Do interspinous process devices function well as fusion adjunct devices?

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Disclosures

Transcendental Spine stockholder

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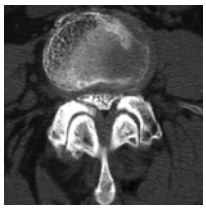
Interspinous Process (ISP) Devices



SI joint fusion using iFuse system. Photo credit spinemd.com

- **Three-joint anatomy**
  - Facets, ligaments, disc
- **Lumbar spinal stenosis (LSS)**
- **Traditional use of ISP for treatment of neurogenic claudication due to LSS**
- **Function as:**
  - Extension limiting devices
    - X-Stop, others
  - Movement control devices
    - Coflex
  - Clamps

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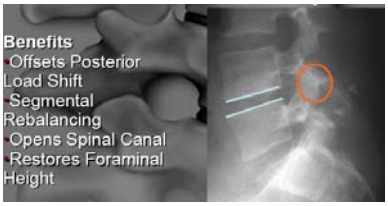
Interspinous Process (ISP) Devices (Extension limiters)



Courtesy of DH Kim

- **Three-joint anatomy**
  - Facets, ligaments, disc
- **Lumbar spinal stenosis (LSS)**
- **Traditional use of ISP for treatment of neurogenic claudication due to LSS**

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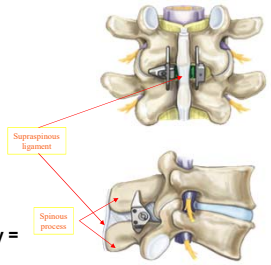
The X STOP Solution

- **Spacer prevents extension**
- **Wings prevent lateral and anterior migration**
- **Supraspinous ligament prevents posterior migration**
- **Technique preserves anatomy = Prevents Kyphosis**



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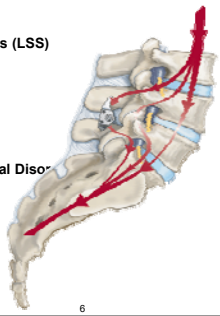
The X STOP Solution

- **First prosthesis for Lumbar Spinal Stenosis (LSS)**
  - Minimally invasive
  - Safe
  - Reversible
- **Published Biomechanical Results in Spine**
- **Published Clinical Results in Spine, European Spine J, and the Journal of Spinal Diso and Techniques**
- **Other indications for IPD beyond LSS**
  - Back Pain
  - Facet Pain
  - Adjacent to a Fusion



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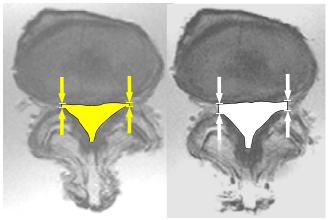
Canal Dimensions

- **Axial MRI slices of extended cadaver specimens showed:**

- canal area: ↑18%
- canal diameter: ↑9%
- subarticular diameter: ↑50%



Intact X STOP

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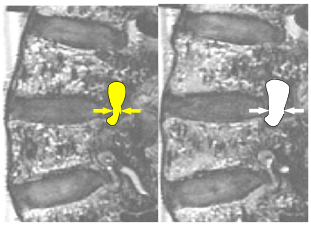
Foramen Dimensions

- Para-sagittal MRI slices of extended cadaver specimens showed:
  - foramen area: ↑25%
  - foramen width: ↑41%



Intact X STOP

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Other ISP devices that limit extension

- **Superion**
  - Deployable wings
  - US FDA approved

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ISP devices that control motion

- **DIAM**
  - MSD
  - Not US FDA approved

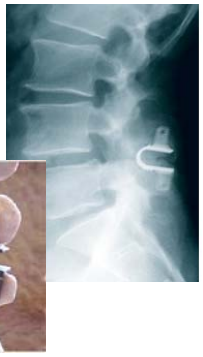
- **Wallis**
  - Australia
  - Not US FDA approved

- **"U" device**
  - Used in Europe
  - Not US FDA approved

- **Coflex**
  - US FDA approved

Coflex

- The coflex® Interlaminar Technology is an interlaminar stabilization device indicated for use in one or two level lumbar stenosis from LI-L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 months of non-operative treatment. The coflex@ is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).



