia

R. W. J. G. Ostelo · S. M. Rubinstein · M. W. van Tulder
Faculty of Earth and Life Sciences, VU University Amsterdam,
Amsterdam, The Netherlands

J. M. Nellensteijn
Department of Orthopedic Surgery, VUmc, Amsterdam,
The Netherlands

W. C. Peul
Department of Neurosurgery, LUMC, Leiden, The Netherlands

W. C. Peul · M. P. Arts
Department of Neurosurgery, Medical Centre Haaglanden,
The Hague, The Netherlands

Introduction

Sciatica due to lumbar disc herniation is responsible for considerable personal and societal costs. Although definitions vary, sciatica is generally defined as leg pain due to lumbosacral nerve-root compression or irritation [1]. Patients with disc-related sciatica may be managed conservatively or via surgery when conservative treatment fails or complaints worsen over time. The goal of surgical management is most commonly to remove disc material to decompress the nerve root. Advances in surgical technique and technology have seen an increase in minimally invasive (MI) techniques whereby access to the disc is gained via a tube, using a microscope or endoscope (camera) for visualisation. Currently available tubular retraction systems and endoscopic systems enable simultaneous visualisation and removal of disc material via one MI working portal. MI techniques are contrasted with open microdiscectomy, which requires a larger incision and hypothetically a greater degree of muscle trauma. On the other hand, safety of the MI approach has been questioned due to the small working channel and compromised visualisation. The minimal working space might make it difficult to avoid and control damage to dural and neural structures. Although many innovative disc treatment methods have been described, open microdiscectomy (MD) remains the usual standard of care for this patient group at the current time [2, 3].

There are several routes by which the surgeon performing MI surgery may access the disc or sequestered disc fragment. Those investigated by this review are the interlaminar route (ILMI) and the transforaminal route (TFMI). At present, it is unclear whether MI surgery is superior to usual operative care (MD) for patients with sciatica due to lumbar disc herniation. This question applies to both clinical effectiveness and cost-effectiveness. As such, a review of relevant studies is necessary to establish the current state of evidence.

This study aims to systematically review controlled clinical studies relevant to determining the clinical- and cost-effectiveness of minimally invasive surgery versus open microdiscectomy for lumbar disc herniation.

Methods

Published randomised and quasi-randomised controlled trials (RCTs) and non-randomised controlled studies were included if they enrolled patients with sciatica caused by herniated lumbar disc, and compared MI surgery with open microdiscectomy. Articles published in English, Dutch or German were included.

The following techniques were compared separately to microdiscectomy (MD):

- Interlaminar MI surgery (ILMI).
- Transforaminal MI surgery (TFMI).

In MD, access to the herniated disc involved a dorsal incision, followed by removal of the lamina. In ILMI, access via a small dorsal working channel was created by tubular retractors, followed by removal of the lamina to access the herniated disc. In TFMI, a lateral percutaneous technique was used to access the herniated disc through a small working channel that runs through the foramen. MD and ILMI require general anaesthetic, whereas TFMI can be performed under local anaesthesia.

Relevant studies were identified via a search of CENTRAL, MEDLINE and EMBASE databases (Appendix Table 2) from inception to January 2013. All identified titles were independently screened for inclusion by two authors, and full-text articles obtained where appropriate. Full-text articles were then independently screened by two authors; a surgeon was consulted where contention over inclusion involved the surgical intervention.

Risk of bias for all included RCTs was assessed using methods endorsed by the Cochrane Collaboration [4]. The risk of bias instrument categorises risk according to 12 criteria, as outlined in Appendix Table 4. Risk of bias was assessed for all RCTs by two authors and points of disagreement resolved by consensus. Non-randomised studies were not formally assessed for risk of bias but the overall quality of evidence was downgraded by one level for risk of bias for all estimates that included a non-randomised study.

Outcomes were extracted into a spreadsheet and pooled within the two comparisons (ILMI vs. MD; TFMI vs. MD) at three time points; short term (up to 3 months), medium term (>3 to <12 months), and long term (12 months or more). Outcomes included: clinical outcomes (back pain, leg pain, function, improvement, work status, satisfaction); perioperative outcomes (operative time, blood loss, length of stay, analgesic use, complications, reoperations); and costs (e.g. costs of interventions, health care utilisation, production losses).

Random effect models were used to calculate pooled estimates, standardised mean differences (SMD), mean differences or odds ratios (OR), and 95 % confidence intervals. Random effect models were selected to account for heterogeneity, as such analyses with a high I^2 were not disregarded. When standard deviations were not reported, if possible an estimate derived from studies within the same comparison was used. The GRADE [5] approach was used to categorise the quality of evidence for each outcome.

A subgroup analysis was conducted to assess the influence on the method of visualisation, i.e. microscope or camera, was conducted. This was performed by inspecting the between-group effect sizes for only those studies that used camera visualisation versus all studies. Further, subgroup analyses were planned to investigate the effectiveness of MI surgery on obese subjects and patients with far-lateral, as opposed to central, disc herniations. However, none of the included studies reported results in such a way to enable these subgroup analyses. Studies in the ILMI vs. MD comparison were coded for the use of a camera or a microscope to assess the influence of this on outcome.

Table 1 Included studies

Study	Study type	Sample size	Av. age	Av. pain duration: months	Inclusion	Outcomes
ILMI						
Arts [6]	RCT	328	41.5	5	MRI confirmed lumbar herniated disc and persistent sciatica, failed cons. Rx	Back pain, leg pain, improvement, Roland Morris, operative time, LOS, blood loss, complications, reoperations, Prolo scale, bothersomeness, SF36, cost
Brock [8]	RCT	125	51	–	First time lumbar discectomy, failed cons. Rx	Leg pain, back pain, oswestry, LOS, analgesics
Franke [9]	RCT	100	44	–	Lumbar disc herniation, Kramer dislocation grade 3-5	Back pain, leg pain, oswestry, RTW operative time, operative time, LOS, neurological
Garg [10]	RCT	112	38	14.2	Persistent radiculopathy, failed cons. Rx, positive SLR	Oswestry, operative time, blood loss, LOS, complications, reoperations
Huang [13]	RCT	22	39	–	Failed cons. Rx or acute intractable back and leg pain, not improved with bedrest	Leg pain, McNab, operative time, blood loss, LOS, complications, incision, blood analyses
Righesso [18]	RCT	40	44	2	MRI confirmed posterolateral disc herniation, persistent radicular pain, failed cons. Rx	Leg pain, oswestry, RTW, operative time, blood loss, LOS, complications, reoperations, incision, neurological status
Ryang [19]	RCT	60	38.7	–	Single-level herniated disc, unilateral radicular symptoms, failed cons. Rx	Pain, oswestry, operative time, LOS, blood loss, incision, SF36
Sasaoka [20]	RCT	26	37	–	Requiring surgery for lumbar disc herniation	Back pain, JOA, operative time, blood loss, blood analyses
Schick [21]	RCT	30	40	28	CT or MRI confirmed disc herniation, recurrent episodes of radiculopathy, failed cons. Rx	Muscle EMG
Shin [23]	RCT	30	45	–	CT or MRI confirmed single-level disc herniation, failed cons. Rx	Back pain, leg pain, operative time, blood loss, blood analyses
Teli [24]	RCT	240	39	3	Symptomatic single-level disc herniation, concordant neurological signs, failed cons. Rx	Back pain, leg pain, oswestry, operative time, complications, reoperations, incision, SF36, cost
Bennis [7]	Pros	83	42	–	MRI or CT confirmed single-level herniation, with persistent radicular symptoms, failed cons. Rx	Pain, operative time, blood loss, complications, LOS, morphine consumption
Martin-Laez [15]	Pros	138	45	5	MRI confirmed disc herniation, radiculopathy, failed cons. Rx	McNab, operative time, LOS, complications, reoperations
Schizas [22]	Pros	28	42	3	Uncontained or large contained disc lesions	Oswestry, operative time, LOS, complications, analgesics
Toyone [25]	Pros	40	–	17	MRI confirmed disc herniation, persistent or recurring leg pain, failed cons. Rx	Satisfaction
German [11]	Retro	172	43	–	First time, single-level lumbar discectomy	Operative time, blood loss, LOS, narcotic usage, physio referrals
Harrington [12]	Retro	66	42	–	Radicular pain due to herniated disc, failed cons. Rx, no prior lumbar surgery	Oswestry, operative time, blood loss, narcotic usage, LOS, complications
Lau [14]	Retro	45	43	–	Neurological deficit or pain, failed cons. Rx	Pain, operative time, blood loss, LOS, complications, neurological
Muramatsu [16]	Retro	40	32	–	Disc herniation and sciatica, resistant to cons. Rx	Operative time, blood loss, MRI findings
Nakagawa [17]	Retro	60	40	–	Painful sciatica refractory to cons. Rx	JOA, RTW, operative time, blood loss, analgesic use, complications, reoperations, blood analyses, days fever
Wu [26]	Retro	1231	42	5	MRI or CT confirmed prolapsed disc, clinical complaints consistent, failed cons. Rx	Back pain, leg pain, oswestry, McNab, RTW, operative time, blood loss, LOS, analgesic use, complications, reoperations

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Table 1 continued

Study	Study type	Sample size	Av. age	Av. pain duration: months	Inclusion	Outcomes
TFMI						
Hermantin [27]	RCT	60	40	>3	LBP and radicular symptoms, imaging confirmed disc herniation at L2-S1, failed cons. Rx	Back pain, improvement, RTW, satisfaction, narcotic usage, complications, reoperations
Krappel [29]	RCT	40	40	>1	MRI confirmed disc herniation, persistent radiculopathy, neurological deficit, failed cons. Rx	McNab, RTW, complications, reoperations, cost
Mayer [32]	RCT	40	41	6.9	Failed cons. Rx, small non-contained disc herniation	Back pain leg pain, disability, symptom score, RTW, operative time, reoperations
Kim [28]	Retro	902	41	11	Intractable radicular symptoms, failed cons. Rx, single-level disc herniation	McNab, operative time, blood loss, complications, reoperations, radiological
Lee [31]	Retro	60	39	>3	CT or MRI confirmed disc herniation, unilateral leg > back pain, failed cons. Rx	McNab, operative time, LOS, radiological
Lee [30]	Retro	54	45	–	Previous open lumbar microdiscectomy, recurrent radicular pain, MRI confirmed disc herniation at same level, failed cons. Rx	Back pain, leg pain, oswestry, operative time, LOS, complications, reoperations
ILMI + TFMI						
Ruetten [33]	RCT	200	43	3	Radicular pain and neurological deficits, >80 % had failed cons. Rx	Back pain, leg pain, oswestry, satisfaction, operative time, blood loss, complications, reoperations, NASS score (pain and neurology)
Ruetten [34]	RCT	100	39	2	Clinically symptomatic recurrent disc herniation after discectomy, MRI confirmed disc herniation, radicular pain and neurological deficits, 79 % had failed cons. Rx	Back pain, leg pain, oswestry, satisfaction, operative time, blood loss, complications, reoperations, NASS score (pain and neurology)

ILMI interlaminar minimally invasive surgery, *TFMI* transforaminal minimally invasive surgery, *Pros* prospective study design, *Retro* retrospective study design, *postop* within 2 weeks of surgery, *RTW* return to work, *cons. Rx* conservative treatment, *LOS* length of hospital stay, *JOA* Japanese Orthopedic Association outcome score

Results

The searches identified 4,138 titles (Appendix Figure 4); after screening and exclusion on the basis of title and abstract, the full-text of 141 articles was reviewed and a further 112 excluded (Appendix Table 3). Finally, 29 studies were included in the review (total $n = 4{,}472$): 16 were RCTs, four prospective cohorts and nine retrospective cohorts. A total of 21 studies [6–26] were included in the ILMI vs. MD comparison and six studies [27–32] in the TFMI vs. MD comparison. Two RCTs [33, 34] included both ILMI and TFMI in their index group and compared these patients to a MD group. The results from these two studies were assessed separately from the above.

Diagnosis usually involved a history of pain with a dermatomal distribution radiating down the leg that corresponded to MRI or CT confirmed nerve root compression by a herniated intervertebral disc. Most included patients had experienced a period of unsuccessful non-operative treatment. The mean age of the participants was approximately 40 years; average symptom duration prior to surgery ranged from approximately 1 month–2 years (Table 1). All RCTs except one had a high risk of bias, several used quasi-randomisation instead of true randomisation, allocation concealment was often uncertain, and blinding was uncommon (Appendix Table 4).

Due to the high risk of bias, the quality of evidence was graded down by one level for risk of bias for all pooled estimates. The quality of evidence was graded down by two levels for risk of bias for all analyses that included non-randomised studies. Evidence level was graded down one further level due to imprecision if the total number of participants was <400 [35].

