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Interspinous implants to treat spinal stenosis

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Abstract
Purpose of review Lumbar spinal stenosis has historically been treated with open decompressive surgery which is associated with significant morbidity and may give rise to various complications. Interspinous spacers (ISS) have been developed as a less invasive strategy which may serve to avoid many of these risks. The two current spacers that are FDA approved and commercially available are the Coflex and Superion devices. The goal is to review these two implants, their indications, and patient selection.
Recent findings The Coflex device has been shown to be analogous to decompression and fusion when treating moderate spinal stenosis. It provides dynamic stability after a decompression is performed, without the rigidity of pedicle-screw instrumentation. Recent results show improved outcomes in Coflex patients at 3 years of follow-up, as compared to decompression and fusion.

The Superion implant is placed percutaneously in the interspinous space with minimal disruption of spinal anatomy. When compared to the X-Stop device (which is no longer available), the Superion implant shows improved outcomes at 3 years of follow-up.

Summary ISS are lesser invasive options as compared to formal decompression and fusion for the treatment of lumbar spinal stenosis.

Keywords Interspinous spacers · Interspinous devices · Coflex · Superion · Lumbar spinal stenosis · Neurogenic claudication

Introduction

Lumbar spinal stenosis (LSS) results in narrowing of the spinal canal, which may lead to compression of the thecal sac and neural elements. LSS is the most common cause of lumbar neurogenic claudication, a syndrome that may be characterized by radiating pain down one or both legs during ambulation. Patients often describe a "heaviness" or weakness in the legs with walking and standing. Typically, there is an improvement with lumbar flexion or resting, and worsening of symptoms with extension. Depending on the cause of stenosis, an element of back pain may also be present.

While the classic pathology resulting in lumbar neurogenic claudication is LSS, a narrow canal by itself is usually not enough to produce symptoms of claudication. This is supported by the fact that LSS is present in various diseases that do not manifest with claudication symptoms. Furthermore, a spinal canal may have reduced dimensions for many years prior to the development of neurogenic claudication [1]. While spinal stenosis can arise from a variety of causes, both congenital and acquired, lumbar spondylosis is the most common etiology [2]. Congenital narrowing of the vertebral canal is a normal variant in the population but may also be present with other conditions such as growth disorders. With congenital narrowing, the pedicles are typically shorter and closer together, so even minor degenerative changes may lead to symptoms. Other conditions that

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result in acquired stenosis include trauma, iatrogenic, infectious, and neoplastic.

An understanding of normal lumbar anatomy helps to explain how LSS can result in claudication symptoms. The spinal canal has three borders—anterior, lateral, and posterior. The vertebral bodies, intervertebral disks, and the posterior longitudinal ligament (PLL) make up the anterior border of the canal. The spinal canal lateral border is bounded by the pedicles, neural foramen, and the lateral ligamentum flavum. Lastly, the posterior border is comprised of the lamina, ligamentum flavum, and facet joints. The shape of the spinal canal varies in the normal population (Fig. 1). In LSS, the lumbar spine undergoes degeneration of the "three-joint complex" of the two posterior facet joints and the intervertebral disc [3]. Bony alterations such as osteophytes and facet enlargement cause narrowing centrally and in the lateral recesses. Soft tissue pathology such as hypertrophic ligamentum flavum and disc protrusions can also compound the problem. With extension, the hypertrophic ligamentum flavum buckles into the canal, worsening the stenosis and exaggerating claudication symptoms. Any added instability, such as degenerative spondylolisthesis, can further narrow the canal. This is frequently seen as a consequence of a degenerative anterolisthesis of L4 on L5 (Fig. 2) [4].

Symptomatic LSS generally responds well to conservative management, including aerobic exercise, medication, activity modification, and/or injection therapy. Failure of conservative treatment warrants consideration for surgical options, as well as signs or findings of progressive neurologic decline. Historically, the mainstay of surgical treatment has been posterior laminectomy/laminoforaminotomy with or without fusion. In addition to being invasive, this surgery is associated with a wide range of serious complications, and a meta-analysis study showed that only 64% of patients treated surgically for LSS reported good-to-excellent outcomes at an average of 4 years of follow-up [5]. Decompression alone may result in worsened instability, especially in the setting of spondylolisthesis. On the other hand, with fusion, there are inherent risks of nerve injury, nonunion, and adjacent segment degeneration. Interspinous spacers (ISS) were developed as an alternative to posterior decompression and fusion, with the goal of providing similar benefits through a less invasive approach without compromising the stability of the lumbar spine.

