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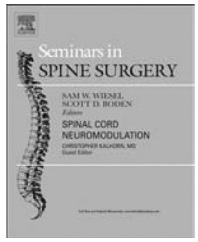

Minimally invasive approaches to the surgical treatment of lumbar stenosis

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ABSTRACT

A literature review of minimally invasive treatment options for lumbar spinal stenosis was conducted to determine the efficacy and outcomes of existing and evolving techniques. This study focuses on minimally invasive interlaminar decompression, unilateral laminectomy for bilateral decompression, and internal indirect decompression devices/interlaminar stabilization. We found that both minimally invasive interlaminar decompression and unilateral laminectomy for bilateral decompression can lead to acceptable and effective outcomes for patients with lumbar spinal stenosis. Indirect decompression via devices that provide interlaminar stabilization, including the Superion, X-STOP, and Coflex implants, has led to mixed results, but further research is still required.

1. Introduction

Symptomatic lumbar spinal stenosis is the most common reason for lumbar spine surgery in patients greater than 65 years old.[1] As the population continues to age it is only reasonable to assume surgical treatment for lumbar stenosis will increase as well. Therefore, it is imperative to continue to improve the types of surgical interventions which limit posterior soft tissue disruption and potentially decrease postoperative lumbar spine instability and low back pain, with the goal of improving patient outcomes.[2,3] It is important that new techniques are as efficacious as the current gold standard of open laminectomy and decompression for surgically indicated lumbar spinal stenosis. In the following article, minimally invasive interlaminar decompression (MILD), unilateral laminectomy for bilateral decompression (ULBD) and internal indirect decompression devices/interlaminar stabilization will be discussed for efficacy and outcome.

2. Materials and methods

A literature review was performed using Pubmed and EBSCO to evaluate articles published within the past five years. Using search queries "lumbar stenosis" and "minimally invasive," Pubmed yielded 283 articles while EBSCO yielded 84. There were duplicates within the two databases which were removed from consideration. Articles covering relatively new approaches or techniques were considered, which included but were not limited to tubular unilateral hemilaminectomy, muscle-sparing interspinous lumbar decompression (MILD), inter-laminal stabilization systems (ILSS) or interspinous process devices (IPD), and unilateral laminectomy with bilateral decompression (ULBD). Meta-analysis publications that compared minimally invasive versus open treatments were also included. Each article was scrutinized for its level of evidence with emphasis placed on level I or II studies. Articles that involved fusion, except for one discussing the Coflex implant, [25] were excluded

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in an effort to eliminate excessive variables. After eliminating articles based on topic, level of evidence and publication date, 24 remained as strong candidates for evaluation in this review. The most relevant articles and results were reviewed.

3. Minimally invasive interlaminar decompression (MILD)

Minimally invasive interlaminar decompression is a technique established by Hatta et al. and the article can be referenced for the complete technique.[4] In short, the incision is centered over the interspinous level to be decompressed, the supraspinous ligament is split longitudinally in the mid-line and retracted laterally with the paraspinal muscles (Fig. 1).[5] A high speed burr is used to resect the cranial and caudal portion of the exposed spinous process, keeping the periosteum intact, to the ligamentum flavum attachments respectively and then decompression is carried out in the standard manner.

Arai et al. prospectively evaluated the clinical and radiologic outcomes of ULBD versus MILD and also conducted a subgroup analysis of single segment versus multi-segment (2 or 3 segment) decompression (Fig. 2).[6] No significant difference in Visual Analog Score (VAS), Japanese Orthopaedic Association (JOA) score or JOA Back Pain Evaluation Questionnaire (JOABPEQ) scores were noted between the MILD and ULBD single level decompression subgroups. However, significant differences where noted in lumbar function effective rate and low back pain effective rate of the JOABPEQ score and VAS low back pain in multilevel decompression, which favored ULBD. Both ULBD and MILD had a 2% secondary operation rate at the decompressed level compared to the 17% for open laminectomy proposed by Herkowitz.[6,7] ULBD resulted in more postoperative lateral wedging when L2/3 or L3/4 were the operated levels. In contrast, increased sagittal translation was observed at L4/5 in the MILD procedure.

