3-25-2022

Endoscopic Decompression versus Open Laminectomy for Lumbar Spinal Stenosis: A Prospective Safety Study

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ENDOSCOPIC DECOMPRESSION VS. OPEN LAMINECTOMY FOR LUMBAR SPINAL STENOSIS: A PROSPECTIVE SAFETY STUDY

A Thesis Presented to
The Faculty of the School of Medicine
Yale University

In Candidacy for the degree of
Master of Medical Science

March 2022

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Abstract

Lumbar spinal stenosis is the narrowing of the vertebral central canal, lateral recess, and/or foramen, compressing the spinal nerves and is a common source of leg and back pain. Fully endoscopic decompressive surgery is a new and evolving surgical technique with proven efficacy. However, evidence of the safety of endoscopic procedures compared to conventional open laminectomy is lacking. **In this prospective cohort study, we seek to investigate the safety of fully endoscopic decompression when compared to open laminectomy, specifically for nerve injury, incidental durotomy, epidural hematoma, and surgical site infection.** We will recruit patients with single level lumbar spinal stenosis without a need for fusion who are refractory to conservative treatment and undergo either fully endoscopic decompression or open laminectomy. Follow-up with patients one-year post-surgery will determine occurrence of adverse events. This evidence can direct the use of endoscopic decompression over open laminectomy for single level lumbar spinal stenosis.

CHAPTER 1: INTRODUCTION

1.1 Background

1.1.1 Lumbar Spinal Stenosis

Degenerative Lumbar spinal stenosis (LSS) is the narrowing of the vertebra in one of three general locations: central canal, lateral recess, and/or intervertebral foramen. Degenerative change from the normal aging process is the most common cause of LSS.[1] Degenerative spondylosis is the wear-and-tear of bones and intervertebral discs that increases the load on the posterior elements of the spine, leading to osteophyte formation, facet hypertrophy, synovial facet cysts, and ligamentum flavum hypertrophy. Spondylolisthesis from degenerative changes or fracture of the pars interarticularis (isthmic spondylolisthesis) can also cause LSS by instability and anterior slippage of the vertebra.[2] Uncommon causes of LSS include spinal lesions, rheumatologic conditions, ankylosing spondylitis, idiopathic skeletal hyperostosis, trauma, infection, or post-surgical proliferation of bone or scar tissue.[2,3]

Lumbar spinal stenosis is the most common reason for spine surgery in the elderly population and the prevalence is expected to rise as life expectancy in the US continues to rise. Though it is difficult to determine exact prevalence, as there are no universally accepted criteria, studies find a frequency ranging from 14.3-47.2% in the 60-69 age range.[1,2,4] Studies agree that the risk of LSS increases with age. The risk can be reduced by maintaining a healthy lifestyle by exercising regularly and keeping a healthy bodyweight as obesity can increase the burden on the spine.[5]

Central canal stenosis more often presents as neurogenic claudication, whereas lateral recess, foraminal, and extraforaminal stenosis more likely presents as

radiculopathy.[6] Neurogenic claudication is caused by compression of the cauda equina and is often bilateral but may be asymmetric. This presents as pain, numbness, and/or tingling exacerbated by standing in erect position, walking, descending stairs, or any movement requiring lumbar extension.[2,4] Neurogenic claudication can be differentiated from vascular claudication in that vascular claudication occurs with flexion as well as extension. Pedal pulse can also help determine the etiology. Radiculopathy is caused by compression of the nerve root and presents typically as pain that travels in a dermatomal fashion, which can help identify the involved nerve roots and level of stenosis. On physical exam, passive and active lumbar extension can elicit symptoms. The pain is described as sharp, burning, radiating pain that is associated with paresthesia, numbness or weakness in roughly half of LSS patients.[7] Saddle anesthesia, numb or abnormal feeling in the perineum, groin, buttocks, and upper thigh, or bladder dysfunction can be identified in approximately 10% of LSS patients.[4]

1.1.2 Treatments

Classically, symptomatic LSS initial treatment is physical therapy, manual therapy, anti-inflammatory medications, analgesics, epidural injections, and lifestyle modifications.[1,8] Physical therapy is considered first-line in all cases of LSS unless there is a surgical emergency, such as cauda equina syndrome. The intention of physical and manual therapy is to strengthen the core, improve flexibility and endurance. Interventions with medications or injections aim to reduce pain or inflammation of the compressed nerve root(s).[8] Conservative treatment has been shown to have similar efficacy regarding a reduction in Oswestry Disability Index (ODI) score after short-term follow up (6 months to 1 year), but a smaller reduction is seen with long-term follow up when

compared to surgical intervention in two of three studies.[8-10] The benefit of conservative treatment is the reduction in frequency and severity of complications. The most common complication of physical therapy is worsening of symptoms. Some of the complications of surgery include incidental durotomy, surgical site infection (SSI), nerve injury, and epidural hematoma. For this reason, surgical intervention is considered only if the patient is refractory to conservative management.

Incidental durotomy, or incidental dural tear, is one of the most common complications in minimally invasive surgery. If properly managed, it presents minor risk to the patient. It can lead to increased muscle dissection, operative time, and risk for secondary complications such as pseudomeningocele. Durotomy discovered intraoperatively should be repaired and may require conversion to open surgery.[11] Surgical site infection (SSI) can be superficial or deep, such as discitis. SSI may require revision surgery, long-term antibiotics, and prolonged hospitalization.[12] Nerve injury can cause motor and sensory deficits of the associated dermatome and may require reoperation.[13] Late identification can lead to a worse prognosis, possibly permanent deficits. Postoperative epidural hematoma is the coagulation of blood at the level of operation. Various degrees can be detected on MRI, though most patients are asymptomatic. MRI is only recommended in patients who experience a new onset of symptoms. Patients may present with severe pain, paresthesia, weakness, dysfunctional defecation, or dysuria. Early detection and surgical intervention are recommended to prevent outcomes such as permanent paralysis.[14,15]

Surgical interventions for LSS have evolved greatly since the first lumbar laminectomy in 1829. Open lumbar laminectomy remained the standard surgical

treatment until the operative microscope was developed in the 1960's and adopted for spine surgery. This allowed for smaller incisions, less blood loss, and a quicker return to daily activities.[16] With the patient in the prone position, the traditional laminectomy involves detachment and retraction of the paraspinous muscles from the spinous process, vertebrae lamina and facets to the lateral laminar border. To expose the ligamentum flavum, the spinous process and dorsal laminae are resected using a bone cutting rongeur or a burr. The ligamentum flavum is resected with a Woodson elevator and spatula. The medial aspect of the facet joint is removed to decompress lateral recess stenosis. A Kerrison rongeur can be used to decompress the foraminal region. To avoid iatrogenic spinal instability, at least 50% of the facet joint complex and pars interarticularis should be preserved.[6,17] A significant disadvantage to open laminectomy is the high proportion of new or worsening symptomatic spondylolisthesis requiring reoperation with fusion in 1.6%-32% of patients.[18,19] The retraction and dissection of paraspinal muscles can also increase post-surgical pack pain and muscle atrophy.[20]

The Spine Patient Outcomes Research Trial (SPORT) was a large prospective study evaluating surgical intervention (open laminectomy) with or without fusion, with nonsurgical treatment (physical therapy, education, counseling, nonsteroidal anti-inflammatory drugs). The study included a randomized arm and an observational arm for those who did not wish to undergo randomization. Many articles have been published evaluating different aspects of the trial at varying intervals (2-year, 4-year, 8-year, etc.).[21-25] At two and four years, surgical intervention was more successful at improving pain and function. Intraoperative or postoperative transfusion was needed in 15% of cases and dural tear occurred in 9%.[24,25] A study of cost-analysis between cases reported higher

net cost in surgical group for spinal stenosis at two years and comparable costs at four years.[22,23]

Minimally Invasive Surgical (MIS) techniques initially developed using a surgical microscope or loupe magnification and a smaller midline incision. The development of microendoscopic decompression involved a tubular retractor which creates a surgical corridor to expose the site of stenosis.[26] This provides a working canal with microscope, loupe magnification, or endoscope for visualization and helps preserve posterior musculature and reduce postoperative pain.[6,16] Fully endoscopic spine surgery has been a recent innovation, which uses a small incision without use of a retractor, allowing for minimal disruption of soft tissues. As advances in medical technology progress, new endoscopic techniques develop. The approaches established for endoscopic decompression can be broadly classified as interlaminar, transforaminal, or extraforaminal.[19,27,28] Endoscopic decompression can also be classified as uniportal or biportal endoscopic spine surgery (BESS). For uniportal intraoperative visualization, surgeons may use a working channel endoscope or a visual trepan.[19,29] In biportal endoscopy, one portal is used as a working portal while the other is used for visualization. All methods described below use x-ray fluoroscopy to confirm the level of stenosis, utilize general or epidural anesthesia, and operate with the patient in prone position. This list is not exhaustive.

