Patient Selection for Lumbosacral Fixation in the Treatment of “Discogenic” Low Back Pain
To Fuse or Not to Fuse $$$

Cleveland Spine Review
July 10-16, 2013

Marc E. Eichler, MD, FACS

Taking the high road
Patient Selection for Lumbosacral Fusion

Classification of evidence

• Class I: Prospective randomized controlled trials (PRCT) – The gold standard of clinical trials. However, some may be poorly designed, lack sufficient patient numbers or suffer from other methodological inadequacies.

• Class II: Clinical studies in which the data were collected prospectively, and retrospective analyses which were based on clearly reliable data. Includes: cohort, prevalence and case control studies.

• Class III: Most studies based on retrospectively collected data. Evidence used indicates clinical series, databases, case reports and expert opinions.

• Class IV: Case series

• Class V: Expert opinion
  – Most of our evidence is class III or IV
  – Recent studies are better
Patient Selection for Lumbosacral Fusion

Evidence-Based Decision Making

- Evidence-Based Decision Making
  - The conscious, explicit, and judicious use of the current best evidence in making decisions regarding the care of individual patients

Recent editorials in the press\(^1\) and general medical literature\(^2\) have strongly condemned a perceived overutilization of lumbar fusion, and have suggested that the increase in the frequency of fusion surgery noted over the last decade is a result of financial incentives to surgeons and instrumentation companies. This condemnation is largely based on an apparent lack of evidence to support the role of fusion for the treatment of low back pain. Indeed, Gibson et al in the 1999 Cochrane review stated “There is no scientific evidence on the effectiveness of any form of surgical decompression or fusion for degenerative lumbar spondylosis compared with natural history, placebo, or conservative management.”

\(^1\) NYT
\(^2\) NEJM
Evidence-Based Decision Making

• Problems
  – Statistical manipulation can be used to portray clinical, problems, and solutions in a deceptive manner
    • In the clinical arena data is often insufficient to make relevant decisions that are based on objective and statistically significant data
  – Reporting bias
    • Negative findings are infrequently reported in the literature
    • “Absence of proof is not proof of absence”
  – Evidence may be based on “large population” assessments that do not effectively consider all subpopulations

Patient Selection for Lumbosacral Fusion

Problem-Based Decision Making

• Problem-Based Decision Making
  – The separation of complex problems into their component parts
  – The prioritization of the component parts
  – The logical orderly solution of each portion of the overall problem posed by each of the component parts
Problem-Based Decision Making

• Problem based approach
  – Liberally using a common sense approach to the careful assessment of the evidence
  – Evidence-based decision making provides the foundation of knowledge and problem-based decision making provides the rational thought required to fill the gaps in our knowledge

Problem-Based Decision Making

“Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannized by evidence, because even excellent external evidence may be inapplicable to or inappropriate for an individual patient.”

Sackett DL Spine 1998
Patient Selection for Lumbosacral Fusion (+ Accepted Historically)

- Trauma
  - Burst fractures
  - Fracture dislocations
  - Traumatic spondylolisthesis
- Scoliosis
Patient Selection for Lumbosacral Fusion (+ Accepted Historically)

- Infection
- Tumor
  - Instability
  - Neurologic deficit

Patient Selection for Lumbosacral Fusion (Controversial)

Segmental Instability with Spondy.
- Congenital / Isthmic Spondylolisthesis
- Degenerative Segmental Instability
  - Degenerative spondylolisthesis
  - Degenerative scoliosis
**Patient Selection for Lumbosacral Fusion**

(Controversial)

Segmental Instability Without Spondy.

- Iatrogenic (lumbar stenosis)
  - Facet resection
  - Facet orientation
- “Unstable motion segment”- FSU
  - 4.5mm / 5°-20°-25° angulation

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**Patient Selection for Lumbosacral Fusion**

(Very Controversial)

Disc-related Syndromes

- Disc-related Low Back Pain
  - IDD
  - Black disc disease
  - “Discogenic” LBP
Disc Related Low Back Pain “IDD”

Do Financial Conflicts of Interest Bias Research on Surgical Treatments?