More recently, Mikami et al. described the MILD procedure with microendoscopy to further decrease the invasiveness of the procedure.[8] Using an endoscope imparts three clear advantages: preservation of the bilateral facet joints, minimal paraspinal muscle removal and retraction and easy midline anatomic orientation (Fig. 3).[5] The initial studies on microendscopic assisted MILD were small in size and there was significant concern regarding the surgical expertise, required operative time, intra operative bleeding, complications and potentially unfavorable outcomes.[5] Yoshimoto et al. attempted to rectify these shortcomings by following 103 consecutive cases of microendoscopically assisted MILD procedures.[5] They found JOA scores improved significantly, from 14.8 to 23.7 on average, and all subsets of the SF-36 improved except for general health. It is important to note that 4.9% of patients underwent revision procedure at the operative level due to juxtafacet cyst formation. Ikuta et al. reported an 8.6% rate of postoperative juxtafacet cyst formation in patients who underwent micorendoscopic decompression, however, the true incidence is unknown due to recent adaptation of the technique.[9] Postoperative juxtafacet cyst formation is a potential major postoperative complication of microendoscopically assisted decompression which can require revision surgery.

4. Unilateral laminectomy for bilateral decompression (ULBD)

Another technique that has gained popularity over the past five years is unilateral laminectomy for bilateral decompression (ULBD), whereby the surgeon performs a unilateral approach just lateral to midline and a minimally invasive (MIS) retractor system is placed to create a surgical corridor and expose the lamina or interspinous space (Mobbs et al.).[10] Unilateral laminectomy is then performed and facet hypertrophy is treated by trimming the lamina and medial facet; the contralateral side is addressed at a later time. The full procedure and description of technique was reported by Mobbs et al.[10]

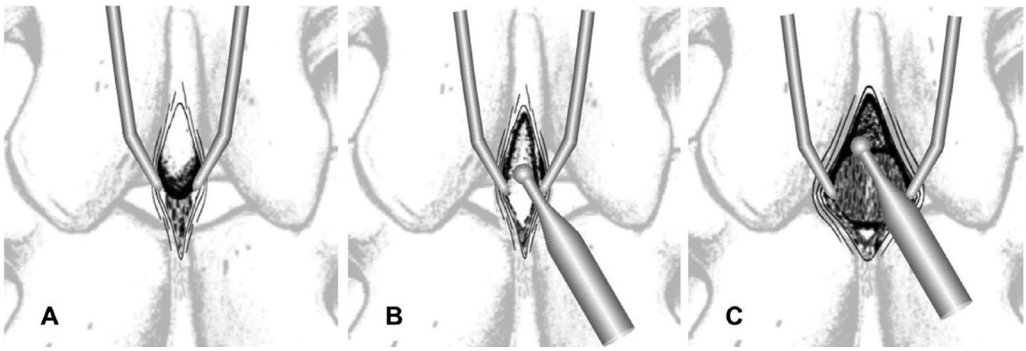

Fig. 1 – Drawings illustrate the first step of the surgical procedure performed under direct viewing. (A) After making a 15- to 20-mm midline skin incision, supraspinous ligament is longitudinally split at the median and dorsal surface of the spinous process is exposed. (B) The interspinous ligament is longitudinally split at the median and the caudal half of the upper adjacent spinous process is excavated using an air drill, preserving the periosteum of the lateral aspects of the spinous process. (C) The surgical field is expanded deeper using the modified Gelpi retractor, and the ligamentum flavum is exposed. Reprinted with permission from Spine: Yoshimoto M, Miayakawa T, Takebayashi T, et al.: Microendoscopy-assisted muscle preserving interlaminar decompression for lumbar spinal stenosis: clinical results of consecutive 105 cases with more than 3 year follow up. Spine March 2014, 39(5) [Fig. 1 (a–c)].

