Operative treatment of lumbar spinal stenosis with interspinous implants. General overview

D. Adam[1], Cristina Adam[2], Ioana Hornea[3]

[1]"Carol Davila" Medicine and Pharmacy University, Bucharest, Romania
[2]Zentral Klinikum Augsburg, Neurologische Klinik, Germany
[3]Emergency Clinic Hospital "St. Pantelimon", Bucharest, Romania

Abstract

Interspinous process devices are an alternative treatment of symptomatic lumbar spinal stenosis (LSS) to conventional surgery. Are presented various kinds of interspinous devices: X-STOP, IN-SPACE, SUPERION, APERIUS, ceramic spacers.

Pathophysiology of lumbar spinal stenosis is presented together with biomechanics of interspinous implants which reduce loads on the facet joints, reduce pressure in the posterior annulus, increase foraminal and spinal canal dimensions.

Indications, contraindications and precautions related to interspinous device surgery are presented.

The results of in vitro studies are confirmed in randomized clinical trials. The improvements are statistically and clinically important, compared to those reported for laminectomy.

Keywords: Lumbar spinal stenosis, interspinous devices.

Introduction

Lumbar spinal stenosis is one of the most common diseases in the elderly.

Spinal stenosis is a narrowing of the spinal canal or neural foramina. Some patients are born with this narrowing, but most often spinal stenosis is the result of a degenerative condition with hypertrophy of the ligamentum flavum and facet joints, osteophytes, spondylolisthesis and disc protrusion.

Symptoms of spinal stenosis constitute neurogenic claudication syndrome first described by Verbiest in 1954 [1]. Symptoms of pain or numbness in the legs are caused by lumbar spinal stenosis (47,4%) and by other diagnoses: diabetic neurophaty, peripheral artery disease [2].

Characteristics associated with lumbar spinal stenosis include age greater than 60, intermitent claudication, exacerbation of symptoms when standing up, improvement upon bending forward, absence of diabetes, good peripheral artery circulation.

A positive straight leg raise test and symptoms induced with lumbar flexion are negatively correlated with the diagnosis of lumbar spinal stenosis.

The lifetime risk has been estimated to be approximately 10% with a slight predominance of women.

Some studies have documented that a large proportion of patients have stable symptoms for many years.

Lumbar spinal stenosis is a progressive disabling condition which compromises an individual`s ability to perform their

activities of daily living, reduces quality of life and threatens one`s independence.

Pathophysiology

In 1954 Verbiest [1] published a series of 7 case reports of patients with intermitent neurogenic claudication. In each case myelography showed a block in the lumbar region, which was confirmed at operation.

In 1978 Kirkaldy-Willis [3] described the pathophysiology of lumbar spinal stenosis based on cadaveric dissections and patients' laminectomy. LSS begins with repetitive minor trauma over many years. LSS is the result of destruction of the posterior joints causing synovial reaction, cartilage destruction, osteophyte formation and intervertebral disc disruption.

These changes lead to loss of disc height, facet instability, buckling of the ligamentum flavum, narrowing of the neural foramina and spinal canal and impinging - each or all together - upon structures within them. This lead to chronic compression of the nerve roots causing decreased blood flow, ischemia and local edema.

The load - bearing structures in each vertebra are the vertebral body and the two facets.

Changes of lumbar facet joints are responsive of 15-40% of chronic low back pain. Facet specific back pain is exacerbated by hyperextension and lessened in a recumbent position or flexion. During extension, deformation of the joint capsule is the source of pain. The capsule surrounding the facet joint is innervated by afferent nociceptive fibers, which are activated by mechanical stresses.

Increased facet loading is a consequence of disc degeneration. In the case of facet joint degeneration or removal, the motion segment is unstable, allowing greater sagital displacement and acceleration of disc degeneration. Long - term lumbar segment instability results in degenerative spondylolisthesis.

Treatment of lumbar spinal stenosis

In the past lumbar spinal stenosis had only a conservative treatment.

Conservative treatment includes physical therapy, non-steroidal anti-inflammatory drugs, opioid analgesics, epidural steroid injections and lumbar corsets.

