Lumbar DDD – Is There a Role for Fusion? When and How?

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Disclosures

• Consultant & Teaching/Speaking Honorariums
  – J&J/Depuy Synthes Spine
  – Nuvasive

• Institutional/Fellowship
  – Globus
  – J&J/Depuy Synthes Spine
  – Nuvasive
  – Biomet
Background

- Epidemiology
  - 25% incidence of LBP in US
  - 80% of back pain patients seek primary care

- Aging Population
  - 2010: >13% US population over 65
  - 2030: ~50% US population over 65

- United States Healthcare Expenditures Rising
  - Direct medical costs $50 billion
  - Indirect medical costs $100 billion

Multifactorial Etiology

- Intervertebral disc
- Facet joints
- Paraspinal musculature/soft tissues
- Neural elements
- Vertebral body
- Retroperitoneal
- Peritoneal/Viscera
- Psychosomatic
Diagnosis

• Difficult to identify specific pain generator

• Modalities
  – Radiographs
  – CT
  – MRI\textsuperscript{1,2}
  – Injections
  – Discography\textsuperscript{3,4,5}
    • Assess concordance
    • High rates of false positives (Smith, Spine 1995)
    • Accelerates degeneration

\textsuperscript{1}Boden SD et al. \textit{J Bone Joint Surg Am} 1990;72:803-8
\textsuperscript{2}Boden SD et al. \textit{J Bone Joint Surg Am} 2001;83:1306-11
\textsuperscript{3}Caragee EJ et al. \textit{Spine} 1999;24:2542-7
\textsuperscript{4}Caragee EJ et al. \textit{Spine} 2009;34:2338-45
\textsuperscript{5}Eck JC et al. JNS 2014; 21:37-41
Challenge: Diagnosis of LBP

  - No clear definition of presumably painful disc
  - No reliable method for diagnosis and treatment

  - Insufficient evidence for discography as an independent predictor
  - Limited evidence suggesting disc block provides superior predictive value
  - Risk of discography leading to acceleration of disc degeneration
• Goal: Evaluate prognostic accuracy of tests to predict clinical outcomes of fusion surgery

• Patient selection, verification bias, poor outcomes assessments preclude strong conclusions for all diagnostic tests

• Conclusion: No subset of patients with CLBP could be identified for whom spinal fusion is predictable and effective
Nonsurgical Management

- Good evidence for pain relief chronic LBP:
  - NSAIDs
  - Skeletal muscle relaxants (acute episodes)
  - Tricyclic antidepressants
Nonsurgical Management

- Good evidence for relief of chronic or subacute LBP
  - Cognitive-behavioral therapy
  - Exercise
  - Spinal manipulation
  - Interdisciplinary rehabilitation
Surgical vs Nonsurgical

- Prospective, randomized trial comparing PLF to structured cognitive/behavioral rehabilitation for chronic LBP secondary to DDD
- At 1 year, no significant differences in any outcome measures between groups
Surgical vs Nonsurgical

- Mannion AF et al. *Comparison of spinal fusion and nonoperative treatment in patients with chronic low back pain: long-term follow-up of three randomized controlled studies* (Spine Journal, 2013)
  - No difference in long-term outcomes between lumbar fusion and CBT and exercise rehab groups
  - Treatment groups with lower chronic LBP disability at long term follow up
Surgery is No Better!

• Systematic review of randomized clinical trials comparing fusion to nonsurgical care for chronic LBP associated with DDD
• Nature of the nonoperative treatments is critical
• Conclusion: Surgery may be NO more effective than a structured rehab program with CBT
Surgery is No Better!

• Systematic literature review assessing benefits of surgery relative to conservative therapies for nonradicular LBP arising from DDD

• Conclusion:
  – *Fusion is NO more effective than intensive rehab program with CBT*
  – *Fusion may be slightly more effective than nonintensive therapy regimen*
Wait, Isn’t Surgery Really Better for DDD?

- Prospective, randomized, controlled, multicenter clinical trial comparing fusion with nonsurgical care for chronic discogenic LBP

- At 2 years, patients undergoing fusion exhibited less pain and disability
Limitations

- Nonoperative regimen was not standardized
- Relatively high crossover between treatment groups
- Overall outcomes after fusion were inconsistent (< 50% good, 16% excellent)
Is Surgery Better for DDD?