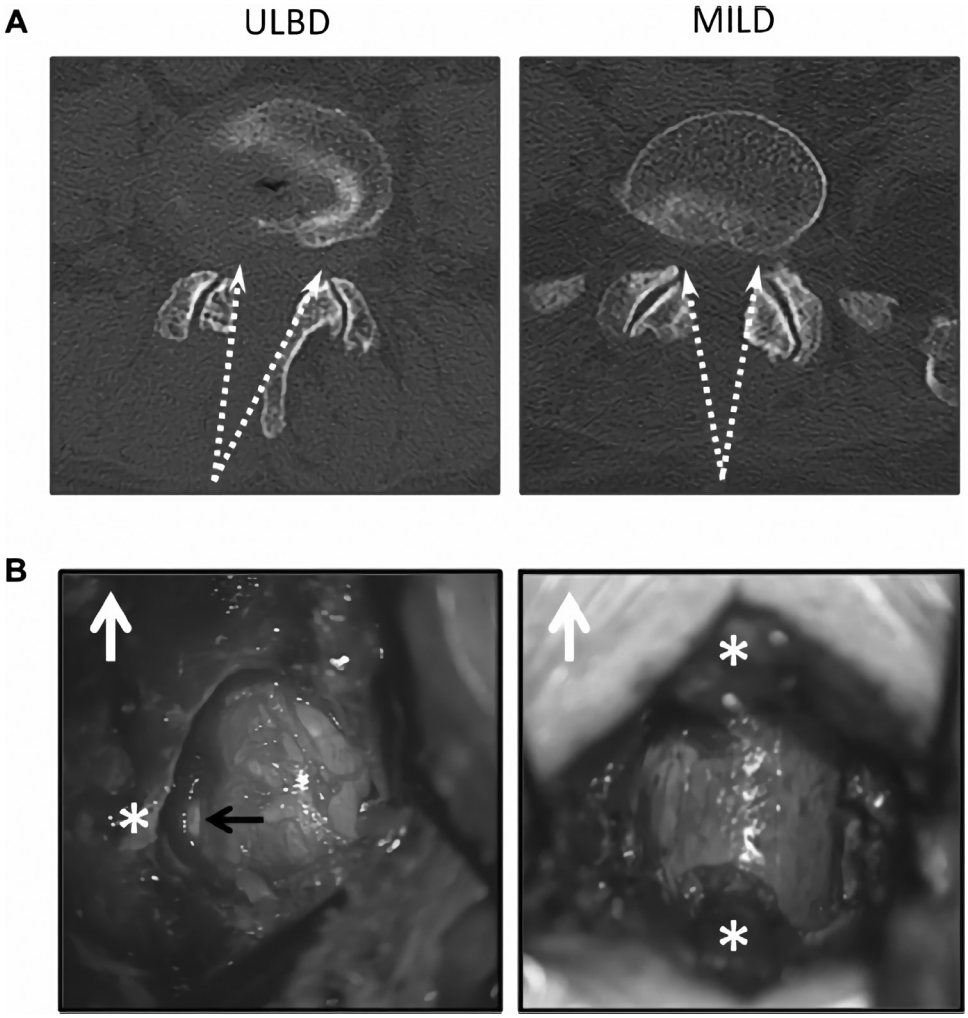

Fig. 2 – (A) Computed tomographic scans of ULBD and MILD procedures. In the approach of the ULBD, the paraspinal muscles were dissected from the midline and the interlaminar space was exposed. A laminotomy was performed by removing a portion of the superior and inferior laminae at the segment, and a small portion of the medial facet. Deep cortical surface of contralateral lamina was undercut and drilling was extended to the contralateral medial facet. In the approach of the MILD, the interspinous ligament is divided on the midline, and the operative field is broadened by laterally expanding the space between each split half of the ligaments. Partial laminotomy of the caudal half of the upper adjacent lamina, a dome-like expansion is performed by removing the inner laminar plate to the extent where the cranial margin of the ligamentum flavum is freed. (B) Intraoperative photographs of ULBD and MILD procedures. White arrows denote cranial side; black arrow, nerve root of the contralateral side in ULBD. *Spinous processes. ULBD indicated unilateral laminotomy for bilateral decompression; MILD, muscle-preserving interlaminar decompression. Reprinted with permission from Spine: Arai Y, Hirai T, Yoshii T, et al. A prospective comparative study of 2 minimally invasive decompression procedures for lumbar spinal canal stenosis: unilateral laminotomy for bilateral decompression (ULBD) versus muscle-preserving interlaminar decompression (MILD). Spine February 2014, 39(4) Fig. 1 (a and b).