Endoscopic unilateral laminotomy and bilateral decompression (Endo-ULBD) is a uniportal technique with a posterior approach. In Endo-ULB, a guide rod is inserted under x-ray fluoroscopy at the level of the lesion. The working sleeve and visual trepan are inserted along the guide rod. Radiofrequency electrodes and nucleus pulposus forceps

are used to expose the facet joints and lamina. The working channel is implanted into the spinal canal by removing the inner edge of the lamina using the visual trepan. The dilator is then replaced with the endoscopic operating system. Decompression of the osseous components is achieved with an Endo-Kerrison punch. The ligamentum flavum is explored and separated with medulla nucleus forceps to expose the nerve root. The trepan is used to bore to the contralateral side through the base of the spinous process. The same methods above are used to decompress the contralateral lesion. Decompression is confirmed by visualization of the dural sac and nerve root. The working channel is removed and the incision is sutured without a drain.[29]

BESS uses similar instruments for resection of osseous and soft tissues, such as arthroscopic burrs, shavers, and a Kerrison punch. Bipolar radiofrequency is used for hemostasis. With a 1 cm incision, two portals are made 1 cm distal and 1 cm proximal to the center of the target level, as close to the spinous process as possible. Either portal can be used for viewing or working at the surgeon's discretion. Continuous irrigation with isotonic saline is necessary for visualization and must be maintained below 30 mm Hg to reduce the risk of postoperative epidural hematoma. The scope is inserted into the viewing portal and a smooth periosteal elevator in the working portal and triangulation is established between instruments. Soft tissue surrounding the interlaminar space is swept away without dissection and soft tissue between the lamina and ligamentum flavum are removed by radiofrequency and shavers. Once half the lower lamina and the ligamentum flavum of the target level are exposed, a burr and punch are used under a magnified visual field to perform an ipsilateral partial laminotomy. The ligamentum flavum is removed until the traversing root is entirely exposed. Contralateral sublaminar

decompression is then performed by removing the ligamentum flavum with a curette or Kerrison punch. Once the contralateral traversing nerve root is entirely exposed, the instruments are removed, a drain is placed, and the incisions is closed.[27,30]

For the BESS transforaminal approach, the two portals are similarly located 1 cm proximal and distal to the center of the target level. The portals differ in that they are placed 2 cm from the lateral margin of the pedicle, near the transverse process. The proximal port is generally used for viewing and the distal for working but switching is similarly up to surgeon's discretion. The arthroscope and periosteal elevator are introduced to their respective ports and a working space is created between the facet and underlying transverse process. Soft tissues that interfere with visualization are removed with radiofrequency or shavers. Continues isotonic saline irrigation is used to establish a clear field of view. Foraminal decompression is performed by removing the hypertrophied segment of the superior articular process with a chisel or punch. The hypertrophied segment is removed in small pieces. The foraminal ligament covering the nerve root is detached from the distal surface of the pedicle and transverse process and removed. Once the nerve root is visualized, the instruments are removed, and the site is closed.[27,30,31]

New approaches and techniques continue to be developed with variation between surgeons based on clinical experience and methods. Other approaches have included extraforaminal approaches[30,32,33], a contralateral interlaminar "keyhole" approach for unilateral stenosis[34], and uniportal paramedian approach[35] to name a few. An "outside-in" technique retracts the exiting nerve root with the working sheath, lessening the risk of dysesthesia and irritation.[36] Some studies evaluate the use of different arthroscope angles

to address the issue of limited visualization.[20,37] Medical technologic advances also play a role in increasing the efficacy and safety of endoscopic spinal surgeries. The use of electromagnetic-based navigation (EMN) allows for virtual, real-time imaging without the use of fluoroscopy. This reduces the amount of radiation exposure for the patient. A reduction in the duration of surgery and intraoperative pain was also observed with EMN.[38]

Most methods of surgical decompression can be done with or without fusion. Spinal fusion is the joining of two or more vertebrae into one immobile segment.[39] Spinal implants are often used to stabilize fused segments.[17] Decompression with fusion is indicated in patients with LSS and spinal instability, spondylolisthesis (degenerative or isthmic), or deformity such as kyphosis or scoliosis. The addition of fusion increases risk or reoperation and complications with increased cost and conflicting evidence of efficacy.[17]

Postoperative care was previously ill-defined and would consist of limited counseling on being active or exercises that a patient would perform independently with the intention of preventing deep vein thrombosis. Within the last decade, active rehabilitation has been used to increase both short-term and long-term functional status.[40]

1.2 Statement of the Problem

The efficacy and safety of endoscopic procedures for discectomy have been sufficiently studied, which led to the adaptation of fully endoscopic procedures in lumbar spinal stenosis decompression. As fully endoscopic methods are a recent development, there are many variations in technique, such as the use of one or two portals, the angle of approach, and the point of access to the area of stenosis. Many if not all the studies

reviewed had only evaluated one endoscopic method, often using a single surgeon. This reduces the generalizability of the findings. The efficacy of endoscopic procedures has been confirmed to be noninferior to open laminectomy for multiple methods.[41-43] Safety, on the other hand, needs to be further evaluated.

Often, studies lack a critical component in the proper evaluation of the safety of fully endoscopic decompression. Many studies have been retrospective in nature and often call for the need of a prospective study.[44] Another limitation commonly found was the lack of a control group to properly compare the novel intervention.[43] Some studies evaluate only a single intervention, while others compare two novel interventions without comparing either to the current gold standard, open laminectomy. Many of the studies include an evaluation of safety, but safety is seldom evaluated as a primary outcome. As such, safety is often poorly evaluated, documented, or discussed.

To our knowledge, there have not been any prospective, multi-institutional safety studies that have been inclusive to the many fully endoscopic decompression methods for treatment of degenerative lumbar spinal stenosis in adult patients.

1.3 Goals and Objective

The purpose of this study is to investigate the safety of fully endoscopic decompression methods compared to open laminectomy for the treatment of degenerative lumbar spinal stenosis. We propose a multi-institutional prospective cohort study comparing the surgical treatments with a primary objective of determining the proportion of complications, including nerve injury, incidental durotomy, epidural hematoma, and surgical site infection. Secondary objectives to be evaluated: operation length, length of stay, rate of recovery, return to normal activities, all-cause mortality, readmission,

reoperation rates, post-surgical Modified Macnab criteria, Visual Analogue Scale (VAS) for pain, and Oswestry Disability Index (ODI) compared to pretreatment.

1.4 Hypothesis

If endoscopic decompression is compared to open laminectomy in patients with lumbar spinal stenosis requiring surgery, then a difference in proportion of postsurgical complications will be observed.

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CHAPTER 2: REVIEW OF THE LITERATURE

2.1 Introduction: Search Criteria

We conducted a systematic review of the literature from November 2021 to March 2022 using Pubmed, Scopus, and Cochrane Library databases. The search was conducted using the terms “lumbar spinal stenosis” in combination with either “open laminectomy”, “endoscopic decompression”, or “minimally invasive surgery”. Due to recent advances in fully endoscopic decompression techniques, articles published after 2015 were given preference. The references of UpToDate articles “Lumbar spinal stenosis: Pathophysiology, clinical features, and diagnosis” and “Subacute and chronic low back pain: Surgical treatment” and references of included articles were evaluated for relevance and inclusion. Articles were evaluated by title and abstract with subsequent evaluation of the full article. We reviewed the surgical techniques performed to ensure relevance. We only included articles written in English.

The articles evaluate a surgical technique using either fully endoscopic methods or traditional open laminectomy with or without microscopy. Articles that evaluate exclusively minimally invasive surgery using tubular retractors were excluded. Articles were excluded if they involved spinal fusion, interspinous spacer placement, stenosis due to herniated disk, or discectomy without bony decompression. Included studies are systematic reviews, meta-analyses, retrospective observational studies, prospective observational studies, randomized controlled trials (RCT), and supportive articles. The literature was analyzed to identify limitations of current studies and the current gap in knowledge related to lumbar spinal stenosis surgery.

2.2 Review of Studies involving Open Laminectomy

Of the empirical studies involving open laminectomy treatment for lumbar spinal stenosis, two were retrospective observational studies. Retrospective observational studies are weaker than prospective or randomized controlled trials, but still provide valuable information. Retrospective studies also have an inherent risk of information bias and selection bias. Antoniadis et al. published a retrospective study in 2017 of 121 patients from age 80 to 89 who underwent open bilateral laminotomy (N=84), laminectomy (N=26), hemilaminectomy (N=6), hemilaminotomy (N=2), and "over-the-top" technique (N=3).[1] Follow-up questionnaire was completed by 72 patients. Complications were not individualized to the corresponding procedure so open laminectomy could not be viewed alone. The study reported two wound infections, three reoperations for decompression, one epidural hematoma, one case of secondary spondylodesis, and five dural lesions. No cases of nerve-root injury were reported. With a mean follow-up time of 36 months, patients visual analogue scale (VAS) for pain improved from an average of 7.2 (95% CI, SD ±1.0) at baseline to 4.5 (SD ±1.2), an improvement of 2.7 points ($p<0.0001$). A statistically significant improvement in walking distance from 147 to 340 meters (SD ±170, $p < 0.001$) was also reported. The perioperative complication rate of this study was 6.6%, which was lower than the anticipated 22.5%. This study only included patients 80-89 years old in Europe at a single center, reducing generalizability. Additionally, a loss to follow-up of 27% reduced available data.[1]

Oichi et al. published a retrospective cohort in 2018 that compared the complication rate of a minimally invasive laminectomy technique with conventional open

laminectomy.[2] The Diagnostic Procedure Combination database of Japan was used to review the records of 1,536 LSS patients who underwent open laminectomy without fusion. One or more major complications such as a cardiac event or stroke was reported in 43(2.8%) patients, SSI 25(1.6%), and delirium 16(2.3%). Median length of stay was 16 days with an interquartile range of 12-22. This study likely underreported complications due to a lack of information after discharge and that the dataset is comprised of administrative data.[2]

A multicenter prospective observational study in Norway by Nerland et al. was published in 2015 comparing open laminectomy to microdecompression.[3] The microdecompression procedure falls under MIS techniques and will not be evaluated here. The laminectomy group consisted of 414 patients with a dropout rate of 22.3% at one-year follow-up. The average length of hospital stay was 3.4 days. By surgeon and patient reporting, 62 (15%) patients had one or more complications. Perioperative complications included dural tears 21 (5.1%), blood replacements/hematoma 4 (1%), anaphylactic reaction 1 (0.2%), and no nerve root injuries, cardiovascular, or respiratory complications. Within three months, 11 (2.7) patients experienced wound infections and 2 (0.5%) had a deep vein thrombosis. At follow-up, a 16 point mean reduction in ODI score was reported in the laminectomy group. The high loss of follow-up can indicate selection bias. A significant strength of this study was the large sample size.[3]

Lurie et al. published eight-year outcomes of open laminectomy versus non-operative care for LSS in 2015.[4] This study included a randomized controlled trial and a concurrent prospective cohort. Data was gathered from the Spine Patient Outcomes Research Trial (SPORT), a study of 13 U.S. centers in 11 states. Of the RCT group, 138

patients were assigned to the surgery. Of the observational (OBS) group, 219 patients chose surgery. Eight-year follow-up rates were 55% for RCT and 52% for OBS group. The proportion of complications for RCT/OBS of dural tear or spinal fluid leak was 15(9%)/23(9%), wound hematoma 3(2%)/1(0%), wound infection 4(2%)/5(2%), and undefined other 10(6%)/14(6%). There were no reported incidents of bone graft complication, cerebrospinal fluid leak, nerve root injury, paralysis, cauda equina injury, wound dehiscence, or pseudarthrosis. The functional assessment using ODI showed statistically significant effects ($p=0.02$) and pain had borderline significance ($p=0.08$) over all time periods in the OBS group, though the difference in effect diminished over time. The rate of re-operation for recurrent stenosis was 10% at eight years. The strength of this study lied in the long-term follow-up of eight years.[4]