Background and rationale of ISS

The development of interspinous process devices has taken a varied course, starting from the 1950's at which time metal "plugs" were placed between the spinous processes [6]. There have been many designs since then, using a variety of materials such as allograft, titanium, and polyetheretherketone (PEEK). The current generation of ISS can be categorized as static or dynamic, but they all have the same goal of distraction of the interspinous space in an attempt to produce relative flexion of the lumbar spine at that level. This results in tightening of the hypertrophic ligamentum flavum and prevents the ligamentum from buckling into the canal, maintaining a bigger canal diameter and enlarging the neural foramen [7].

Examples of static ISS are the X-Stop (Medtronic), Wallis (Zimmer), and Superion (Vertiflex) devices whereas the Coflex (Paradigm Spine) and DIAM (Medtronic) implants are considered to be dynamic ISS [8]. A comprehensive review of every ISS is beyond the scope of this article, but there are a few key points that should be made. The X-Stop device received FDA premarket approval in 2005, and it has historically been the most popular ISS in the USA. Initial data showed promising results in the short-term, but further research demonstrated minimal benefit with longer-term follow-up, along with relatively high complication rates including spinous process fracture (Figs. 3 and 4). As a consequence, Medtronic discontinued the distribution of the X-Stop system in 2015.

The goal of this review article is to present the latest research and current trends in ISS, focusing on the two ISS that are FDA approved and currently commercially available in the USA—the Coflex and Superion devices.

Coflex

The Coflex device was initially marketed as the "interspinous U" in France (Fig. 5), but its correct designation is "interlaminar" device. It is made of a titanium alloy and designed to fit between two adjacent spinous processes in the lumbar spine, appearing as a U-shape on a lateral radiograph. There are clips on the superior and inferior aspects of the "U" which anchor

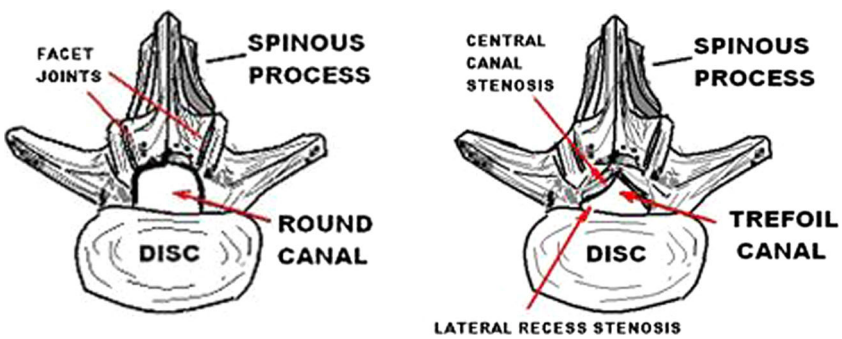

Fig. 1 Spinal canals are usually one of the three shapes—round, trefoil, and ovoid (not pictured). Patients with trefoil-shaped canals are predisposed to spinal stenosis symptoms, as these canals have the smallest cross-sectional area

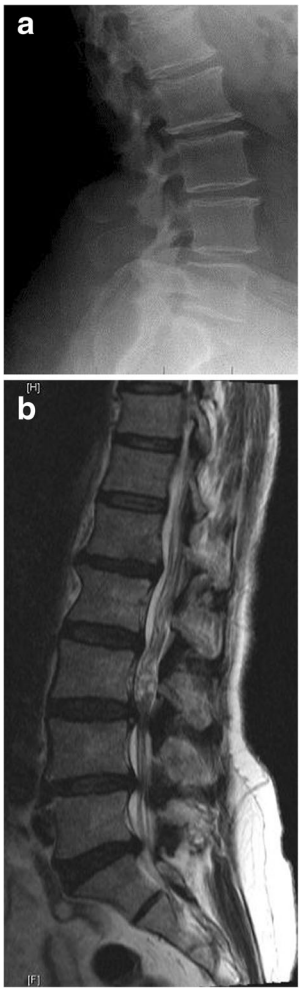

Fig. 2 **a** Radiograph of mild anterolisthesis of L4 on L5 in the setting of degenerative discovertebral and facet joints. **b**. The sagittal view of T2 MRI showing spinal stenosis. Note the disc protrusions and hypertrophic ligamentum flavum.