Open decompression can have good-to-excellent outcomes in 64% of patients.[11] This technique does lead to disruption of posterior structures which may lead to paraspinal muscle weakness or atrophy, flexion instability, and the potential for hematoma or seroma in the dead space surrounding the dura.[12] Muscle-sparing procedures which preserve posterior ligamentous structures hypothetically decrease these risks and for this reason, ULBD is an attractive alternative procedure to treat lumbar spinal stenosis. There are a limited number of recent high quality studies investigating ULBD efficacy and durability. In a prospective randomized controlled trial, Mobbs et al. assessed patients treated with ULBD versus open laminectomy and compared the two groups using Oswestry Disability Index (ODI) scores, VAS scores, length of hospital stay, opioid requirement and time to mobilize patients.[12] They demonstrated a significant improvement in VAS scores with ULBD as compared to open laminectomy, whereas ODI scores were equivalent. Additionally, the ULBD had significantly shorter hospital stay duration, opioid usage and time to mobilize (Mobbs et al.). The study, however, was based on a small sample size (n = 54), and the follow-up of the two groups were different, with a mean of 44.3 months for ULBD and 36.9 months for open laminectomy groups.

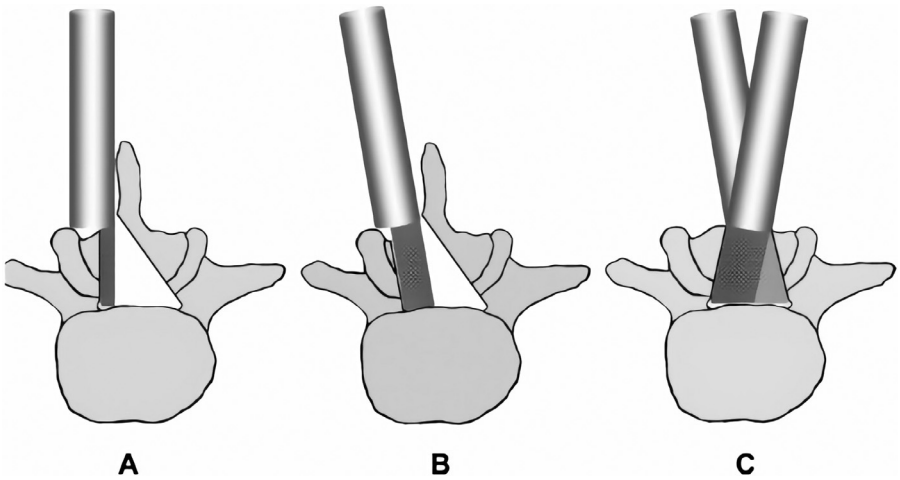

Fig. 3 – Schematic drawings of the working space. The shaded portion indicates the working space during decompression on the approach side. (A) Working space during decompression on the approach side is very small when the facet joint is preserved. (B) Extensive resection of the facet joint increases the working space. (C) Midline approach increases the working space during decompression on both sides with minimal damage to facet joints. Reprinted with permission from Spine: Yoshimoto M, Miayakawa T, Takebayashi T, et al. Microendoscopy-assisted muscle-preserving interlaminar decompression for lumbar spinal stenosis: clinical results of consecutive 105 cases with more than 3 year follow up. Spine March 2014, 39(5) [Fig. 10 (a–c)].

Komp et al.[13] described an approach to ULBD utilizing endoscopy to achieve bilateral decompression. In their prospective randomized controlled study, this method was compared to bilateral microsurgical laminotomy with two year follow-up using measures of VAS, ODI and the German equivalent of the North American Spine Society Instrument (NASS). Both of their groups had similar clinical outcomes. However, the rate of complications and revisions were significantly less in the endoscopic group. The authors concluded that full endoscopic treatment provided the advantages of operation time, less complications, less trauma and improved rehabilitation. They did note that this procedure carries with it a steeper learning curve and limited options for approach extension in the event of unforeseen complications.

