Interspinous Spacers in the Lumbar Spine

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Recently, a new class of spinal devices called interspinous spacers (ISPs) has been introduced. A number of designs have been developed, which vary from non-compressible metallic spacers to compressible cushion-like devices. Following the path of other spinal devices, they are composed of materials ranging from allograft bone, titanium alloy, polyethylene-terketone (PEEK), and elastomeric preparations. Though they are unique in their details, they share the common mechanical goal of effecting distraction between adjacent spinous processes, whereby they block intervertebral extension at that level. The proposed indications for ISPs include degenerative spinal stenosis, discogenic low-back pain, facet syndrome, disc herniations, and non-traumatic instability.

History of Interspinous Spacers

As with many other fields of technology, there is a plethora of new devices based on a handful of old ideas. Though touted as modern technology, the idea of an ISP distraction device actually dates back at least four decades. According to reports from the 1950s, Dr Fred Knowles devised a metallic implant that was described as a ‘plug’ that could be inserted between the spinous processes of the lumbar spine.1 Similar to the rationale of the X STOP® (Medtronic Sofamor Danek, Memphis, Tennessee) device, he intended his implant to be a treatment for spinal stenosis. Unfortunately, the device dislodged easily, which necessitated removal, and its usage ceased. A true pioneer, his name has been immortalized by some of his other inventions, such as the Knowles’s pin used for stabilization of the hip. Another innovator, Dr Jacques Senegas, has also been credited with an early proposal for an ISP.2 Like Dr Knowles, the more enduring invention of Dr Senegas was an anterior cervical plate that, though transformed through numerous iterations by other developers, is strikingly akin to those used today.

Description of Devices

Rubber and Rocks—Categorization of Available Interspinous Spacers

ISPs can be organized into two categories: static (or compressible) and dynamic (or non-compressible). For want of a better analogy, static devices might be likened to using a rock to hold a door open, while dynamic ones can be likened to using a rubber stopper. Examples of static devices include the X STOP, ExtenSure™ (NuVasive, San Diego, California), and Wallis (Abbott Spine, Bordeaux, France) implants. These are made of non-compressible materials such as metal, bone, or synthetic. As they are non-compressible, they produce a nearly constant amount of distraction between the spinous processes. However, the mobility of the lumbar spine must be considered. The amount of distraction between the spinous processes changes with flexion and extension. In flexion, there is greater distraction; in extension, the spinous processes may touch. Static implants fit loosely in flexion and tightly in extension. Thus, they function primarily as a block to extension.

To maintain implant positioning during all modes of movement, some static devices, such as the Wallis system, use stabilizing straps that are affixed around the upper and lower spinous processes. In addition to blocking extension, this method of stabilization could also limit flexion. Something of a hybrid design, the ExtenSure device is stabilized only to the upper spinous process so that it maintains its position but does not restrict flexion or rotation.

Dynamic ISP devices have a degree of compressibility. This can be provided by the material, such as use of an elastomeric compound, or by structure, such as using a metallic spring-like dampener. An example of the latter is the Coflex™ (Paradigm Spine, New York) device, formerly known as the Interspinous ‘U.’ It is composed of an axially compressible U-shaped piece of metal, which is interposed between the spinous processes. It is inserted in a compressed (pre-loaded) mode so that it exerts a distraction force between the bones. This, in combination with its geometry, helps keep it in its intended location. An example of the former is the DIAM (Medtronic Sofamor Danek, Memphis, Tennessee), which is made of an elastomeric polymer that acts as a rubbery bumper between the spinous processes. Although it can also be inserted in a pre-loaded mode, it gains additional stability from fixation straps.

X STOP

Though it shares the market with many other devices, the introduction of the X STOP was likely the catalyst for the recent deluge of ISP...
devices. The X STOP comprises a cylindrical central core, which is stabilized by two flanges that center it between the spinous processes. It is in two pieces so that the second flange is fixed to the flange–core complex. The X STOP is composed of titanium, which—among other reasons for its use—allows post-operative magnetic resonance imaging (MRI). Among metals used for spinal implants, it also has an elastic modulus closer to that of bone compared with steel or cobalt–chrome.