on both sides of the superior and inferior spinous processes. The clips are staggered such that the superior clips are more anterior, which allow for consecutive levels to be implanted. The Coflex is also slightly different from other ISS in that it is intended to be implanted after a decompression of the canal has been performed at the affected levels. The device provides dynamic stabilization (it compresses on lumbar extension but also permits flexion) while providing relative distraction of the posterior elements throughout the range of motion (Fig. 6).

The FDA approved indications for Coflex is one- or two-level lumbar stenosis from L1 to L5 producing at least moderate impairment in skeletally mature patients [9]. The approval letter specifies that patients should experience relief of symptoms with flexion of the lumbar spine and have undergone at least 6 months of non-operative treatment. The presence of back pain does not exclude someone from receiving Coflex, but axial back pain only without leg/buttock/groin pain is a contraindication. The following are other factors that are contraindications for the use of this device: prior fusion or

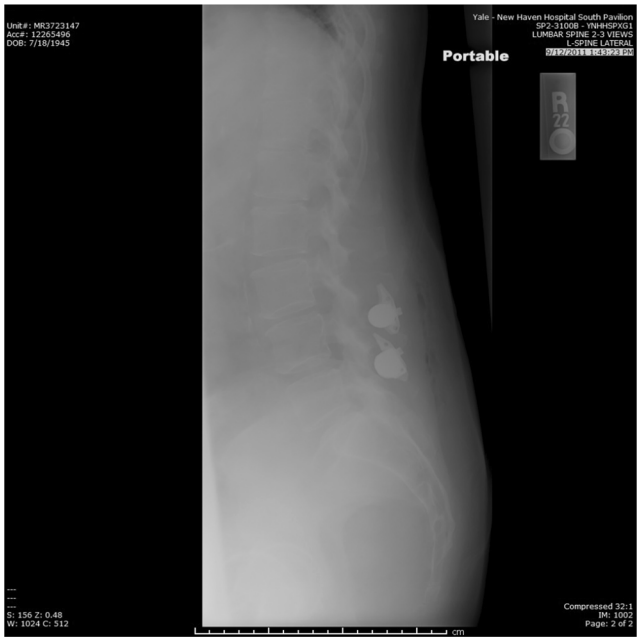

Fig. 3 Lateral radiograph taken after implantation of the X-Stop device at two contiguous levels in the lumbar spine. Note the position of the implants

decompression at the index level, lumbar compression fracture, severe facet hypertrophy necessitating bone excision leading to instability, grade II or greater spondylolisthesis, spondylolytic spondylolisthesis, lumbar scoliosis with a Cobb angle greater than 25°, osteoporosis, and body mass index (BMI) greater than 40.

The most recent data from the FDA post-approval study was published in 2016, presenting the 3-year follow-up results [10••]. In this randomized, controlled, multicenter trial, patients were randomized to either direct decompression via laminectomy and subsequent implantation of Coflex, or direct decompression with subsequent posterolateral instrumented fusion. In both groups, 64% of patients underwent single-level surgery, while 36% of patients underwent two-level surgery [10••].

Composite clinical success (CCS) at 36 months was defined as no reoperations, revisions, removals, or modifications at the treated level(s); no epidural steroid injections; an improvement in Oswestry Disability Index (ODI) score of at least 15 points; no new or worsening persistent sensory or motor deficit; and no major adverse event that was definitely device related. According to these criteria, 62.2% of patients (122/196) in the Coflex group, and 48.9% of patients (46/94) in the control group achieved CCS at 36 months. This 13.3% difference in groups favoring Coflex was found to be statistically significant (P = 0.008). For patients with grade I spondylolisthesis, 59.3% of subjects (51/86) in the Coflex group and 59.5% (25/42) of the control group achieved CCS at 36 months. The difference here was not statistically significant and was suggestive of comparable outcomes in this subset of patients.

