Interspinous Fusion Devices.
Midterm results.

ROME SPINE 2012, 7th International Meeting
Rome, 6-7 December 2012
Interspinous Fusion Device: Real alternative to Pedicle Screws or Anterior Plates?

- Posterior distraction and decompression
- Secure Fixation and Stabilization
- Integrated Bone Graft Enclosure for Minimally Invasive Fusion
- Option for Minimal invasive 360° Fusion
Several IFD on the market

ASPEN (LANX)    ILIF (Nuvasive)    CD HORIZON SPIRE (Medtronic)
PrimaLOK (Osteomed)

AXLE (Axis Spine)    ROMEO®₂ PAD (Spineart)
Allo-Span (SpineFrontier)
Different construct for using Interspinous Fusion device (IFD)

- **IFD stand alone**: using bone from the decompression and the device for the instrumentation, biomechanical tests showed ROM restriction with a stabilizing result *(Karahalios D.G. et al, J Neurosurg. Spine, 2010)*

- **Posterolateral fusion + IFD**: significantly increasing fusion rate with adjunctive instrumentation *(Kornblum M.B. et al, Spine, 2004)*

- **ALIF (Anterior Lumbar Interbody Fusion) + IFD**: equivalent biomechanical results to ALIF + bilateral pedicle screws *(Wang J.C. et al, J. Neurosurg., 2007)*

- **TLIF (Transforaminal Lumbar Interbody Fusion) with unilateral pedicle screws + IFD**: equivalent biomechanical stability to TLIF + bilateral pedicle screws *(Deutsche H, Neurosurg Focus, 2006)*
Different construct for using Interspinous Fusion device

- **TLIF** (Transforaminal Lumbar Interbody Fusion) + **IFD**: similar ROM respect to TLIF with unilateral pedicle screws + interspinous fusion device, but lateral bending and axial rotation increased *(Deutsche H, Neurosurg Focus, 2006)*
Indications

- Mild DLSS + NIC
- Chronic Low Back Pain, DDD (Pfirrmann IV)
- Spondylolisthesis grade 1 (stable on dynamic X-Ray)
- Iatrogenic Instability

32 patients
21 cases ALIF + IFD
11 cases ALIF + pedicle screws
Mean f.u.: 11 months (9-20)

IFD (CD HORIZON SPIRE):
Less blood loss
Shorter hospitalization
No failure hardware
No pseudoarthrosis increase

Biomechanical and clinical studies show Aspen device for decompression and fusion as a *construct stability system comparable to pedicle screws, but with fewer risks*.

Wokshoor A.: *Aspen MIS system fusion rate*. Presented at *Western Neurosurgical Society Annual Meeting (September 2012)*

85 patients submitted to lumbar fusion with Aspen device
Mean f.u.: 24 months (18-30)
Posterior fusion detected on CT Scan of more than 85%
VAS preop 6.5
VAS postop 2.9

Review literature studies over an average postop 23 – 42.9 months

- Reduction in flexion/extension, ROM increasing in lateral bending and axial rotation
- Radiographic improvement in foraminal area, at 1 – 2 yrs return to initial values

Complications rate:
- 23% spinous process fracture at an average of 42.9 postop months (*Bowers C. et al: Neurosurg. Focus, 2010*)
- 22% spinous process fracture at CT Scan, asymptomatic in 50% (*Kim D.H. et al: Spine 2010*)

Reoperation rate:
58% in spondylolisthesis grade 1 (*Weerhoof O.J., Eur. Spine J., 2008*)
6% persisting pain at 3 months due to spinous process fracture (*Kim D.H. et al: Spine 2010*)


High Cost expensive

Criticism:
Epstein ‘s review included studies fucused only on X-STOP
Aspen
Diagnosis: DLSS/NIC

*J. Korean Neurosurg*, 2012

76 patients
40 PLIF + IFD (CD HORIZON SPIRE, Medtronic)
- 26 spinal stenosis
- 12 spondylolisthesis grade 1
- 2 disc herniation with severe disc height loss
36 PLIF + pedicle screw

X-Ray dynamic evaluation at 1, 6, 12 months postop
CT Scan at 6 months
Bone fusion: trabecular bone on the sagittal view CT or an angle change of less than 2 degrees in dynamic X-Ray (Zdeblick T.A., Spine 1993)

Mean f.u.: 14 months (12 – 22)
Results

VAS preop: 7.1
VAS postop: 1.3
No difference in VAS improvement (better VAS improvement in IFD group immediate postop)
No difference in ODI improvement

Statistically significant ROM increase in pedicle screw group at upper adjacent segment (adjacent segment degeneration?)