Effects of interventions

Interlaminar minimally invasive surgery versus microdiscectomy (ILMI vs. MD)

Eleven RCTs [6, 8–10, 13, 18–21, 23, 24], four prospective studies [7, 15, 22, 25] and six retrospective studies [11, 12,

Study or Subgroup	ILMI Mean	ILMI SD	ILMI Total	MD Mean	MD SD	MD Total	Weight	Std. Mean Difference IV, Random, 95% CI
Arts 2009	20.1	22	167	15.6	23.3	161	34.8%	0.20 [-0.02, 0.42]
Brock 2008	0.9	1.4	66	1.4	1.4	59	20.9%	-0.35 [-0.71, -0.00]
Huang 2005	1.5	1.4	10	1.4	1.4	12	5.3%	0.07 [-0.77, 0.91]
Righesso 2007	1.5	1.4	21	1.2	1.4	19	9.0%	0.21 [-0.41, 0.83]
Shin 2008	2.5	1.6	15	2.4	2.1	15	7.0%	0.05 [-0.66, 0.77]
Teli 2010	1	1	70	1	1	72	22.9%	0.00 [-0.33, 0.33]
Total (95% CI)			**349**			**338**	**100.0%**	**0.02 [-0.18, 0.22]**

Heterogeneity: Tau² = 0.02; Chi² = 7.16, df = 5 (P = 0.21); I² = 30%
Test for overall effect: Z = 0.20 (P = 0.84)

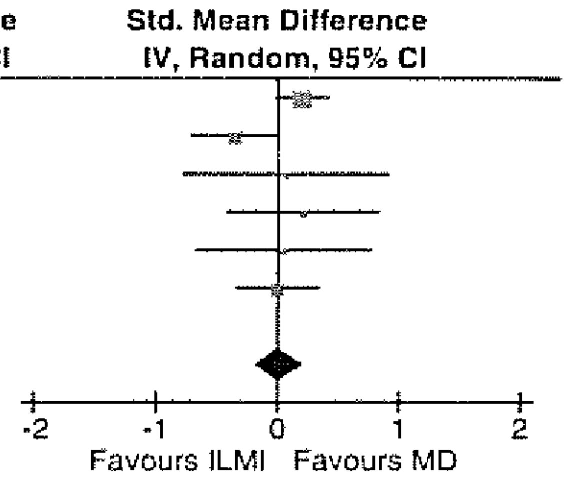

Fig. 1 Short-term leg pain: interlaminar minimally invasive versus microdiscectomy

Study or Subgroup	ILMI Mean	ILMI SD	ILMI Total	MD Mean	MD SD	MD Total	Weight	Std. Mean Difference IV, Random, 95% CI
2.19.1 RCTs								
Arts 2009	4.7	6.5	167	3.4	6.3	161	36.4%	0.20 [-0.01, 0.42]
Franke 2009 (Index)	9	15	27	15.5	15	23	7.9%	-0.43 [-0.99, 0.14]
Franke 2009 (Transfer)	11.6	15	25	11.6	15	25	8.1%	0.00 [-0.55, 0.55]
Garg 2011	1.75	15	55	2.14	15	57	16.5%	-0.03 [-0.40, 0.34]
Righesso 2007	10	15	21	8	15	19	6.6%	0.13 [-0.49, 0.75]
Teli 2010	14	4	70	13	4	72	19.9%	0.25 [-0.08, 0.58]
Subtotal (95% CI)			**365**			**357**	**95.5%**	**0.10 [-0.06, 0.26]**
Heterogeneity: Tau² = 0.00; Chi² = 5.53, df = 5 (P = 0.35); I² = 10%								
Test for overall effect: Z = 1.28 (P = 0.20)								
2.19.2 Non-randomized								
Schizas 2005	22.3	12	14	15	12	14	4.5%	0.59 [-0.17, 1.35]
Subtotal (95% CI)			**14**			**14**	**4.5%**	**0.59 [-0.17, 1.35]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.52 (P = 0.13)								
Total (95% CI)			**379**			**371**	**100.0%**	**0.12 [-0.04, 0.29]**

Heterogeneity: Tau² = 0.01; Chi² = 6.98, df = 6 (P = 0.32); I² = 14%
Test for overall effect: Z = 1.43 (P = 0.15)
Test for subgroup differences: Chi² = 1.51, df = 1 (P = 0.22), I² = 33.6%

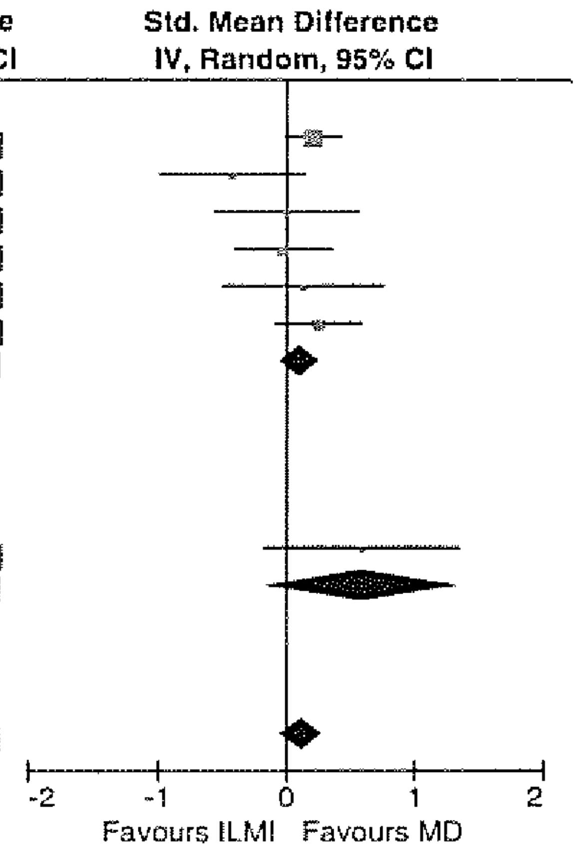

Fig. 2 Long-term function: interlaminar minimally invasive versus microdiscectomy

14, 16, 17, 26] were included in the ILMI vs. MD comparison (Appendix Table 5).

There is moderate quality evidence that ILMI is not superior to MD on clinical outcomes of back pain [6–8, 23, 24] (four RCTs, one non-randomised studies; $n = 640$) and leg pain [6, 8, 13, 18, 23, 24] (six RCTs; $n = 687$) (Fig. 1) and low quality evidence of no difference on composite pain (back and leg) [9, 19, 26] (two RCTs, one non-randomised study; $n = 1{,}391$) or patient satisfaction [25] (one non-randomised study; $n = 40$) at any time point. There is moderate quality evidence from six RCTs [6, 8–10, 24, 36] ($n = 847$) and two non-randomised studies [12, 26] that short-term function outcomes are better in the MD group. This difference is small (SMD 0.17, 95 % CI 0.0–0.34) and is not maintained at medium or long term (Fig. 2). There is low quality evidence from two RCTs [6, 13] ($n = 338$) that long-term general improvement is greater in the MD groups; the difference is not significant when two non-randomised studies are included (total $n = 1{,}985$). Although three studies ($n = 1{,}271$) report time to return to work [17, 18, 26], none report sufficient data to calculate a pooled estimate of the between-group difference.

There is moderate quality evidence from eight RCTs [6, 10, 13, 18–20, 23, 24] (total $n = 760$) that ILMI takes longer than MD (mean increase in minutes; 11.64, CI 5.04–18.23); the estimate was similar when eight non-randomised studies [7, 11, 12, 14–17, 26] are included (total $n = 2{,}595$). Mean operative time for the ILMI was 89.4 min and for MD; 64.9 min. There is moderate quality evidence from five RCTs [6, 10, 13, 18, 19] (total $n = 562$) that length of hospital stay is not different; however, when six non-randomised studies [7, 11, 14, 15, 22, 26] (total $n = 2{,}259$) are included there is low quality evidence that it is reduced in the ILMI group (number of days fewer; 1.49, CI 0.43–2.54). There is low quality evidence from six RCTs [10, 13, 18–20, 23] (total $n = 290$) that blood loss is not different, but when six non-randomised studies [11, 12, 14, 16, 17, 26] (total $n = 1{,}904$) are included there is low

Study or Subgroup	ILMI Events	ILMI Total	MD Events	MD Total	Weight	Odds Ratio M-H, Random, 95% CI
2.35.1 RCTs						
Arts 2009	19	167	14	161	19.6%	1.35 [0.65, 2.79]
Franke 2009 (Index)	2	52	3	48	3.1%	0.60 [0.10, 3.76]
Garg 2011	5	55	5	57	6.1%	1.04 [0.28, 3.81]
Huang 2005	1	10	1	12	1.2%	1.22 [0.07, 22.40]
Righesso 2007	2	21	0	19	1.1%	5.00 [0.23, 111.05]
Ryang 2008	2	30	6	30	3.6%	0.29 [0.05, 1.55]
Teli 2010	11	70	7	72	10.1%	1.73 [0.63, 4.76]
Subtotal (95% CI)		**405**		**399**	**44.9%**	**1.18 [0.73, 1.91]**
Total events	42		36			
Heterogeneity: Tau² = 0.00; Chi² = 4.78, df = 6 (P = 0.57); I² = 0%						
Test for overall effect: Z = 0.68 (P = 0.49)						
2.35.2 Non-randomized						
Bennis 2009	5	57	3	26	4.5%	0.74 [0.16, 3.35]
German 2008	4	49	6	123	6.0%	1.73 [0.47, 6.43]
Lau 2011	4	20	6	25	5.1%	0.79 [0.19, 3.31]
Martin-Laez 2012	3	37	10	101	5.7%	0.80 [0.21, 3.09]
Nakagawa 2003	2	30	0	30	1.1%	5.35 [0.25, 116.31]
Schizas 2005	2	14	0	14	1.1%	5.80 [0.25, 132.56]
Wu 2006	35	873	19	358	31.6%	0.75 [0.42, 1.32]
Subtotal (95% CI)		**1080**		**677**	**55.1%**	**0.90 [0.58, 1.38]**
Total events	55		44			
Heterogeneity: Tau² = 0.00; Chi² = 4.18, df = 6 (P = 0.65); I² = 0%						
Test for overall effect: Z = 0.50 (P = 0.62)						
Total (95% CI)		**1485**		**1076**	**100.0%**	**1.01 [0.74, 1.40]**
Total events	97		80			
Heterogeneity: Tau² = 0.00; Chi² = 9.65, df = 13 (P = 0.72); I² = 0%						
Test for overall effect: Z = 0.09 (P = 0.93)						
Test for subgroup differences: Chi² = 0.71, df = 1 (P = 0.40), I² = 0%						

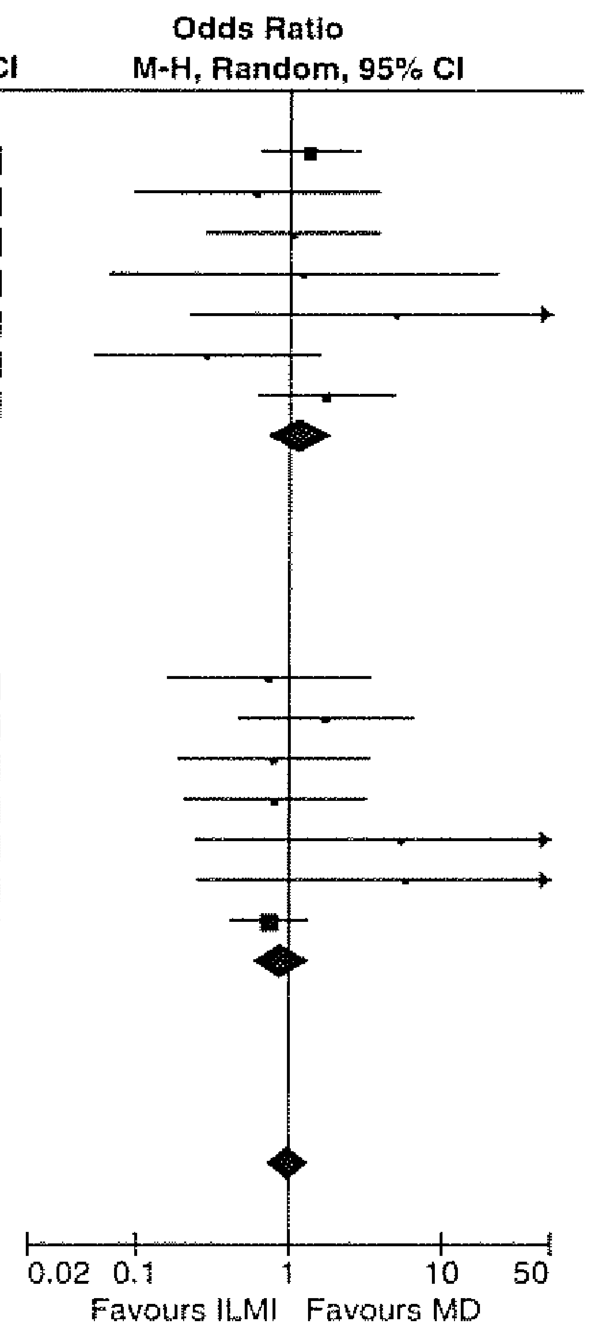

Fig. 3 Complication rates: interlaminar minimally invasive versus microdiscectomy

quality evidence that blood loss is less in the ILMI group (millilitres of blood loss less; 51.64, CI 22.34–80.94). There is low quality evidence (six RCTs; $n = 804$) that there is no difference in the rate of complications [6, 7, 9–11, 13–15, 17–19, 22, 26], the estimate being largely unaffected by the addition of seven non-randomised studies (total $n = 2{,}561$) (Fig. 3), and moderate quality evidence (six RCTs; $n = 782$) that there is no difference in rate of reoperation [6, 9, 10, 12, 15, 17–19, 24, 26], the estimate being largely unaffected by inclusion of four non-randomised studies (total $n = 2{,}277$). There is low quality evidence from three non-randomised studies [7, 11, 12] (total $n = 321$) that ILMI results in reduced postoperative morphine requirement and four [8, 17, 22, 26] further studies ($n = 1{,}445$) also reported data suggesting reduced analgesic usage in the ILMI group, but these could not be pooled.

Two RCTs reported data regarding costs. One high quality RCT [6, 37] ($n = 328$) reported quality-adjusted life-years, and costs of the treatments from a societal perspective. They found non-significant differences on both measures. Per-patient intervention costs for the two groups were US$5,529 for ILMI and US$5,070 for MD and total societal costs were; US$16,858 and US$15,367, respectively. One RCT [24] ($n = 142$) reported that ILMI is more expensive than MD (mean difference; US$728), but did not conduct a cost-effectiveness analysis. The costs[a] were limited to direct medical costs; surgical instrumentation, operating theatre, inpatient costs and reoperations. The average costs were US$3,913 for ILMI and US$3,185 for MD.

[a]Costs were converted from Euros using the formula: 1 € = 1.3 US$, the approximate conversion rate at the time of publication (2010). http://www.x-rates.com/average/?from=EUR&to=USD&amount=1&year=2010 .

A subgroup analysis was conducted to assess whether the method of visualisation (camera or microscope) influenced the findings. Excluding studies that used a microscope for visualisation had only a small impact on the results; in most cases, point estimates were very similar but, as would be expected, confidence intervals wider. The overall conclusions of the comparison between ILMI discectomy and conventional discectomy are not substantially influenced by the method of visualisation.

Transforaminal minimally invasive surgery versus microdiscectomy (TFMI vs. MD)

Three RCTs [27, 29, 32] and three retrospective studies [28, 30, 31] were included in the TFMI vs. MD comparison (Appendix Table 6).

There is low quality evidence that TFMI is not superior to MD for back pain [27, 30, 32] (three RCTs, one non randomised; $n = 154$), leg pain [30, 32] (one RCTs, one non randomised; $n = 100$) or patient satisfaction [27] (one RCT; $n = 60$) and very low quality evidence that there is no difference in function or general improvement [27–29, 31, 32] (three RCTs, three non-randomised; $n = 1,169$) at any time point. There is low quality evidence from two RCTs ($n = 80$) that there is no difference in the proportion of people who return to work [29, 32], one further RCT [27] ($n = 60$) measured return to work in days but does not report sufficient detail to estimate the between-group difference.