Haddadi and Qazvini published a study in 2016 comparing conventional laminectomy to bilateral laminotomy and trumpet laminectomy.[5] For our purposes, only conventional laminectomy results are analyzed. Through randomization, 40 patients were assigned to the conventional laminectomy group with follow-up at 12 months. The reported perioperative complications were incidental durotomy 5(12.5%), increased radicular pain 1(2%), wound infection 1(2%), epidural hematoma 1(2%), postoperative urinary retention 4(10%), and progressive radicular deficit 1(2%). VAS score of back pain at 12 months decreased from 8.22 ± 1.75 to 3.85 ± 0.28 ($p<0.05$), leg pain from 7.52 ± 1.44 to 1.6 ± 0.44 ($p<0.05$), and ODI score from $75 \pm 33\%$ to $28 \pm 12\%$ ($p<0.01$). The surgeries were performed by a surgical team who specialized in bilateral laminotomy over the conventional laminectomy, which could influence reported results.[5]

In 2019, a randomized control trial by Ko and Oh compared bilateral decompression via unilateral laminotomy (BDUL) with conventional laminectomy.[6] The BDUL technique was in line with MIS surgery. Conventional laminectomy was performed on 25 patients with LSS. This study did not evaluate any forms of perioperative or postoperative complications. The VAS for back, buttock, and leg pain decreased from 5.20 ±2.843, 5.20 ±2.958, and 7.20 ±1.633 respectively to 1.56 ±1.734, 1.08 ±1.631, and 1.04 ±1.744 respectively at 24 months. ODI scores at baseline were not recorded, reducing the value of the score at 24 months. The conventional laminectomy group had an ODI score of 11.44 ±6.740. This study lacked much information regarding functional outcomes and was devoid of data regarding safety.[6]

A study by Soliman and Ali published in 2019 compared a bilateral interlaminar technique with open laminectomy.[7] The participants were randomized to each intervention with 109 patients undergoing open laminectomy. Perioperative complications were reported as dural tear 9(8.3%), radicular deficit 3(2.8%), and wound infection 4(3.7%). There were no cases of epidural hematoma, and no other complications were evaluated. VAS of lower back and leg pain improved from 6.82 ±1.18 and 8.06 ±0.94 to 3.08 ±1.02 and 1.08 ±0.31 respectively at three-year follow-up. ODI score improved from 33.77 ±5.65 to 14.06 ±6.27. The authors speculate that though no nerve root injury or compression was identified, it could have been the cause of radicular deficit.[7]

A systematic review and meta-analysis by Phan et al. reviewed 12 articles regarding minimally invasive unilateral laminectomy for bilateral decompression (ULBD) compared with conventional open laminectomy.[8] The reported complications of

patients who underwent open laminectomy were dural injury 18(4.8%), reoperations 16(5.8%), and cerebrospinal fluid leak 8(2.9%). No other complications were evaluated. Open laminectomy achieved 75.4% patient reported satisfaction and a significant reduction in VAS scores was reported in each study. ODI scores were mentioned but not included by the review, likely due to only two studies evaluating ODI scores. Publication bias was internally assessed using funnel plots, which did not detect a risk of publication bias.[8]

2.3 Review of Studies involving Endoscopic Decompression

The reviewed studies that included fully endoscopic decompression but did not include open laminectomy consisted of 20 retrospective studies, 4 prospective studies, 3 RCTs, and 2 meta-analyses.

2.3.1 Retrospective Studies of Endoscopic Decompression

Retrospective studies have an increased risk of selection bias by inclusion and exclusion criteria and information bias from underreporting.

In 2014, Lewandrowski reviewed 220 cases of lumbar lateral recess stenosis with or without disc herniations using an "outside-in" technique for endoscopic decompression.[9] Mean follow-up was 46 months (26-52 months). This study claims that there are no approach-related complications, though it does not define what is considered an approach related complication. An excellent or good result by Macnab criteria was achieved in 186(85%) patients and the mean VAS score decreased from 7.5 ±1.5 to 2.8 ±1.9. The study only evaluated leg pain. A strength of this study is in further classifying lateral recess stenosis into entry zone, middle zone, and exit zone.[9]

In 2018, Lewandrowski published a study evaluating readmissions after outpatient transforaminal endoscopic decompression for lumbar lateral recess and foraminal stenosis utilizing the "outside-in" technique.[10] In 2019, Lewandrowski published a second study with the same study participants, evaluating complications and associated cost. [11] Of the 1839 patients at a mean of 33 months follow-up, complications were identified by emergency room visits or hospital readmissions. Reported complications were incidental durotomy 2(0.11%), extravasation of irrigation into subcutaneous tissue 69(3.8%), spinal headaches 8(0.4%), foot drop 2(0.11%), and successfully managed dysesthetic leg pain 10(0.54%). Hospital readmissions included dysesthetic leg pain 9(0.49%), wound infections 2(0.11%), and poorly controlled incisional pain 5(0.27%). There were no reported approach or anesthesia-related complications. According to Macnab criteria, 75% of patients with spinal stenosis achieved good or excellent results. This study had a significant study population and a low rate of complications reported, though underreporting is a risk due to use of electronic medical records and only reports from emergency room visits or hospitalization being included.[10,11]

In the same year, Kim and Choi published a study evaluating the clinical and radiological outcomes following biportal endoscopic decompression with of lumbar spinal stenosis in 55 patients.[12] Reported complications consisted of dural tear 2(3.6%) and epidural hematoma 1(1.8%). Both dural tears were 5 mm or less and did not require repair. The epidural hematoma was evacuated via percutaneous method. No nerve root injuries or infections were reported. The VAS for leg pain decreased from 7.7 ±1.5 to 1.7 ±1.5 ($p<0.01$) and ODI score from 67.4 ±11.5 to 19.3 ±12.1 ($p < 0.01$) at two-year

follow-up. Modified Macnab criteria recorded outcomes were excellent 25(45%), good 20(36%), fair 9(16%), and poor 1(2%). This study lacked a control group but was novel in the use of a 30° arthroscope.[12]

Kim and Choi also published a study in 2019 which evaluated biportal endoscopic decompression compared to microscopic decompression and decompression with fusion and instrumentation.[13] Of the 98 patients with single or multi-level LSS included in two-year follow-up, 35 were treated with endoscopic decompression of the central canal with or without foraminal stenosis. The total complication rate was 8.6% with dural tear 2(5.7%) and nerve root injury 1(2.9%). No cases of SSI or epidural hematoma were reported. Back pain VAS improved from 6.8 ±1.0 to 2.8 ±1.0 and leg pain VAS from 6.3 ±1.1 to 2.2 ±0.8. Though insufficiently powered to evaluate complications, this study did identify the need to properly evaluate and decompress concurrent foraminal stenosis to avoid reoperation.[13]

Kim and Choi were also involved with a study led by Min published in 2020.[14] The study also compared biportal endoscopic decompression to microscopic decompression for single-level LSS patients. Of the 89 patients, 54 were treated with biportal endoscopic decompression with a follow-up of two years. Like the 2018 study, there were 2(3.7%) cases of dural tear treated without repair and 1(1.9%) case of epidural hematoma evacuated postoperatively through prior incisions. Given the study was conducted at the same hospital with a similar timeline, the reported complications are likely from the same cases as the 2018 study. The clinical outcomes differed slightly but had the same trend of effect. Leg pain VAS improved from 7.38 ±0.65 to 1.48 ±0.94, back pain VAS from 5.27 ±0.91 to 1.64 ±0.91, ODI score from 60.4 ±6.88 to 15.4 ±8.49,

and 83% of patients reporting excellent or good outcomes by Modified Macnab criteria. A limitation identified in the three previous studies was the lack of consideration for the learning curve associated with endoscopic decompression.[14]

Two studies were published by Kim and Choi (with one[15] and five[16] additional authors) published in 2019 and 2020. Both studies included patients with single-level LSS. The first study investigated the impact of epidural hematoma after biportal endoscopic decompression on clinical outcome.[15] Hematoma was identified on MRI on the day of drain removal (day 1 or 2). Hematoma grades included grade 0 (no hematoma) with 119(75.3%) patients, grade I (<25% compression of spinal canal) with 14(8.8%), grade II (25%–50% compression) with 19(12%), grade III (50%–75% compression) with 5(3.1%), and grade IV (>75% compression) with 1(0.6%). Two patients, grade III, underwent revision surgery due to hematoma evacuated through prior portal incisions. Group A included the 39 patients with grade 1-4 hematoma. Clinical outcomes at one-year or more follow-up reported VAS for leg pain from 7.7 ±0.61 to 2.2 ±0.9, VAS for back pain from 4.8 ±0.9 to 2.2 ±0.9, and change in ODI score from 61.2 ±5.2 to 35.6 ±7.6. Group B VAS for leg pain from 7.2 ±0.6 to 1.2 ±0.8, VAS for back pain from 4.9 ±0.9 to 1.2 ±0.8, and ODI score from 60.5 ±6.4 to 14.3 ±7.5. By Macnab criteria, 29(74.3%) of patients in Group A and 103(86.5%) in Group B answered excellent or good. The differences in all clinical assessments were statistically significant ($p<0.05$) in favor of Group B (Grade 0).[15]

The second study evaluated the effectiveness of a Gelatin-Thrombin Matrix Sealant (GTMS) in preventing or reducing severity of epidural hematoma with the same treatment.[16] GTMS began use at the study location in 2017. Group A consisted of 117

patients who did not receive GTMS; with the same authors as the previous study, there is likely overlap in this study population. Group B consisted of 89 patients that did receive intraoperative GTMS. Group B had statistically significant improvements to ODI score compared to Group A, 13.6 ±6.4 and 16.0 ±8.5 respectively (p=0.019). A significant improvement was also seen in VAS for leg, back, and Modified Macnab criteria. This study conveys the effect of epidural hematoma on clinical outcomes of decompressive surgery and provides a novel method of reducing occurrence and severity.[16]