Review of randomized and non-randomized studies

- Lumbar spine fusion may result in meaningful improvement in pain and function
- Acceptable satisfaction scores
Is Surgery Better for DDD?

Clinical Study

One-year outcomes of surgical versus nonsurgical treatments for discogenic back pain: a community-based prospective cohort study

Sohail K. Mirza, MD, MPH\textsuperscript{a,*}, Richard A. Deyo, MD, MPH\textsuperscript{b,c,d,e}, Patrick J. Heagerty, PhD\textsuperscript{f}, Judith A. Turner, PhD\textsuperscript{g}, Brook I. Martin, PhD\textsuperscript{a}, Bryan A. Comstock, MS\textsuperscript{f}

• Surgical group showed greater improvement in pain scores at one year than nonsurgical group

• Limitations:
  – Short-term results
  – Treatment non-randomized
  – Nonsurgical treatment was not standardized and not compliant with major guidelines
Is Surgery Better for DDD?


Long-term Treatment Effects of Lumbar Arthrodeses in Degenerative Disk Disease: A Systematic Review With Meta-Analysis.

Noshchenko A¹, Hoffecker L, Lindley EM, Burger EL, Cain CM, Patel VV.

- Slight improvement of spinal fusion versus nonsurgical management
- Equal effect of fusion to arthroplasty at 24 months
- Fusion may be an effective treatment for DDD following three months of failed conservative treatment
Effectiveness of Surgery

- Glassman SD et al. *Lumbar fusion outcomes stratified by specific diagnostic indication* (Spine Journal, 2008)
  - Analysis of prospectively collected clinical outcomes following lumbar fusion stratified by diagnosis
  - Evaluate SF-36, ODI, BP and LP scores at 1- and 2-yrs
  - Most substantial improvements observed with spondylolisthesis and scoliosis

**DIAGNOSIS MATTERS!**
Remember the Golden Rule...

  - “If you experienced chronic LBP with degenerative changes at 1 level, what course of treatment would you opt for?”
  - Non-operative treatment
  - No treatment
  - Fusion
  - TDR
What Would You Do?

  – “If you experienced chronic LBP with degenerative changes at 1 level, what course of treatment would you opt for?”
  – Non-operative treatment – 60%
  – No treatment – 38%
  – Fusion – 1%
  – TDR – 1%
Clinical Guidelines

- Eck JC et al. *Guideline update for the performance of fusion procedure for degenerative disease of the lumbar spine. Part 7: Lumbar fusion for intractable low back pain without stenosis or spondylolisthesis* (JNS, 2014)
  - Lumbar fusion may be performed for patients refractory to conservative treatment
  - 1- or 2-level degenerative disc disease without stenosis or spondylolisthesis (Level II)
Who is the Ideal Candidate?

• Significant clinical and functional disability despite undergoing a reasonable regimen of nonoperative treatments

• Imaging studies confirming the diagnosis of single-level disease with minimal degenerative changes at adjacent levels

• Absence of confounding psychosocial issues
Interbody Fusion

• Advantages
  – Provides anterior column support
  – Increases the surface area for fusion
  – May improve arthrodesis rates
  – Facilitates deformity reduction

• Disadvantages
  – Subjects patient to additional morbidity
  – More expensive
Interbody Fusion

• Indications
  – Deformity (scoliosis, spondylolisthesis)
  – Recurrent HNP
  – DDD/discogenic pain

• Approaches
  – Anterior
  – Posterior (PLIF, TLIF)
  – Direct lateral
  – Stand-alone vs. circumferential
Interbody Fusion - Anterior

**Advantages**
- Direct visualization of disc space
- More complete discectomy
- Larger implant placement
- Avoid scar tissue

**Disadvantages**
- Approach Morbidity
- May require cosurgeon
- Direct decompression may be difficult
- Challenging revision strategies
Interbody Fusion - Posterior

- **Advantages**
  - May achieve circumferential fusion through a single approach
  - Permits direct neural decompression