Pain relief from epidural injection may be temporary and patients are usually advised to get no more than 3 injections per 6 - month period.

Physical therapy and / or exercises help stabilize the spine, build endurance and increase flexibility.

While some patients obtain relief from symptoms with this "conservative" therapy, others do not.

Patients often fail conservative therapy because these treatment options do not alter the anatomic pathology that causes symptoms, do not enlarge the spinal canal or foramina. When conservative management fails is indicated surgical intervention in the form of mechanical decompression of the posterior spinal elements.

The conventional surgical treatment for spinal stenosis is a lumbar laminectomy. Wide decompressive laminectomy has been the standard procedure, though recently less invasive surgical approaches have been tried. Gibson [4] in a systematic review of recent studies suggests that laminectomy alone had better results than laminectomy associated with instrumented or non-instrumented fusion. The author concluded that there was no clear evidence regarding

the most effective technique for surgical decompression of spinal stenosis.

Studies have been unable to identify patient characteristic that predict who is likely to respond best to surgery and who will respond to conservative management [5].

The study of Weinstein et all [6] suggests that surgical management of degenerative lumbar spinal stenosis achieves better than nonsurgical care.

However, major surgery, an invasive surgical treatment, especially can lead to complications, therapy, miminimally invasive surgery is an important option for elderly patients who tend to present with comorbidities and other health risks.

As a result, interspinous process distraction with different spacers has been used widely over the past years.

Devices

The first interspinous implant for the lumbar spine was developed in the 1950s by Knowles (cited by Kondrashov, 2006). Owing to flaws in design, material, surgical technique and applied indications its use was abandoned. Technological advances, which have contributed to improved safety and efficacy, have rekindled an interest in IPD implantation. Now exist various kinds of interspinous devices:

1. The X-STOP Interspinous Process Decompression (IPD) (St. Francis Medical Technologies, Concord System CA) is the first alternative to conventional spinal stenosis surgery proven to significantly improve symptom severity and physical function.

The X-STOP device is a titanium metal implant designed to fit between spinous processes of the vertebrae (Figure 1). It is designed to remain safely and permanently in place without attaching to the bone or ligaments. It is MRI safe but can produce artifacts on MR image.