In 2019, Khalsa et al. published the clinical and radiographic outcomes of fully endoscopic decompression for 19 patients with lumbar stenosis of the central canal with or without lateral recess stenosis.[17] The mean VAS score improved from 7.9 (95% CI 7.4–8.5) preoperatively to 2.2 (95% CI 1.9–2.5) postoperatively (p<0.001). This article's primary focus was regarding the volume of bone resected during this procedure therefore data regarding complications was not reported. The study weaknesses include limited functional evaluation, such as ODI, small sample size, and the lack of a comparison group.[17]

Lim et al. published a study in 2019 that evaluated the efficacy of a uniportal endoscopic decompression technique for LSS in one to three spinal levels.[18] The study sample included 450 patients with central canal and/or lateral recess stenosis. A new endoscopic instrument, a stenoscope developed for translaminar and interlaminar approach, was used during all procedures. There were 13(2.9%) reported complications of incidental dural tear 7(1.6%), epidural hematoma 5(1.1%), nerve root injury 2(0.4%), and reoperation 6(1.3%). The reported complications for 1, 2, or 3 levels of decompression were combined. For single level decompression, operation time was 32.3

±15.25 and duration of hospitalization was 1.42 ±0.1 days. At 12 months postoperative VAS score for back pain improved from 6.00 ±4.21 to 2.13 ±3.01, leg pain from 7.10 ±2.51 to 2.31 ±4.15, and ODI score from 58.81 ±11.65 to 23.72 ±4.12. Study strengths include a large sample size and clearly interpreted data. Weaknesses include a lack of control group and high loss to follow-up (250/450).[18]

Heo, Lee and Park published a retrospective analysis comparing microscopic laminotomy, uniportal endoscopic decompression and biportal endoscopic decompression.[19] Biportal endoscopy was used in 37 patients and uniportal in 27. Reported complications for biportal endoscopy were dural tear 1(2.7%) and epidural hematoma 1(2.7%). For uniportal endoscopy, dural tear 1(3.7%), transient weakness 1(3.7%), and epidural hematoma 1(3.7%). The severity and treatment of complications was not discussed. SSIs were not evaluated. For biportal endoscopy, VAS for back pain improved from 7.02 ±1.34 to 1.95 ±0.81, VAS for leg pain from 8.05 ±1.08 to 2.16 ±0.79, and ODI score from 58.68 ±5.57 to 23.14 ±2.69. Respective changes for uniportal decompression were 7.04 ±1.48 to 1.81 ±0.68, 7.93 ±1.07 to 1.89 ±0.80, and 56.70 ±5.66 to 23.54 ±2.67. Macnab criteria was not evaluated.[19]

The following four retrospective studies were published in 2020. First of which by Kim, Choi, and Park evaluated risk factors and management of incidental dural tears.[20] The study included 1,551 cases of lumbar disk herniation (LDH) or LSS treated with biportal endoscopic spine surgery (BESS) up to two years after one of four surgeons started using BESS in practice. Incidental durotomy was reported in 25(1.6%) cases. Fourteen (56%) of cases were in the first six months of the surgeon's learning-curve period. The initial diagnosis for sixteen cases were LSS, six were LDH, two were

recurrent disc herniation, and one was revision surgery for LSS. Twenty cases of dural tear were 10 mm or less, 19 of which were improved with a patch without need for conversion to open surgery and one was detected 3 days postop and treated with delayed open repair. Five cases had a larger than 10 mm dural tear, three of which were repaired via immediate conversion to open surgery, one was sutured by endoscopic clipping, and one failed patch compression with fibrin glue and required open repair at week five postop. This study places dural tear at a higher risk during the first six months of the learning-curve, so further reduction could be seen with experience beyond two years.[20]

A study by Li et al. examined outcomes of transforaminal endoscopic decompression for single-level lumbar lateral recess stenosis in 56 patients older than 65 (group A) compared to 61 patients younger than 65 (group B).[21] Eight patients experienced complications including three dural tears without residual problems and five with temporary leg numbness that recovered in two weeks. The study did not account for epidural hematoma, SSI, or nerve root injury. Group A VAS for leg pain improved from 6.5 ±1.0 to 1.0 ±1.1 and ODI score from 62.4±12.9 to 15.4 ±12.1. Group B VAS from 6.3±1.1 to 1.3±1.1 and ODI from 60.9±11.3 to 16.3 ±9.5. This study's weaknesses are the small study size and lack of a compare group.[21]

A study by Xie et al. was published investigating the efficacy of transforaminal endoscopic decompression for single-level LSS.[22] A total of 45 patients were included, 22 with lateral recess stenosis, 13 with central canal stenosis, and 10 with foraminal stenosis. Patients had a final follow-up at one year. Complications were not evaluated. VAS for low back pain improved from 6.70 ±1.15 to 2.58 ±1.11, VAS for leg pain from 7.01 ±0.84 to 2.28 ±1.43, and ODI scores from 46.18 ±10.11 to 14.40 ±9.59. There was

no clinically significant difference in results by location of stenosis. This study's limitations were lack of control group, small sample size, and a single surgeon at a single institution. Detailed evaluation by location of stenosis was a unique strength of the study.[22]

Kim et al. compared endoscopic decompression to microscopic laminectomy using tubular retractor.[23] Thirty patients underwent endoscopic decompression for lumbar central canal stenosis with a final follow-up at one year. Reported complications included only 1(3.3%) case of cerebrospinal fluid leak which resolved with conventional treatment. There were zero reported infections in the endoscopic group. Epidural hematoma and nerve root injury were not discussed. VAS for pain (unspecified) improved from 7.13 ±0.86 to 1.23 ±0.43, ODI score from 71.20 ±4.29 to 23.53 ±3.51, and a Modified Macnab score of 76.66%.[23]

Ito et al published a study in 2021 which compared biportal endoscopic decompression to microendoscopic laminectomy for single-level LSS.[24] The fully endoscopic group included 42 patients with an average duration of surgery of 51 ±12.2 minutes. The reported complications consisted of 2(4.8%) dural injuries, with no cases of epidural hematoma or reoperation. SSI and nerve root injury were not considered. The VAS for lower back pain decreased from 3.7 ±1.1 to 1.5 ±0.6, VAS for leg pain from 3.9 ±1.3 to 1.0 ±0.4, and ODI score from 23.5 ±9.2 to 11.3 ±5.6. This study included only a six-month follow-up so long-term effects were not analyzed. The sample size was also too small to evaluate complications.[24]

The following four studies were retrospective case studies describing technique and clinical outcomes and lacked a comparative group. First, in 2016, Hwa Eum et al.

studied biportal endoscopic decompression with bilateral foraminal decompression.[25] The 58 enrolled patients had a final follow-up at one year. Of the 2(3.4%) occurrences of dural tear, one was repaired by conversion to microscopy and sutured, the other was repaired with clips endoscopically. Additional reported complications were postoperative headache 3(5.2%), transient leg numbness 2(3.4), and epidural hematoma 1(1.7%), all of which resolved after conservative management. VAS for leg pain improved from 8.3 ±1.1 to 2.4 ±1.1 and ODI score improved from 67.2 ±11.7 to 24.3 ±8.5. Patients reported good or excellent results in 47(81%) cases by Modified Macnab criteria. The study had a contradiction in the discussion that 66 patients were included in the study. The above percentages were based on 58 patients reported throughout the article.[25]

Of the same year, Li et al. evaluated a uniportal transforaminal approach for lateral recess stenosis in 85 patients with a two-year follow-up.[26] The only reported complication was temporary dysesthesia in 3(3.5%) patients that resolved in 1-2 weeks with conservative management. There were no SSI or nerve root injuries reported. Incidental durotomy and epidural hematoma were not discussed. Clinical outcomes of VAS for low back pain (1-100) improved from 25.29 ±13.50 to 8.59 ±8.75, VAS for sciatica from 75.76 ±9.43 to 2.47 ±5.32, and ODI from 74.96 ±9.51 to 14.72 ±4.87. Functional outcome using Modified Macnab criteria was reported as excellent or good in 77(90.6%) cases.[26]

In 2017, Kim et al. published a study evaluating a uniportal decompression technique for bilateral stenosis with 48 patients with follow-up 5-13 months postop.[27] The only complication reported was 3(6.25%) cases of dural tear, one requiring conversion to open surgery. The other two required lumbar interbody fusion, but the

article does not address the treatment or severity of the dural tear. There is no mention of infection, nerve injury, or hematoma. VAS for leg pain improved from 7.41 ±1.07 to 2 ±1.05, VAS for back pain from 5.7 ±1.1 to 1.75±0.52 and ODI score from 65.13 ±24.21 to 23.77 ±3.98. Functional outcome by Modified Macnab criteria reported as excellent or good in 46(96%) cases. A limitation of this study is the review of electronic medical record which could be a source of underreporting of complications.[27]

In 2019, similar to the 2016 case series[26], Ahn et al. published on the technique and outcomes of uniportal transforaminal decompression for lumbar lateral recess stenosis.[28] This study included 45 patients with two-year follow-up. Postoperative dysesthesia was reported in 2(4.4%) cases controlled by epidural block and medications. The study reported zero cases of infection, hematoma, or dural tears. Nerve injury was not discussed in results, though the discussion segment comments on the approach having minimal risk of nerve injury. Clinical outcomes at two years reported improvement of VAS for leg pain from 7.93 ±0.78 to 1.71 ±0.84 and ODI score from 75.87 ±8.60 to 17.87 ±8.66%. By Modified Macnab criteria, excellent or good outcomes were reported in 39(86.7%) cases. One patient required reoperation due to incomplete decompression, attributed to severity of central canal stenosis.[28]