Clinical Evidence in Co-Flex Patients

- **Davis R, Errico TJ, Bae H, Auerbach JD Decompression and Coflex interlaminar stabilization compared with decompression and instrumented spinal fusion for spinal stenosis and low-grade degenerative spondylolisthesis: two-year results from the prospective, randomized, multicenter, Food and Drug Administration Investigational Device Exemption trial. Spine 38;1529-39, 2013**
- **OBJECTIVE:** To evaluate the safety and efficacy of Coflex interlaminar stabilization compared with posterior spinal fusion in the treatment of 1- and 2-level spinal stenosis and degenerative spondylolisthesis.
- **SUMMARY OF BACKGROUND DATA:** Long-term untoward sequelae of lumbar fusion for stenosis and degenerative spondylolisthesis have led to the search for motion-preserving, less-invasive alternatives.

Clinical Evidence in Co-Flex Patients

- **Davis R, Spine 38;1529-39, 2013 (cont)**
- **METHODS:** Three hundred twenty-two patients (215 Coflex and 107 fusions) from 21 sites in the United States were enrolled between 2006 and 2010. Subjects were randomized to receive laminectomy and Coflex interlaminar stabilization or laminectomy and posterolateral spinal fusion with spinal instrumentation in a 2:1 ratio. Overall device success required a 15-point reduction in Oswestry Disability Index, no reoperations, no major device-related complications, and no postoperative epidural injections.
- **CONCLUSION:** Coflex interlaminar stabilization is a safe and efficacious alternative, with certain advantages compared with lumbar spinal fusion in the treatment of spinal stenosis and low-grade spondylolisthesis.
- **LEVEL OF EVIDENCE:** 1

So…..

- We have good evidence that ISP devices can limit or modify movement
- Can they be used to augment fusion?
- Do they require supplemental fixation (pedicle screws, interbody support)?
- Risks?
  - Posterior spinous process fractures?
  - Decompression necessary?
  - Dislodgement?
  - Use in spondylolisthesis?
  - Others?

Posterior spinous process clamps

- **Spire (MSD)**
- **Aspen (Lanx/Zimmer/Biomet)**
- **StabiLink (Southern Spine)**
- **Affix (Nuvasive)**
- **Bridgepoint (Alphatec)**
- **SP-Fix (Globus)**
- **InSpan (Spine Frontier)**
- **Minuteman (Spine Simplicity)**
- **Others**

Posterior spinous process clamps

- **FDA clearance through 510(K) process.**
- **Indications:**
  - Help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The system is intended for use with autograft or allograft.
  - Posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (Ti-S 1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor.
  - Adjunct to fusion in the treatment of the following instabilities or deformities: degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

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Posterior spinous process clamps fusion evidence

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Spinal Simplicity
innovative simple solutions

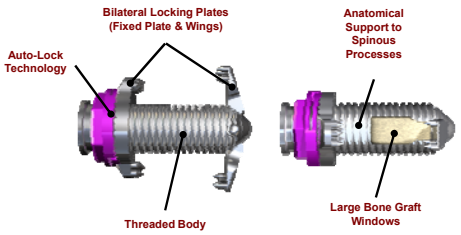
What is the [illegible]?

The World's 1st **MIS Lateral approach Spinous Process Fusion Plating System** that achieves FUSION through:

- Minimal Tissue dissection & disruption
- Consistent bone preparation for fusion
- High volume of Bone Graft delivery
- Hydroxyapatite (HA) coated
- Rigid fixation adaptable to bone quality
- 5 sterile packaged sizes (8mm to 16mm)

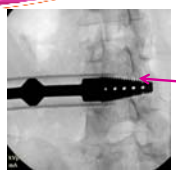
Spinal Simplicity

Minuteman G3 Innovation

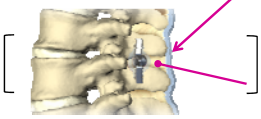


Spinal Simplicity

Minimal Dissection & Anatomical Support



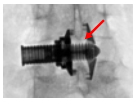
- "Sized to fit" bone tap lightly decorticates, for bleeding bone at the graft location
- Intact Supraspinous Ligament maintains posterior stabilization
  - Most ISP devices require complete removal or sectioning of the Supraspinous Ligament
- Minimal removal of the Interspinous Ligament



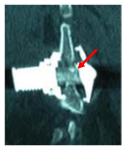
Spinal Simplicity

Bone Graft Window Promotes Fusion

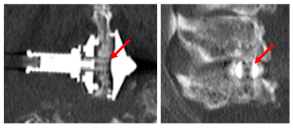
Example images at implantation



63 year old male 2.5 months post-op



90 year old female - 7 months post-op



Spinal Simplicity

Clinical Trial in U.K.