The manufacturer’s recommended indication for X STOP insertion is mild to moderate intermittent neurogenic claudication from degenerative lumbar spinal stenosis. Following the pivotal multicenter, randomized study,1 the importance of patient selection is critical. The patient’s symptoms should be entirely or substantially relieved by lumbar flexion. This is a common clinical feature of patients with spinal stenosis. It is widely known that flexion of the stenotic lumbar spine can relieve lower-extremity claudication and, in contrast, standing or extension can exacerbate it. Relief in flexion is the basis for the so-called ‘shopping cart’ theory whereby patients feel they can walk further if they are leaning forward on a shopping cart. The anatomical explanation for this phenomenon is that flexion reduces the redundancy of the ligamentum flavum and opens the intervertebral foramina, whereby neural compression is lessened.

Stated simply, the X STOP device produces local flexion of the lumbar spine. Based on clinical observations such as the shopping cart theory, the developers hypothesized that if segmental flexion could be maintained, stenotic symptoms could be relieved. Clinical data from the Investigation Device Exemption (IDE) trials have been promising,3,4 though less favorable results have been reported by independent investigators.5,6 The device has recently been cleared for general use by the US Food and Drug Administration (FDA).

ExtensSure

The ExtensSure device is a cylindrically fashioned piece of allograft bone. As an ISP device, it is intended to effect distraction. The allograft is inserted between the spinous processes while preserving the supraspinous ligament, and short-term stabilization is attained by bilateral tightening of sutures securing it to the superior spinous process. The procedure recommends decortication of only the inferior aspect of the superior spinous process and inclusion of an osteoinductive agent with the intention of promoting fusion of the allograft to the spinous process above, while allowing motion between the allograft and the spinous process below. It is thought that this would provide a long-term biological solution to implant stability while retaining segmental motion. At the time of writing, hundreds of implantations of the ExtensSure device have been carried out. Indications appear to be similar to those for X STOP. Currently, it is approved by the FDA and available for use in the US.

Wallis

Over the years, the Wallis implant has been revised a number of times. Currently, it is made of a PEEK block. Like the X STOP, it is a static device. However, the elastic modulus of PEEK is much closer to that of human bone than titanium. Thus, the manufacturers might argue that the Wallis device should be considered compressible. However, PEEK has micro-compressibility in comparison with other materials. The PEEK spacer is held in place by two Dacron® bands that wrap around the superior and inferior surfaces of the spinous processes. A third band crosses from right to left over the posterior interspinous region.

The manufacturer’s purported clinical indication is treatment of low-back pain from mild to moderate degenerative disc disease. A multicenter trial comparing it with total disc replacements is under way in the US. The proposed mechanism for its possible clinical efficacy is the unloading of the posterior anulus by intervertebral distraction. The posterior anulus is thought to be a common source of low-back pain from degenerative disc disease.

Coflex

The Coflex device—formerly the Interspinous U—was developed in France. This name is apt as the metallic device is U-shaped in its side view. Stabilizing flanges on the upper and lower ends of the U straddle the spinal processes. The upper flange is more anterior than the lower flange so that two adjacent levels might be instrumented without impingement of the devices. The Coflex device requires removal of the supraspinous and interspinous ligaments for insertion. As described above, this compressible device is inserted in a pre-loaded (pre-compressed) mode. This allows it to push against the superior and inferior edges of the spinous processes in both flexion and extension, which helps to maintain its position.

The proposed indications for interspinous spacers include degenerative spinal stenosis, discogenic low-back pain, facet syndrome, disc herniations, and non-traumatic instability.

DIAM

The DIAM is composed of a silicone core contained in a polyester cover. Similar to the Wallis, it is held in position by three stabilizing bands: one above, and one below the spinous processes and one over the supraspinous ligament. The manufacturer’s proposed indications are degenerative stenosis; however, recent reports have documented promising results for a broader range of diagnoses.7,8 In 2006, the FDA granted the device an IDE for a multicenter clinical trial.