2.3.2 Prospective Studies of Endoscopic Decompression

In 2018, Heo, Quillo-Olvera, and Park published a case-control study investigating the clinical and radiological outcomes of biportal endoscopic decompression compared to microscopic laminotomy for treatment of single-level central canal lumbar spinal stenosis.[29] Forty-six patients were assigned to the endoscopic group and were operated on by one of two surgeons with at least five years of endoscopic

experience. There was 1(2.2%) case each of incidental durotomy and postoperative hematoma in the endoscopic group. There were no instances of postoperative instability or infection. Mean operation time was 61.1 ±5.2 minutes. VAS for back pain decreased from 7.04 ±1.38 to 1.98 ±0.80, VAS for leg pain from 7.96 ±1.07 to 2.07 ±0.77, and ODI score from 57.98 ±5.83 to 21.98 ±2.82 at 12-month follow-up. The dural area was evaluated with MRI, which described an increase from 398.7 ±97.8 mm^2 to 719.5 ±116.4 mm^2 postoperatively.[29]

In 2019, Kim and Jung published a prospective case series of 58 patients who underwent interlaminar biportal endoscopic decompression for single-level LSS.[30] The only reported complications were two dural tears that resolved with conservative treatment. MRI or CT was performed at 72 hours postop to evaluate for hematoma with none discovered. SSI and nerve root injury was not discussed. At 18-month follow-up, the mean clinical outcomes reported for VAS for back pain improved from 7.1 ±1.2 to 1.9 ±1.3 and VAS for leg from 7.9 ±0.8 to 1.6 ±1.5. ODI score was not assessed. By Modified Macnab criteria, 54(93.1%) patients reported excellent or good outcome.[30]

Aygun and Abdulshafi published a study in 2021 comparing biportal endoscopic decompression to microendoscopic decompression using tubular retractor.[31] The patients were randomly assigned to each surgical intervention to be performed by a single surgeon. Neither the patient nor treatment team were blinded, though the researcher collecting data was. There were 77 patients with single-level LSS who were enrolled in each group and completed follow-up at two years. This study did not evaluate or mention complications. The endoscopic group did not require any reoperations. Success rates for the endoscopic method by ODI and Modified Macnab criteria were 84% and 92%

respectively. In this trial, unilateral biportal endoscopic decompression was superior to tubular microendoscopic, though the study lacked any data on complications. A benefit to this study was the inclusion of foraminal stenosis in the study sample.[31]

A study by Wang et al. published in 2021 investigated a novel technique for treatment of LSS referred to as precise safety decompression via double percutaneous lumbar foraminoplasty and percutaneous endoscopic lumbar decompression (DPLF–PELD).[32] The mean duration of final follow-up was 13 months. Of the 69 included cases, only 2(2.9%) incidents of dural tear were reported. The tear was successfully treated with conservative methods. The study did report that there were no instances of hematoma or nerve root injury. SSI was not discussed. VAS for leg pain improved from 7.05 ± 1.04 to 0.75 ± 0.63 ($p<0.05$) and ODI score improved from 69.8 ± 9.05 to 19.6 ± 5.21 ($p<0.05$). Lower back pain VAS showed a trend toward effect but was not statistically significant. Functional outcome by Modified Macnab criteria was excellent or good in 94.2% of cases. To minimize selection bias, three observers blinded to the patient analyzed preoperative CT or MRI and confirmed lumbar stenosis in both the retrodiscal space (zone 1) and the upper bony lateral recess (zone 2).[32]

2.3.3 Randomized Controlled Trials involving Endoscopic Decompression

In 2015, Komp et al. compared full endoscopic interlaminar decompression to microsurgical laminotomy for lumbar central canal stenosis.[33] The final follow-up at two years included 71 patients that underwent endoscopic decompression, though intraoperative and perioperative complications were evaluated in the entire 80 patients included in enrollment. Reported complications include transient dysesthesia 4(5%), transient urinary retention 1(1.25%), dural injuries 2(2.5%), increased foot dorsiflexion

paresis 1(1.25%), and delayed wound healing without infection 1(1.25%). There were no cases of epidural hematoma or SSI. Mean VAS (1-100) for leg pain improved from 85 to 17, VAS for back improved from 23 to 17, and ODI score from 84 to 28.[33]

In 2019, Kang et al. published a study that compared biportal endoscopic decompression to microscopic laminotomy with a final follow-up at six months.[34] Of the 32 patients included in the endoscopic group, only 1(3.1%) case of hematoma was reported, requiring revision surgery. There were zero cases of infection reported. Evaluation of dural tear and nerve root injury was not evaluated. For clinical outcomes, VAS score for back pain improved from 6.3 to 1.6 and ODI score from 55 to 5. VAS for leg pain was not included. The small sample size was a limitation to appropriately assessing the rate of complication.[34]

Park et al. published the preliminary results of a study in 2019 with final results in 2020 comparing biportal endoscopic decompression to mini–open microscopic decompressive laminectomy.[34,35] The follow-up at two years included 29 patients in the modified intention to treat analysis. Intraoperative and perioperative complication reported of the 29 endoscopic patients include dural tear without repair 2(7%) and epidural hematoma requiring revision surgery 1(3%). There were zero cases of infection or nerve damage reported. VAS for back pain improved from 6.1 ±2.6 to 2.75 ±2.70, VAS for leg from 6.5 ±1.7 to 2.61±2.86, and ODI score from 46.2 ±20.5 to 19.79 ±19.67.[34,35]

2.3.4 Meta-analyses involving Endoscopic Decompression

In 2018, Lee et al. published an analysis investigating uniportal or biportal interlaminar endoscopic decompression for central or lateral recess LSS.[36] Five studies

published up to August 2017 were included in the analysis and included a total of 156 patients in Korea (4) or Thailand (1). Two of the studies have been included in this review[25 27]. The article published by Hwang was not included in the review due to lack of surgeon experience with the employed endoscopic procedure and small sample size.[37] Combined complications reported include transient paresthesia 4(2.6%), incidental durotomy 5(3.2%), epidural hematoma 3(1.9%), and postoperative headache 3(1.9%). There were zero reported infections. Four (2.7%) cases were converted to open surgery, two for dural tear and two for adhesions. Clinical outcomes reported as mean difference improvement from baseline at 12-month follow-up: ODI score of 65.48 (95% CI, 63.39–67.57) improved by 42.19 (95% CI, 39.80–43.62), VAS for leg pain of 7.99 (95% CI, 7.48–8.49) improved by 5.95 (95% CI, 5.70–6.21), and VAS for back pain of 6.39 (95% CI, 5.59–7.18) improved by 4.22 (95% CI, 3.88–4.56). The limited number of studies inhibits a statistical analysis of the complication rates. Lack of surgeon experience evaluation or criteria may impart bias on results as well.[36]

A meta-analysis by Laing et al. published in early 2022 included 13 studies from 2016 to 2021 investigating biportal endoscopic decompression.[38] Studies were conducted in Japan (1), Turkey (1), Thailand (1) and Korea (10). Though some studies included comparison to open laminectomy, those results were not included in the analysis. All 13 of the studies are included in this review, as such there is overlap with these results and those mentioned elsewhere. Combined complication rate was 5% (95% CI, 3%–8%; P = 0.07). Dural tears were reported in 2% (95% CI, 1%–4%; P = 0.55) and epidural hematoma in 1% (95% CI, 0%–2%; P = 0.84). Nerve root injury, incomplete decompression and postoperative headache were mentioned but a statistical analysis was

not performed. Mean VAS for leg pain improved from 7.23 (95% CI, 6.59%–7.78%; P < 0.001) to 1.83 (95% CI, 1.54%–2.13%; P < 0.001) postoperatively, VAS for back pain from 6.30 (95% CI, 5.55%–7.06%; P < 0.001) to 1.95 (95% CI, 1.53%–2.38%; P < 0.001), and ODI score from 56.99 (95% CI, 51.55%–62.44%; P < 0.001) to 17.83 (95% CI, 12.84%–22.83%; P < 0.001). Outcome by Modified Macnab criteria was excellent or good in 86% (95% CI, 82%–89%; P = 0.10). This recent meta-analysis concluded that large prospective studies and randomized trials are needed.[38]

2.4 Studies involving Endoscopic Decompression and Open Laminectomy

In 2020, Chiu et al. published a retrospective cohort study in conjunction with a systematic review.[39] The cohort gathered de-identified data on patients who underwent lumbar decompression for single-level LSS in 2017. Patients across 650 hospitals were identified as "endoscopic" or "open" using Current Procedural Terminology (CPT) codes in the American College of Surgeons' National Surgical Quality Improvement Program (ACS-NSQIP) database. The open group included 10,692 patients and the endoscopic group included 34. The endoscopic group reported no instances of SSI, epidural hematoma, or dural tear. The open group reported dural tear 5(0.05%), epidural hematoma 3(0.03%), and SSI 47(0.4%). Only adverse events that caused readmission to the hospital within 30 days were obtainable from the database. This limit could account for the abnormally low proportion of adverse events. Another limitation to this study is that the CPT codes used include a heterogenous group of surgical techniques. The "open" or "nonendoscopic" code includes minimally invasive procedures and traditional open laminectomy without specifying the intervention. The code for endoscopic procedures was introduced in 2017 and many institutions or surgeons may not yet use the code as

regularly. A limitation of the database was the lack of functional outcome measures such as VAS or ODI.[39]

According to our literature search, the only recent randomized controlled trial which compared fully endoscopic decompression to traditional open laminectomy was published in 2021.[40] Cuo et al. randomized patients from one hospital in China to endoscopic decompression or open laminectomy group with 69 patients in each. Final follow-up was three months after surgery. Complications of the endoscopic group included SSI 1(1.45%) and gastrointestinal dysfunction 1(1.45%). The open laminectomy group reported infection 2(2.90%), necrosis of incision 1(1.45%), dural tear 2(2.9%), and GI dysfunction 3(4.35%). Total proportion of complications was 8(11.59%) in the open group compared to 2(2.9%) in the endoscopic group. Functional outcome of VAS (unspecified) for endoscopy was 7.36 ±0.62 preop to 1.82 ±0.17 postop compared to open of 7.27 ±0.58 to 2.33 ±0.21. Endoscopic ODI score improved from 78.82 ±4.93 to 28.44 ±2.27 and open from 77.21 ±5.51 to 37.73 ±2.09. Limitations of this study are in generalizability as a single-center study in China. Also, only one method of endoscopic decompression was evaluated.[40]

2.5 Possible Confounding Variables

A retrospective study published in 2014 evaluated the risk of complications in LSS patients over the age of 80.[1] The overall complication rate of 6.6% found by this study contradicted the results from previous studies, which have shown up to 22.5% complication rate in open decompression. The discrepancy in results is likely due to the observed patient population. Differences in baseline comorbidities have been shown to effect rate of complications and readmission. Though the study had significant limitations

due to the database used, Kimmell et al. showed significant correlation between comorbidities and complication rates.[41] The study identified 14 preoperative and 5 intraoperative risk factors for complication, with one point attributed to each. Patients score and associated risk of complication as follows: 0(1.2%), 1(2.3%), 2(2.6%), 3(3.6%), 4(5.5%), 5(10.3%), 6(14.7%), 7(23.2%), 8(31.7%), 9(41.9%), 10(58.1%), 11(53.3%), 12(63.6%), 13(100%).[41] A multi-institutional retrospective study by Kim et al. investigated predictors of unplanned readmissions in 7016 patients who were treated with lumbar decompression.[42] In the multivariate analysis, anemia (OR 1.48, 95% CI 1.04–2.10; p = 0.029), dependent functional status (OR 3.03, 95% CI 1.86–4.92; p < 0.001), total operative duration (OR 1.003, 95% CI 1.001–1.004; p < 0.001), and ASA class 4 (OR 3.61, 95% CI 1.58–8.25; p = 0.002) were predictors of unplanned readmissions. The patients with readmissions had a mean age of 59.78 ±16.40 compared to 55.98 ±15.55 (<0.001) in patients without readmission. The relation between age and comorbidities may be what attributes older age with increased risk of complications and readmission.