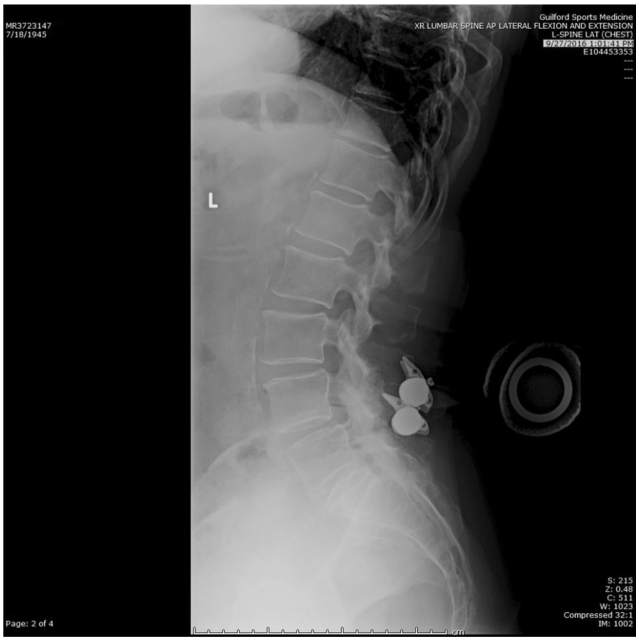

Fig. 4 Lateral lumbar radiograph of the same patient 5 years later, which shows that the proximal X-Stop implant has migrated in the setting of spinous process fracture

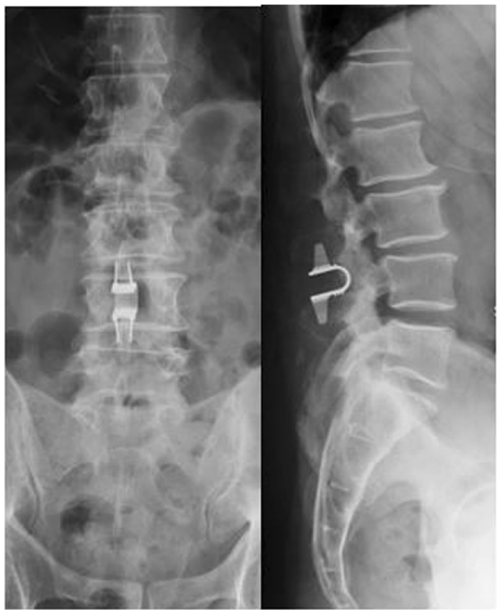

Fig. 6 AP and lateral lumbar radiographs taken after implantation of Coflex device. The device is placed between the spinous processes after decompression is performed

In terms of complications, 19 patients (8.8%) in the Coflex group and 16 individuals (15%) in the fusion group had adverse events related to the device. Surgery-related adverse events occurred in 26 Coflex patients (12.1%) and 19 fusion patients (17.8%). Overall, 76% of Coflex patients and 79% of fusion patients did not require a reoperation or an epidural steroid injection. None of these differences were noted to be statistically significant.

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Of note, there has been recent interest in using the "topping-off technique," which is a potential benefit unique to Coflex [11•]. With this approach, patients with multilevel lumbar stenosis may undergo decompression and fusion in the inferior levels with decompression and placement of a Coflex device at the superior stenotic level, i.e., the transition segment. The purported advantage of this method is that it may reduce the incidence of adjacent segment disease (ASD) in upper adjacent segments, since Coflex stabilization is not as rigid as an instrumented fusion. A biomechanical study evaluated this principle and showed that Coflex implantation could stabilize a transition segment without affecting the range of motion of superior segments, as compared to a fusion which did result in an increased motion in these superior segments [12•]. Another cadaver study demonstrated that combining L4–5 pedicle screw-rod fixation with an upper L3–4 Coflex device provided a greater stability in upper segments than L4–5 fusion alone [13•]. Thus, the authors theorize this technique could protect against ASD in the upper segments.