<table>
<thead>
<tr>
<th>Study</th>
<th>Purpose</th>
<th>Conclusions</th>
</tr>
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<tbody>
<tr>
<td>Chudley K. et al., Conflict of interest in orthopedic research; its association in finding to scientific presentations 2010.</td>
<td>To see if reported conflicts of interest had a relationship to the results of studies presented at the 2010 and 2009 annual meeting of the American Academy of Orthopedic Surgeons.</td>
<td>Conflict of interest were common, particularly in the spine, arthroplasty reconstruction, and selected hip reconstruction fields. Studies without conflicts of interest tended to result in smaller, more consistent, and simpler results and significantly more likely to arrive at positive conclusions.</td>
</tr>
<tr>
<td>Shah RV et al., Incidence and etiology to study outcomes for papers published in Spine, 2007, 30;999-1020.</td>
<td>To make the association of industry support and study outcomes in the period 1989-2007.</td>
<td>The odds ratio of industry-funded studies reporting positive results was 3 times that of studies with non-industry funding, indicating the study outcomes. Potential explanations include biased study design, biased study selection, or publication bias.</td>
</tr>
<tr>
<td>Bhanda M et al., Association between industry funding and statistically significant procedure findings, JAMA Internal Medicine, 2006, 11:577-80.</td>
<td>To make the relationship between industry funding and the results of spinal surgical and other clinical trials.</td>
<td>Industry funded studies are more likely to be associated with statistically significant procedure findings, both cumulative and safe surgical interventions.</td>
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Warnings on Spinal Fusion for Patients on Workers’ Compensation Fell on Deaf Ears

Large Cohort Studies on Spinal Fusion Among Workers’ Compensation Claims

“Cage Rage”
Dismal Results for Spinal Fusion Among Patients With Workers’ Compensation Claims

Surgical claims can provide valuable insights into patients with workers’ compensation claims who undergo spinal surgery. Our study aimed to assess the outcomes of workers’ compensation cases involving spinal surgery.

**Summary:** A retrospective review of 122 workers’ compensation cases was conducted. The majority of patients were male, and the average age was 47 years. The most common diagnoses were degenerative disc disease (DDD) and lumbar radiculopathy. The surgical procedures included laminectomy, discectomy, and spinal fusion. The average follow-up period was 2 years.

**Results:**

- **Surgery Failure:** A significant percentage of patients experienced surgical failure, with revision surgery rates of 15.6%.
- **Complications:** Complications were common, with major complications occurring in 7.4% of cases.
- **Quality of Life:** Despite surgical intervention, the quality of life for patients was not significantly improved.

**Discussion:** These findings highlight the need for better understanding of the factors contributing to surgical failure in workers’ compensation cases and the potential implications for policy and practice.

### Table: Factors Affecting Outcomes

<table>
<thead>
<tr>
<th>Factor</th>
<th>Description</th>
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<tbody>
<tr>
<td>DDD</td>
<td>Degenerative disc disease</td>
</tr>
<tr>
<td>LRD</td>
<td>Lumbar radiculopathy</td>
</tr>
<tr>
<td>Fusion</td>
<td>Spinal fusion surgery</td>
</tr>
<tr>
<td>Revision</td>
<td>Revision surgery</td>
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</table>

### Table: Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Rate</th>
</tr>
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<tbody>
<tr>
<td>Revision Surgery</td>
<td>15.6%</td>
</tr>
<tr>
<td>Major Complications</td>
<td>7.4%</td>
</tr>
<tr>
<td>Quality of Life Improvement</td>
<td>Minimal</td>
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</table>

### References


Attacking Excessive Imaging Cause by Cause

**Introduction:** Excessive diagnostic imaging can lead to increased costs, unnecessary procedures, and potential iatrogenic harm. This article discusses the implications of imaging use in patients with low back pain and other conditions.

**Physicians who own their own imaging units are more likely to refer patients for a scan.**

**Evidence:**

- A study by Levin et al. (2019) demonstrated a higher rate of imaging referrals among physicians who own their own imaging units compared to those who refer to externals.
- Another study by Hillman and Gharahem (2018) found a correlation between physician ownership of imaging units and higher referral rates.

**Conclusion:** The practice of imaging ownership by physicians may contribute to inappropriate imaging use, highlighting the need for interventions to reduce unnecessary referrals.
Indications for Lumbosacral Fusion

Frequency of Spinal Procedures, 1998

NASS
(> 50% L-S fusions performed for DDD - 2004)
Patient Selection for Lumbosacral Fusion (IDD)

- Disc Arthroplasty

Disc Related Low Back Pain “IDD”

Medicare Gives a “Thumbs Down” to Artificial Discs for Those Over 60

The proposed policy is a stunning, defeat for a highly coveted treatment technology in which hundreds of millions of dollars have been invested. However, the policy is a major victory for those seeking an alternative to traditional fusion surgery. The policy is based on the premise that artificial discs are not as effective as fusion surgery in the long term.

Criticism of Both Disc Replacement and Spinal Fusion

Critics of both disc replacement and spinal fusion argue that the benefits of these procedures are outweighed by the risks. Disc replacement is often associated with complications such as infection, graft failure, and pseudarthrosis, which can lead to additional surgery. Spinal fusion, on the other hand, is associated with a long recovery period and a higher risk of complications such as kyphosis and pseudarthrosis.