Though considered a risk factor for complications in previous studies, obesity in two more recent studies showed no significant effect on the rate of perioperative complications of lumbar decompression.[43,44] A third study analyzing data from a Swiss prospective cohort determined that body habitus was not associated with decreased clinical outcomes, though complications were not evaluated in the study.[45]

The learning curve of endoscopic decompression has been investigated by two recent retrospective studies of two surgeons new to endoscopic decompression for lumbar spinal diseases, including LSS, disk herniation, and cyst.[46,47] Both studies observed an

increase in perioperative complications early in a surgeon's experience with endoscopy. The study of 68 patients reported a dural tear on case 3, root injury on 5, dural tear and incomplete decompression on 11, and incomplete decompression on 2, 18, and 20th cases. No hematoma or SSI was observed.[46] The second study of 60 patients observed a trend of increased complication rate in the surgeon's first 30 patients who underwent endoscopic decompression. The overall complication rates reported in the first 30 and second 30 patients was 5(17%) and 1(3%) (p=0.085) respectively. One dural tear occurred in the latter 30 patients.[47]

A study in 2016 investigated the effect of wait time between referral and surgical treatment for lumbar spinal disease. The study showed no significant difference in complications for LSS comparing those with a wait time less than 12 months to those with a wait time longer than 12 months. A difference was seen in functional outcome at 6 and 12 months postoperatively and the difference in effect was similar at 24 months.[48]

An interesting finding of a study by Clemens et al published in 2017 was the lack of effect of severity of LSS on clinical outcomes and complications of microsurgery or laminectomy. The study evaluated 7(3.5%) patients with mild LSS, 38(18%) with moderate, 108(53.5%) with severe, and 49(24.3) with extreme stenosis. In single-level LSS, severity had no significant effect on complication, outcomes, or length of stay.[49]

2.6 Review of Methodology

2.6.1 Study Design and Surgical Interventions

Of the reviewed laminectomy studies, 2(25%) were retrospective studies, 1(12.5%) was prospective, 3(37.5%) were RCT, 1(12.5%) were systematic review with meta-analysis, and 1(12.5%) included both RCT and prospective study. The studies

compared open laminectomy to minimally invasive/microsurgery in 7(87.5%) studies with the remaining study being compared to conservative management.

Of the endoscopic studies, 20(64.5%) were retrospective, 4(12.9%) were prospective, 4(12.9%) were RCT, and 3(9.7%) were systematic reviews with meta-analysis. Endoscopic decompression was compared to nothing in 15(48%) studies, minimally invasive/microsurgery in 8(26%) cases, and open laminectomy in only 2(6.5%).

2.6.2 Inclusion and Exclusion Criteria

Though there were minor variations in the wording of inclusion criteria, inclusion criteria were homogenous in reviewed studies with primary criteria of degenerative lumbar stenosis confirmed by MRI, CT, or x-ray, symptoms of claudication and/or radiculopathy with pain predominantly in the lower extremities, and failure of conservative for a minimum of three months. The exclusion criteria had more variation than inclusion, though the general concepts were similar throughout. Exclusion criteria most included prior surgery at the current level of stenosis, recent spine fracture, infection, malignancy, instability/spondylolisthesis. Open laminectomy studies differed from endoscopic decompression in number of levels involved in patient LSS. Laminectomy studies included multi-level stenosis in 87.5% of studies, while endoscopic studies included single-level stenosis in 90%.

2.6.3 Outcome Variables

Outcome variables relevant to primary objectives (complications) of this proposal were nerve injury, incidental durotomy, epidural hematoma, SSI, and overall rate of complications. All outcomes were not included in each study, as was described

previously. The most common complications reported or discussed were dural tears and epidural hematoma.

Outcomes related to the secondary objective (efficacy) included VAS for leg and/or back pain and ODI in most studies. Evaluation of outcome by Modified Macnab criteria was the next most common tool for measure of outcome. Studies intermittently included readmission, reoperation, and intraoperative duration data.

2.6.4 Sample Size and Testing Statistical Significance

Sample size, excluding meta-analyses, ranged from 19 to 1,839 patients. A total of 6,129 patients were included with a mean sample size of 185.7 and a median of 66. Tests for statistical significance most used were Chi-squared and Fisher exact test for dichotomous variables (complications), Student t-test for parametric continuous variables and Wilcoxon Rank Sum test for nonparametric continuous variables. Paired t-test and ANOVA were seldom used.[12 34]

2.7 Conclusion

The reviewed literature involving fully endoscopic decompression for lumbar spinal stenosis was primarily retrospective in nature, which has a risk of information bias by underreporting or misclassification and selection bias depending on inclusion and exclusion criteria. Many of the studies involving endoscopic decompression lacked a control or comparative group and only one prospective study compared endoscopic decompression to traditional open laminectomy. Though both treatments have been compared to open microsurgery, few head-to-head prospective trials have been performed. Another limitation to previous studies is the lack of focus on safety and complications related to surgery. Studies were focused on efficacy and powered as such.

There were zero studies with sufficient sample size to properly evaluate complication rates of endoscopic decompression and open laminectomy, though a trend towards lower rates in endoscopic decompression was often observed. Endoscopic decompression for LSS has been proven to be non-inferior to open laminectomy. As such, a large, multi-institutional prospective study to properly evaluate complications of surgical treatment is needed.

2.8 References

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CHAPTER 3: STUDY METHODS

3.1 Study Design

This study will be a multi-center prospective cohort comparing fully endoscopic decompression to open laminectomy for lumbar spinal stenosis. All surgeons included in this study who perform fully endoscopic decompression will have a minimum of 60 previous endoscopic procedures or five years of experience. Hospitals that utilize electronic medical records (EMR) will be preferred to increase reporting. Surgical interventions must use one of the methods defined in Chapter 3.4. Institutions considered for inclusion will report data of surgical interventions performed at the site, experience of surgeons who perform the included interventions, average number of patients treated for LSS each month, and use of EMR to the Principal Investigator.

3.2 Population, Sampling, and Recruitment

This study will include patients 18 years or older with symptomatic lumbar spinal stenosis who have been approved as a surgical candidate using endoscopic decompression or open laminectomy. Enrolled patients must meet the inclusion and exclusion criteria (**Table 1**). Institutions from across the country will be evaluated for inclusion (**Appendix A**). Convenience sampling of all patients who are willing to participate and are without any hinderance to properly report any adverse event will be included in the study. Patients must be able to speak, read, and write English. A medically certified translation service is acceptable if used at all patient interactions.

Table 1: Subject Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
• Age ≥18 years	• Prior surgery at spinal level • Recent trauma at the site • Infection or malignancy of spine

• Degenerative lumbar stenosis confirmed by MRI or CT requiring decompression • Symptoms of claudication and/or radiculopathy (VAS≥4) • Daily activity restrictions due to LSS • Failure of conservative treatment for a minimum of three months • Single level to be operated on • Competent and understands study protocol • Written informed consent to participate	• Instability • Spondylolisthesis (Meyer grade ≥II) • Requires fusion • Deformity of spine • Stenosis without bony involvement • Neurologic/psychiatric disorder • Coagulopathy • Any reason to be unable to participate in follow-up or provide accurate recall

3.3 Subject Protection and Confidentiality

Approval from the Yale Institutional Review Board (IRB) will be obtained prior to initiation of this study. The research proposal will be submitted for pre-review through the Yale Human Research Protection Program (HRPP) and subsequent submission to the Yale IRB. External institutions will enter into an IRB Authorization Agreement (IAA) with Yale to serve as the IRB of record for that institution's IRB or to apply for Federalwide Assurance (FWA) in addition to any IRB requirements of their institution. External investigators not covered under an IRB will submit an Unaffiliated Investigator Request to Yale's University's Institutional Signatory Official. A Consent for Participation in a Research Project form 200 FR. 1 (2016-2) (**Appendix B**) signature from the subject will be required prior to enrollment. Consent form will include details of the study, risks, benefits, confidentiality, participation, and withdrawal. Instructions will be provided by a research team member to ensure informed consent. All research team members will be required to be certified in and compliant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Subjects will be de-identified by

each investigator using number codes unique to each intervention group prior to submission to the principal investigator. All subject data will be stored by using web-based encryption software with access provided only to approved investigators.

