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LUMBAR INTERSPINOUS DEVICES

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1. Introduction:

Lumbar spinal stenosis (LSS) is a common disorder causing low back pain, leg pain and neurogenic claudication. A variety of treatment options have been described to treat 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 treatment of ligamentous lumbar spinal stenosis (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 to be easy implantation, minimal invasive approach, minimal necessity for tissue retraction, short operation duration, the opportunity for application under local anesthesia, and less risk of corrosion.

2. Indications

The effectiveness of ISDs have been reported in a variety of indications including LSS, degenerative spondylolisthesis (Grade I), facet joint disease, disc 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 CT or MRI scan
- Neurological intermittant claudication
- No response to conservative therapy
- Only one or two stenotic level
- Age over 50 years old

3. Contraindications

There are only a limited number of contraindications, including an allergy to titanium or alloy, severe osteoporosis, anatomical degenerations such as ankylosing spondylitis, high grade spondylolisthesis, scoliosis, fracture of spinous process or pars interarticularis, cauda equina syndrome, widespread spinal stenosis, and infection

Kinds of ISDs

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

The *X-Stop* interspinous decompression system (St. Francis Medical Tech., Alameda,CA) was developed to treat neurological claudication in spinal stenosis. The X-Stop composed of an oval titanium spacer, which separates the spinous processes and limits extension, and two lateral wings which prevents anteriorly or laterally migration of the device **(1)**. It was designed to limit extension on the affected level or levels while allows flexion, axial rotation and lateral bending motions.

Wallis System (Abbott spine, inc, Austin, TX) was devoloped to prevent low back pain from intervertebral segmental instability. Although both preclinical and clinical studies were limited, Senegas reported that this system have restored the stability due to the degenerative instablity, reduced loading on facet joints and disc, increased disc hydration, and pre-

served lumbar lordosis. Indications of Wallis 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 repoted to be contraindicated in cases with high grade degenerative lesions, spondylolisthesis, osteoporosis, L5-S1 level, litigation, and non-specific low back pain [2,3].

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. Taylor and Ritland 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 [4].

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. There a limited number of clinical and biomechanical studies addressing these systems.

Recently, preclinical and clinical studies are increasing, particularly in the X-stop decompression system.

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 to prevent extansion. 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 dilatators are inserted into the interspinous process area (figure 1 and 2). After this stage, sizing instrument is inserted and dilated until the supraspinous ligament become taught. Suitable device is inserted between the spinous processes as close to the aspect of the lamina as possible (figure 3) and universal wing is attached to the tissue expander (figure 4). Then the incision is closed. In our experience mean operation time is approximately 20 minutes.

Figure 2: Measurement of the interspinous space

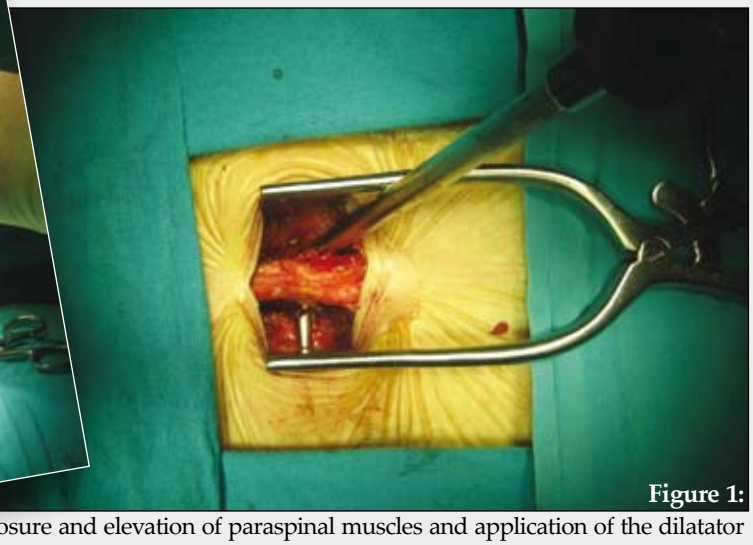

Figure 1: Exposure and elevation of paraspinal muscles and application of the dilatator

5. Complications

Most of complications are related to the inappropriate size of the implant, and inappropriate location. A complication avoidance 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 the spinous process during implantation
Failure of the procedure, continuation of the symptoms
Additional surgery
Mechanical failure of implant
Foreign body reactions