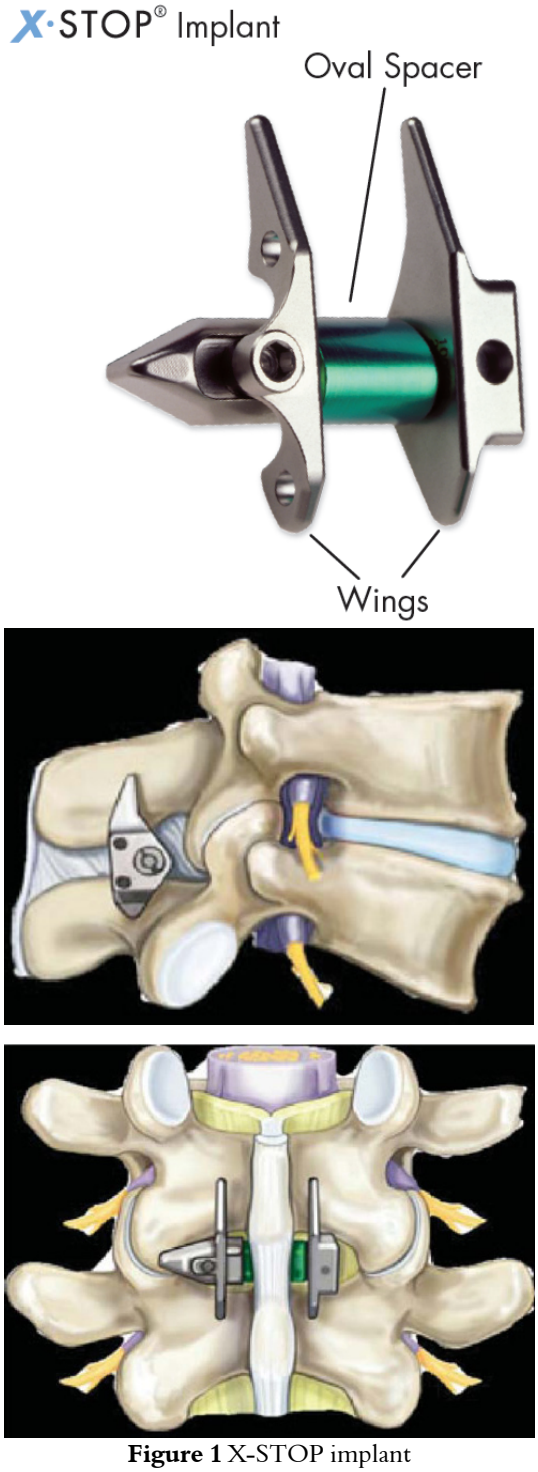


Figure 1 X-STOP implant

X-STOP IPD is available in Europe since 2002 and received FDA approval in 2005. X-STOP is currently the only IPD device available in the United States.

2. The IN - SPACE Interspinous spacer (Synthes USA, LLC) is another percutaneous minimally invasive device which put the stenotic segment in slight flexion, enlarge the spinal canal and foramen (Figure 2).

Senegas [7] found positive long - term results with the first ISS, which was implanted in 1986.

3. In Japan, since 2002 is used a new distraction device (Pentax Co, Tokyo, Japan) made of hydroxy-apatite and calcium phosphate. His shape is cylindrical and on the surface of the midportion it harbors grooves (Figure 3)[8].

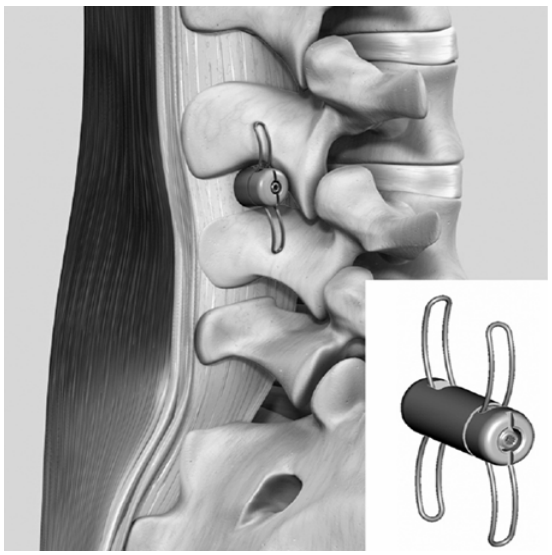


Figure 2 IN - SPACE Interspinous spacer

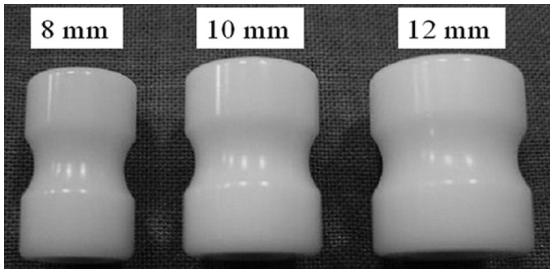
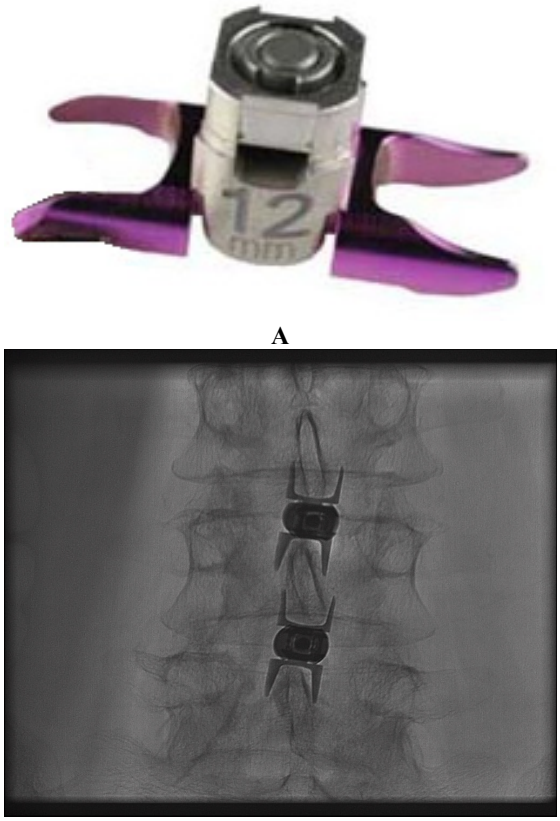