3.4 Study Variables, Measures, and Assignment

As the intention of this study is to evaluate the safety of procedures performed by experienced surgeons, patients will not be randomized to treatment groups. Participating surgeons will use clinical judgment to assign each subject to the most appropriate intervention on a case-by-case basis. This will help assess safety in an environment that is as close to clinical practice as possible. Group A will include subjects who undergo fully endoscopic decompressions. The procedure for group A must exclusively use endoscopic equipment for visualization and decompression with a minimal incision and dilation without significant disruption of musculature. The procedure may not initially use a large midline incision, surgical microscope, loupe magnification, or retractors including tubular retractors. Group B will include subjects who undergo decompression by open laminectomy with or without use of a microscope, without the use of tubular retraction or endoscopic guidance. Primary outcome measures of safety will include proportion of nerve injury, incidental durotomy, epidural hematoma, and surgical site infection. Secondary outcome measures will include operation length, length of stay, rate of return to normal activities/work, all-cause mortality, readmission, reoperation, post-surgical Modified Macnab criteria, Visual Analogue Scale (VAS) for pain, and Oswestry Disability Index (ODI). Secondary outcomes can be used to assess if surgical technique was adjusted to increase safety at the cost of efficacy. Intraoperative and postoperative complications will be reported in detail at the time of occurrence. Occurrence or absence

of adverse events will be confirmed at six-month follow-up via clinical interview and questionnaire (**Appendix C**). Patient EMR will also be reviewed for occurrence of adverse events. VAS and ODI score will be obtained preoperatively, at six-month follow-up, and normal intervals as required by treatment team. Rate of return to normal activities, readmission, reoperation, and post-surgical Modified Macnab criteria will be evaluated at final follow-up.

The early learning curve effect on rate of complications has been addressed by requiring a minimum level of surgeon experience. Comorbidities and baseline characteristics will be documented preoperatively, including all ongoing medical conditions, medications, and risk factors described by Kimmell et al.[1]

3.5 Analysis

Dichotomous variables including proportion of nerve injury, incidental durotomy, epidural hematoma, and surgical site infection, mortality, readmission, and reoperation will be reported as frequencies. Dichotomous variables will be analyzed by two proportion Z-test. Continuous variables include operation length, length of stay, rate of return to normal activities, Visual Analogue Scale (VAS) for pain, and Oswestry Disability Index (ODI). Distribution will be evaluated with Shapiro-wilk test. Normally distributed continuous variables will be reported as mean and standard deviation (SD) and will be evaluated by Student t-test. Non-normally distributed variables will be reported as median and interquartile range (IQR) and analytically evaluated by Wilcoxon rank-sum test. Modified Macnab criteria will be reported as frequency.

3.6 Sample Size Calculation

Sample size was calculated using data from the two most recent systematic reviews regarding endoscopic decompression and open laminectomy (**Appendix D**). The Alpha value was set to 0.05 with a power of 0.8. To sufficiently power the study, reported frequency of dural tear of 2% in endoscopic decompression and 4.8% in open laminectomy was used in the calculation.[2,3] Due to the short follow-up period, an estimation of 10% loss to follow-up was included in calculation. A total of 729 participants will be required for each arm of the study. Assuming a rate of four patients per month, 31 surgical institutions will need to be recruited to obtain sufficient sample size. As the procedures have established efficacy, there is no upper limit to the number of enrolled subjects within the recruitment period.

3.7 Timeline and Resources

We anticipate the study to take two years from initiation to finalization. The first three months will be focused on recruitment and training of research personnel. An approved institution may begin enrollment of subjects once all compliance criteria have been satisfied. The enrollment window will remain open until 15 months after initiation of the study. Each month, participating institutions may submit cases that have concluded with proper six-month follow-up. Data analysis will be an ongoing effort from first submission of data to completion. The final two months of the study will be dedicated to data synthesis and finalization. Timeline is represented by **Table 2**.

Additional research assistants will be required to aid in recruitment of institutions, ensuring compliance, and collecting/organizing data. Three to five assistants will be recruited and need for assistants will be reevaluated monthly. Research assistants will be

trained to use software for data input and statistical analysis. It will be the responsibility of the assistant investigator at each institution to decide required resources. No additional surgical equipment will be required as the intervention must be established at the location.

Table 2: Timeline

Month:	1	2-3	4-8	9-15	16-22	23-24
Recruitment and training	X	X				
Enrollment and treatment		X	X	X		
Data collection				X	X	
Finalization						X

3.8 References

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CHAPTER 4: CONCLUSION

4.1 Advantages

The primary advantage to our study is the large sample size. Most studies completed thus far have had insufficient sample size to properly evaluate the safety of our surgical interventions. Complications of interventions has been proven to be low and studies have been conflicting, underpowered, or incomplete regarding safety. Our proposed sample size and clearly defined reporting instructions will accurately assess the occurrence of adverse effects.

This study also has the advantages of increased generalizability. Many previous studies have been performed outside of the United States, followed a single surgeon, or took place at a limited number of surgical centers. Our study will follow over 30 surgeons and institutions within the US. This will help study a broad range of demographics in an ever-aging population.

The prospective nature of our study allows us to reduce the risk of information bias and underreporting by training included researchers on adverse events of concern and thorough follow-up reporting in conjunction with EMR review. Many studies have been retrospective in nature and very few have had a primary interest in the safety of the intervention. This lack of focus on adverse events could be a source of underreporting or misclassification.

A benefit to evaluating endoscopic decompression and open laminectomy is that they have proven efficacy for the treatment of degenerative lumbar spinal stenosis. This should allow us to study these procedures with experienced surgeons, as there is a

significant learning-curve with endoscopic methods which has skewed reports of adverse events in the past.

4.2 Disadvantages

A disadvantage of this study is the lack of randomization. The observational aspect of our study increases the risk of selection bias. The lack of blinding is of lesser concern due to the objective nature of the primary outcome. The adverse event either occurred or it did not. Secondary outcomes may be more influenced this.

Studying all endoscopic decompression techniques presents an issue to whether certain techniques or approaches are safer than others. This is also influenced by the inclusion of stenosis in any area of the lumbar spine (interlaminar, transforaminal, or extraforaminal). Additional studies comparing endoscopic techniques to one another are warranted.

Inclusion of multiple institutions nationwide also comes with a risk. The lack of direct oversight at each location has potential to effect results, especially if there is a high variation of electronic medical records. Some EMRs may not be as easy as others in determining the occurrence of adverse events. Subjects may also seek treatment for a complication at a site outside of this study and fail to report the incident on final follow up, though this is a small likelihood with minimal effect.

The six-month follow-up is sufficient for the evaluation of the primary outcomes, as most symptomatic adverse events occur intraoperatively or within 30 days of surgery.1 This short follow-up is not sufficient for evaluation of clinical and functional outcomes, as these can vary over time. Secondary outcomes will be obtained and reported for

completeness. Reoperation for incomplete decompression or restenosis of the same lumbar level may not be reported within this time frame.

4.3 Clinical Significance

Concrete evidence of the improved safety of endoscopic decompression should encourage surgeons to consider employing this method. More evidence is being collected and evaluated as the technique gains popularity.[2] The large sample size, increased generalizability, and prospective nature should reduce the knowledge gap and provide sufficient evidence to influence surgical practices across the United States.[3,4] Though upfront cost for equipment is more expensive, the reduction in hospital stays and readmission rates should offset this cost.[5] This is in the best interest of the patient, as a safer intervention with shorter recovery time and without reduced efficacy can improve quality of life.

4.4 References

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APPENDICES

Appendix A: Recommended Institutions for Inclusion

The following list includes the minimum 31 hospitals and 5 additional sites for contingency.

1. Yale Hospital Spine Center, New Haven, CT
2. AdventHealth, Orlando, FL
3. Adventist Health Howard Memorial, Willitis, CA
4. Arizona Spine and Joint Hospital, Mesa, AZ
5. Arkansas Surgical Hospital, North Little Rock, AR
6. Baylor Scott and White Orthopedic and Spine Hospital, Arlington, TX
7. Cypress Pointe Surgical Hospital, Hammond, LA
8. Duke University Hospital, Durham, NC
9. Hospital for Special Surgery, New York, NY
10. Hospital of the University of Pennsylvania, PA
11. Intermountain The Orthopedic Specialty Hospital, Murray, UT
12. Kansas Spine and Specialty Hospital, Wichita, KS
13. Johns Hopkins Hospital, Baltimore, MD
14. Tulsa Spine and Specialty Hospital, Tulsa, OK
15. Nebraska Spine Hospital, Omaha, NE
16. Black Hills Surgical Hospital, Rapid City, SD
17. Oakleaf Surgical Hospital, Altoona, WI
18. Ohio Valley Surgical Hospital, Springfield, OH
19. Unity Medical and Surgical Hospital, Mishawaka, IN
20. Beaumont Hospital, Grosse Pointe, MI
21. Huntsville Hospital, Huntsville, AL
22. South County Hospital, Wakefield, RI
23. Prisma Health Baptist Parkridge Hospital, Columbia, SC
24. Alice Peck Day Memorial Hospital, Lebanon, NH
25. OrthoColorado Hospital, Lakewood, CO
26. University of Washington Medical Center, Seattle, WA
27. University of Virginia Medical Center, Charlottesville, VA
28. Vanderbilt University Medical Center, Nashville, TN
29. Rothman Orthopaedic Specialty Hospital, Bensalem, PA
30. St. Luke's Des Peres Hospital, Saint Louis, MO
31. Maine Medical Center, Portland, ME
32. Middlesex Center for Advanced Orthopedic Surgery, Middletown, CT
33. St. Luke’s Regional Medical Center, Boise, ID
34. Morristown Medical Center, Morristown, NJ
35. OSHU Hospital, Portland, OR
36. Emory University Hospital, Atlanta, GA

Appendix B: A Consent for Participation in a Research Project

CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

200 FR. 1 (2016-2)

YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: *Endoscopic Decompression vs. Open Laminectomy for Lumbar Spinal Stenosis: A Prospective Safety Study*
Principal Investigator: *Peter Whang, MD, FACS, FAAOS*

Invitation to Participate and Description of Project

You are invited to participate in a research study designed to look at the safety of surgical treatments for lumbar spinal stenosis (LSS). You have been asked to participate because your surgical team identified you as a patient with LSS who is a candidate for decompressive surgery. There will be at least 729 participants over 31 different sites.

To decide whether you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, and possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

Your surgical team has determined that you are eligible for endoscopic decompression or an open laminectomy for the treatment of your LSS. This is an observational study, so there will be no change to the procedure that has been determined to be best for you. Your selected treatment will not be changed due to this study and both procedures have been proven effective.