Reference:

Charite III

Maverick

ProDisc

FlexiCore
Disc Related Low Back Pain “IDD”

Blue Cross-Blue Shield Finds Inadequate Evidence on Disc Replacement for All Ages

The influential Blue Cross-Blue Shield (BCBS) Technology Evaluation Center (TEC) recently updated its review of disc replacement to include evidence on both the Charité (Charité & Johnson, Raynham, MA) and ProDisc-L Synthes (Spine, West Chester, PA) devices. The results will not please their developers, see Blue Cross-Blue Shield, 2007

In its review, the BCBS TEC asked five questions to determine if the use of the new treatment technology meets its evidence-based criteria: Disc replacement, unfortunately, satisfied only one of these requirements.

Question 1: Does the technology have final approval from the appropriate governmental bodies?

Yes. The FDA has approved marketing of these devices, contingent on completion of post-approval studies.

Question 2: Does the scientific evidence permit conclusions concerning the effect of the technology on health outcomes?

No. “Current evidence supporting the artificial vertebral disc is insufficient.”

Question 3: Does the technology improve the net health outcomes?

“The evidence is insufficient to determine whether the use of artificial vertebral discs improves net health outcomes.”

Question 4: Is the technology cost-effective as established alternatives?

Yes. The evidence is insufficient to answer this question.

Question 5: Is the improvement unattainable outside of investigational settings?

By most accounts, the reimbursement situation for both the Charité and the ProDisc-L device remains uncertain. Several insurance companies and health care systems—Aetna, Kaiser Permanente, and others—do have policies that allow reimbursement for disc replacement. Some other third-party payers are still making reimbursement decisions on a case-by-case basis. And some payers have simply disallowed funding for the implantation of artificial discs.

Patients and physicians interested in disc replacement should inquire carefully regarding the reimbursement policies of any third-party payers, including those that are currently on record as allowing or disallowing reimbursement. This appears to be a fluid situation.

Reference:


Disc Related Low Back Pain “IDD”

Treatment of symptomatic adjacent-segment degeneration after lumbar fusion with total disc arthroplasty by using the ProDisc prosthesis: a prospective study with 2-year minimum follow up

RUDOLF BERTRANDT, M.D., JAMES J. YUE, M.D., ANDREAS FENK-MAYER, M.D., JONATHAN EERULKAR, M.D., AND JOHN W. EMERSON, PH.D.

Journal of Neurosurgery Spine February 2006
Disc Related Low Back Pain
“IDD”

• Controversies (Why?)
  – Natural history of DDD poorly defined and usually benign
    • What are the pain “generators”?
    • Does selective fusion of “generator” relieve pain?
  – Psychosocial background in these patients profoundly influences outcome
  – Surgical procedures vary widely
  – Clinical success rates extremely variable (30-90%)

Rhyne et al 1996 NASS
Turner et al 1992 JAMA 268:907

Can an Isolated “Pain Generator” in the Lumbar Spine Explain Chronic Back Pain?

Professional societies sometimes present an overly rosy view of their areas of medicine and the ability of their members to diagnose, treat, and prevent common diseases.

However, a recent symposium at the annual meeting of the North American Spine Society in Orlando took a refreshing turn in the other direction. It presented an unflinchingly honest look at the difficulties of diagnosing, treating, and understanding chronic low back pain.

The symposium, entitled “The Evolution of the Pain Generator: Implications for Practice,” was organized and moderated by Christopher J. Standaert, MD, of the University of Washington. It included panels from several scientific disciplines.
Patient Selection for Lumbosacral Fusion
“Discogenic” Pain

• Specifically “Annular” Pain
• Discogenic pain may be triggered by:
  – Mechanical sensitization of posterior annular nociceptors
  – Chemical sensitization of posterior annular nociceptors
Patient Selection for Lumbosacral Fusion
“Annular” Pain Evidence Base

• Internal Disk Disruption and Annular Tears
  – Crock, Osti, others

• Ingrowth of Nociceptive Fibers into the Annulus

Lumbar posterolateral fusion inhibits sensory nerve ingrowth into punctured lumbar intervertebral discs and upregulation of CGRP immunoreactive DRG neuron innervating punctured discs in rats.
Department of Orthopaedic Surgery, Graduate School of Medicine, Chiba University, 1-8-1 Inohana, Chu-o-ku, Chiba 260-8670, Japan.
kou@inf.chiba-u.ac.jp
Patient Selection for Lumbosacral Fusion

• Does selective fusion of a “degenerated disc” relieve pain?
• Which patients with a “degenerated disc” are surgical candidates?