Clinical Results

X STOP

Recently, Anderson et al.9 reported the results of a randomized, controlled study comparing the X STOP device with non-operative care—consisting of an
epidural injection—for neurogenic claudication in patients with degenerative spondylothesis and stenosis. Improvements in Zurich Claudication Questionnaire (ZCQ) scores, patient satisfaction ratings, and Short Form (SF)-36 Questionnaire were significantly better in the ISP device group. Overall clinical success was reported in 69.2% of the study group but in only 9.1% of the control group at two-year follow-up.

The two-year results from a pivotal multicenter, randomized, controlled study in 191 patients were published by Zucherman et al. in 2005. Patients were randomized to either X STOP or conservative care. Inclusion criteria included symptoms that improved with flexion of the lumbar spine and the ability to walk at least 50 feet. Sixty percent of X STOP patients reported a clinically significant improvement compared with 18.5% in the conservative group at final follow-up. Six of the 100 patients in the X STOP group underwent a laminectomy before the two-year mark.

The author wishes to highlight the previously published work of the one-year follow-up results from the randomized trial carried out by Zucherman and colleagues. Frustratingly, the SF-36 scores were reported in the one-year but not in the two-year study, making a side-by-side comparison difficult. Similar problems were found with the group’s recently published four-year results. Data from only 18 of the X STOP patients were provided. The authors cited that 78% of patients had a successful outcome by measurement using the Oswestry Disability Index (ODI). It is unclear why the ODI scores were reported instead of ZCQ scores, as were documented in the pivotal study.

Results of two independent series have been published, i.e. the authors had no affiliation with the development of the device. Lee et al. documented results in 10 patients with lumbar stenosis who had the X STOP inserted. Seventy percent of the patients were at least somewhat satisfied with the outcomes at a minimum of nine months of follow-up. In a prospective, observational study, Siddiqui et al. found 54% of 24 patients had significant improvement of symptoms, while 29% required epidural injections for symptom recurrence. The authors concluded that their results were inferior to those of Zucherman and colleagues.

**ExtenSure**

In the author’s review of the literature, no published reports of the clinical results for this device were found.

**Coflex**

In an unpublished report by Samani, 106 patients had the Coflex device implanted. Indications were a variety of degenerative diagnoses including scoliosis, lumbar stenosis, instability, and herniated discs. They were used in conjunction with fusion and pedicle screws in some patients. Seventy-four percent of cases had good or excellent results, although there was a 10% revision rate. Only one recently published report could be found. Kong et al. found comparable pain and ODI outcomes with Coflex as a posterior lumbar interbody fusion at L4-5 in 40 patients with spinal stenosis and mild instability at 12-months follow-up.

**Wallis System**

In one abstract from a society meeting, a European group reported 12 months of follow-up in 137 patients. They showed a significant reduction in pain severity. While US trials are under way, there are no available published data concerning clinical results.

**DIAM**

In an unpublished European study, the DIAM device reduced pain and had a high rate of satisfaction in 912 patients. There was a complication rate of 3.8%. Complications included infections and spinous process fractures, some of which necessitated removal and fusion.

Since the current author’s previous review, a number of reports have been found. Kim et al. compared the results of simple laminectomy and/or discectomy with (31 patients) and without (62 patients) use of the DIAM device in an uncontrolled, retrospective study. At 12-month follow-up, they found no statistical differences in outcomes between the groups. In addition, they found no radiographic differences in disc space height or sagittal alignment. In a study of 104 patients with a variety of degenerative lumbar disorders, Taylor et al. found that only 46.2% of patients reported improvements in activities of daily living at 18-month follow-up. Importantly, 20 patients had so-called adverse events, 13 of which required subsequent surgery.

**Conclusions**

Interest in ISP devices seems to be growing. While development of a number of new products continues, the definition of reasonable indications for these minimally invasive implants is crucial. These indications are best derived and adjusted based on thoughtful consideration of findings from randomized, controlled studies.