Certain information will be collected from yourself and your surgical team before, during, and after your procedure. You will be asked to return for follow-up visits with a member

of your team with a minimum of one follow-up at six months. The primary focus will be to evaluate if any complications have occurred such as:
Surgical site infection – an infection at the site of operation requiring treatment
Nerve injury – injury of the nerve root during surgery that causes symptoms
Incidental dural tear – any damage to the protective layer of the spinal cord
Epidural hematoma – a collection of blood in the canal of the spine

Your surgical team will discuss signs of these complications and medical treatment needed. You will be asked by a questionnaire at six months to recall if any of their complications occurred. There will also be a review of your medical records. Only information pertaining to this study will be collected. We will not collect any personal data such as name, date of birth, family relations. Your information will be assigned a number for study purposes.

If you agree to participate in this study, you will be asked to describe any current medical conditions, medications, and an assessment of your symptoms related to LSS. The assessment tools are a normal part of your preoperative assessment, such as Visual Analogue Scale for pain and the Oswestry Disability Index.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Risks and Inconveniences

There are no additional risks due to participation in this study as the surgical procedure selected by your treatment team will remain unchanged.

Benefits

There are no additional benefits associated with this study.

Economic Considerations

There will be no compensation for participation. There will be no additional costs to you from this study. Treatment will be billed through insurance as appropriate. You will still be responsible for any co-pays required by your insurance company for standard treatment.

Confidentiality

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a

child or elderly person, or certain reportable diseases. Physical documents will be stored in a locked key or room only accessible by medical staff and will be destroyed once properly submitted to the principal investigator. Your data will be assigned a number associated with your treatment and will not have any identifiable information. Data will be stored with encryption software on a password protected computer. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

Representatives from the Yale Human Research Protection Program, the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

You do not give up any of your legal rights by signing this form.

Voluntary Participation and Withdrawal

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits).

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments not associated with standard care.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or treatment team. When you withdraw from the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – if you feel is necessary – before you decide.

Authorization

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

Name of Subject:_____

Signature:_____

Relationship:_____

Date:_____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Peter Whang at (203) 867-5309.
If, after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.

Appendix C: Patient Questionnaire

Full Name: _____

Date of Birth (mm/dd/yyyy): _____

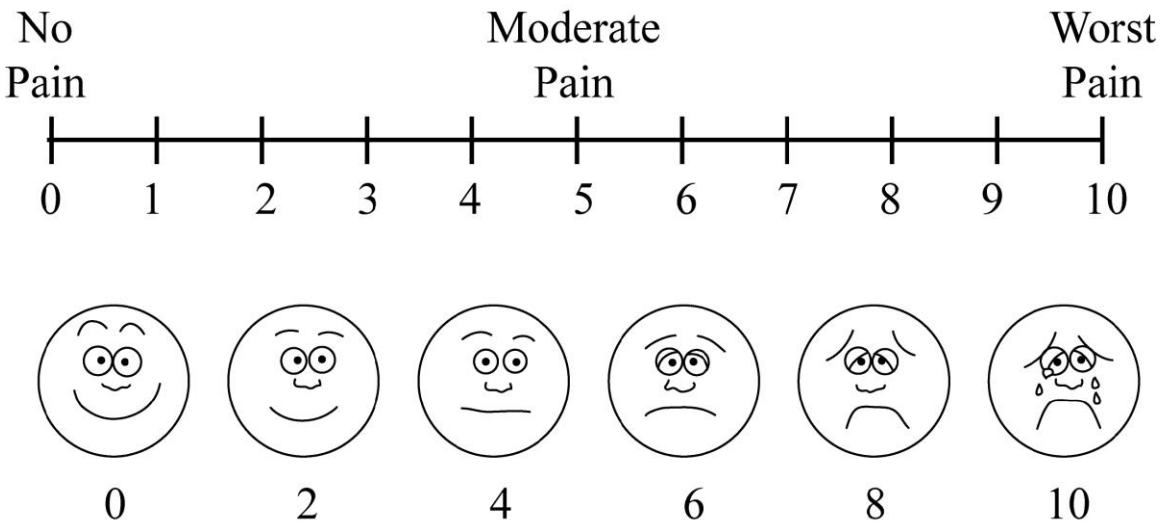
Today's Date (mm/dd/yyyy): _____

<u>To be completed with a member of the research team at 6-month follow-up</u>

To the best of your knowledge, did you experience any of the following:

Surgical site infection – an infection at the site of operation requiring treatment	Y	N
Nerve injury – injury of the nerve root during surgery that causes symptoms	Y	N
Incidental dural tear – any damage to the protective layer of the spinal cord	Y	N
Epidural hematoma – a collection of blood in the canal of the spine	Y	N
Any other complication related to surgical intervention	Y	N
Readmission related to surgical intervention	Y	N
Reoperation at the same site of this study intervention	Y	N

If so, include the date and required treatment below:



Using the above scale, how would you rate and describe your current pain for:

Lower back: _____ Description: _____

Right leg: _____ Description: _____

Left leg: _____ Description: _____

Oswestry Low Back Pain Disability Questionnaire

Sources: Fairbank JCT & Pynsent, PB (2000) The Oswestry Disability Index. *Spine*, 25(22):2940-2953.

Davidson M & Keating J (2001) A comparison of five low back disability questionnaires: reliability and responsiveness. *Physical Therapy* 2002;82:8-24.

The Oswestry Disability Index (also known as the Oswestry Low Back Pain Disability Questionnaire) is an extremely important tool that researchers and disability evaluators use to measure a patient's permanent functional disability. The test is considered the 'gold standard' of low back functional outcome tools [1].

Scoring instructions

For each section the total possible score is 5: if the first statement is marked the section score = 0; if the last statement is marked, it = 5. If all 10 sections are completed the score is calculated as follows:

Example: 16 (total scored)

50 (total possible score) x 100 = 32%

If one section is missed or not applicable the score is calculated:

16 (total scored)

45 (total possible score) x 100 = 35.5%

Minimum detectable change (90% confidence): 10% points (change of less than this may be attributable to error in the measurement)

Interpretation of scores

0% to 20%: minimal disability:	The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting sitting and exercise.
21%-40%: moderate disability:	The patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity and sleeping are not grossly affected and the patient can usually be managed by conservative means.
41%-60%: severe disability:	Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation.
61%-80%: crippled:	Back pain impinges on all aspects of the patient's life. Positive intervention is required.
81%-100%:	These patients are either bed-bound or exaggerating their symptoms.

Oswestry Low Back Pain Disability Questionnaire

Instructions

This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking ONE box in each section for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement which most clearly describes your problem.

Section 1 – Pain intensity

- ☐ I have no pain at the moment
- ☐ The pain is very mild at the moment
- ☐ The pain is moderate at the moment
- ☐ The pain is fairly severe at the moment
- The pain is very severe at the moment
- The pain is the worst imaginable at the moment

Section 2 – Personal care (washing, dressing etc)

- I can look after myself normally without causing extra pain
- I can look after myself normally but it causes extra pain
- It is painful to look after myself and I am slow and careful
- I need some help but manage most of my personal care
- I need help every day in most aspects of self-care
- I do not get dressed, I wash with difficulty and stay in bed

Section 3 – Lifting

- ☐ I can lift heavy weights without extra pain
- ☐ I can lift heavy weights but it gives extra pain
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed eg. on a table
- Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- I can lift very light weights
- I cannot lift or carry anything at all

Section 4 – Walking*

- Pain does not prevent me walking any distance
- Pain prevents me from walking more than 1 mile
- Pain prevents me from walking more than 1/2 mile
- Pain prevents me from walking more than 100 yards
- I can only walk using a stick or crutches
- I am in bed most of the time

Section 5 – Sitting

I can sit in any chair as long as I like

I can only sit in my favourite chair as long as I like

Pain prevents me sitting more than one hour

Pain prevents me from sitting more than 30 minutes

Pain prevents me from sitting more than 10 minutes

Pain prevents me from sitting at all

Section 6 – Standing

I can stand as long as I want without extra pain

I can stand as long as I want but it gives me extra pain

Pain prevents me from standing for more than 1 hour

Pain prevents me from standing for more than 30 minutes

Pain prevents me from standing for more than 10 minutes

Pain prevents me from standing at all

Section 7 – Sleeping

My sleep is never disturbed by pain

My sleep is occasionally disturbed by pain

Because of pain I have less than 6 hours sleep

Because of pain I have less than 4 hours sleep

☐ Because of pain I have less than 2 hours sleep

☐ Pain prevents me from sleeping at all

Section 8 – Sex life (if applicable)

My sex life is normal and causes no extra pain

My sex life is normal but causes some extra pain

My sex life is nearly normal but is very painful

My sex life is severely restricted by pain

My sex life is nearly absent because of pain

Pain prevents any sex life at all

Section 9 – Social life

My social life is normal and gives me no extra pain

My social life is normal but increases the degree of pain

Pain has no significant effect on my social life apart from limiting my more energetic interests eg, sport

Pain has restricted my social life and I do not go out as often

Pain has restricted my social life to my home

I have no social life because of pain

Section 10 – Travelling

I can travel anywhere without pain

I can travel anywhere but it gives me extra pain

Pain is bad but I manage journeys over two hours

Pain restricts me to journeys of less than one hour

☐ Pain restricts me to short necessary journeys under 30 minutes

☐ Pain prevents me from travelling except to receive treatment

.

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Modified Macnab Criteria	
Excellent	Free of pain No restriction of mobility Able to return to normal work/activities
Good	Occasional non-radicular pain Relief of presenting symptoms Able to return to modified work/activities
Fair	Some improvement of functional capacity Still unable to return to work/activities
Poor	Continued objective symptoms of root involvement Additional operative intervention needed at operative level irrespective of repeat or length of postop period

Appendix D: Sample Size Calculation

Sample Size was calculated using https://clincalc.com/stats/samplesize.aspx

Proportions based off occurrence of incidental durotomy

Study Parameters	
Proportion, open laminectomy	4.8%
Proportion, endoscopic decompression	2%
Alpha	0.05
Beta	0.2
Power	0.8
Sample Size	
Group A	656
Group B	656
Total:	1312

656 ÷ 0.9 = 729 required for each group due to expected loss to follow-up

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