No difference bone fusion (≥ 90%)

Complications:
1 (2.5%) spinous process fracture (IFD)
2 (5%) hardware retropulsion (IFD)
3 (8%) deep infection (pedicle screws)
2 (5.5%) CSF leakage (pedicle screws)
52 patients (17 male, 35 female)
- Perioperative data and complications are reported for all patients at 12 months
- Clinical outcomes available for 43 patients
- 12 months radiographic data available for 38 patients

The primary diagnosis for surgery was stenosis: secondary diagnosis included
- 47% Spondylolisthesis grade 1 (X Ray stable)
- 35% Degenerative disc disease
- 15% Herniated nucleus pulposus
- 3% Degenerative scoliosis

Levels treated
- L1-2 (n=2, 3.8%)
- L3-4 (n=2, 3.8%)
- L4-5 (n=48, 92.3%)

Patient Demographics

<table>
<thead>
<tr>
<th>Age</th>
<th>69 (range 39 – 82)</th>
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<tr>
<td>Body Mass Index</td>
<td>27</td>
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Comorbidities

<table>
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<tr>
<th>Diagnosis</th>
<th>Percentage</th>
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<tr>
<td>Diabetes</td>
<td>14%</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>5%</td>
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<tr>
<td>Smokers</td>
<td>10%</td>
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Prior lumbar Sx (treatment, or an adjacent level) 16%

Operative Data

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<tr>
<th>Procedure time</th>
<th>69 (SD 30) minutes</th>
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<tr>
<td>Blood loss</td>
<td>93% ≤100 cc</td>
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<tr>
<td>Hospitalization</td>
<td>1.7 (SD 1.1) days</td>
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Results at 12 months

Minimal Clinical Important Difference

- ODI, MCID (score improvement ≥10 points) was achieved in 75% of patients
- VAS, MCID (score improvement ≥2 points in any VAS score) was achieved in 69.0% of patients
- 80% of patients achieved MCID improvements with respect to either VAS or ODI outcomes

Complications

2 (3.8%) early wound complications occurring in the first 2 weeks postoperatively
- 1 infection requiring irrigation and debridement,
- 1 wound drainage responding to oral antibiotics

3 (5.7%) supplemental interventions of the surgical site
- 2 RF treatment for persistent pain
- 1 expanded decompression to treat recurrent stenosis

3 (5.7%) non-surgical site complications
- 1 vertebroplasty at a non-adjacent lumbar level after a traumatic incident 12 mo post-op
- 1 incident of cardiac arrest 2 weeks after surgery
- 1 incident of mild congestive heart failure 3 weeks after surgery
Results at 12 months

Radiographic Review
There were no reports
- Graft fracture
- Plate fracture
- Spinous process fracture
- Plate migration

Graft migration was observed in 2/38 (5.3%)
Graft subsidence was documented in 2/38 (5.3%) levels

All patients with flexion/extension films (n=30) were stable in flexion/extension
Radiological observation of new bone growth
Pedicle screws complications

Esses S.I.: *Spine, 1993*
- **Screw misplacement:** 5.2%
- **Pedicle fracture and CSF leak:** 4.2%
- **Transient neuropraxia:** 2.4%
- **Permanent nerve root injury:** 2.3%
- **Screw breakage:** 2.9%

Lonstein J.E. et al: *JBJS, 1999*
- **Screw misplacement:** 5.2%
- **Screw breakage:** 2.2%
- **Late-onset disconfort or pain due to pseudoarthrosis:** 23%
- **Root irritation:** 1%
- **Pedicle fracture:** 0.4%
- **Dural tear:** 0.4%
Pedicle screws complications

Amiot L.P.: *Spine* 2000
- Screw misplacement: 15%

- Deep infection: 4.7%
- Screw misplacement: 6.5%
- Screw breakage: 12.4%

- Pedicle perforation in percutaneous procedure, after CT Scan: 23%
Over Treatment Case

62 yrs old female, 2 operations: 3 yrs f.u. → FAILED BACK SURGERY

1) L4-L5, L5-S1 posterior instrumentation
2) ALIF
Conclusion

- In WELL SELECTED CASES, IFD could be considered as a viable alternative to traditional posterior instrumented decompression and fusion in mild DLSS and instability, also in aging population with increased comorbidities.

- DO NOT PRECLUDE INCREASING SURGICAL STEPS (i.e. PEDICLE SCREWS)

- Improvements in clinic outcomes and minimal complications provide confidence in the procedure’s success.

- Our experience: no significant fusion rate (X Ray, CT Scan), even in case MICD (VAS, ODI)
Thank You