Figure 3 Ceramic spacers

4. The SUPERION Interspinous Spacer (ISS) (VertiFeex, CA, USA) (Figure 4) is an device composed of titanium alloy, and consists of a single component with deployable superior and inferior projections that engage the spinous processes to secure it is opened, thus providing distraction at the affected spinal segment.

SUPERION has been CE marked since 2007 and is currently an investigational device in the U.S. It is the most advanced and least invasive spacer and allows for the procedure to be done local anesthesia on an outpatient basis.

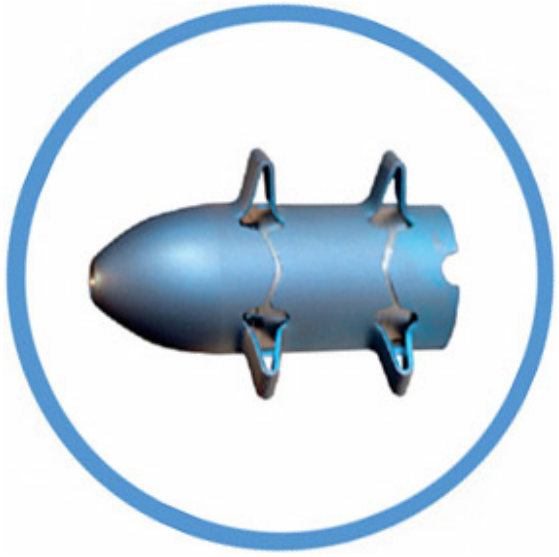
5. APERIUS PercLID System (Figure 5) can be used at any level between L1 and L5 [9].



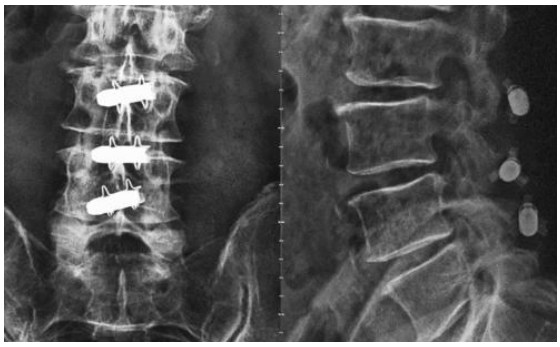
A

B

Figure 4 SUPERION Implant: device (**A**) and intraoperative fluoroscopic image (**B**)



A



B

Figure 5 APERIUS PercLID System: device (**A**) and postoperative spine radiographs (**B**)

Biomechanics of interspinous spacers

Biomechanical results reported by Panjabi et all [10], anatomic results reported by Inufusa et all [11] and clinical results reported by Fredericson [12] et all have shown that when individuals shift their spine from an extended position, the cross-sectional foraminal area increases and nerve root compression is relieved.

An interspinous spacer is designed to hold the stenotic level in flexion.

An interspinous spacer produce an unloading of the stenotic middle column of the spine, which is evident as an increase in foraminal height, related to increased foraminal area and decreased canal stenosis.

Lazaro et all [13] observed that foraminal height, after the ISS was inserted, decreased during extension with 1.4% compared with 4.7% decreased without ISS. Foraminal area is with 4.2% larger during extension after ISS implantation. With ISS facet loads were reduced by more than 50% during full extension.

Richards et all [14] found that foraminal area increased by 25% during extension after X-STOP implantation.