There is low quality evidence from two RCTs and three non-randomised studies ($n = 1,109$) that operative time [28–32] is not different; mean operative time was 55.2 min for TFMI and 60.3 min for MD. Very low quality evidence suggests that there is no difference in length of hospital stay [29–31] (one RCT, two non-randomised; $n = 154$) or rate of complications [27–30] (two RCTs, two non-randomised; $n = 1,056$). There is low quality evidence from three RCTs [27, 29, 32] (total $n = 160$) of no difference in reoperation rate, but low quality evidence that TFMI results in more reoperations when two non-randomised, retrospective studies [28, 30] (total $n = 1,129$) are included (OR; 1.69, CI 1.06–2.71).

One RCT [29] ($n = 40$) reported that TFMI is more expensive than MD. The costs included in this comparison were a per-minute calculation of operation theatre costs, per-day calculation for hospital in-patient stay, cost of equipment sterilisation and the cost of two endoscopes per operation. The total costs[b] were US$7,707 for TF and US$1,417 for MD. It is noted that most of the difference is accounted for by the cost of two endoscopes (US$3,422) and further that technological advances since the publication of this study limit the generalizability of these results to the current situation.

[b]Costs were converted from Deutschmarks using the formula: 1 Deutschmark = 0.5 US$, the approximate conversion rate at the time of publication (2001) (http://www.history.ucsb.edu/faculty/marcuse/projects/currency.htm).

Mixed RCTs

Two RCTs [33, 34] ($n = 200$ and $n = 100$) allocated patients either to MI surgery (interlaminar or transforaminal approach) or to MD (Appendix Table 7). In the MI arm, IL approach was generally used for herniations inside the spinal canal and TF for intra- and extra-foraminal herniations, although the final decision was at the discretion of the surgeon. One study included patients with first time disc herniations [33], the other only patients with recurrent disc herniations who previously had discectomy surgery [34] at the same level. These studies were both judged to have a high risk of bias (Appendix Table 4). As such all pooled analyses provide low quality evidence.

There is low quality evidence that the effects of minimally invasive surgery (IL or TF) for patients with first time [33] and recurrent disc herniations [34] are not different to MD on back pain, leg pain or function at any time point. There is low quality evidence that more patients are satisfied with MI (OR: 2.26, CI 1.23–4.15) and low quality evidence that the pooled Oswestry score is lower (better function) at one year follow-up in the MI group (SMD: −0.29, CI −0.51 to −0.06). It is noted that this latter difference is not significant in either individual study or at any of the other time-points.

There is low quality evidence that operative time (mean decrease in minutes; 27.33, CI 40.06–14.59) was reduced compared to MD. Mean MI surgery time was 23 min and MD 50.5 min. There is low quality evidence that complications (OR; 0.23, CI 0.09−0.58) are reduced compared to MD and low quality evidence that rate of reoperation is not different.

Discussion

There is moderate to low quality evidence of no differences in clinical outcomes between MI surgery, using either the interlaminar or the transforaminal approach, and conventional microdiscectomy. This finding relates to the key outcomes of back pain, leg pain, function and general improvement and is not affected by length of follow-up or inclusion of non-randomised studies. The few significant differences found were too small to be of clinical relevance and not maintained over time. While studies reported data related to return to work rates, the heterogeneity with which this outcome was measured made synthesis problematic. As such it is not possible to provide a conclusion regarding the relative effectiveness on return to work. With regard to perioperative outcomes, there was also low to moderate evidence of no difference between MI and MD for most outcomes; this is particularly notable for complication and reoperation rates. Two RCTs [6, 24, 37] assessed the costs of ILMI vs. MD: one was a high quality study and conducted a full cost-effectiveness analysis. They reported no significant difference on quality-adjusted life-years or total costs from a societal perspective.

The results regarding operative times are difficult to interpret; while there was moderate quality evidence that ILMI surgery takes 10−15 min longer than MD, there is considerable heterogeneity amongst operative times in the included studies. This may be explained by the learning curve associated with MI surgery [38], variability in the techniques used and differences in how operative time was defined, for example whether or not total time under anaesthesia was measured. Similarly, there was low quality evidence of a difference of 1.5 days in mean length of hospital stay in favour of ILMI, but times were quite variable between the included studies. It is not clear what the source of this variability was.

A review of TFMI surgery compared to MD was recently published [39] and reports on findings from four studies also included in this review. The review does not provide a formal evidence synthesis but it concludes strongly in favour of transforaminal surgery. On the basis of our more comprehensive review process, we contend that the available evidence suggests no real difference with respect to clinical outcomes. Part of this review (TFMI vs. MD) updates that conducted by Nellensteijn et al. [36]; since then one relevant RCT and one controlled retrospective study have been published. The conclusion that there is no difference in clinical outcomes between the surgical types remains the same. A review by Jacobs et al. [40] includes many of the same studies included in this review and concluded that it was not possible to estimate the difference in clinical outcomes between the surgery types.

Assigning an acceptable definition for minimally invasive surgery in such a dynamic field is challenging. The interventions investigated in this review involve use of a tubular system to retract tissues overlying the disc and to provide a working portal. It is recognised that other procedures are sometimes designated as minimally invasive surgery, including automated percutaneous discectomy [41], nucleoplasty [42], chemonucleolysis [43] and laser disc decompression [44]. The decision to adopt the above definition to focus the scope of the review was made to ensure sufficient homogeneity to draw clinically applicable conclusions.

The strengths of this review include the sensitive search strategy and the use of best-practice systematic review methodology as endorsed by the Cochrane Collaboration [45]. This includes a protocol established prior to commencement of the review, independent screening of identified studies for eligibility, risk of bias assessment and explicit report of decisions. Evidence was synthesised and assessed using a standardised method which takes into account risk of bias and sample size when assessing the quality of the evidence. The review is up-to-date, and provides a synthesis of both randomised and non-randomised studies, with appropriate treatment of the increased risk of bias associated with the latter study type.

There are several limitations associated with the findings of this review, particularly with respect to the number and size of RCTs included in the TFMI vs. MD comparison. Lack of power is a problem common to most of the included RCTs, and even the pooled analyses in the TFMI vs. MD comparison often included only small total samples. It is conceivable that the lack of difference observed between TFMI and MD in studies conducted to date is a Type II error due to insufficient power. An RCT, with robust methodology and adequate sample size, comparing transforaminal surgery to conventional microdiscectomy, is yet to be conducted. Such a study should pay appropriate attention to clinical concerns, such as indications for surgery, location of the disc fragment, surgical complications, muscle damage, operative time, standardised measurement of patient-relevant outcomes, and methodological features such as; sample size, concealed allocation, random allocation and blinding where possible. As MI methods might hypothetically lead to a shorter hospital stay and earlier return to work, a comprehensive cost-effectiveness study including a societal perspective should be conducted alongside the RCT.

With respect to the ILMI vs. MD comparison, the number of included studies ensured satisfactory power for many of the analyses. This comparison also contains one well-powered, low risk of bias RCT [6]; the results of the pooled analyses are very similar to those found in this study. This increases confidence in the conclusion that there is no substantial difference in terms of clinical outcomes between ILMI and MD.

Conclusions

There is evidence from a substantial number of comparative studies that suggest that clinical outcomes are not different between interlaminar minimally invasive discectomy and conventional microdicectomy. The available evidence also points towards no difference on perioperative and cost outcomes, although in some cases it is less compelling. Conclusions regarding the differences in effect between transforaminal discectomy and conventional microdiscectomy are difficult to draw due to the lack of high quality studies. While available evidence also suggests that outcomes are comparable, well-designed research of sufficient power could change estimates of effect.

Conflict of interest Part of this study was funded by the Dutch College for Health Insurance (CVZ). RO has received research funding from AO Spine, Netherlands Organisation for Health Care Research (ZonMW), Netherlands Scientific College for Physiotherapy, WP has received research funding from ZonMW, Medtronic, Braun, Pardigm Spine, MvT has received research funding from ZonMW

Appendix

See Tables 2 3 4 5 6, 7 and Fig. 4.

Table 2 MEDLINE search strategy

(Spinal diseases.af OR Intervertebral disk displacement.af OR Spinal osteophytosis.af OR Spinal stenosis.af OR Spondylarthritis.af OR Spondylitis.af OR Spondylolisthesis.af OR "Spinal Osteophytosis".af OR Back pain.af OR sciatica.af OR radiculopathy.af OR "Spinal Cord Compression".af OR back.af OR spine.af OR ((stenosis.ti,ab OR osteophytosis.ti,ab.) AND (spine.ti,ab OR spinal.ti,ab OR vertebr*.ti,ab)) OR discopath*.ti,ab OR diskopath*.ti,ab OR disk displacement.ti,ab OR disc displacement.ti,ab OR spondylarthritis.ti,ab OR spondylitis.ti,ab OR spondylolisthesis.ti,ab OR sciatica.ti,ab OR back pain.ti,ab.)
AND
("Endoscopy".af. or "Arthroscopy". af. or "Video-Assisted Surgery". af. or "Surgical Procedures, Minimally Invasive". af. or "Microsurgery". af. or "Diskectomy, Percutaneous". af. or endoscop*.ti,ab. or microendoscop*.ti,ab. or microsurgery.ti,ab. or microsurgical.ti,ab. or arthroscop*.ti,ab. or Foraminotom*.ti,ab. or foraminoplast*.ti,ab. or minimally invasive surgery.ti,ab. or video assisted surgery.ti,ab. or discoscop*.ti,ab. or Percutaneous transforminal endoscopic discectomy. af. or Percutaneous transforminal endoscopic discectomy.ti,ab. or Surgical procedures. af. or Surgical procedures.ti,ab. or Discectomy Spinal cord compression. af. or Discectomy Spinal cord compression.ti,ab. or Discectomy Spinal cord decompression. af. or Discectomy Spinal cord decompression.ti,ab. or Percutaneous Sciatica. af. or Percutaneous Sciatica.ti,ab.)
AND
(randomized controlled trial.pt. OR controlled clinical trial.pt. OR randomized.ab. OR placebo.ab. OR randomly.ab. OR trial.ab. OR groups.ab.)

Table 3 Excluded studies

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Table 3 continued

Surgery type
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Ongoing studies

1. Arthur C, Gibson JNA. Long-term functional outcomes following trans-foraminal endoscopic surgery RCT data to two years. European Spine Journal. 2013;22(Suppl 1):S57. Full paper estimated 2015
2. ClinicalTrials.gov identifier: NCT01622413. Furstenberg CH. Trial to Show Non-inferiority/Superiority of an Endoscopic Transforaminal Discectomy to Standard Microdiscectomy (TESCORT). Status; Not yet recruiting (planned 4 year follow-up)
3. ClinicalTrials.gov identifier: NCT00927056. Johnson M. Evaluation of Minimally Invasive Microdiscectomy Versus Conventional Open Microdiscectomy For Lumbar Herniated Disc. Status; enrolling by invitation

Table 4 Risk of bias assessments

Study	1. Randomisation	2. Concealed allocation	3. Patient blinding	4. Surgeon blinding	5. Assessor blinding	6. Dropouts	7. ITT	8. Selective reporting	9. Baseline	10. Co-interventions	11. Compliance	12. Outcome timing
ILMI												
Arts [6]	Low	Low	Low	High	Low	Low	Low	Unclear	Low	Unclear	Low	Low
Brock [8]	High	High	Low	High	Low	Unclear	Unclear	Unclear	High	Unclear	Low	Unclear
Franke [9]	Unclear	Unclear	Unclear	High	Unclear	Unclear	Unclear	Unclear	Low	Unclear	Low	Low
Garg [10]	Unclear	Unclear	Unclear	High	Unclear	Unclear	Unclear	Unclear	Low	Unclear	Low	Low
Huang [13]	Unclear	Unclear	High	High	High	Unclear	Unclear	Unclear	Unclear	Low	Low	High
Righesso [18]	Unclear	Unclear	High	High	High	Unclear	Unclear	Unclear	Low	Unclear	Low	Low
Ryang [19]	Unclear	Unclear	High	High	High	Unclear	Unclear	Unclear	Low	Unclear	Low	High
Sasaoka [20]	Unclear	Unclear	Unclear	High	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Low	Low
Schick [21]	High	High	Unclear	High	High	Unclear	Unclear	Unclear	Unclear	Low	Low	Low
Shin [23]	Low	High	High	High	High	Unclear	Unclear	Unclear	Unclear	Unclear	Low	Low
Teli [24]	Unclear	Unclear	High	High	High	Low	High	Unclear	Low	Low	Low	Low
Bennis [7]	–	–	–	–	–	–	–	–	–	–	–	–
Martin-Laez [15]	–	–	–	–	–	–	–	–	–	–	–	–
Schizas [22]	–	–	–	–	–	–	–	–	–	–	–	–
Toyone [25]	–	–	–	–	–	–	–	–	–	–	–	–
German [11]	–	–	–	–	–	–	–	–	–	–	–	–
Harrington [12]	–	–	–	–	–	–	–	–	–	–	–	–
Lau [14]	–	–	–	–	–	–	–	–	–	–	–	–
Muramatsu [16]	–	–	–	–	–	–	–	–	–	–	–	–
Nakagawa [17]	–	–	–	–	–	–	–	–	–	–	–	–
Wu [26]	–	–	–	–	–	–	–	–	–	–	–	–
TFMI												
Hermantin [27]	Low	Unclear	High	High	High	Low	Low	Unclear	Low	Unclear	Low	Low
Krappel [29]	High	High	High	High	High	High	High	Low	Unclear	Unclear	Low	High
Mayer [32]	Unclear	Unclear	High	High	High	Low	Unclear	Unclear	Low	Unclear	Low	Low
Kim [28]	–	–	–	–	–	–	–	–	–	–	–	–
Lee [31]	–	–	–	–	–	–	–	–	–	–	–	–
Lee [30]	–	–	–	–	–	–	–	–	–	–	–	–
ILMI + TFMI												
Ruetten [33]	High	High	High	High	High	Low	Unclear	Unclear	Low	Unclear	Low	Low
Ruetten [34]	High	High	High	High	High	Low	Unclear	Unclear	Low	Unclear	Low	Low

Low low risk of bias, *High* high risk of bias, *Unclear* unclear risk of bias, – risk of bias not assessed (non-randomised study)

