Florida Society of Interventional Pain Physicians

FLORIDA SOCIETY OF INTERVENTIONAL PAIN SOCIETY POSITION STATEMENT

Interspinous Indirect Decompression Systems Without Fusion
Indicated for Patients With Moderate Lumbar Spinal Stenosis (ISIDD Without Fusion)

December 2021

The Florida Society of Interventional Pain Physicians supports the use of the SuperionTM Indirect Decompression Systems (IDS) as an option for the treatment of lumbar stenosis patients as it augments the prevailing solutions and reaches additional patients who would otherwise be left untreated.

Lumbar spinal stenosis (LSS) is a condition in which the spinal canal becomes increasing narrowed from degenerative changes. Patients with LSS may experience symptoms of neurogenic claudication, including pain or discomfort that radiates to their lower leg, thigh, and/or buttocks while walking. Patients with more pronounced LSS report symptoms of develop lower extremity of weakness, muscle cramping, numbness, and imbalance. LSS is a debilitating, degenerative condition that worsens over time when left untreated. Because of the dynamic nature of LSS, the pain is worsened when walking or standing, and relieved when bending forward, sitting or in the forward flexing position.

Offering an alternative option for the symptomatic LSS patient, which restores functional capacity and alleviates back and leg pain as well as other associated symptoms such as cramping, numbness and weakness without the reliance on medication is a much-needed therapy option.

Interspinous spacer decompression using the Superion device offers a less invasive procedure for patients who fail conservative treatment before traditional more invasive surgery. It serves as an extension blocker, which in turn relieves pressure on the affected nerves, helping to minimize the clinical impact of dynamic spinal stenosis while fully preserving the patient's nascent architecture and anatomy. Superion's mechanism of action addresses the root cause of stenosis in moderately stenosed patients rather simply palliating the symptoms. Its effectiveness mirrors those of the most invasive procedures without exposing patients to longer recovery times and complication risks. In Florida, many of our senior aged patients have significant comorbidities that prevent them from having laminectomies or more invasive, complicated, and more costly surgeries. It provides an option to those too frail to undergo more invasive procedures because it preserves the spinal anatomy for the patient as well as the surgeon should a future decompression become necessary.

FDA Indication and Labeling

The Superion ISS received FDA approval in 2015 based on a prospective, multi-site randomized clinical trial of Superion (n=190 patients) versus XSTOP (n=201 patients) with 3 year follow up.
"This device is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate degenerative lumbar spinal stenosis….

- Impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain
- numbness and/or cramping with or without back pain
- patients have undergone at least 6 months of non-operative treatment

Burden of Disease

Our Society supports the use of indirect decompression systems, also known as interspinous spacers or interspinous process distraction systems without fusion for patients diagnosed with moderate stenosis. Patients afflicted with the condition do not have credible alternatives, albeit surgical or conservative[1]. Spinal stenosis refers to a narrowing of the spinal column or spinal anatomy in the areas of the central canal, lateral recess, and/or neural foramina. Stenosis may be congenital, but more likely degenerative in origin. Lumbar spinal stenosis affects more than 200,000 people in the United States and is considered the most common reason for spinal surgery in patients >65 years[2].

In a claims-bases analysis, Parenteau et al (2021) reported the prevalence of a stenosis diagnosis over the age of 65 was >5% of the U.S. Medicare population, with women reporting a slightly higher prevalence than men[3]. Prevalence of lumbar spinal stenosis increases with age and body mass index[4].

Procedure

The Superion ISS may be implanted at one or two adjacent lumbar levels in patients whom treatment is indicated and at no more than two levels., from L1 to L5. The device is inserted through a canula about the size of a dime and thus requires no surgical dissection of the spinal musculature. The procedure is preformed in an outpatient setting or ambulatory surgery center. The device may be implanted by an interventional pain specialist or surgeon having completed an FDA approved training course.