Study Object: A prospective randomized trial on the efficacy and quality of life following treatment of lumbar spinal stenosis or degenerative disc disease with the Minuteman G1 implant verses surgical decompression.

Interim Report scope

- Three surgical sites in U.K.
- 32 of 50 patients enrolled
- 5yr monitoring objectives:
  - VAS Leg & Back pain scores
  - Oswestry Disability Index
  - Zurich Claudication Questionnaire
  - Physical function
  - PGIC/CGIC
  - device adverse events
  - Employment status changes

Principal Investigator's assessment to date:

"We have found this new and innovative <Minuteman> device very promising. We have had reasonable experience with inter-spinous distraction devices. This <device> has been very different due to its ability of forming a fusion. So far we haven't had any device taken out for the reason of recurrent stenosis, unlike our past experience with other devices.

Minuteman results compared to Decompression:

- Shorter surgical procedure time
- Minimal post-surgical pain
- Negligible blood loss
- Shorter hospital stays (ready to discharge in few hours)
- Effective pain reduction (as good or better in the interim period than the gold standard decompression)
- Effective on stenosis"

Posterior spinous process clamps fusion evidence

- **Presentation:**
- Amir Vokshoor, M.D., of the Institute of Neurosurgical Innovation, Marina del Rey, California, evaluated 85 consecutive patients who underwent lumbar fusion with the Aspen system. An independent radiologist, according to the company, used post-operative CT imaging to assess posterior fusion, as well as interbody fusion when applicable, and found it was successfully achieved in 94% of patients. Additionally, pain reduction was evaluated using Visual Analog Scale (VAS) values measured pre-operatively and post-operatively for up to two years, with findings demonstrating a clinically and statistically significant improvement from an average score of 6.5/10 pre-operatively to 2.9/10 within three months following surgery. This level of improvement was maintained throughout the follow-up period.

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Posterior spinous process clamps fusion evidence

- **Paper**
- Gonzalez-Blohm et al. evaluated the biomechanical performance of an interspinous fusion device as a stand-alone device, after lumbar decompression surgery, and as supplemental fixation in a posterior lumbar interbody fusion (PLIF) construct. They suggested that IPD may be a suitable device to provide immediate flexion-extension balance after a unilateral laminotomy. PLIF constructs with IPD and pedicle screws performed equivalently in flexion-extension and axial rotation, but the PLIF-bilateral pedicle screws construct was more resistant to lateral bending motions. The authors requested further biomechanical and clinical evidence to strongly support the recommendation of a stand-alone interspinous fusion device or as supplemental fixation to expandable posterior interbody cages

S. A. Gonzalez-Blohm, J. J. Doulgeris, K. Aghayev, W. E. Lee III, A. Volkov, and F. D. Vrionis, "Biomechanical analysis of an interspinous fusion device as a stand-alone and as supplemental fixation to posterior expandable interbody cages in the lumbar spine," Journal of Neurosurgery: Spine, vol. 20, no. 2, pp. 209–219, 2014.

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Complications of ISP devices

- **Paper:**
- Reviewing the spinal literature concerning the postoperative status of IFD followed over an average of 23–42.9 postoperative months revealed that IFD resulted in 11.6–38% complication rate, 4.6–85% reoperation rate, and 66.7–77% frequency of poor outcomes. Additionally, the 31 devices implanted in 16 patients at a single university hospital in 2010 cost a total of $576,407

Epstein NE. A review of interspinous fusion devices: High complication, reoperation rates, and costs with poor outcomes. Surg Neurol Int 2012:3;7-10

Premera BC/BC considers ISP fusion devices, with or without supplemental fixation as investigational

Conclusions

- **Motion limiting devices have a role**
  - Older and more infirm patients
- **Coflex**
  - Strongest literature support
- **Clamps**
  - Some supportive evidence
  - Usually with supplemental fixation
  - Appears to require further evidene

Thank you!