- **Disadvantages**
  - More limited working channel
  - Discectomy more difficult
  - Smaller implants
  - Greater risk of neurologic injury
  - Generally requires instrumentation
Interbody Fusion - Lateral

• Advantages
  – Minimally invasive
  – Avoids morbidity of anterior exposure and revision posterior cases
  – Facilitates placement of large grafts

• Disadvantages
  – Transpsoas approach
  – Requires neuromonitoring
Minimally Invasive Options

• Morbidity of open procedures
  – Extensive muscle stripping
  – Devitalize soft tissues
  – Iatrogenic instability/deformity
  – Debilitating postop pain
  – Prolonged rehabilitation/impaired function
Minimally Invasive Techniques

• Advantages
  – Minimal EBL
  – Decreased pain/muscle atrophy
  – Shorter hospital LOS/more rapid rehab
  – Maintain spinal stability
  – Improved function/clinical outcomes

• Disadvantages
  – Impaired visualization of pathology
  – Steep learning curve/longer OR times
  – Necessitates fluoroscopy
  – Failure to achieve surgical goals
Disc Replacement

• Advantages
  – Maintain/restore motion of diseased segment
  – Avoid morbidity of fusion
  – Facilitate earlier return to function
  – Prevent adjacent segment degeneration
Disc Replacement

• Disadvantages
  – Requires long-term implant survival
  – Introduces new modes of failure
  – Significant hazards of revision cases
  – Utilization still affected by unresolved coverage issues
Complications

- Intraoperative
  - Nerve/vessel injury
  - Dural tears
  - Blood loss
  - Skin breakdown
  - Blindness
  - Graft material morbidity

- Perioperative
  - Thromboembolic events
  - Infection

- Postoperative
  - Device/instrumentation failure
  - Nonunion
  - Adjacent segment degeneration
  - Persistent symptoms
  - Need for revision surgery
  - Failed back syndrome

[Images of spinal X-rays showing fusion devices and bone growth.]
## Costs of Lumbar Surgery

### Lumbar Spinal Fusion Versus Anterior Lumbar Disc Replacement

The Financial Implications

Vikas V. Patel, MA, MD, Susan Estes, NP, Emily M. Lindley, PhD, and Evalina Burger, MD

<table>
<thead>
<tr>
<th>TABLE 1. Average Hospital Costs of Surgical Procedures</th>
<th>Fusion TLIF</th>
<th>Fusion ASF/PSF</th>
<th>ADR</th>
<th>ASF</th>
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<tbody>
<tr>
<td>Implant cost</td>
<td>$10,524</td>
<td>$10,999</td>
<td>$11,666</td>
<td>$9270</td>
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<tr>
<td>Average hospital stay</td>
<td>3.0</td>
<td>5.0</td>
<td>2.6</td>
<td>2.9</td>
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<tr>
<td>Average OR time</td>
<td>274</td>
<td>439</td>
<td>222</td>
<td>212</td>
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<tr>
<td>Average EBL</td>
<td>790</td>
<td>1250</td>
<td>567</td>
<td>454</td>
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<tr>
<td>Direct costs</td>
<td>$17,898</td>
<td>$23,979</td>
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<td>Indirect costs</td>
<td>$11,362</td>
<td>$15,254</td>
<td>$10,785</td>
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<td>Total hospital costs</td>
<td>$29,260</td>
<td>$39,233</td>
<td>$27,972</td>
<td>$26,767</td>
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<tr>
<td>Total hospital costs (rhBMP-2 cost included)</td>
<td>$34,660</td>
<td>$44,633</td>
<td>$27,972</td>
<td>$32,167</td>
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</tbody>
</table>
Costs of Lumbar Surgery

- Economic evaluation comparing cost-effectiveness of lumbar fusion and non-operative treatment for chronic LBP
- Societal and health care sector 2-year costs significantly higher for lumbar fusion compared with nonsurgical treatment
Conclusions

• There are no reliable diagnostic tests to guide operative treatment for LBP
• The clinical outcomes of surgery for lumbar DDD are NOT good
• Surgery is expensive and subjects patients to significant morbidity
• Careful patient selection is critical if surgical management is employed
• The data supports NONOPERATIVE care for the treatment of chronic discogenic LBP