5. Internal indirect decompression devices/ interlaminar stabilization

The implementation of indirect decompression via devices that provide interlaminar stabilization has become more popular over the past decade as a minimally invasive surgical option for lumbar spinal stenosis. These devices are attractive due to the perceived benefits of unloading facet joints, preservation of spinal mechanics, restoration of foraminal height, decreased surgical exposure, preservation of spinal anatomy, shorter operative time, decreased blood loss, and less severe complications from failure as compared to lumbar spinal decompression. Several studies were found comparing such devices both to each other and against the gold standard of open posterior decompression.

One such device is the X-Stop (Medtronic, Minneapolis, MN), which was the first to be approved by the US Food and Drug Administration (FDA).[14] A 2004 study showed improvement in lumbar spinal stenosis patients treated with X-Stop versus nonoperative management.[15] More recently, a prospective randomized controlled multicenter study by Lonne et al. compared X-Stop versus MIS decompression after two years of follow-up.[14] They found both options provided comparable results with regard to patient-reported outcomes (PROs) including the Zurich Claudication Questionnaire (ZCQ), ODI, EuroQol 5-dimensional questionnaire (EQ-5D) and Numerical Rating Scale 11 (NRS11). More importantly, they found a significant increase in secondary operations within the X-Stop group due to persistence or return of symptoms in ten of forty patients, which were treated with MIS decompression.[14] MIS decompression was found to result in more serious complications because it included a postoperative cauda equina syndrome in one participant.

The Superion InterSpinous Spacer (Vertiflex, Inc., San Clemente, CA) is another implant which is marketed as an even less invasive option compared to X-Stop. Patel et al. recently published a study comparing these two implants in a randomized controlled noninferiority trial.[16] The study showed that both Superion and X-Stop achieved similar success rates with regard to PROs, reoperation, adverse events and neurological complications. Nunley et al. extracted the FDA's investigational device exemption trial data to provide five year outcome results for Superion.[17] They demonstrated that 25% of patients treated with Superion required revision, reoperation, or supplemental fixation during this period. Additionally, they found a diminishing risk of these complications with time.[17] They noted that other published data has shown up to 33% of patients treated with MIS decompression required reoperation within four years.[18,19] Nunley et al. published a second study that same year detailing the four year results of Superion in a similar manner; that study confirmed a 25% reoperation rate with 84.3% clinical success with Superion treatment in

moderate lumbar spinal stenosis.[20] Within recently published literature, only one article directly compared Superion to decompression. Lauryssen et al. used 19 published studies on decompressive laminectomy as a control against the FDA-published data on Superion and found that both provided effective, durable relief of symptoms with Superion being less invasive with less surgical risk.[21]

Another FDA-approved option is Coflex (Paradigm Sine, Germany), which can limit extension of the spinal segment in addition to indirect decompression. It has been reported that over 14,000 Coflex devices have been implanted worldwide.[22] One perceived benefit of Coflex is its potential for earlier improvement in symptomology and patient satisfaction. This was demonstrated in a previous publication from India, however this study was limited to a four month mean follow-up.[23] The authors did compare the results of Coflex against the same institution's isolated decompression results, which confirmed better early results on the VAS with the internal decompression device.[23] This finding was not corroborated in another study by Moojen et al., which showed that after one year there was no short term superior effect as compared to decompression.[24] While Coflex had similar outcome measures with regard to symptomology, it also had significantly higher rates of reoperation despite its decreased operative time. Another study providing one year outcomes demonstrated that Coflex recipients had decreased hospital stay duration, blood loss during and after surgery, and incidence of adjacent segment degeneration with improved rehabilitation time as compared to the decompression and fusion control group.[25] Theoretically, the decreased adjacent segment degeneration is intuitive since fusion was utilized in this study and not in the aforementioned others.