Poor Operative and Non-Operative Alternatives

Conservative options including physiotherapy, bracing, cane, opioid and non-opioid medications, and exercises are offered, but in practice, the lack of consistent and durable relief with these options decreases the usefulness for the patients afflicted with spinal stenosis. Even epidural injections, with or without steroids, though effective in some cases, are often precluded due to the dose of steroids that the patient can receive[5]. In many cases, the epidural injections may provide temporary relief, but over the longer term, benefits of the therapy fade, leading the patients to seek surgical solutions. Cairns et al found persistent conservative care (>12 weeks) for lumbar spinal stenosis showed only minimal improvement in pain and function. Compared with extending conservative therapies or traditional spine surgery, interspinous lumbar decompression reduces both direct and indirect costs associated with lumbar spinal stenosis. Additionally, the costs of these conservative care options are not insignificant[6]. Nonetheless, contemporary algorithms advocate for conservative care before indirect decompression systems [7]. Diwan et al (2019) recommend the use of minimally invasive indirect decompression systems which deliver indirect decompression for moderate lumbar spinal stenosis after a treatment of 6 months of conservative care. FSIPP recommends conservative care for at least 6 months, the choice of what options for which should be individualized to the specific needs of the patients and be at the discretion of the treating physician.

The other extreme of the therapeutic spectrum is open spinal surgery – with or without fusion – and is reserved for those with severe spinal stenosis, cauda equina syndrome, instability, or severe scoliosis. This is because the benefits of surgery in even the best-case scenarios is time limited, the perioperative morbidity and mortality are higher with open spinal surgeries, and the hospital stays and post-surgical rehabilitation requiring skilled nursing facility costs are greater with open spine surgeries[8]. Published literature questions the benefits of complex fusion over simple laminectomy[9]. Regardless of outcomes, the rates of simple decompression surgery and simple fusions have declined while complex fusion surgery increased from 1.3 per 100,000 (just under 1% of operations) to 19.9 per 100,000 (14.6% of operations), a 15-fold increase (2002-2007). Adjusted mean hospital charges for complex fusion procedures were $80,888 compared to $23,724 for decompression alone [10]. Thus, there is a large unmet need and a void in the therapeutic armamentarium[11].

Physician Qualification and Patient Selection

- Physician Qualifications

Implantation of indirect decompression systems without fusion should be performed only by qualified physicians, trained in the management of patients suffering from lumbar spinal stenosis and experienced in the placement of devices for whom patients would be indicated.

- Inadequate Response or Contraindicated for Conservative Therapies (including, but not limited to, physical therapy, oral analgesics, epidural steroid injection)

Conservative care of no less than six months in duration should be provided to patients before implantation of indirect decompression systems. Physicians must be granted latitude based upon their clinical training, experience and what the physician and patient determine are best for the individual based upon circumstances unique to the individual.

Clinical Evidence

Indirect decompression systems used to treat moderate lumbar spinal stenosis are implanted posteriorly using minimally invasive techniques without disruption to the osseous or ligamentous tissue. Implantation typically occurs within the hospital outpatient or ambulatory surgical center using cannulas under fluoroscopic guidance. Contraindications for indirect decompression systems include patients at risk for spinous process fracture (e.g., severe osteoporosis), spondylolisthesis with dynamic instability >than Grade 1[12]. Allergies to titanium or titanium alloy, cauda equina syndrome, scoliosis (Cobb angle >10 degrees) and morbid obesity defined as a body mass index >40.

Mechanisms of action associated with indirect decompression systems of the spinal cord and nerve roots lead to immediate symptom relief[13]. Cadaveric studies have shown increases in the spinal dimensions. For example, Falowski et al (2019)[14].

Results from a prospective, randomized controlled clinical trial were published by Patel et al (2015)[15]. This Level Ib evidence found the Superion indirect decompression system (Boston Scientific; Marlborough MA) relieved moderate lumbar spinal stenosis through two years post implant. Twenty-nine sites enrolled 391 patients, randomized to the index procedure or FDA approved control (X-STOP; Medtronic, Minneapolis MN). At two years post implant, study subjects reported a 70% reduction in leg pain, 68% reduction in back pain, and clinical success measured by the Oswestry Disability Index (ODI) achieved in 65% of the patients. Superion success rates were reported as 99.5% for the index procedure, and 99.0% for the control.

