EBM morning meeting

Lumbar Interspinous Spacers - A Systematic Review of Clinical and Biomechanical Evidence

~2010, Spine
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2011-04-26 脊椎科 謝明凱
2069523,71 F
low back pain with right sciatica for 1 year
s/p at LMD with post-op motor weak
History

— 1950s, Dr Fred L. Knowles
Metal “plugs” between the spinous processes for spinal stenosis.

— 1997, Spine, Minns, R. J. Beng
Preliminary Design and Experimental Studies of a Novel Soft Implant for Correcting Sagittal Plane Instability in the Lumbar Spine
the Minns Device – the first soft interspinous spacer
Pathophysicsology and Indication

• ↓Intradiscal pressure → ↓ DDD
• Unloading facet → ↓ facet degeneration
• Restrict extension → ↑ Canal diameter (18%) → ↓ stenosis
• ↑ neural foramen area (25%)
• Transition zone from fusion segment (Coflex)
• Post-disketomy → ↓ recurrent disc

~2007, JSDT
~2005, Spine
OKU 10- Indication

Mild to moderate intermittent neurogenic claudication

produce relative kyphosis in index level without affect global sagittal balance
Lumbar Interspinous Spacers

- **Static (noncompressible, restrict extension)**
  - X STOP
  - Wallis
  - ExtenSure

- **Dynamic (compressible, allow extension)**
  - Coflex (interspinous U)
  - DIAM™

~2007, JSDT
~ 2005, Spine
X-STOP

1. From 2002 (St Francis Medical)
2. All-titanium
3. FDA approved for clinical use
4. Preserves supraspinous ligament
Wallis

1. From 2002 (Abbott Spine, Bordeaux, France)
2. A PEEK block + Dacron ribbons
3. FDA approved for clinical use
4. Remove supraspinous ligament
1. NuVasive, San Diego, CA
2. Allograft
   - Short term \(\rightarrow\) suture
   - long term stability \(\rightarrow\) osteoinductive agent
3. FDA approved for clinical use
1. From 1994 (Paradigm Spine, New York)
2. Titanium alloy
3. FDA approved for clinical trial
4. Remove supraspinous ligament
1. From 2001 (Medtronic Sofamor Danek, Memphis, Tennessee)
2. Silicone Core with polyester Sleeve
3. FDA approved for clinical trial
4. Preserve supraspinous ligament
Materials and Methods

• **Inclusion Criteria:**
  1. Clinical and biomechanical studies including cadaveric studies.
  2. Delicate intervention
  3. Intact outcome measurement

• **Exclusion Criteria:**
  1. Technique
  2. Case reports
  3. F/U <1 year
Biomechanical Study: X-Stop

10 studies
(1) decrease in flexion-extension at instrumented level
(2) increase in foramen and canal dimension
(3) decrease intradiscal pressure
(4) decrease average contact force at the facets
(5) no accelerated disc degeneration at adjacent levels
Biomechanical Study : Wallis

- 2 study
- a decrease in disc stress
- Increase in loads transmitted through the spinous processes.
- changed the natural history of adjacent degeneration
Biomechanical Study : Coflex

3 studies

(1) significant reduction in flexion-extension at instrumented level

(2) decrease the natural history of adjacent degeneration compare with PLIF
Biomechanical Study: DIAM

3 studies
(1) decrease range of motion at instrumented level with no significant change at adjacent level
(2) decrease in intradiscal pressure at instrumented level
(3) no significant change in disc height or sagittal alignment,
(4) after discectomy, the angular motion was restored to below the level of the intact segment in flexion-extension.
Conclusion of Biomechanical Study

(1) decrease in flexion-extension at instrumented level
(2) increase foramen and canal dimension
(3) decrease intradiscal pressure
(4) decrease average pressures, force at facets
(5) decrease the natural history of adjacent degeneration compare with PLIF
## Clinical systemic review

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A prospective randomized multi-center study for the treatment of lumbar spinal stenosis with the X STOP interspinous implant: 1-year results

~J. F. Zucherman, Eur Spine J, 2004

Inclusion criteria:
1. >50y/o
2. leg, buttock, or groin pain, with or without back pain, relieved during flexion
3. CT, MRI: 1 or 2 levels stenosis
3. conservative > 6 months

Excluded
1. could not walk at least 50 feet (15meters) and/or were unable to sit for at least 50 minutes
2. Instability or s/p lumbar surgery
• **X-STOP**: 100 patients (1-level: 76, 2-levels: 24)
• **Non Op**: 91 patients (1-level: 80, 2-levels: 20)

**Assessment**:
• SF-36
• Zurich Claudication Questionnaire (ZCQ)
• Swiss Spinal Stenosis Questionnaire (SSS)
Quality of life of lumbar stenosis–treated patients in whom the X STOP interspinous device was implanted

~Ken Y. Hsu, J Neurosurg Spine, 2006

A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results.

~J. F. Zucherman, Spine, 2005
Treatment of neurogenic claudication by interspinous decompression: application of the X STOP device in patients with lumbar degenerative spondylolisthesis


- Prospective RCT, spondylolisthesis ≤25%
- Overall clinical success rates
  X STOP (33 patients) 63.4%
  Control (42 patients) 12.9%
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**Wallis:**
1. cannot reduce recurrent HIVD
2. Poor evidence clinical result: 14/37 F/U

**Coflex:**
1. less stress on the superior adjacent level than PLIF
2. ODI, VAS: no significant difference

**DIAM:**
1. “satisfying” results in 97% of cases
2. Analgesic usage decreased in 63.1%
Conclusion

1. Biomechanical evidence: beneficial effect

2. Clinical:
   - X-Stop is good in >50 y/o + stenosis
   - Others?

X-STOP:
- Strong Biomechanical evidence and strong clinical evidence

Wallis, Coflex, DIAM:
- Strong Biomechanical evidence and weak clinical evidence
Indication of Lumbar Interspinous Spacers:

1. Mild to moderate intermittent neurogenic claudication (walking ability > 15 meters) without LBP
2. X-ray: no obvious instability
3. MRI: single level stenosis
4. Not enter canal

Disclosure

Dr. Anderson is a consultant for and stockholder of the company manufacturing the X STOP device.
Lumbar Interspinous Spacer is
A less invasive prosthesis instead of a non-fusion technique

Thank you