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INTERSPINOUS
SPACERS

Bilgehan SOLMAZ M.D., Ahmet Levent AYDIN M.D.

Lumbar spinal stenosis (LSS) is a common disorder causing low back pain, leg pain and neurogenic claudication.

LSS is first defined by Sarpyener⁽¹⁾ in literature. The definitions of the neurogenic claudication was commonly attributed to Verbiest⁽²⁾. This syndrome shows itself with numbness, weakness and radicular leg pain that radiates from the lower back down into the legs when standing up or walking.

Symptoms tend to decrease when the patient sits or leans forward. A variety of treatment options have been described to manage the LSS. However, high complication rates of decompression operations, likelihood of adjacent segment disease after spinal fusion and elder age of this patient population led to development of minimal invasive approach to patients with LSS.

Interspinous devices (ISD), the implants placed between lumbar spine spinous processes, were developed as minimal invasive option for the treatment of ligamentous LSS. They restrict the lumbar spine extension, and widen the spinal canal AP diameter, and in turn, reduce neurogenic claudication. The advantages of the ISDs were reported as easy implantation, minimal invasive approach, minimal necessity for tissue retraction, short operation duration, the possibility of application under local anesthesia, and less risk of corrosion.

1. Indications

The effectiveness of the interspinous devices has been reported in a variety of indications including

ligamentous LSS, degenerative spondylolisthesis (Grade I), facet joint disease, disk instability and discogenic low back pain. However, the main indication is ligamentous LSS associated with the following criteria:

- Central or lateral lumbar spinal stenosis confirmed by computed tomography (CT) and magnetic resonance imaging (MRI),
- Neurological intermittent claudication
- Unresponsive to conservative therapy
- Only one or two stenotic level
- Age over 50 years old

2. Contraindications

The contraindications are allergy to titanium or alloy, severe osteoporosis, anatomical degenerations such as ankylosing spondylitis, spondylolisthesis of grade II or higher, anatomic degenerations such as scoliosis, fracture of spinous processes or pars interarticularis, cauda equina syndrome, widespread spinal stenosis, and infection.

3. Kinds of Interspinous Device (ISD)

Currently more than 10 ISDs are used in clinical practice. They are similar to each other in regard to the design and biomechanical standpoints. Here, the general aspects of some of these devices are reviewed.

3.a. X-Stop Interspinous Decompression System

This system (St. Francis Medical Tech, Alameda, USA), was developed to treat for the symptomatic lumbar spinal stenosis. The X-stop composed of an oval titanium spacer, which separates the spinous processes and limits titanium alloy separates the spinous processes from each other and restricts the extensions; the wings that the device has on the both sides avoids gliding of the device to the front or the sides⁽³⁾ (Figure 1).

3.b. Wallis System

Wallis System (Abbott spine, inc, Austin, USA) was developed to prevent low back pain from intervertebral segmental instability (Figure 2). Although both preclinical and clinical studies were limited, Senegas⁽⁴⁾ reported that this system have restored the stability due to the degenerative instability, reduced loading on facet joints and disc, increased disc hydration, and preserved lumbar lordosis. Indications of Wallis system were reported to be recurrent herniated disc, voluminous herniated disc in young adults, degenerative disc disease at a

segment adjacent to fusion, and Modic 1 degenerative lesions. It was reported to be contraindicated in cases with high grade degenerative lesions, spondylolisthesis, osteoporosis, L5-S1 level problem, litigation, and non-specific low back pain⁽⁵⁾.