Table 5 ILMI vs. MD GRADE evidence summary

Quality assessment							No. of patients		Effect (95 % CI)	Quality
No. of studies	Design	RoB	Inconsistency	Indirectness	Imprecision	Other	ILMI	Control		
Back pain short term (follow-up 1 week; measured with: VAS; better indicated by lower values)										
4	RCT	Serious[1]	No Serious inconsistency	No Serious indirectness	No Serious imprecision	None	318	307	SMD 0.28 (−0.79 to 0.23)	⊕⊕⊕O MODERATE
5	Mixed	Very serious[3]	No serious inconsistency	No serious indirectness	No serious imprecision	None	307	333	SMD 0.18 (−0.55 to 0.19)	⊕⊕OO LOW
Back pain medium term (follow-up 6 months; measured with: VAS; better indicated by lower values)										
2	RCT	Serious[1]	No serious inconsistency	No serious indirectness	No serious imprecision	None	237	233	SMD 0.11 (−0.08 to 0.29)	⊕⊕⊕O MODERATE
Back pain long term (follow-up 12 months; measured with: VAS; better indicated by lower values)										
2	RCT	Serious[1]	No serious inconsistency	No serious indirectness	No serious imprecision	None	237	233	SMD 0.14 (−0.04 to 0.33)	⊕⊕⊕O MODERATE
Back pain long term (follow-up 24 months; assessed with: proportion with ongoing pain)										
1 [13]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	70	72	SMD 0 (−0.33 to 0.33)	⊕⊕OO LOW
Leg pain short term (follow-up 4 weeks; measured with: VAS; better indicated by lower values)										
6	RCT	Serious[1]	No serious inconsistency	No serious indirectness	No serious imprecision	None	349	338	SMD 0.02 (−0.18 to 0.22)	⊕⊕⊕O MODERATE
Leg pain medium term (follow-up 6 months; measured with: VAS; better indicated by lower values)										
3	RCT	Serious[1]	No serious inconsistency	No serious indirectness	No serious imprecision	None	258	252	SMD 0.05 (−0.12 to 0.23)	⊕⊕⊕O MODERATE
Leg pain long term (follow-up 12 months; measured with: VAS; better indicated by lower values)										
3	RCT	Serious[1]	No serious inconsistency	No serious indirectness	No serious imprecision	None	258	252	SMD 0.12 (−0.05 to 0.29)	⊕⊕⊕O MODERATE
Leg pain long term (follow-up 24 months; measured with: VAS; better indicated by lower values)										
3	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	91	91	SMD 0.45 (−0.51 to 1.4)	⊕⊕OO LOW
Back/leg pain short term (follow-up 1 week; measured with: VAS; better indicated by lower values)										
2	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	52	48	SMD −0.12 (−1.65 to 1.41)	⊕⊕OO LOW
3	Mixed	Very serious[3]	No serious inconsistency	No serious indirectness	No serious imprecision	None	925	406	SMD −0.13 (−0.78 to 0.53)	⊕⊕OO LOW
Back/leg pain medium term (follow-up 6 months; measured with: VAS; better indicated by lower values)										
2	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	52	48	SMD −0.49 (−1.69 to 0.72)	⊕⊕OO LOW
Back/leg pain long term (follow-up 12 months; measured with: VAS; better indicated by lower values)										
3	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	82	78	SMD −0.09 (−0.40 to 0.22)	⊕⊕OO LOW

Table 5 continued

Quality assessment							No. of patients		Effect (95 % CI)	Quality
No. of studies	Design	RoB	Inconsistency	Indirectness	Imprecision	Other	ILMI	Control		
Function short term (follow-up 3 months; measured with: VAS; better indicated by lower values)										
7	RCT	Serious[1]	No serious inconsistency	No serious indirectness	No serious imprecision	None	431	416	SMD 0.17 (0.0–0.34)	⊕⊕⊕O MODERATE
9	Mixed	Very serious[3]	No serious inconsistency	No serious indirectness	No serious imprecision	None	1,335	809	SMD 0.15 (0.04–0.26)	⊕⊕OO LOW
Function pain medium term (follow-up 6 months; measured with: VAS; better indicated by lower values)										
6	RCT	Serious[1]	No serious inconsistency	No serious indirectness	No serious imprecision	None	365	357	SMD 0.07 (−0.07 to 0.22)	⊕⊕⊕O MODERATE
Function long term (follow-up 12 months; measured with: VAS; better indicated by lower values)										
6	RCT	Serious[1]	No serious inconsistency	No serious indirectness	No serious imprecision	None	365	357	SMD 0.10 (−0.06 to 0.26)	⊕⊕⊕O MODERATE
7	Mixed	Very serious[3]	No serious inconsistency	No serious indirectness	No serious imprecision	None	379	371	SMD 0.12 (−0.04 to 0.29)	⊕⊕OO LOW
Function pain long term (follow-up 24 months; assessed with: proportion with ongoing pain)										
2	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	91	91	SMD −0.28 (−0.57 to 0.02)	⊕⊕OO LOW
General improvement pain medium term (follow-up 6 months; assessed with: proportion improved)										
1	RCT	No serious risk	No serious inconsistency	No serious indirectness	Serious[2]	None	112/167 (67.1 %)	124/161 (77 %)	OR 0.61 (0.37–0.99)	⊕⊕⊕O MODERATE
General improvement long term (follow-up 12 months; assessed with: proportion improved)										
2	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	121/172 (70.3 %)	133/166 (80.1 %)	OR 0.59 (0.36–0.98)	⊕⊕OO LOW
4	Mixed	Very serious[3]	No serious inconsistency	No serious indirectness	No serious imprecision	None	918/1030 (89.1 %)	520/617 (84.6 %)	OR 1.24 (0.57–2.7)	⊕⊕OO LOW
Return to work (assessed with: proportion returned to work)										
1	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	21	19	Not estimable	–
3	Mixed	Very serious[3]	No serious inconsistency	No serious indirectness	No serious imprecision	None	872	399	Not estimable	–
Satisfaction with surgery (assessed with: proportion satisfied)										
1	Mixed	Very serious[3]	No serious inconsistency	No serious indirectness	Serious[2]	None	16/20 (80 %)	19/20 (95 %)	OR 0.21 (0.02–2.08)	⊕OOO VERY LOW
Operative time (measured with: minutes)										
8	RCT	Serious[1]	No serious inconsistency	No serious indirectness	No serious imprecision	None	383	377	SMD 11.64 (5.04–18.23)	⊕⊕⊕O MODERATE
16	Mixed	Very serious[3]	No serious inconsistency	No serious indirectness	No serious imprecision	None	1,495	1100	SMD 10.63 (4.01–17.24)	⊕⊕OO LOW

Table 5 continued

Quality assessment							No. of patients		Effect (95 % CI)	Quality
No. of studies	Design	RoB	Inconsistency	Indirectness	Imprecision	Other	ILMI	Control		
Length of hospital stay (measured with: days)										
5	RCT	Serious[1]	No serious inconsistency	No serious indirectness	No serious imprecision	None	285	277	SMD −2.38 (−6.32 to 1.57)	⊕⊕⊕O MODERATE
11	Mixed	Very serious[3]	No serious inconsistency	No serious indirectness	No serious imprecision	None	1335	924	SMD −1.49 (−2.54 to −0.43)	⊕⊕OO LOW
Blood loss (measured with: millilitres)										
6	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	146	144	SMD −69.55 (−150.94 to 11.84)	⊕⊕OO LOW
12	Mixed	Very serious[3]	No serious inconsistency	No serious indirectness	No serious imprecision	None	1164	740	SMD −51.64 (−80.94 to −22.34)	⊕⊕OO LOW
Complications (assessed with: number of complications)										
6	RCT	Serious[1]	No serious inconsistency	Serious	No serious imprecision	None	42/405 (10.4 %)	36/399 (9 %)	OR 1.18 (0.73–1.91)	⊕⊕OO LOW
13	Mixed	Very serious[3]	No serious inconsistency	Serious	No serious imprecision	None	19/1485 (6.5 %)	80/1076 (7.4 %)	OR 1.01 (0.74–1.4)	⊕⊕OO LOW
Reoperations (assessed with: number of reoperations)										
6	RCT	Serious[1]	No serious inconsistency	No serious indirectness	No serious imprecision	None	31/395 (7.8 %)	24/387 (6.2 %)	OR 1.24 (0.65–2.38)	⊕⊕⊕O MODERATE
10	Mixed	Very serious[3]	No serious inconsistency	No serious indirectness	No serious imprecision	None	52/1366 (3.8 %)	34/911 (3.7 %)	OR 1.25 (0.57–2.73)	⊕⊕OO LOW
Analgesic use (measured with: milligrams of morphine)										
3	Non-randomised	Very serious[3]	No serious inconsistency	No serious indirectness	Serious[2]	None	137	184	−2.83 (−5.6 to −0.06)	⊕OOO VERY LOW

[1] Unclear allocation concealment, possible selective reporting, no blinding

[2] Small total sample size

[3] Non-randomised study included

[4] Unclear which complications were recorded

[5] Types of medication not specified

[6] Potentially different complications reported

Table 6 TFMI vs. MD GRADE evidence summary

Quality assessment							No. of patients		Effect (95 % CI)	Quality
No. of studies	Design	RoB	Inconsistency	Indirectness	Imprecision	Other	TFMI	Control		
Back pain short term (follow-up 1 week; measured with: VAS; better indicated by lower values)										
1 [8]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	30	30	SMD −0.28 (−0.79 to 0.23)	⊕⊕OO LOW
2 [8, 11]	Mixed	Very serious[3]	No serious inconsistency	No serious indirectness	Serious[2]	None	55	59	SMD −0.18 (−0.55 to 0.19)	⊕OOO VERY LOW
Back pain long term (follow-up 24 months; assessed with: proportion with ongoing pain)										
1 [1, 3]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	10/20 (50 %)	15/20 (75 %)	OR 0.33 (0.09–1.27)	⊕⊕OO LOW
Leg pain short term (follow-up 1 weeks; measured with: VAS; better indicated by lower values)										
1 [11]	Non-randomised	Very serious[3]	No serious inconsistency	No serious indirectness	Serious[2]	None	25	29	SMD −0.21 (−0.72 to 0.30)	⊕OOO VERY LOW
Leg pain long term follow-up 24 months; assessed with: proportion with ongoing pain)										
1 [13]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	4/20 (20 %)	7/20 (35 %)	OR 0.46 (0.11–1.94)	⊕ ⊕ OO LOW
Function short term (follow-up 3 months; measured with: days of disability/oswestry; better indicated by lower values)										
1 [13]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	20	20	Not estimable	⊕⊕OO LOW
1 [11]	Non-randomised	Very serious[3]	No serious inconsistency	No serious indirectness	Serious[2]	None	25	29	SMD 0.16 (−0.38 to 0.69)	⊕OOO VERY LOW
General improvement long term (follow-up 24-36 months; assessed with: proportion improved)										
3 [8, 10, 13]	RCT	Serious[1]	No serious inconsistency	Serious[4]	Serious[2]	None	65/70 (92.9 %)	58/70 (82.9 %)	OR 2.64 (0.84–8.33)	⊕OOO VERY LOW
5 [8–10, 12, 13]	Mixed	Very serious[3]	No serious inconsistency	Serious[4]	No serious imprecision	None	320/401 (79.8 %)	608/714 (85.2 %)	OR 1.40 (0.49–4.0)	⊕OOO VERY LOW
Return to work (assessed with: proportion returned to work)										
2 [10, 13]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	38/40 (95 %)	32/40 (80 %)	OR 3.82 (0.4–36.7)[4]	⊕⊕OO LOW
Satisfaction with surgery (assessed with: proportion satisfied)										
1 [8]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	22/30 (73.3 %)	20/30 (66.7 %)	OR 1.38 (0.45–4.17)	⊕⊕OO LOW
Operative time (measured with: minutes)										
2 [10, 13]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	40	40	MD 13.26 (−47.01 to 73.53)	⊕⊕OO LOW
5 [9–13]	Mixed	Very serious[3]	No serious inconsistency	No serious indirectness	No serious imprecision	None	396	713	MD −7.03 (−29.49 to 15.43)	⊕⊕OO LOW

Table 6 continued

Quality assessment							No. of patients		Effect (95 % CI)	Quality
No. of studies	Design	RoB	Inconsistency	Indirectness	Imprecision	Other	TFMI	Control		
Length of stay (measured with: days)										
3 [10–12]	Mixed	Very serious[3]	No serious inconsistency	No serious indirectness	Serious[2]	None	75	79	MD −1.31 (−3.8 to 1.17)	⊕OOO VERY LOW
Complications (assessed with: number of complications)										
2 [8, 10]	RCT	Serious[1]	No serious inconsistency	Serious[6]	Serious[2]	None	0/50 (0 %)	1/50 (2 %)	OR 0.32 (0.01–8.24)	⊕OOO VERY LOW
4 [8–11]	Mixed	Very serious[3]	No serious inconsistency	Serious[6]	No serious imprecision	None	10/376 (2.7 %)	16/693 (2.3 %)	OR 1.19 (0.54–2.63)	⊕OOO VERY LOW
Reoperations (assessed with: number of reoperations)										
3 [8, 10, 13]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	6/80 (6.3 %)	1/80 (1.3 %)	OR 3.17 (0.62–16.26)	⊕⊕OO LOW
5 [8–11, 13]	Mixed	Very serious[3]	No serious inconsistency	No serious indirectness	No serious imprecision	None	36/406 (8.9 %)	41/723 (5.7 %)	OR 1.69 (1.06–2.71)	⊕⊕OO LOW
Analgesic use (measured with: days of narcotic use)										
1 [8]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	30	30	Not estimable	⊕⊕OO LOW