Lee et all [15] reported that the mean dural sac area increased by 23% after X-STOP placement and intervertebral foraminal area improved by 36%.

Siddiqui et all [16] found that the spinal cross section examination with MRI, the mean canal dimension increased 20% in standing patients, and 27% in extension with X-STOP implantation.

Wiseman et all [17] showed that the mean pressure of the facet joint was reduced by 39% at the X-STOP implanted level.

Chiu [18] reported that X-STOP unloads posterior annulus pressure by 63%, posterior nucleus pulposus pressure by 41% and facet force by 68%.

These in vitro studies of interspinous spaces have shown increased foraminal and spinal canal dimensions at the implanted level in extension, a reduction of the pressure in the posterior annulus in extension and off-loading of the facet joints without altering the dimensions or pressures in the adjacent non-operated levels. Thus, these spaces may prevent the development of disorders at there levels.

Indications for use of interspinous devices

All kind of interspinous implants are indicated for the treatment of patients aged 50 or older, suffering from pain or intermitent neurogenic claudication in the legs secondary to a confirmed diagnosis of central and/or lateral process lumbar spinal stenosis and not responding to at least 6 month of non-operative treatment.

These patients have to have lumbar stenotic symptoms of moderate severity with pain relief in flexed lumbar - and exacerbation when in an extended position.

Other indication for interspinous implants are contained HNP, spondylolisthesis up to 35% (grade 1.5/4) with intermitent neurogenic claudication, facet syndrome, degenerative and/or iatrogenic (post-discectomy) disc syndrome, Baastrup`s syndrome (Kissing spine) and for unloading of disc adjacent to a lumbar fusion procedure.

Interspinous devices can be implanted at one or two lumbar levels.

Contraindications of interspinous devices

These devices are contraindicated in patients with:

- an allergy to titanium or titanium alloy
- spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in the body:
- significant instability of the lumbar spine
- acute fracture of the spinous process or pars interarticularis
- significant scoliosis (Cobb angle greater than 25 degrees)
- an ankylosed segment at the affected level
- cauda equina syndrome
- severe osteoporosis in the spine, defined as bone mineral density more than 2,5 SD below the mean of adult normal.
- active systemic infection or infection localized to the site of implantation

Precautions

Implantation of interspinous devices can be an effective treatment option, but it is not a panacea for all patients with degenerative lumbar spine conditions.

The interspinous device does not replace microsurgical decompression in patients with massive stenosis and continuous claudication. To avoid the postoperative complications of X-STOP interspinous distractor, not only the clinical indications deserve attention, but also the patient's lumbar anatomic characteristics.

Barbagallo et all [19] scrutinized these characteristics and proposed a novel anatomic scoring system to classify the patient's anatomic features and to make a good patient selection, for this decompression procedure (Table 1).

TABLE 1

Anatomic scoring system according to Barbagallo

Score	Inferior SP morphology	Accessible SP length	Interspinous area shape
1	Concave	Entire SP length	Parallel
2	Straight	Posterior 2/3 of the SP	Posterior V shape
3	Convex / Dysmorphic	Posterior 1/3 of the SP	----

SP - spinous process.

There are 17 possible combinations in the scoring system:

- a score of 3-4, suitable conditions for placement of an interspinous device
- a score of 5-6, risk conditions
- a score of 7-8, potential contraindications.

A V-shaped posterior interspinous area is a risk factor for device dislocation, and a potential contraindication. A parallel interspace is a more suitable anatomic finding.

The issues analyzed by Barbagallo et all have to thoroughly considerent among the inclusion / exclusion criteria before surgery, to obtain a high success rate.

Insertion of an interspinous devices is not without risk.

The potential adverse events of interspinous implants are: implant dislodgement / migration, fracture of the spinous process, foreign body reaction, mechanical failure of the device, additional surgery with removal of the implant.

The anatomic improvements demonstrated in prior cadaveric studies were confirmed in vivo, in randomized clinical trials [8, 20, 21, 22, 23].

The outcomes were strongly in favor of interspinous devices when compared to those reported for laminectomy. The improvements were statistically and clinically important.

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