Our review yielded a maximum longitudinal study period of two years for Coflex implants. Kumar et al. compared patients treated with lumbar decompression alone to a group treated with both decompression and Coflex implantation.[26] Their results showed sustained improvement in the Coflex group to be significantly greater ($P < 0.001$) than isolated decompression. They additionally performed a radiographic evaluation and found that within the Coflex group preserved disc height was not sustained after one year; however, foraminal height and sagittal angle were preserved. Schmidt et al. published their two year results with isolated decompression versus decompression with Coflex implantation as well.[27] They found no perceivable differences in PROs between the two groups, although they did have other notable findings. Composite clinical success, which takes into account survivorship, ODI success, absence of neurological deterioration, and device or procedure-related adverse events, was significantly superior for isolated decompression. This agrees with other studies that showed increased reoperation rates for indirect decompression devices.[27,28] Schmidt et al. additionally found that Coflex recipients had decreased average opioid usage at every follow-up time metric.[29] Radiographic foraminal height was also improved with Coflex along with a more than two fold increase in walking distance. The authors concluded that these findings, when paired with the decrease in compensatory pain medication, showed an extension in the durability and sustainability of decompression procedures with Coflex implantation. This is in contrast to another implant, the Aperius (Medtronic, Switzerland), which resulted in significantly worse outcomes compared with open decompression, in an observational cohort study after two years.[30] Patients treated with Aperius alone had a high rate of recurrent or persistent symptomology with significantly higher implant failure rate.[30]

Our search found two meta-analysis studies, both of which compared usage of traditional decompression to internal indirect decompression devices with minimum one year follow-up.[27,28] Both reviews noted their small size, with Zhao et al. including four randomized controlled studies and Wu et al. including five such studies. Both of these reviews demonstrated similar overall success with regard to PROs and complication rates. Zhao et al. additionally found that both treatments provided a similar duration of hospital stay. An increase in both reoperation rates and total cost with use of internal decompression devices were seen in both studies, however.[27]

6. Discussion

As minimally invasive treatment options continue to progress and evolve it is important to recognize the potential benefits, limitations and complications of each technique. It is unrealistic to expect one technique to be the best in all applications, as the location and severity of lumbar stenosis is not constant among all individuals. When evaluating ULBD and MILD, Aria et al. concluded both can lead to acceptable and effective outcomes for patients with lumbar spinal stenosis.[6] It was noted that utilizing MILD for the upper and middle lumbar spine and ULBD for the lower lumbar spine could help prevent postoperative degenerative changes by using the inherent and anatomical advantages of the two MIS procedures to minimize facet disruption and damage. In an effort to further decrease facet disruption Mikami et al. combined the MILD procedure with microendoscopy.[8] Although the procedures ensure minimal bilateral facet disruption, the technique had a relatively high rate of juxtafacet cyst formation postoperatively that may require revision decompression.[5,9] Further study is needed to determine the exact cause and true incidence of postoperative cyst formation with microendoscopically assisted MILD procedure.

When comparing ULBD to open laminectomy Mobbs et al. found ULBD was superior in VAS scores, hospital length of stay and opioid usage during the hospital stay.[12] In light of the current healthcare environment of cost control and opioid epidemic these findings may carry increased weight, importance and consideration. Komp et al. went further and compared endoscopically assisted ULBD with bilateral microlaminotomy.[13] Both techniques had similar ODI, VAS and German equivalent of NASS outcome scores. Endoscopically assisted MILD had a steep learning curve yet was found to have shorter operative room times and decreased complications. The decrease in complications was likely secondary to a single exposure and increased visualization with an endoscope. A potential drawback of endoscopically assisted MILD is the limited ability for open extension should a complication occur on the contralateral decompression side.[13]

ULBD as an MIS procedure is gaining popularity since it allows the surgeon to preserve posterior anatomy without resection of contralateral structures. One study demonstrated

a significant improvement in VAS scores with ULBD as compared to open laminectomy.[12] The same study also showed that ULBD had significantly shorter hospital stay duration, opioid usage and time to mobilize the patient.[12] Comparing ULBD to MILD, one study showed that both procedures had similar clinical and radiographic outcomes for single level treatments after two years overall.[6] In patients requiring multilevel treatment, ULBD patients had improved low back pain and function scores in both VAS and JAOBPEQ. Comparing endoscopic ULBD to microsurgical bilateral laminotomy, Komp et al. found similar outcome scores with both treatments but the endoscopic treatment provided the advantages of shorter operation time, less complications, less trauma and improved rehabilitation.[13] Overall, recent high quality studies show ULBD is an acceptable MIS treatment for lumbar spinal stenosis.