1 Unclear allocation concealment, possible selective reporting, no blinding

2 Small total sample size

3 Non-randomised study included

4 Different measures used

5 Data from Krappel 2001 adjusted to enable pooling, 19 out of 20 subjects substituted for 20 out of 20 in both groups

6 Potentially different complications reported

Table 7 ILMI + TFMI vs. MD GRADE evidence summary

Quality assessment							No. of patients		Effect (95 % CI)	Quality
No. of studies	Design	RoB	Inconsistency	Indirectness	Imprecision	Other	ILMI + TFMI	Control		
Back pain short term (follow-up 3 months; measured with: VAS; better indicated by lower values)										
2 [35, 36]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	150	150	SMD −0.12 (−0.35 to 0.11)	⊕⊕OO LOW
Back pain medium term (follow-up 6 months; measured with: VAS; better indicated by lower values)										
2 [35, 36]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	150	150	SMD −0.16 (−0.39 to 0.07)	⊕⊕OO LOW
Back pain long-term 1 year (follow-up 12 months; measured with: VAS; better indicated by lower values)										
2 [35, 36]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	150	150	SMD −0.04 (−0.27 to 0.19)	⊕⊕OO LOW
Back pain long-term 2 years (follow-up 24 months; measured with: VAS; better indicated by lower values)										
2 [35, 36]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	150	150	SMD −0.15 (−0.46 to 0.16)	⊕⊕OO LOW
Leg pain short term (follow-up 3 months; measured with: VAS; Better indicated by lower values)										
2 [35, 36]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	150	150	SMD −0.13 (−0.36 to 0.09)	⊕⊕OO LOW
Leg pain medium term (follow-up 6 months; measured with: VAS; better indicated by lower values)										
2 [35, 36]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	150	150	SMD 0.03 (−0.2 to 0.25)	⊕⊕OO LOW
Leg pain long-term 1 year (follow-up 12 months; measured with: VAS; better indicated by lower values)										
2 [35, 36]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	150	150	SMD −0.01 (−0.24 to 0.21)	⊕⊕OO LOW
Leg pain long-term 2 years (follow-up 24 months; measured with: VAS; better indicated by lower values)										
2 [35, 36]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	150	150	SMD −0.05 (−0.28 to 0.17)	⊕⊕OO LOW
Function short term (follow-up 3 months; measured with: oswestry; better indicated by lower values)										
2 [35, 36]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	150	150	SMD −0.02 (−0.54 to 0.5)	⊕⊕OO LOW
Function medium term (follow-up 6 months; measured with: oswestry; better indicated by lower values)										
2 [35, 36]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	150	150	SMD 0.05 (−0.47 to 0.56)	⊕⊕OO LOW
Function long-term 1 year (follow-up 12 months; measured with: oswestry; better indicated by lower values)										
2 [35, 36]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	150	150	SMD −0.29 (−0.51 to −0.06)	⊕⊕OO LOW
Function long-term 2 years (follow-up 24 months; measured with: oswestry; better indicated by lower values)										
2 [35, 36]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	150	150	SMD −0.2 (−0.43 to 0.03)	⊕⊕OO LOW

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Table 7 continued

Quality assessment							No. of patients		Effect (95 % CI)	Quality
No. of studies	Design	RoB	Inconsistency	Indirectness	Imprecision	Other	ILMI + TFMI	Control		
Satisfaction with surgery (assessed with: proportion satisfied)										
2 [35, 36]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	131/150 (87.3 %)	113/150 (75.3 %)	OR 2.26 (1.23–4.15)	⊖⊕OO LOW
Operative time (measured with: minutes)										
2 [35, 36]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	150	150	MD −27.33 (−40.06 to −14.59)	⊖⊕OO LOW
Complications (assessed with: number of complications)										
2 [35, 36]	RCT	Serious[1]	No serious nconsistency	No serious indirectness	Serious[2]	None	6/150 (4 %)	23/150 (15.3 %)	OR 0.23 (0.09–0.58)	⊖⊕OO LOW
Reoperations (assessed with: number of reoperations)										
2 [35, 36]	RCT	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	None	12/150 (8 %)	8/150 (5.3 %)	OR 1.54 (0.61–3.9)	⊖⊕OO LOW

[1] Inappropriate randomisation, unclear allocation concealment, possible selective reporting, no blinding

[2] Small total sample size

Fig. 4 Flow of studies

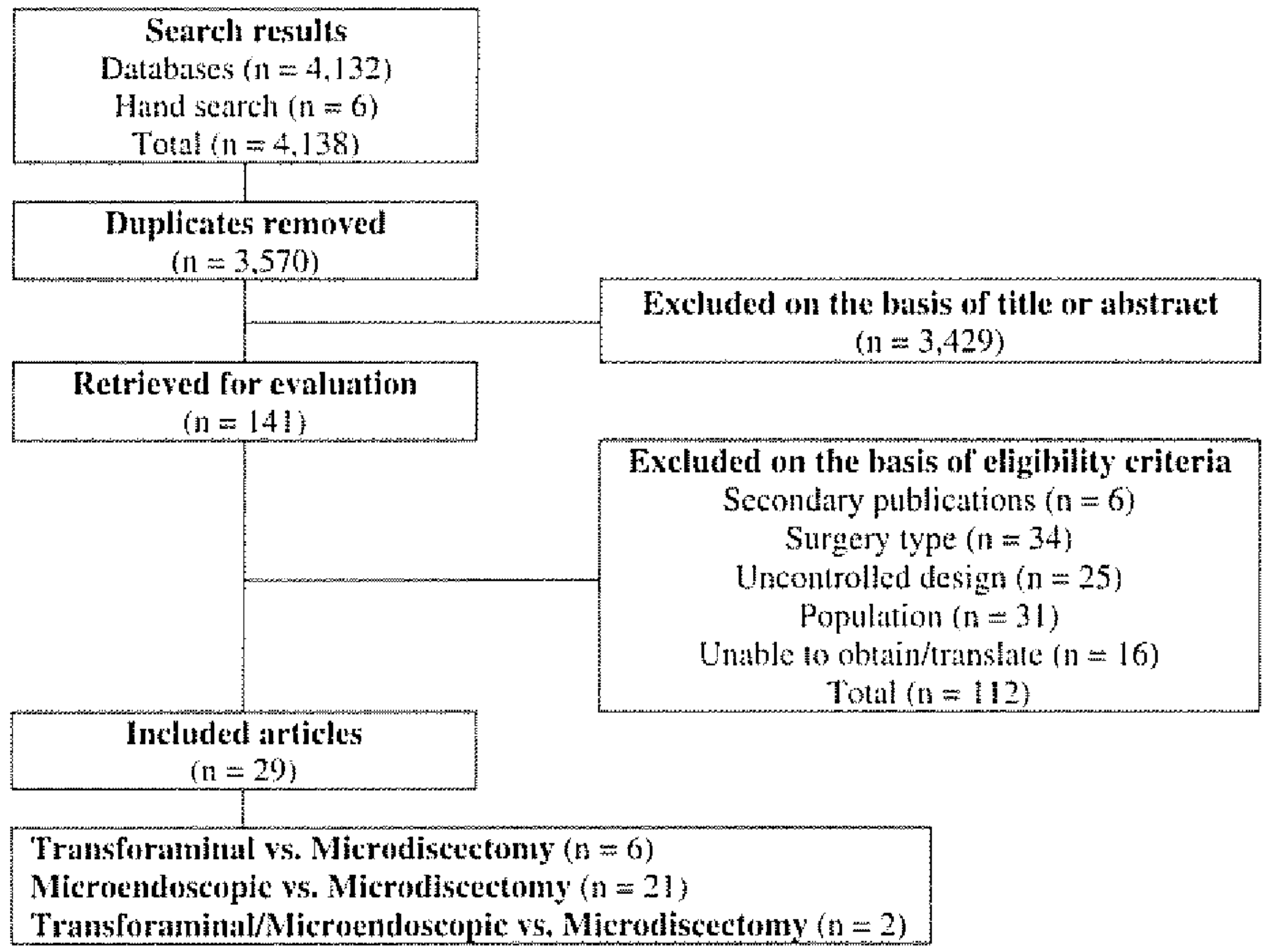

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EXHIBIT 31

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Abstract

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Br J Neurosurg. 2014 Apr;28(2):247-51. doi: 10.3109/02688697.2013.829555. Epub 2013 Aug 19.

Is the rate of re-operation after primary lumbar microdiscectomy affected by surgeon grade or intra-operative lavage of the disc space?

Ellenbogen JR[1], Marlow W, Fischer BE, Tsegaye M, Wilby MJ.

Author information

[1]The Walton Centre NHS Foundation Trust , Fazakerley, Liverpool , UK.

Abstract

STUDY DESIGN. Retrospective audit of consecutive patients. OBJECTIve. To investigate the re-operation rate **following** elective primary lumbar **microdiscectomy** and to determine whether principal surgeon grade and/or disc space lavage is a factor in recurrence. SUMMARY OF BACKGROUND DATA. Recurrent herniation of disc material **following** lumbar microdiscecomy **surgery** is one of the commonest complications of the procedure. Any reduction in the number of revision microdiscectomies performed per year would have a significant impact on patients' lives and on the health service economy. We undertook this study to ascertain whether principal surgeon grade and/or disc space lavage has an impact in reducing the re-operation rate. METHODS. We undertook a retrospective audit of patients who underwent elective primary lumbar **microdiscectomy**, over a 3-year period (n = 971). RESULTS. The overall re-operation rate for primary elective **microdiscectomy** was 3.8%, consistent with the published literature. The relative risk of re-operation in patients primarily operated by registrar surgeons was 1.2 fold the risk in patients operated by consultants (95% CI: 0.62, 2.35) although not statistically significant (p = 0.568). The risk of re-operation in the 'non lavage' group was 2.15 times the risk in the 'lavage' group (95% CI: 0.63, 7.34), but it did not reach significance (p = 0.222). CONCLUSIONS. Principal surgeon grade and intervertebral disc lavage have not been found conclusively to be factors in the rate of recurrence. This information is useful to reassure patients that their outcome from such **surgery** is not dependent on the grade of surgeon performing the operation. There is a possible trend towards intervertebral disc lavage reducing the rate of recurrence.

PMID: 23957779 [PubMed - indexed for MEDLINE]

MeSH Terms

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EXHIBIT 32

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J Orthop Sci. 2012 Mar;17(2):107-13. doi: 10.1007/s00776-011-0184-6. Epub 2011 Dec 22.

Reoperation for recurrent lumbar disc herniation: a study over a 20-year period in a Japanese population.

Aizawa T[1], Ozawa H, Kusakabe T, Nakamura T, Sekiguchi A, Takahashi A, Sasaji T, Tokunaga S, Chiba T, Morozumi N, Koizumi Y, Itoi E.

Author information

[1]Department of Orthopaedic **Surgery**, Tohoku University School of Medicine, 1-1 Seiryo-machi, Aoba-ku, Sendai, Japan. toshi-7@ra2.so-net.ne.jp

Abstract

BACKGROUND: Many studies have been reported on recurrent lumbar disc herniations covering several pathological conditions. In those studies, **reoperation** rate of revised disc excisions was calculated by simple division between the number of reoperations and that of the total primary disc excisions. To determine the real **reoperation** rate, strict definition of pathologies, a large number of patients, a long observation period, and survival function method are necessary.

METHODS: Between 1988 and 2007, 5,626 patients with disc excision were enrolled by the spine registration system of the Department of Orthopaedic **Surgery**, Tohoku University, Japan. Among them, 192 had revised disc **surgery**, and we obtained data of 186 patients whose clinical features were assessed and **reoperation** rates analyzed using the Kaplan-Meier method.

RESULTS: In total, 205 disc herniations were excised in the revision **surgery** (including contralateral herniation at the same level and new herniation at a different level), and 101 were real recurrent herniations (recurrence at the same level and side as the primary herniation). The kappa coefficient of the spinal level and side between the primary and revision surgeries was 0.41, indicting moderate correlations. Real recurrent herniations showed shorter intervals between primary and revision surgeries. Male patients with **surgery** at a younger age carried a higher risk of **reoperation**. In the revision **surgery**, transligamentous extrusion was significantly more common than other types of herniation. On Kaplan-Meier analysis, the **reoperation** rate of overall revised excisions was 0.62% at 1 year, 2.4% at 5 years, 4.4% at 10 years, and 5.9% after 17 years. That of real recurrent herniations was 0.5%, 1.4%, and 2.1%, respectively, and 2.8% after 15.7 years.

CONCLUSION: **Reoperation** rate of real recurrent herniations calculated using survival function method gradually increased year by year, from 0.5% at 1 year after primary **surgery** to 2.8% at 15.7 years.

PMID: 22189996 [PubMed - indexed for MEDLINE]

EXHIBIT 33

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PubMed

Abstract

Full text links

Neurocirugia (Astur). 2011 Jun;22(3):235-44.

[Long-term outcomes of lumbar microdiscectomy in a working class sample].

[Article in Spanish]

Martínez Quiñones JV[1], Aso J, Consolini F, Arregui R.

Author information

[1]Servicio de Neurocirugía. Hospital MAZ. Zaragoza. chevimq@gmail.com

Abstract

INTRODUCTION: In the treatment of the **lumbar** disc herniaton (LDH) **microdiscectomy** constitutes one of the standard procedures. In the present study we have analyzed the clinical outcome of the **lumbar** microdis- cectomy in a series of worker patients who underwent surgery in our service.

METHODS: Retrospective analysis and a 5-year follow up, of a series of 142 patients operated on by means of **lumbar microdiscectomy** in the 2004-2005 period. The clinical outcome was analyzed according to the "Herron and Turner" outline: pain reduction, use of medical treatment, restriction in the ability to perform physical activities, and return to work.

RESULTS: 116 men and 26 women, with an average age of 37.9 and 45.4 years respectively, underwent surgery because of LDH. In the clinical aspect, sciatica was predominant over low back pain in a ratio of three to one. The L5-S1 discal level was operated on in 68.3% of the cases. It was considered that occupational activities gave rise to damage in 107 patients (75.3%). Besides a symptomatic disc, there was an additional injured disc in 44.3% of the cases. An initial unfavourable outcome was seen in 42 patients (33%), 15 of which recovered from in an interval of 3 months, and another fifteen within a one year period. A re-operation was necessa ry in 16 patients because of recurrent **lumbar** disc herniation (11%). Work reintegration was achieved in 83.3% (119/142) of the cases. After a 5-year follow up, we stated the consistency of the clinical result.

DISCUSSION: We analyzed the intervertebral disc behaviour as regards sex, age, variety of discal herniation, additional disc, outcome and re-operation variables. After the analysis of the type of discal herniation and additional disc we defined three disc injury patterns. We consider **microdiscectomy** as the technique of choosing for the treatment of recurrence disc herniation.

CONCLUSIONS: Between the working class, discal injury predominates in young men, as a consequence of the annulus breakage, or an annulus plus posterior longitudinal ligament breakage (traumatic herniae). Frequently it was observed that more than one disc was involved, and a left lateralization.

EXHIBIT 34

EXHIBIT 34

Abstract

J Neurosurg Spine. 2012 May;16(5):452-62. doi: 10.3171/2012.1.SPINE11404. Epub 2012 Mar 9.

