Interspinous Fixation in the Stable Motion Segment

Frank La Marca M.D.
Associate Professor of Neurosurgery, Orthopedics and Biomedical Engineering,
Director of the Spine Program,
Department of Neurosurgery
University of Michigan, Ann Arbor MI, USA
Degenerative Disease Overview

Basic Biomechanics

- The **motion segment** is the functional unit of the spine and consists of:
  - Adjacent vertebrae
  - Ligaments (passive restraints)
  - Muscle (motion activators)
  - A 3 “joint” complex of two facet joints and the disc (which is a unique type of “joint”)

- Degeneration can begin in one or more of these “joints”, but ultimately all three will be affected
**Spinal Stenosis**

- **Narrowing of the spinal canal** and/or lateral foramen through which the nerves travel
- **Three types:**
  - **Central stenosis:** in central spinal canal where spinal cord or cauda equina are located
  - **Lateral recess stenosis:** in the corners where nerve roots travel before exiting canal
  - **Foraminal stenosis:** in lateral foramen where nerve roots exit
Lateral Recess Stenosis - Treatment
Lumbar Spinal Stenosis

- **Neurogenic Claudication:** Thigh pain increases with walking/standing
  - Relief with flexing forward
Spinous Process Fixation and Distraction Devices

- Theoretic advantages
  - Ease of placement, flat learning curve, rapidly deployed.
  - Minimize risk to neurovascular structures
  - Easily revised (no bridges burned)

- Potential disadvantages
  - Limits decompression
  - Suboptimal fixation rigidity?
  - Loosening under repetitive cycling?
  - Potential for overuse?
Spinous Process Devices

• Historical perspectives
  – Wiring techniques
  – Rigid Fixation
    • Daab, Wilson plates
• Renewed interest
  – Interspinous spacers
    • X-stop
• Contemporary SP fixation
  – Spire (Medtronic)
  – Aspen (Lanx), Nuvasive
Aspen Device Indications - EU

- The Aspen Spinous Process System is a spinous process fixation device intended to provide stabilization in the thoracic, lumbar and sacral spine (T1—S1). It can be used as an adjunct to interbody and/or posterior fusion or as a standalone fixation device. The Aspen Spinous Process System is indicated in the treatment of the following conditions:
  - Degenerative disc disease
  - Spinal stenosis
  - Spondylolisthesis
  - Trauma (e.g. fractures, dislocation)
  - Spinal deformities (scoliosis, kyphosis, lordosis)
  - Spinal tumors
  - Pseudoarthrosis or failed previous fusion surgery
  - Spinal instability
- The Aspen Spinous Process System can be used in single- or multi-level constructs. It can be used alone or in combination with other spinal devices (e.g. pedicle screws, facet screws, anterior plates or interbody cages). The ASPEN Spinous Process System can be used with or without bone grafting.
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Integrated Bone Graft Enclosure

- Open fenestrated bone graft enclosure (central barrel)
- Facilitates placement of bone graft
- Mitigates migration of posterior bone graft material
- Ability to place bone graft inside the barrel, anterior and posterior to the barrel
- Central barrel supports interbody and/or posterior fusions by sharing compressive loads
Histopathological Preparation and Evaluation of Sheep Lumbar Arthrodesis

Fusion permits long term maintainance of stability parameters as compared to ISA without fusion.

Figure 5: Representative histologic medial section of the spinous process fusion site 6 months following Aspen device implantation. Note the complete fusion and the presence of mature lamellar bone above (A), within (I) and below (B) the hollow spacer bridging the spinous processes. Stevenel’s blue stain.
Radiographic fusion
Aspen’s Clinical Applications in the U.S.