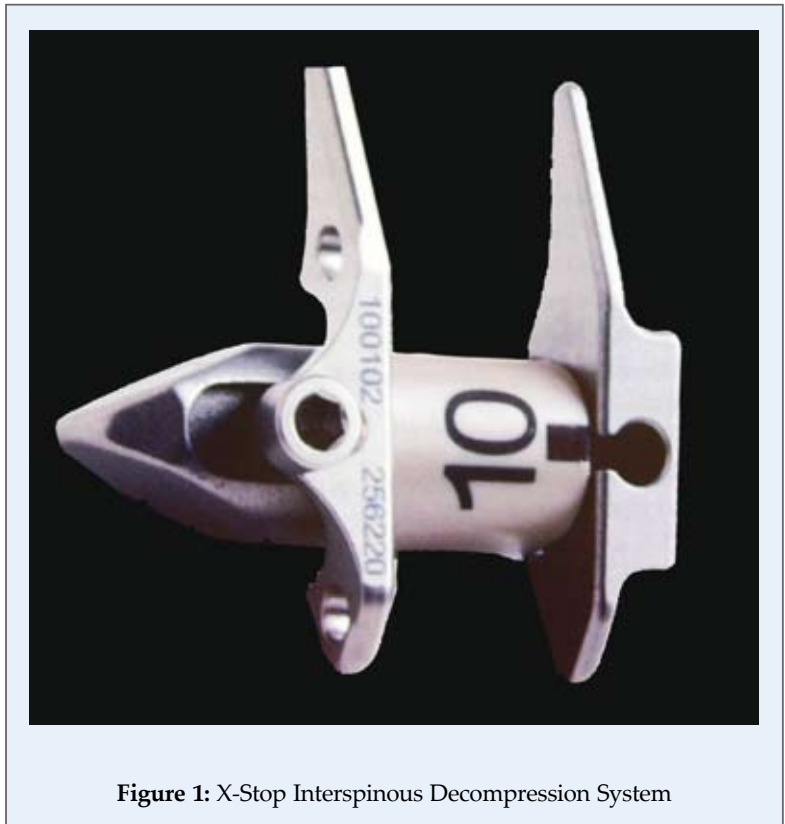


Figure 1: X-Stop Interspinous Decompression System

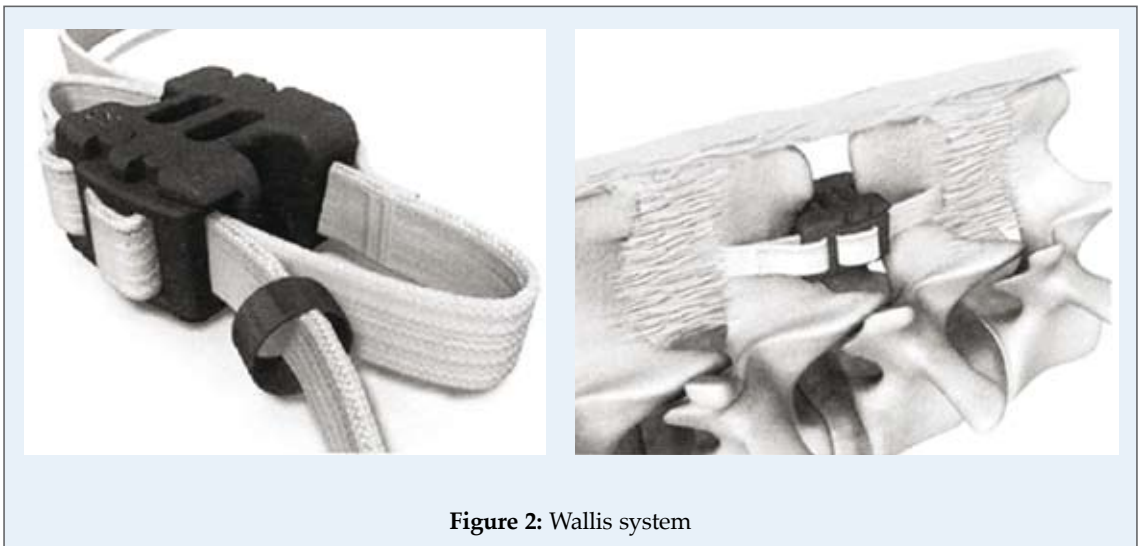


Figure 2: Wallis system

3.c. Dynamic Stabilization Device (DIAM)

The *DIAM* (Medtronic Sofamor Danek, Memphis, Tennessee, USA) is a dynamic stabilization device, designed to reduce segmental motion at the degenerative segment by shock absorber structure (Figure 3). Taylor and Ritland⁽⁶⁾ have reported the effectiveness of this interspinous device in reducing the increased segmental flexion-extension motion after a discectomy or partial facetectomy. The reported indications include disc herniation, lumbar spinal stenosis, facet syndrome, black disc and adjacent segment pathologies after fusion.

ISS (Interspinous System-Biomet), *U-Device* or *Coflex Spine Motion U-Device* (Fixano), *PEEK* (Optima) are the other kinds of the ISDs available in the market (Figure 4). There a limited number of clinical and biomechanical studies addressing these systems. Recently, experimental and clinical studies are increasing, particularly in the X-stop decompression system.



Figure 3: DIAM dynamic stabilization device

4. Surgical Procedure

The surgical technique for implantation of the ISDs is similar in various devices. Here, we describe the technique used for X-stop ISD implantation. This minimally invasive surgical procedure spell about 20 minutes to one hour. Surgical implantation is performed under local anesthesia or general anesthesia. The patient is placed on the right lateral decubitus position on the operating table in slight flexion position. A midsagittal approximately 3 cm incision is made over the spinous processes. The paraspinal muscles are elevated from spinous process and medial lamina. After fluoroscopic identification of the correct level, firstly small then large dilators are inserted into the interspinous process area. After this stage, sizing instrument is inserted and dilated until the supraspinous ligament become tight. Suitable device is inserted between the spinous processes as close to the aspect of the lamina as possible and universal wing is attached to the tissue expander. The incision is then closed. In our experience mean operation time is approximately 20 minutes.

5. Complications

Most of complications are related to the inappropriate size of the implant, and inappropriate location. An intervention free of complications requires a careful decision making with regard to the implant size and implant location (Table 1).