The efficacy of minimally invasive discectomy compared with open discectomy: a meta-analysis of prospective randomized controlled trials.

Dasenbrock HH[1], Juraschek SP, Schultz LR, Witham TF, Sciubba DM, Wolinsky JP, Gokaslan ZL, Bydon A.

Author information

[1]Department of Neurosurgery, Brigham and Women's Hospital/Children's Hospital of Boston/Harvard Medical School, Boston, MA, USA.

Abstract

OBJECT: Advocates of minimally invasive discectomy (MID) have promoted this operation as an alternative to open discectomy (OD), arguing that there may be less injury to the paraspinal muscles, decreased postoperative pain, and a faster recovery time. However, a recently published large randomized controlled trial (RCT) comparing these approaches reported inferior relief of leg pain in patients undergoing MID. The authors conducted a meta-analysis to evaluate complications and improvement in leg pain in patients with radiculopathy enrolled in RCTs comparing OD to MID.

METHODS: The authors performed a literature search using Medline and EMBASE of studies indexed between January 1990 and January 2011. Predetermined RCT eligibility included the usage of tubular retractors during MID, a minimum follow-up duration of 1 year, and quantification of pain with the visual analog scale (VAS). Trials that only evaluated patients with recurrent disc herniation were excluded. Data on operative parameters, complications, and VAS scores of leg pain were extracted by 2 investigators. A meta-analysis was performed assuming random effects to determine the difference in mean change for continuous outcomes and the risk ratio for binary outcomes.

RESULTS: Six trials comprising 837 patients (of whom 388 were randomized to MID and 449 were randomized to OD) were included. The mean operative time was 49 minutes during MID and 44 minutes during OD; this difference was not statistically significant. Incidental durotomies occurred significantly more frequently during MID (5.67% compared with 2.90% for OD; RR 2.05, 95% CI 1.05-3.98). Intraoperative complications (incidental durotomies and nerve root injuries) were also significantly more common in patients undergoing MID (RR 2.01, 95% CI 1.07-3.77). The mean preoperative VAS score for leg pain was 6.9 in patients randomized to MID and 7.2 in those randomized to OD. With long-term follow-up (1-2 years postoperatively), the mean VAS score improved to 1.6 in both the MID and OD cohorts. There was no significant difference in relief of leg pain between the 2 approaches with either short-term follow-up (2-3 months postoperatively, 0.81 points on the VAS, 95% CI -4.71 to 6.32) or long-term follow-up (2.64 on the VAS, 95% CI -2.15 to

7.43). Reoperation for recurrent herniation was more common in patients randomized to the MID group (8.50% compared with 5.35% in patients randomized to the OD group), but this difference was not statistically significant (RR 1.56, 95% CI 0.92-2.66). Total complications did not differ significantly between the operations (RR 1.50, 95% CI 0.97-2.33).

CONCLUSIONS: The current evidence suggests that both OD and MID lead to a substantial and equivalent long-term improvement in leg pain. Adequate decompression, regardless of the operative approach used, may be the primary determinant of pain relief-the major complaint of many patients with radiculopathy. Incidental durotomies occurred significantly more frequently during MID, but total complications did not differ between the techniques.

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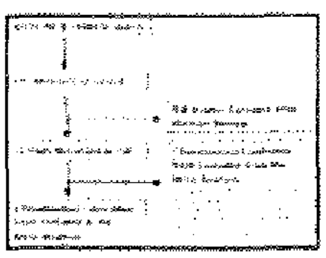

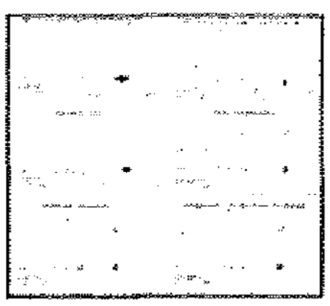

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Spine J. 2013 Oct;13(10):1230-7. doi: 10.1016/j.spinee.2013.06.069. Epub 2013 Sep 7.

Reoperation rate after surgery for lumbar spinal stenosis without spondylolisthesis: a nationwide cohort study.

Kim CH[1], Chung CK, Park CS, Choi B, Hahn S, Kim MJ, Lee KS, Park BJ.

Author information

[1]Department of Neurosurgery, Seoul National University Hospital, Seoul National University College of Medicine, 101 Daehak-Ro, Jongno-gu, Seoul 110-744, South Korea; Neuroscience Research Institute, Seoul National University Medical Research Center, 103 Daehak-Ro, Jongno-Gu, Seoul 110-744, South Korea; Clinical Research Institute, Seoul National University Hospital, 101 Daehak-Ro, Jongno-Gu, Seoul 110-744, South Korea.

Abstract

BACKGROUND CONTEXT: Lumbar spinal stenosis is one of the most common degenerative spine diseases. Surgical options are largely divided into decompression only and decompression with arthrodesis. Recent randomized trials showed that surgery was more effective than nonoperative treatment for carefully selected patients with lumbar stenosis. However, some patients require reoperation because of complications, failure of bony fusion, persistent pain, or progressive degenerative changes, such as adjacent segment disease. In a previous population-based study, the 10-year reoperation rate was 17%, and fusion surgery was performed in 10% of patients. Recently, the lumbar fusion surgery rate has doubled, and a substantial portion of the reoperations are associated with a fusion procedure. With the change in surgical trends, the longitudinal surgical outcomes of these trends need to be reevaluated.

PURPOSE: To provide the longitudinal reoperation rate after surgery for spinal stenosis and to compare the reoperation rates between decompression and fusion surgeries.

STUDY DESIGN/SETTING: Retrospective cohort study using national health insurance data.

PATIENT SAMPLE: A cohort of patients who underwent initial surgery for lumbar stenosis without spondylolisthesis in 2003.

OUTCOME MEASURES: The primary end point was any type of second lumbar surgery. Cox proportional hazards regression modeling was used to compare the adjusted reoperation rates between decompression and fusion surgeries.

METHODS: A national health insurance database was used to identify a cohort of patients who underwent an initial surgery for lumbar stenosis without spondylolisthesis in 2003; a total of 11,027 patients were selected. Individual patients were followed for at least 5 years through their encrypted unique resident registration number. After adjusting for confounding factors, the reoperation rates for decompression and fusion surgery were compared.

RESULTS: Fusion surgery was performed in 20% of patients. The cumulative reoperation rate was 4.7% at 3 months, 7.2% at 1 year, 9.4% at 2 years, 11.2% at 3 years, 12.5% at 4 years, and 14.2% at 5 years. The adjusted reoperation rate was not different between decompression and fusion surgeries (p=.82). The calculated reoperation rate was expected to be 22.9% at 10 years.

CONCLUSIONS: The reoperation rate was not different between decompression and fusion surgeries. With current surgical trends, the reoperation rate appeared to be higher than in the past, and consideration of this problem is required.

KEYWORDS: Decompression; Fusion; Lumbar spine; Reoperation rate; Surgery

PMID: 24017959 [PubMed - indexed for MEDLINE]

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Wolters Kluwer

Spine (Phila Pa 1976). 1998 Apr 1;23(7):814-20.

5-year reoperation rates after different types of lumbar spine surgery.

Malter AD[1], McNeney B, Loeser JD, Deyo RA.

Author information

[1]Department of Health Services, University of Washington, Seattle, USA.

Abstract

STUDY DESIGN: Population-based cohort study of Washington State patients who underwent lumbar spine surgery for degenerative conditions in 1988.

OBJECTIVES: To compare complications and reoperation rates during the 5-year period after surgery between patients who have undergone lumbar spine fusion surgery and those who have undergone laminectomy or discectomy alone.

SUMMARY OF BACKGROUND DATA: Spinal fusion is associated with wider surgical exposure, more extensive dissection, and longer operative times than lumbar surgery without fusion, and previous studies have shown higher complication rates and hospital charges associated with these more complex procedures. In elderly patients, spinal fusion operations were associated with higher mortality rates than laminectomy or discectomy alone, and reoperation rates were not lower. In the current study, reoperations, mortality, and complications following lumbar spine surgery were examined for the general population.

METHODS: A statewide hospital discharge database was used to identify all Washington patients who underwent spine surgery in 1988 and to determine the rate of reoperation during the subsequent 5 years. Administrative records also were used to identify complications, mortality, and hospital charges associated with the operations. Unadjusted complication and reoperation rates for the groups were compared using chi-square statistics. Adjusted rates were compared using logistic regression and proportional hazards (Cox) regression after controlling for age, gender, prior spine surgery, diagnosis, comorbidity, type of surgery, and coverage by Workers' Compensation.

RESULTS: Of 6376 patients who underwent lumbar surgery for degenerative conditions in Washington in 1988, 1041 (16%) had operations involving spine fusion. Diagnoses of degenerative disc disease or possible instability were more frequent among patients undergoing fusion surgery, whereas herniated discs were more frequent among those undergoing discectomy or laminectomy alone. Complications were recorded in 18% of fusion patients and 7% of nonfusion patients ($P < 0.01$), but mortality rates did not differ. Unadjusted reoperation rates over the 5-year period were greater for patients who underwent fusion than for patients who underwent nonfusion surgery (18% vs. 15%, respectively), but after adjustment for baseline characteristics, fusion patients had only a slightly greater (and nonsignificant) risk of reoperation (relative risk 1.1, confidence interval .9-1.3).

CONCLUSION: As in previous studies, complications in the current study occurred more frequently among patients who underwent lumbar spine fusion than among those who underwent laminectomy or discectomy alone. Reoperations were at least as frequent after fusion, but the authors could not assess treatment efficacy in terms of pain relief or improved function. Although the characteristics of patients undergoing fusion differed from those undergoing a laminectomy or discectomy alone, there appeared to be sufficient overlap in the clinical populations to warrant closer scrutiny of the safety, efficacy, and indications for spinal fusions, preferably in randomized trials.

PMID: 9563113 [PubMed - indexed for MEDLINE]

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Abstract

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J Bone Joint Surg Am. 2011 Nov 2;93(21):1979-86. doi: 10.2106/JBJS.J.01

Revision surgery following operations for lumbar stenosis.

Deyo RA[1], Martin BI, Kreuter W, Jarvik JG, Angier H, Mirza SK.

Author information

[1]Department of Family Medicine, Oregon Health and Science University, Portland, OR 97239, USA. deyor@ohsu.edu

Abstract

BACKGROUND: For carefully selected patients with lumbar stenosis, decompression surgery is more efficacious than nonoperative treatment. However, some patients undergo repeat surgery, often because of complications, the failure to achieve solid fusion following arthrodesis procedures, or persistent symptoms. We assessed the probability of repeat surgery following operations for the treatment of lumbar stenosis and examined its association with patient age, comorbidity, previous surgery, and the type of surgical procedure.

METHODS: We performed a retrospective cohort analysis of Medicare claims. The index operation was performed in 2004 (n = 31,543), with follow-up obtained through 2008. Operations were grouped by complexity as decompression alone, simple arthrodesis (one or two disc levels and a single surgical approach), or complex arthrodesis (more than two disc levels or combined anterior and posterior approach). Reoperation rates were calculated for each follow-up year, and the time to reoperation was analyzed with proportional hazards models.

RESULTS: The probability of repeat surgery fell with increasing patient age or comorbidity. Aside from age, the strongest predictor was previous lumbar surgery: at four years the reoperation rate was 17.2% among patients who had had lumbar surgery prior to the index operation, compared with 10.6% among those with no prior surgery ($p < 0.001$). At one year, the reoperation rate for patients who had been managed with decompression alone was slightly higher than that for patients who had been managed with simple arthrodesis, but by four years the rates for these two groups were identical (10.7%) and were lower than the rate for patients who had been managed with complex arthrodesis (13.5%) ($p < 0.001$). This difference persisted after adjusting for demographic and clinical features (hazard ratio for complex arthrodesis versus decompression 1.56, 95% confidence interval, 1.26 to 1.92). A device-related complication was reported at the time of 29.2% of reoperations following an initial arthrodesis procedure.

CONCLUSIONS: The likelihood of repeat surgery for spinal stenosis declined with increasing age and comorbidity, perhaps because of concern for greater risks. The strongest clinical predictor of repeat surgery was a lumbar spine operation prior to the index operation. Arthrodeses were not

significantly associated with lower rates of repeat surgery after the first postoperative year, and patients who had had complex arthrodeses had the highest rate of reoperations.

Comment in

Can statistics alone add clinical meaning to non-specific billing databases? Commentary on an article by Richard A. Deyo, MD, MPH, et al.: "Revision surgery following operations for lumbar stenosis". [J Bone Joint Surg Am. 2011]

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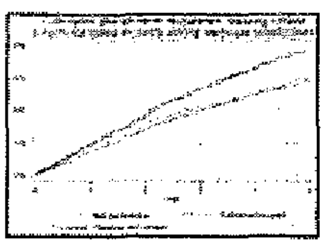

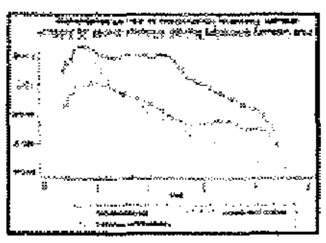

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Spine (Phila Pa 1976). 2014 May 20;39(12):978-87. doi: 10.1097/BRS.0000000000000314.

Surgery for spinal stenosis: long-term reoperation rates, health care cost, and impact of instrumentation.

Lad SP[1], Babu R, Ugiliweneza B, Patil CG, Boakye M.

Author information

[1]*Division of Neurosurgery, Department of Surgery, Duke University Medical Center, Durham, NC †Department of Neurosurgery, University of Louisville, Louisville, KY; and ‡Department of Neurosurgery, Cedars-Sinai Medical Center, Los Angeles, CA.

Abstract

STUDY DESIGN: Retrospective cohort analysis.

OBJECTIVE: To examine the complications, reoperation rates, and resource use after each of the surgical approaches for the treatment of spinal stenosis.

SUMMARY OF BACKGROUND DATA: There are no uniform guidelines for which procedure (decompression, decompression with instrumentation, or decompression with noninstrumented fusion) to perform for the treatment of spinal stenosis. With no clear evidence for increased efficacy, the rate of instrumented fusions is rising.

METHODS: We performed a retrospective cohort analysis of patients who underwent spinal stenosis surgery between 2002 and 2009 in the United States. Patients included (n = 12,657) were diagnosed with spinal stenosis without concurrent spondylolisthesis and had at least 2 years of preoperative enrollment. A total of 2385 patients with decompression only and 620 patients with fusion had follow-up data for 5 years or more.