There were no reported instances of device component fracture, disassembly or collapse. There was no device dislodgement for the index procedure, while 11.9% reported for control subjects. Use of the stand-alone indirect decompression system preserves treatment options and may obviate the need for decompressive laminectomy and or fusion in the majority of patients carefully selected and within the approved indications for use[16].

Long-term outcomes reported at five-years post implantation have demonstrated sustained and durable treatment effect. Nunley et al (2017)[17] reported 84% of patients demonstrated clinical success on at least two of three ZCQ domains. Individual ZCQ domain success rates were 75%, 81% and 90% for ZCQss, ZCQpf, and ZCQps, respectively. Leg and back pain success rates were 80% and 65%, respectively, and the success rate for ODI was 65%. Percentage improvements over baseline were 42%, 39%, 75%, 66%, and 58% for ZCQss, ZCQpf, leg and back pain VAS, and ODI, respectively (all $P<0.001$). Within-group effect sizes were classified as very large for four of five clinical outcomes (i.e., >1.0; all $P<0.0001$). Seventy-five percent of patients were free from reoperation, revision, or supplemental fixation at their index level at five years.

To collect real-world outcomes, a registry for patients treated with interspinous indirect decompression spacers for lumbar spinal stenosis with intermittent neurogenic claudication was conducted. Tekmeyster et al (2019)[18] evaluated data from three-hundred sixteen physicians at 86 clinical sites located within the United States. Patient data were captured from in-person interviews and a phone survey. Outcomes included intraoperative blood loss, procedural time, leg and back pain severity (100 mm VAS), patient satisfaction and treatment approval at 3 weeks, 6 and 12 months. The mean age of registry patients was 73.0 ± 9.1 years of which 54% were female. Mean leg pain severity decreased from 76.6 ± 22.4 mm preoperatively to 30.4 ± 34.6 mm at 12 months reflecting an overall 60% improvement. Corresponding responder rates were 64% (484 of 751), 72% (1,097 of 1,523) and 75% (317 of 423) at 3 weeks, 6 months and 12 months, respectively. Back pain severity

improved from 76.8 ± 22.2 mm preoperatively to 39.9 ± 32.3 mm at 12 months (48% improvement); 12-month responder rate of 67% (297 of 441). For patient satisfaction at 3 weeks, 6 months and 12 months, 89%, 80%, and 80% were satisfied or somewhat satisfied with their treatment and 90%, 75%, and 75% would definitely or probably undergo the same treatment again. In the phone survey the rate of revision was 3.6% (51 of 1,426).

For elderly patients suffering from significant comorbidities, implantation of indirect decompression systems were successfully shown to treat these patients at one or two levels. Doing so, Hartman et al (2019) reported avoidance of open spine surgery, anesthesia and risk of hospitalization commonly associated with this vulnerable patient population[19].

Diwan et al (2019) published their care algorithm based upon review of published evidence following inadequate response or failure of conservative care[20]. Researchers recommend the use of minimally invasive indirect decompression systems which deliver indirect decompression for moderate lumbar spinal stenosis. Implantation of these devices were supported due to long-term comparative trials and durability of treatment effect.

Cost Effectiveness

Using a Markov model evaluating cost-effectiveness of three treatment strategies for lumbar spinal stenosis, Parker et al (2015) concluded indirect decompression system implantation fell well below the QALY threshold of $50,000[21] and that such intervention versus sustained conservative care provided superior value. Cairns et al (2019) found persistent conservative care (>12 weeks) for lumbar spinal stenosis showed only minimal improvement in pain and function. Compared with extending conservative therapies or traditional spine surgery, indirect decompression system reduces both direct and indirect costs associated with lumbar spinal stenosis[22].

Conclusions and Recommendations

The body of Level I-IV published evidence, long-term outcomes demonstrating durable treatment effect, avoidance of more invasive procedures and drug therapies, as well as consideration for the patient populations most likely to be candidates for indirect decompression systems should be considered within the standards of care for moderate lumbar spinal stenosis.
Policymakers and payers are strongly encouraged to enable timely access to FDA approved or cleared technologies, when deemed medically necessary and indicated for this procedure.

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