As mentioned previously, decompression alone can sometimes lead to instability. In addition, many patients with neurogenic claudication have a component of back pain, which is often not addressed with decompression alone. The use of the Coflex may at least theoretically bridge the gap between nonfusion and arthrodesis in terms of stability and also addresses back pain generators, while avoiding the risks associated with instrumented fusions. This was evaluated in a small study with less than 1 year follow-up and showed better improvements in back pain in the Coflex group as compared to a cohort who underwent decompression alone [14•].

Superion

The Superion InterSpinous Spacer was FDA approved in 2015 and is an H-shaped implant composed of titanium alloy (Fig. 7). Unlike X-Stop, the Superion is delivered percutaneously as a single-piece through a cannula after dilators have opened the interspinous space [15, 16]. The implant has superior and inferior cam lobes that rotate during deployment, so as to capture the superior and inferior spinous processes (Fig. 8).

The FDA approved indication for the Superion implant is the treatment of skeletally mature patients with neurogenic claudication secondary to moderate degenerative LSS, with up to grade I spondylolisthesis [17]. The implant can be used at one or two adjacent levels from L1–L5. As with the Coflex, these individuals should experience relief of symptoms with flexion of the lumbar spine and have failed at least 6 months of conservative treatment. Similarly, the presence of back pain does not exclude a patient from receiving Superion, but axial back pain only without symptoms of leg/buttock/groin pain is a contraindication for this device. Patient selection is slightly more defined with Superion, as there should be radiographic evidence of 25–50% reduction in central canal and/or foraminal dimensions. The contraindications for the Superion are similar to those established with the Coflex.

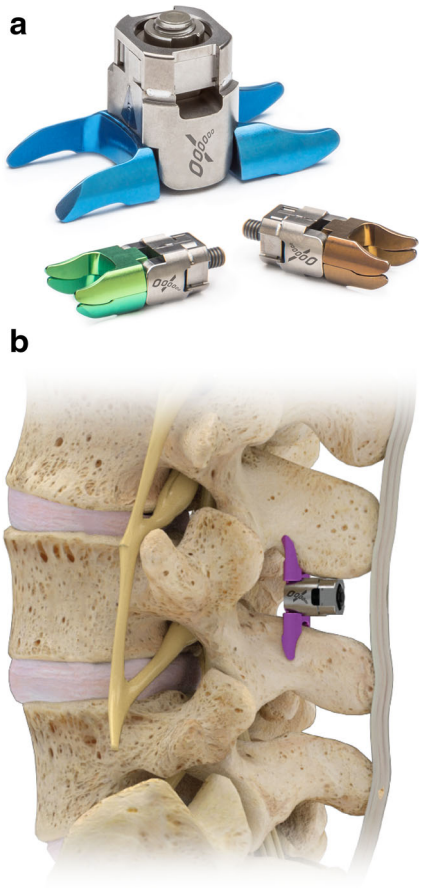

Fig. 7 Images provided by Vertiflex® and published with permission. **a** Image of the Superion implant, showing the superior and inferior cam lobes. **b** The Superion implant is an interspinous device that is delivered percutaneously

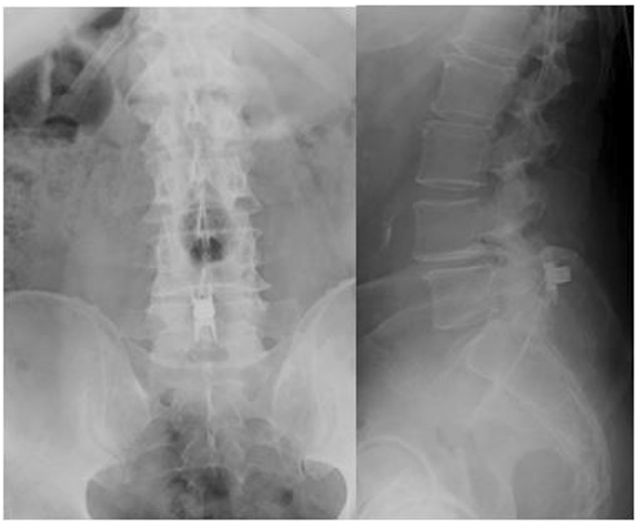

Fig. 8 AP and lateral lumbar radiographs depicting the Superion implant. This device is implanted percutaneously

The Superion implant is often compared to the X-Stop device, as they are both "stand-alone" interspinous devices (i.e., not requiring surgical decompression) that have been approved by the FDA. To date, there has not been a randomized trial comparing Superion to decompressive surgery although the outcomes of Superion have been compared to prior published reports of laminectomy. The data showed a similar improvement at 2 years of follow-up, with trends favoring Superion [18•]. These results suggest that Superion can provide comparable benefits with possibly less surgical risk.