RESULTS: Complication rates during the initial procedure hospitalization and at 90 days were significantly higher for those who underwent laminectomy with fusion than for those who underwent laminectomy alone, with reoperation rates not differing significantly between these groups. Long-term (≥5 yr) reoperation rates were similar for those undergoing decompression alone versus decompression with fusion (17.3% vs. 16.0%, P = 0.44). Those with instrumented fusions had a slightly higher rate of reoperation than patients with noninstrumented fusions (17.4% vs. 12.2%, P = 0.11) at more than 5 years. The total cost including initial procedure and hospital, outpatient, emergency department, and medication charges at 5 years was similar for those who received decompression alone and fusion. The long-term costs for instrumented and noninstrumented fusions were also similar, totaling $107,056 and $100,471, respectively.

CONCLUSION: For patients with spinal stenosis, if fusion is warranted, use of arthrodesis without

instrumentation is associated with decreased costs with similar long-term complication and reoperation rates.

Comment in

[Lumbar Spinal Stenosis - decompression with vs. without instrumented fusion]. [Z Orthop Unfall. 2014]

PMID: 24718058 [PubMed - indexed for MEDLINE]

Publication Types, MeSH Terms

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EXHIBIT 39

EXHIBIT 39

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Abstract

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JBJS FULL TEXT

J Bone Joint Surg Am. 2013 Nov 6;95(21):e162. doi: 10.2106/JBJS.L.00730.

Complications, reoperation rates, and health-care cost following surgical treatment of lumbar spondylolisthesis.

Lad SP[1], Babu R, Baker AA, Ugiliweneza B, Kong M, Bagley CA, Gottfried ON, Isaacs RE, Patil CG, Boakye M.

Author information

Abstract

BACKGROUND: Surgery remains the mainstay for management of lumbar spondylolisthesis and is considered an effective therapeutic modality following unsuccessful nonoperative treatment. Surgical procedures include decompression, decompression with instrumented arthrodesis, and decompression with noninstrumented arthrodesis. The purpose of this study was to examine the complications, reoperation rates, and health-care costs associated with each of these procedures.

METHODS: The MarketScan database was utilized to identify 16,556 patients with a primary diagnosis of lumbar spondylolisthesis who underwent surgical treatment from 2000 to 2009. Outcomes were evaluated in propensity score-matched cohorts, with complication rates analyzed with the chi-square test, reoperation rates analyzed using the Mantel-Haenszel test, and health-care resource use analyzed using the Wilcoxon signed-rank test.

RESULTS: Complication rates were significantly higher in patients who underwent arthrodesis compared with those who had decompression alone during the initial hospitalization (8.3% versus 4.8%; $p < 0.0001$) and at the time of the ninety-day follow-up (9.6% versus 5.5%; $p < 0.0001$). Complication rates were similar for those who received instrumented and noninstrumented arthrodesis. Patients who underwent decompression alone had higher reoperation rates at two years or more than those who received arthrodesis (15.7% versus 11.9%; $p = 0.034$). Patients with instrumented arthrodesis trended to have higher reoperation rates than those without instrumentation at five years or more (18.4% versus 10.6%; $p = 0.063$). Initial hospital costs and two-year and five-year overall costs (in 2009 U.S. dollars) were higher for patients managed with arthrodesis than for those who had decompression only ($102,906 versus $89,337; $p = 0.0018$). Also, patients who received instrumentation had higher hospitalization costs than those without instrumentation ($39,997 versus $27,309; $p = 0.023$) and higher overall costs at two years ($73,482 versus $60,394; $p < 0.0001$), although the difference was not significant at five years ($p = 0.29$).

CONCLUSIONS: Patients with lumbar spondylolisthesis who underwent decompressive laminectomy and spinal arthrodesis had lower reoperation rates but higher overall costs than patients treated with laminectomy alone. Noninstrumented arthrodesis was also associated with lower long-term reoperation rates and health-care costs compared with instrumented arthrodesis.

The long-term outcomes and costs of these procedures should be evaluated in conjunction with clinical efficacy to ensure the most cost-effective treatment is utilized.

LEVEL OF EVIDENCE: Therapeutic level III. See Instructions for Authors for a complete description of levels of evidence.

PMID: 24196474 [PubMed - indexed for MEDLINE]

MeSH Terms

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EXHIBIT 40

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Abstract

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Wolters Kluwer

Spine (Phila Pa 1976). 2013 Apr 1;38(7):581-90. doi: 10.1097/BRS.0b013e318274f9a7.

Reoperation rate after surgery for lumbar herniated intervertebral disc disease: nationwide cohort study.

Kim CH[1], Chung CK, Park CS, Choi B, Kim MJ, Park BJ.

Author information

Abstract

STUDY DESIGN: Retrospective cohort study using national health insurance data.

OBJECTIVE: To provide a longitudinal reoperation rate after surgery for lumbar herniated intervertebral disc (HIVD) disease, and to compare the reoperation rates of surgical methods.

SUMMARY OF BACKGROUND DATA: Herniated intervertebral disc disease is the most common cause of lumbar spinal surgery. Despite improved surgical techniques and instrumentation, reoperation cannot be avoided. The reoperation rates were in the range of 6% to 24% in previous studies. A population-based study is less subject to bias; hence, a nationwide longitudinal analysis was warranted.

METHODS: A national health insurance database was used to identify a cohort of patients who underwent first surgery for herniated intervertebral disc disease in 2003 and 18,590 patients were selected. Individual patients were followed for at least 5 years through their encrypted unique resident registration number. The primary endpoint was any type of second lumbar surgery. After adjusting for confounding factors, 5 surgical methods (fusion, laminectomy, open discectomy, endoscopic discectomy, and nucleolysis [including mechanical nucleus decompression]) were compared. Open discectomy was used as the reference method.

RESULTS: Open discectomy was the most common procedure (68.9%) followed by endoscopic discectomy (16.1%), laminectomy (7.9%), fusion (3.9%), and nucleolysis (3.2%). The cumulative reoperation rate was 5.4% at 3 months, 7.4% at 1 year, 9% at 2 years, 10.5% at 3 years, 12.1% at 4 years, and 13.4% at 5 years. The reoperation rates were 18.6%, 14.7%, 13.8%, 12.4%, and 11.8% after laminectomy, nucleolysis, open discectomy, endoscopic discectomy, and fusion, respectively. Compared with open discectomy, the reoperation rate was higher after laminectomy at 3 months, whereas the other surgical methods had similar rates.

CONCLUSION: The cumulative reoperation rate after 5 years was 13.4% and half of the reoperations occurred during the first postoperative year. With the exception of laminectomy, the reoperation rates of the other procedures were not different from that of open discectomy.

PMID: 23023591 [PubMed - indexed for MEDLINE]

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Spine J. 2012 Feb;12(2):89-97. doi: 10.1016/j.spinee.2011.11.010. Epub 2011 Dec 21.

Repeat surgery after lumbar decompression for herniated disc: the quality implications of hospital and surgeon variation.

Martin BI[1], Mirza SK, Flum DR, Wickizer TM, Heagerty PJ, Lenkoski AF, Deyo RA.

Author information

[1]Department of Orthopaedics, HB7541, Dartmouth-Hitchcock Medical Center, One Medical Center Dr, Lebanon, NH 03756-0001, USA. Brook.I.Martin@Dartmouth.edu

Abstract

BACKGROUND CONTEXT: Repeat lumbar spine surgery is generally an undesirable outcome. Variation in repeat surgery rates may be because of patient characteristics, disease severity, or hospital- and surgeon-related factors. However, little is known about population-level variation in reoperation rates.

PURPOSE: To examine hospital- and surgeon-level variation in reoperation rates after lumbar herniated disc surgery and to relate these to published benchmarks.

STUDY DESIGN/SETTING: Retrospective analysis of a discharge registry including all nonfederal hospitals in Washington State.

METHODS: We identified adults who underwent an initial inpatient lumbar decompression for herniated disc from 1997 to 2007. We then performed generalized linear mixed-effect logistic regressions, controlling for patient characteristics and comorbidity, to examine the variation in reoperation rates within 90 days, 1 year, and 4 years.

RESULTS: Our cohort included 29,529 patients with a mean age of 47.5 years, 61% privately insured, and 15% having any comorbidity. The age-, sex-, insurance-, and comorbidity-adjusted mean rate of reoperation among hospitals was 1.9% at 90 days (95% confidence interval [CI], 1.2-3.1), with a range from 1.1% to 3.4%; 6.4% at 1 year (95% CI, 3.9-10.6), with a range from 2.8% to 12.5%; and 13.8% at 4 years (95% CI, 8.8-19.8), with a range from 8.1% to 24.5%. The adjusted mean reoperation rates of surgeons were 1.9% at 90 days (95% CI, 1.4-2.4) with a range from 1.2% to 4.6%, 6.1% at 1 year (95% CI, 4.8-7.7) with a range from 4.3% to 10.5%, and 13.2% at 4 years (95% CI, 11.3-15.5) with a range from 10.0% to 19.3%. Multilevel random-effect models suggested that variation across surgeons was greater than that of hospitals and that this effect increased with long-term outcomes.

CONCLUSIONS: Even after adjusting for patient demographics and comorbidity, we observed a large variation in reoperation rates across hospitals and surgeons after lumbar discectomy, a

relatively simple spinal procedure. These findings suggest uncertainty about indications for repeat surgery, variations in perioperative care, or variations in quality of care.

Comment in

Commentary: The degenerative lumbar spine: a chronic condition in search of a definitive solution. [Spine J. 2012]

PMID: 22193055 [PubMed - indexed for MEDLINE] PMCID: PMC3299929 **Free PMC Article**

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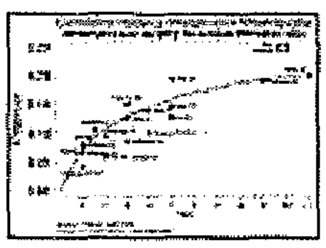

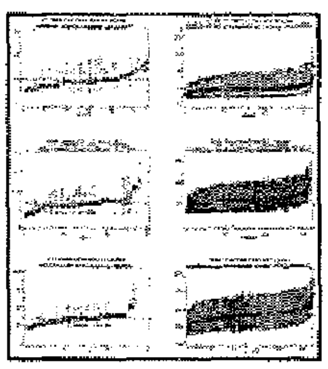

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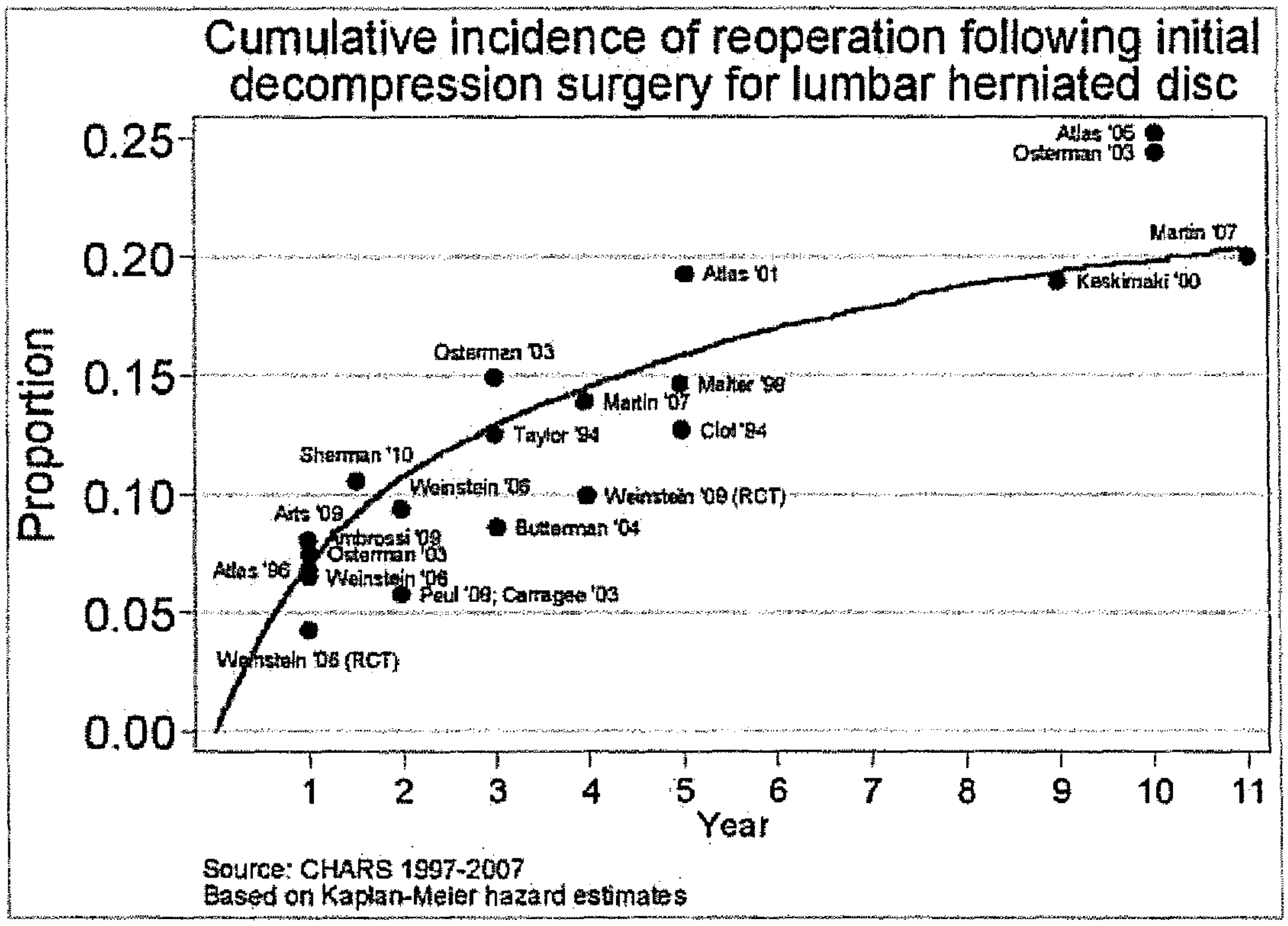
Published in final edited form as:
Spine J. 2012 Feb; 12(2): 89–97.
Published online 2011 Dec 21. doi: 10.1016/j.spinee.2011.11.010

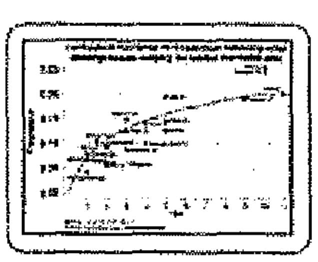
<< Prev Figure 1 Next >>

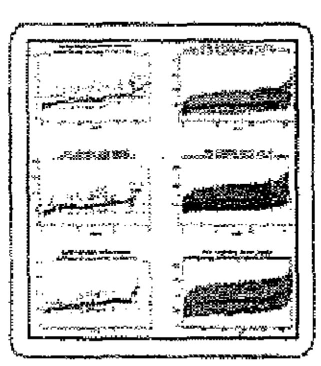
Figure 1



11-year cumulative incidence of reoperation following decompression surgery for herniated disc in Washington State (solid line). The figure is annotated with point estimates for reoperation rates from other studies on decompression surgery (clinical and administrative).