Indirect decompression via devices that provide interlaminar stabilization have recently become more popular as a minimally invasive surgical option for lumbar spinal stenosis. X-Stop was one of the first interlaminar stabilization devices. Our literature review garnered a high quality study which demonstrated significant increase in secondary operations within X-Stop patients due to persistence or return of symptoms compared to those treated with MIS decompression.[14] The X-Stop implant performed similarly to the Superion implant according to Patel et al.[16] Nunley et al. then showed that the Superion implant required no revision, reoperation or supplemental fixation for 75% of patients with five year follow-up.[17] Comparing Superion to decompressive laminectomy, Lauryssen et al. found that Superion provided effective, durable relief of symptoms, with Superion being less invasive with less surgical risk.[21] Another popular implant is the Coflex device, which was shown to provide earlier improvement in symptomology and patient satisfaction in the short term.[23] Other studies disputed this finding and found higher revision rates compared to decompression despite Coflex having shorter hospital stay and surgical blood loss.[24] Implant sustainability was shown to be superior to lumbar decompression by Kumar et al. over a two year period, which complicates our understanding of how well this implant is working for patients.[26] The composite clinical success of this implant was also improved with lumbar decompression versus Coflex by Schmidt et al.,[29] which supports criticism of the implant. They did, however, find decreased opioid usage in the Coflex group, which is significant in today's medical climate with opioid use becoming a larger issue on the national stage.

Our search also garnered two meta-analysis studies, both of which compared traditional decompression to internal indirect decompression devices with minimum one year follow-up.[27,28] Both publications demonstrated similar overall success with regard to PROs and complication rates. An increase in both reoperation rates and total cost with use of internal decompression devices were seen in both studies, however. These studies are inherently of greater power than any other mentioned publication which makes their results more applicable on a larger scale. The results essentially corroborate criticisms of internal devices such as the X-Stop, Superion, Coflex, and Aperius, which suggest that the implants add cost and require more surgical intervention at later times. Although some have reported up to 33% reoperation rates with isolated decompression patients which is comparable to the rates with internal indirect devices. No studies examined long term outcomes beyond five years, which remains unknown with these devices.

In conclusion, minimally invasive treatment options are evolving and it is important to recognize their benefits, limitations and complications. Among these options, both ULBD and MILD can lead to acceptable and effective outcomes for patients with lumbar spinal stenosis. Combining the MILD procedure with microendoscopy ensures minimal facet disruption but also has potentially higher rates of juxtafacet cyst formation requiring revision. ULBD preserves posterior anatomy and was shown to have improved outcomes over MILD. ULBD also performed better than open laminectomy in terms of outcomes, length of stay and opioid usage. When compared with bilateral microlaminectomy, endoscopically-assisted ULBD had equivocal outcome scores but shorter operative time and less complications. Indirect decompression via devices that provide interlaminar stabilization have recently become more popular as a minimally invasive surgical option for lumbar spinal stenosis. The Superion implant performed as well as decompressive laminectomy with less need for revision, reoperation or supplemental fixation compared to X-Stop. The Coflex device has mixed results compared to lumbar decompression with studies showing inconclusive maintenance of symptom reduction when comparing the two treatments. Coflex required less opioid medication use along with decreased hospital stay and surgical time. Using both MIS decompression with the Coflex improved clinical success. In meta-analysis studies ILSS devices increased overall reoperation and added cost compared to traditional decompression but had similar outcomes.

Disclosure

No authors have actual or potential conflicts of interest in relation to this manuscript.

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