The most recent clinical trial data was published in 2015, reporting on the randomized trial comparing patients who received Superion to those who received X-Stop [19••]. At 36 months of follow-up, 120 subjects with the Superion implant and 129 patients treated with the X-Stop implant were available for revaluation. In both groups, approximately 50% of patients underwent treatment at a single level.

In this study, CCS was defined as a clinically significant improvement in two of the three domains of the Zurich Claudication Questionnaire (ZCQ); no reoperations, revisions, removals, or supplemental fixation at the treated level(s); no major implant or procedure-related complications; and no clinically significant confounding treatments such as epidural injections, nerve block procedures, or rhizotomies. At 36 months, 63 of the 120 patients (52.5%) in the Superion group and 49 of the 129 patients (38.0%) in the X-Stop cohort achieved CCS; these results favoring Superion over X-stop were found to be statistically significant ($P = 0.023$) [19••]. When compared to the 24-month analysis, the Superion group showed no reduction in CCS rates (53 to 52.5%), while the X-

Stop cohort exhibited a decrease in CCS rates (50 to 38.0%) [20•]. There were 49 patients in the Superion group and 44 patients in X-stop group who underwent reoperation/revision/removal of the device by 36 months.

Summary

As with any new device, proper patient selection is critical to achieving successful outcomes. Both the Coflex and Superion implants are indicated for the treatment of moderate degenerative LSS with neurogenic claudication. Severe stenosis or greater than 50% reduction in central canal/nerve root canal diameter often necessitates significant bony excision which may preclude the implantation of the Coflex or Superion; at this point, these devices have not been studied in these patient populations. Candidates for ISS should note an improvement in their symptoms with flexion in order for them to be effective. Isolated back pain may also be a contraindication for the use of these devices, although they may potentially offer some benefit in this population compared to decompression surgery alone. These devices can be used in the presence of low-grade degenerative slips, but should probably be avoided in grade II or higher degenerative slips and spondylolytic spondylolisthesis. Of note, the outcomes of Coflex appear to be comparable to decompression and fusion in the setting of low-grade slips, while the outcomes of Coflex appear to exceed decompression and fusion when no spondylolisthesis is present [10••].

The Coflex represents an adjunct to decompressive surgery, offering stability without the rigidity of an instrumented fusion while also maintaining flexion of the lumbar segment. Since a formal decompression is still completed prior to placing the Coflex device, individuals are still subject to the risks associated with laminectomy. There may be some value for implanting a Coflex device at "transition segments" as part of the "topping-off" technique, although there is still limited evidence corroborating the efficacy of this approach. In regard to its cost-effectiveness, Coflex has been shown to provide higher utility with lower costs than posterolateral fusion [21•].

The Superion device is placed percutaneously with limited changes to the spinal anatomy, through a minimally invasive approach. The associated length of hospital stay is generally shorter with minimal blood loss [20•]. This system promotes its use as a "first line" treatment for moderate LSS and more invasive approaches can still be performed later as indicated [19••]. The Superion has also been shown to be far more cost-effective than conservative care and equivalent in value to decompression [22•].

In conclusion, ISS may play a role in the treatment of LSS. While ongoing research is still needed to clarify the safety and adverse event profiles of these devices, ISS have been shown to provide at least comparable results to decompression surgery while mitigating the risks associated with open laminectomy. Nevertheless, additional studies need to be performed in order to assess the long-term results for these implants and to document their durability over time.

Compliance with ethical standards

Conflict of interest Peter G. Whang reports personal fees from Paradigm Spine and institutional support from Vertiflex during the conduct of study.

Raj J. Gala and Glenn S. Russo declare that they have no conflict of interest.

Human and animal rights and informed consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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