Images in this article





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PMC full text: Spine J. Author manuscript; available in PMC 2013 Feb 1.
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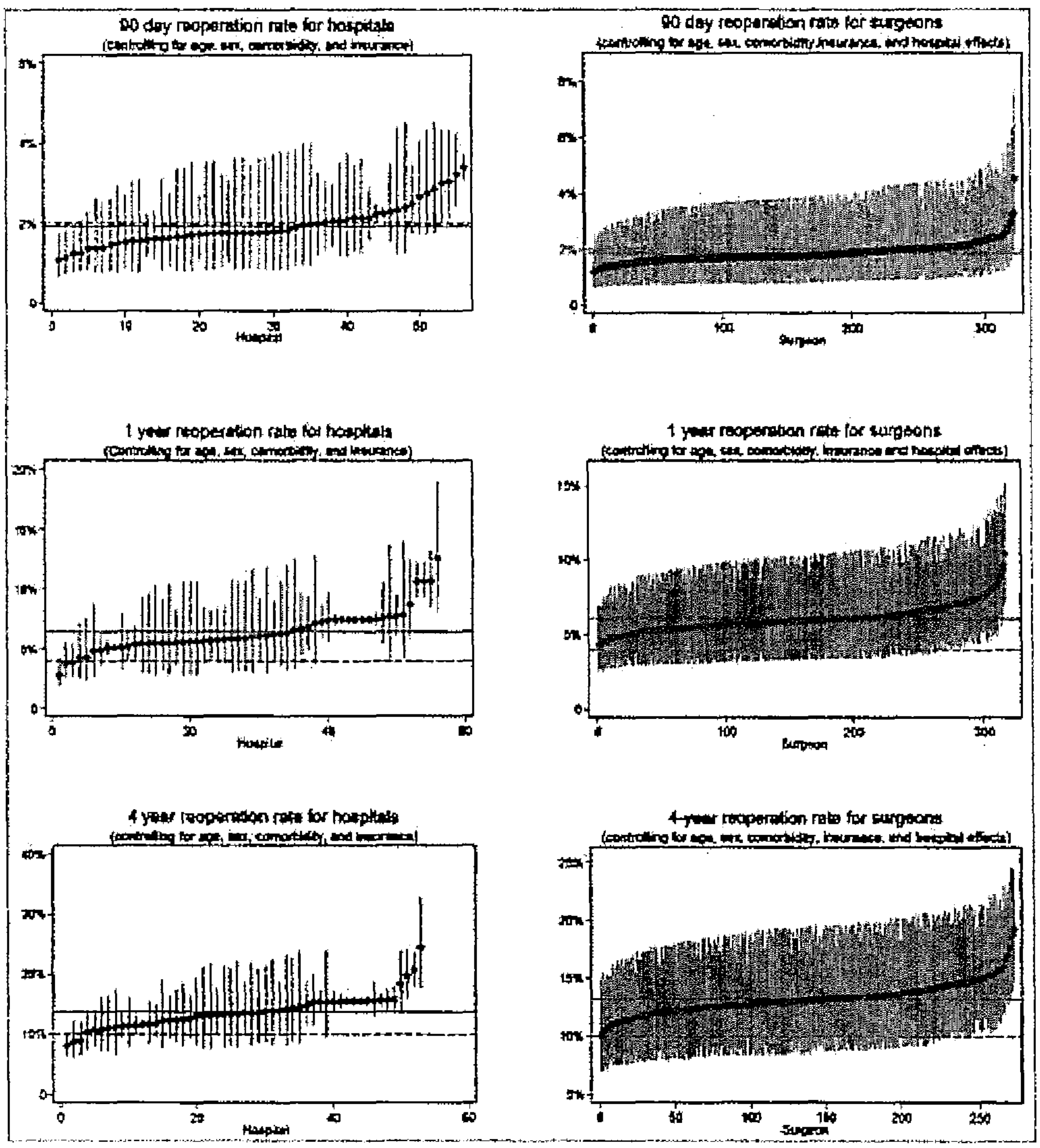
Spine J. 2012 Feb; 12(2): 89–97.
Published online 2011 Dec 21. doi: 10.1016/j.spinee.2011.11.010

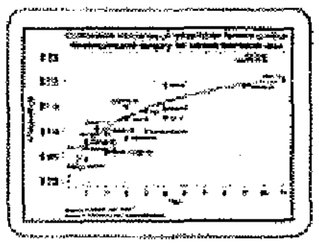
<< Prev Figure 2 Next >>

Figure 2



The reoperation rates within 90-days, 1-year, and 4-years following inpatient lumbar decompression surgery for herniated disc. Each spike represents 95% Bayesian confidence interval for the probability of reoperation within hospitals (figures on left) and surgeons nested within hospitals (figures on right) in Washington State. For the purposes of presentation we excluded those surgeons who have fewer than 10 cases (because of their uninformative low volumes, we could not identify any of them as being significantly above or below the SPORT benchmark). The solid horizontal line represents the overall reoperation rate, while dashed lines represent the reoperation benchmark from SPORT.

Images in this article



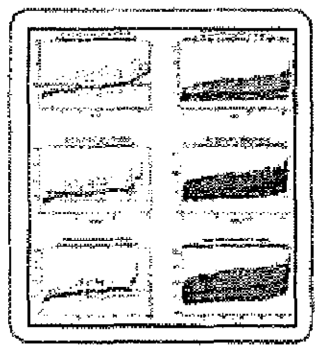


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EXHIBIT 42

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Abstract

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Wolters Kluwer

Spine (Phila Pa 1976). 2003 Mar 15;28(6):621-7.

Risk of multiple reoperations after lumbar discectomy: a population-based study.

Osterman H[1], Sund R, Seitsalo S, Keskimäki I.

Author information

[1]ORTON Orthopaedic Hospital, Invalid Foundation, Helsinki, Finland. heikki.osterman@fimnet.fi

Abstract

STUDY DESIGN: Retrospective follow-up study of patients undergoing multiple (two or more) reoperations after initial lumbar discectomy using an administrative database.

OBJECTIVES: To identify the population-based risk of multiple reoperations after lumbar discectomy and to analyze factors associated with the risk.

SUMMARY OF BACKGROUND DATA: Although multiple reoperations after initial lumbar discectomy are likely uncommon, research to better understand reasons for and outcomes of reoperations is needed because of the large number of discectomies performed.

METHODS: Data on all lumbar spine operations during 1987-1998 were obtained from the Finnish Hospital Discharge Register. The patient's initial disc operation during the study period was linked to subsequent operations, and patients with two or more reoperations were analyzed further. The risk of multiple reoperations was determined using the methods of event history analysis.

RESULTS: Among 35,309 patients undergoing an initial discectomy, 4943 (14.0%) had at least one reoperation and 803 (2.3%) had two or more reoperations. A total of 63% of the second reoperations were discectomies, 14% were fusions, and the remaining 23% were decompressions. Patients with one reoperation after lumbar discectomy had a 25.1% cumulative risk of further spinal surgery in a 10-year follow-up. Reduced risk was seen when the first reoperation took place more than 1 year after the initial discectomy (relative risk 0.83, 95% confidence interval 0.72-0.96), in patients for whom the first reoperation had been a fusion (relative risk 0.27, 95% confidence interval 0.12-0.61), and in patients 50-64 years of age (relative risk 0.62, 95% confidence interval 0.48-0.79).

CONCLUSION: Patients with one reoperation after lumbar discectomy are at considerable risk of further spinal surgery.

PMID: 12642772 [PubMed - indexed for MEDLINE]

MeSH Terms

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DOEW
Anthony D. Lauria
Nevada Bar No.: 4114
Kimberly L. Johnson
Nevada Bar No.: 10554
LAURIA TOKUNAGA GATES & LINN, LLP
601 South Seventh Street, 2nd Floor
Las Vegas, Nevada 89101
(702) 387-8633; Fax: (702) 387-8635

Attorneys for *Defendant ALBERT H. CAPANNA, M.D.*

DISTRICT COURT

CLARK COUNTY NEVADA

BEAU R. ORTH, Plaintiff, v. ALBERT H. CAPANNA, M.D.; DOES I THROUGH X; ROE BUSINESS ENTITIES I THROUGH X, Defendants.	CASE NO. : A-11-648041-C DEPT. NO. : 3 **SUPPLEMENTAL EXPERT WITNESS DISCLOSURE STATEMENT OF DEFENDANT ALBERT H. CAPANNA, M.D.**

Pursuant to N.R.C.P. 16(a)(2), Defendant ALBERT H. CAPANNA, M.D., through his attorneys, Anthony D. Lauria, Esq., of the law firm of Lauria Tokunaga Gates & Linn, LLP, hereby serves this supplemental expert witness disclosure statement as follows:

DOCUMENTS

1. Reynold L. Rimoldi, M.D. supplemental report dated July 24, 2015 attached hereto as Exhibit "N".

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Defendant reserves the right to supplement the above list of documents as discovery continues.

DATED: July 27, 2015.

LAURIA TOKUNAGA GATES & LINN, LLP

By: /s/ *Anthony D. Lauria*

Anthony D. Lauria
Nevada Bar No.: 4114
Kimberly L. Johnson
Nevada Bar No.: 10554
601 S. Seventh Street, 2nd Floor
Las Vegas, Nevada 89101
(702) 387-8633
Attorneys for Defendants

CERTIFICATE OF SERVICE

Pursuant to N.R.C.P. 5(b), I certify that I am an employee of Lauria Tokunaga Gates & Linn, and that on the 27nd day of July, 2015, I served a true and correct copy of the foregoing, SUPPLEMENTAL EXPERT WITNESS DISCLOSURE STATEMENT OF DEFENDANT ALBERT H. CAPANNA, M.D.:

☐ By placing same to be deposited for mailing in the United States Mail, in a sealed envelope upon which first class postage was prepared in Las Vegas, Nevada; and/or

X Via electronic mail; and/or

☐ Via facsimile; and/or

☐ Via Receipt of Copy to the interested parties

as follows:

Dennis M. Prince, Esq.
Eglet Prince
400 South 7th Street, Box 1, Suite 400
Las Vegas, NV 89101
Fax: (702) 450-5451

John T. Keating, Esq.
9130 West Russell Road, Suite 200
Las Vegas, Nevada 89148
Fax: (702) 228-0443
Attorneys for Plaintiff
BEAU R. ORTH

MARISA PEREZ, an employee of
Lauria Tokunaga Gates & Linn

EXHIBIT N

EXHIBIT N

Northwest Location
7455 W. Washington Avenue
Suite 160
Las Vegas, NV 89128

Workers' Compensation Liaison
(702) 258-3744 voice

NEVADA
ORTHOPEDIC & SPINE CENTER

Southwest Location
1505 Wigwam Parkway
Suite 330
Henderson, NV 89074

Medical-Legal/Liens Department
(702) 258-3748 voice

Patient Name: Beau Orth
Patient ID: 496711
Date of Birth: 11/02/1989
Date of Examination/Report: 7-24-15

SUPPLEMENT

For previous opinions please see my previous report. I will state that my last report was authored on June 26, 2015 and it indicates that I disagree with the opinions of other healthcare providers who feel that Mr. Orth has a probability of requiring fusion surgery. I specifically mentioned Dr. Andrew Cash as being one of the healthcare providers who opines that because of the lumbar decompression within the next 10 years he will require an L4 to the sacrum fusion. Certainly this opinion is not supported in the literature. I have reviewed multiple articles including the following out of evidence based spine care journal entitled "Microdiskectomy for the Treatment of Lumbar Disk Herniation and Evaluation of Reoperations and Long Term Outcomes". In that paper patients were followed for greater than five years and a minority required further spine surgery which was related to the initial microdiskectomy. There was no evidence of long term fusion surgery required in that article authored by Aichmairl in October of 2014. Likewise in the Journal of Spinal Disorders, a February of 2014 article entitled "Limited Microdiskectomy for Lumbar Disk Herniation: A Retrospective Long Term Analysis", there were reoperations for recurrent disk herniations in a small number of patients. There was no report of patients requiring fusions in the long term. This article was authored by Soliman, et al. The Journal of Neurosurgery 2009, February, entitled "Recurrent Disk Herniation and Long Term Back Pain After Primary Lumbar Diskectomy: Review of Outcomes" reported for limited versus aggressive disk removal by McGirt, et al., indicates that there were no fusions performed. Journal of Neurosurgery of the Spine, February of 2010, "Long Term Back Pain After Single Diskectomy for Radiculopathy" showed after long term follow-up there was no probability of patients going on to require lumbar fusion. This article was authored by Parker, et al. Additional articles including the Spine Journal, July of 2006, "Mid to Long Term Outcome of Disk Excision in Adolescent Disk Hernias" in which patients were followed between 1984 and 2002 with an average time from surgery to follow-up of 8.9 years. There was only one patient that required a fusion. These articles and others would suggest against Dr. Cash's recommendation that the patient will require a lumbar spine fusion in the next 10 years. Certainly I can state to a reasonable degree of medical probability that the patient will not go on to require a lumbar fusion, and that is based not only on opinions that I've authored prior, but based on a literature review which does not indicate that patients undergoing disk decompressive surgery or microdiskectomy will be subjected to fusions in the future. Certainly a small number of patients require reoperation for recurrent disk hernia but it would be improbable for patients undergoing microdiskectomy whether it be at one or two levels that would go on to require lumbar spine fusion. The literature supports my opinion that this patient will not require future surgical treatment in the way of a fusion. If there are any other questions or concerns please feel free to contact me.

Reynold L. Rimoldi, MD/DA
DT: 7-24-15