Table 1: Complications of interspinous devices:
● Implant not positioned correctly
● Implant dislodgement or movement
● A fracture of spinous processes during implantation
● Failure of the procedure, continuation of the symptoms
● Additional surgery
● Mechanical failure of the implant
● Foreign body reactions

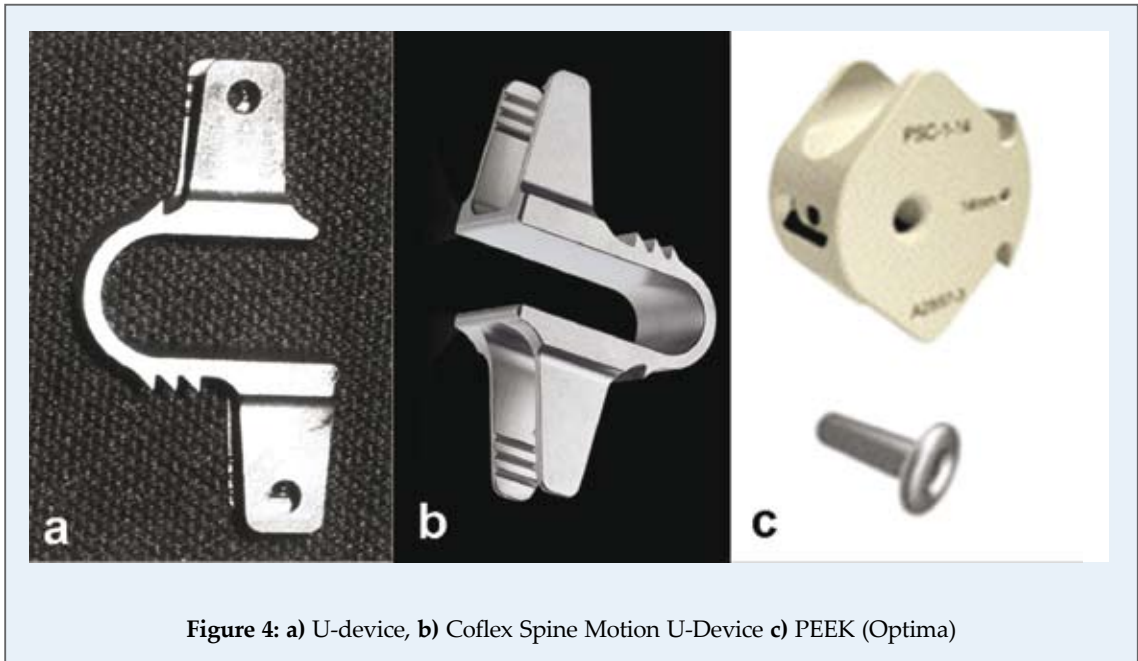


Figure 4: a) U-device, b) Coflex Spine Motion U-Device c) PEEK (Optima)

6. Post-Operative Care

After placement of the implant with interspinous devices the patient could be mobilized a few hours after the surgery. Since the minimal invasive surgery is an intervention done under local anesthesia the patients do not have much problems after the surgery. The post-operative pains can be relieved with simple analgesics. Patients move on to their daily lives after the surgery.

7. Results

The results of recent studies have shown that ISDs are effective and safe treatment options for patients with neurological intermittent claudication secondary to ligamentous LSS. In a cadaver study, Swanson *et al*⁽⁷⁾ demonstrated the effectivity of ISDs on disc pressure at instrumented level, while Lindsay *et al*⁽⁸⁾ showed that the implant reduced the range of motion during flexion-extension and not affected at the adjacent levels. The other studies showed that implant prevented narrowing of the lumbar spinal canal and neural foramen in extension and reduced facet loading at the implanted level^(8,9)

In a clinical study, Zucherman *et al*⁽¹⁰⁾ reported that X-Stop improved symptoms and physical functions compared with conservative treatment and steroid injections in two-year prospective randomized trial multicenter study. Richard *et al*⁽¹¹⁾ have also reported similar results. They have also reported no major complications after the surgery. Short operation time (mean operative time was 54 minutes in Zucherman study and 51.2 minutes in Richards study) and minimal blood volume loss (mean blood loss volume 46 ml in Zucherman study and 40.1-57.9 ml in Richards study) were other advantageous aspects of this surgery.

Other clinical studies focused on other aspects of ISDs. While Lee *et al*⁽¹²⁾ have shown that 40% of patients improved at 9 and 18 months following surgery, Siddiqui *et al*⁽¹³⁾ shown that its effectivity in only short time period. Siddiqui have also reported two spinous process fracture during the operation. On the other hand, in a study by Verhoof *et al*⁽¹⁴⁾, X-Stop interspinous device showed high failure rate in lumbar spinal stenosis with degenerative spondylolisthesis. Finally it can be concluded that the interspinous devices are effective in old age patients who suffer from ligamentous narrow lumbar canal.

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