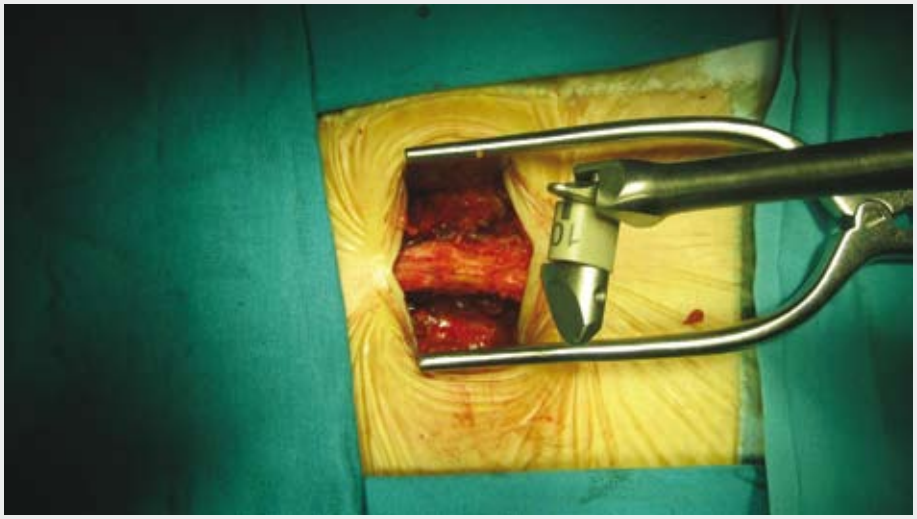

Figure 3: The application of the device

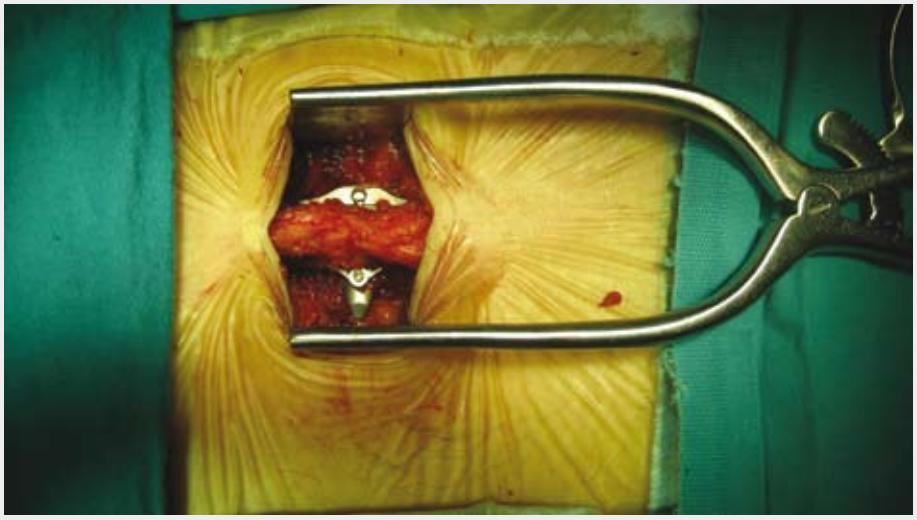

Figure 4: Final position of the ISD

6. Postoperative Care

There is no special consideration regarding postoperative care after this procedure. Patients could be mobilized within the first hours after this minimal invazive surgery.

7. Conclusion

The results of recent studies have shown that ISDs are effective and safe treatment options for patients with neurological intermitant claudication secondary to ligamentous LSS. In an invitro study, Swanson *et al* [5] demonstrated the effectivity of ISDs on disc pressure at instrumented level, while Lindsay *et al* [1] shown that the implant reduced the range of motion during flexion-extension and not affected at the adjacent levels. The other studies shown that implant prevents narrowing of the lomber spinal canal and neural foramen in extension and reduced facet loading at the implanted level [6,7].

In a clinical study, Zucherman *et al* [8] 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* [9] 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 minimaly blood volume loss (mean blood lose volume 46mL in Zucherman study and 40.1-57.9 mL in Richards study) were other adventageous aspects of this surgery.

Other clinical studies focused on other aspects of ISDs. While Lee *et al* [10] have shown that 40% of patients improved at 9 and 18 months following surgery, Siddiqui *et al* [11] 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* [12], X-Stop interspinous device showed high failure rate in lumbar spinal stenosis with degenerative spondylolisthesis.

Finally, it can be concluded that ISDs are effective in aged patients with ligamentous LSS. There is need to studies comparing long term results of different ISDs.

8. References:

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