POSTERIOR FUSION
- No interbody
- Alternative to decompression alone
- Fills gap between decompression alone and pedicle screws

ASPEN + INTERBODY
- TLIF, PLIF, ALIF, LLIF
- Alternative to pedicle screws

OTHER
Tumor, trauma, etc.
An Alternative to Pedicle Screws or Anterior Plates

- Minimally Invasive Fusion Device
- Provides Efficient Placement for Secure Fixation
- Innovative Design Accommodates Wide Range of Anatomical Variation
- Integrated Bone Graft Enclosure
Combined with Screws for Additional Rigidity

Supplemental fixation to augment lateral bending (ideal to support TLIF)
Foramen Height
Foramen Height
Scientific Data
Biomechanics of a lumbar interspinous anchor with anterior lumbar interbody fusion

Laboratory investigation

DEAN G. KARAHALIOS, M.D.,¹ TARO KAIBARA, M.D.,² RANDALL W. PORTER, M.D.,² UDAYA K. KAKARLA, M.D.,² PHILLIP M. REYES, B.S.E.,² ALI A. BA AJ, M.D.,² ALI S. YAQOOBI, M.D.,² AND NEIL R. CRAWFORD, PH.D.²

¹NorthShore University Health System, Evanston, Chicago Institute of Neurosurgery and Neuroreasearch, Skokie, and Rush Medical College, Chicago, Illinois; and ²Barrow Neurological Institute, Phoenix, Arizona
Study Rationale

- To determine if the ISA in the setting of ALIF and TLIF provides adequate limitation in ROM as compared to more conventional fixation techniques
- To determine if the use of an ISA has any bearing on foraminal height
- To determine if the ISA leads to any significant changes in focal or regional sagittal balance
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Methods

- 7 human specimen (L3-S1)
- Instrumented at L4-L5
- 3-D motion analysis using Optotrak IR system
- Loading apparatuses:
  - Pure moment testing using MTS
  - Compression flexion apparatus
- Studied
  - Nondestructive flexibility (angular range of motion in response to controlled load)
  - Foraminal height change
  - Changes in sagittal balance
Methods

- Pure moments (7.5 Nm maximum) to induce:
  - Flexion, extension
  - Left and right lateral bending
  - Left and right axial rotation
There was a greater and more consistent increase in foraminal height in conditions in which the ISA was used.

The differences seen between groups were not statistically significant.

There was a large degree of variability in height restoration achieved when ISA not used.
Mean Upright Foramen Height Change

- Bilat PS (N=5)
- ISA Only
- TLIF + ISA
- TLIF + ISA + Unilat PS
- TLIF + Unilat PS
- TLIF + Bilat PS

Height Change (mm)

- p > 0.33
- p > 0.48
Fatigue

• **Fatigue Protocol:**
  – PS at L2-L3, ISA at L4-L5 (half of specimens)
  – ISA at L2-L3, PS at L4-L5 (half of specimens)
  – 500 cycles fatigue at 7.5 Nm pure moment applied in flexion, extension, left lateral bending, right lateral bending, left axial rotation, right axial rotation (3000 cycles total)
  – Angular motion recorded at each cycle
  – Peak load increased in 1.5 Nm increments and cycling repeated until visible failure at one or both levels
The ISA limited changes in foraminal height with flexion/extension to a greater degree than other constructs.
Mean Angular Increase after Fatigue (N=6)

(no statistically significant differences; p>0.16)
ISA caused an increase in flexion at the index level.
Under load, there was compensatory extension at the adjacent levels.
Single Surgeon
Aspen Clinical Experience
-Preliminary Results-
Courtesy of Dean Karaholios MD

• Overall experience >100 cases
• 40 levels in 2008 (approximately 21 cases)
• 35 levels in 2009 (approximately 19 cases)
• 10 levels in 2010 through March
Indications

- Backup ALIF
- Backup TLIF
- Decompression and Fusion
  - Herniated disc
  - Hemi laminectomy
- Decompression in Scoliosis
- Tumor Resection
- No stand-alone (without arthrodesis)
Clinical Results

• N=50
• 38 patients improved (76%)
• 8 patients without significant improvement (16%)
• 4 patients with worse symptoms (8%)
• 1 reoperation for hematoma evacuation
• 2 reoperations for revision of construct
• No new neurological deficits
Conclusions

- Foraminal height is increased and maintained with ISA
- ISA does not create a change in regional sagittal balance under load
- Fatigue testing appears to show that ISA constructs withstand repetitive cycling better than constructs without ISA
Conclusions

- With respect to immediate fixation rigidity, the Aspen ISA appears to be a viable fixation solution when used in conjunction with ALIF and/or TLIF.
- Appears to better assure long standing maintenance of foraminal height along with fusion.
Thank You

Interspinous Vertebral Fixation with Fusion or with Distraction Alone: Reasons Why One is Better than the Other

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