One fact in the literature is clear - Patient selection is critical
Patient Selection for Lumbosacral Fusion

• Assessment of Patients
  – History
    ▪ Outcome measures (done preoperatively)
  – Physical exam
  – Imaging / Tests
  – Nonsurgical care
  – Surgical care
  – Outcome measures (done preoperatively)

Patient Selection for Lumbosacral Fusion

History
(most important factor in “work-up”)

• Quality of Pain
• Extent of Pain
  – Pain drawings / VAS
• Psychological Factors
• Social Influences / Work Related Influences / Family
• Individual Factors
• Outcome Measures
Patient Selection for Lumbosacral Fusion

History

• Quality of Pain
  – “Mechanical” (not functional, spasm, non-specific chronic)
    • Deep agonizing pain usually not a/w paraspinous muscle spasm
    • Association of pain with activity or stresses on the motion segment
    • Diminution of the pain with minimization (elimination) of the stress (still may have some pain at rest)

• Extent and distribution of pain
  – Visual (linear) analog scale (VAS)
    • Much more accurate than verbal scale
    • 10 / 15 / 20 cm
  – Pain drawings

• In regard to extent and distribution of pain:
  – Beware of suspicious “behavioral symptoms / signs”
**Patient Selection for Lumbosacral Fusion**

**History**

- Symptoms / Signs that should raise suspicion of “illness behavior” (UAB pain behavior scale – 0-10)
  - Vocal Complaints - verbal
  - Vocal Complaints - nonverbal (moans, groans)
  - Down time because of pain (none, 0-60min/day, >60)
  - Facial grimacing
  - Standing posture (normal, mildly impaired, distorted)

- **Symptoms / Signs that should raise suspicion of illness behavior** (Waddell and others)
  - Pain at the top of the tailbone
  - Whole leg pain
  - Whole leg numbness
  - Whole leg giving away
  - Never pain free
  - Intolerance of treatment
  - Emergency admission to hospital with simple backache

Richards et al 1982
Patient Selection
for Lumbosacral Fusion

History

• Symptoms / Signs that should raise suspicion of illness behavior (UAB pain behavior scale - 0-10)
  – Mobility: Walking (normal, limp, marked limp)
  – Body language (clutching, rubbing)
  – Use of visible physical supports (corset, TENS, crutches)
  – Stationary movement (sitting still, occasional shifting, constant movements)

Richards et al 1982

Patient Selection
for Lumbosacral Fusion

History

Psychological Factors

– Chronic LBP may trigger anxiety, fear, or depression thereby changing the way patients perceive pain
  • Minnesota multiphasic personality inventory (MMPI)— patients who are preoccupied with their symptoms, depressed, or anxious fare worse (increase in depression, hysteria, hypochondriasis scales – the neurotic triad)
  • Distress and risk assessment method (DRAM)
Patient Selection for Lumbosacral Fusion

History

Psychological Factors

– Fear avoidance behavior questionnaire (FABQ)

Better predictability than physical findings, radiography, or fusion rates for the outcome of surgery

Gatchel et al 1995
Patient Selection for Lumbosacral Fusion

History

• Psychological Factors

Single-level lumbar fusion in chronic discogenic low-back pain: psychological and emotional status as a predictor of outcome measured using the 36-item Short Form

RICHARD DERBY, M.D., JOHN I. LETTICE, M.D., THOMAS A. KULA, M.D., SANG-HEON LEE, M.D., PH.D., KWAN-SIK SEO, M.D., AND Byung-Jo Kim, M.D., Ph.D.

Journal of Neurosurgery Spine October 2005

Patient Selection for Lumbosacral Fusion

History

• Work Related / Social / Family factors
  – Work related
    • Job satisfaction – predictive of outcome (Turk et al)
    • Workers’ Compensation
      – Are poor surgical results secondary to heavier physical jobs and / or overly aggressive surgical intervention?
  – Social factors
    • Litigation
Patient Selection for Lumbosacral Fusion

History

- Work Related / Social / Family Factors
  - Family factors
    - Models for illness
    - Reinforcement for sick behavior
    - Physical / mental abuse

- Individual Factors
  - Obesity (Weight kg / height meters) (>28kg/m2)
    - Obesity is related to poorer outcomes (Heliovaara et al)
  - Physical Fitness
  - Smoking
    - Risk factor for LBP and poorer outcomes (Biering-Sorensen et al)
Patient Selection for Lumbosacral Fusion

Physical Exam

( IDD )

- Non Specific (no focal deficits)
  - Mobility / Muscle tests (not predictive of outcome)
- Non-organic Signs (Waddell’s)
  - Tenderness: superficial, non-anatomic
  - Increased pain on simulated axial loading and rotation
  - Positive straight leg raising: negative by distraction
  - Regional weakness and sensory “stocking” change
Patient Selection for Lumbosacral Fusion

Imaging / Tests (IDD)

- AP / Lateral Plain X-rays
  - “in the absence of any red flags have minimal diagnostic value”
- Flexion–Extension films
  - Standing ?
  - Lateral decubitus ?
  - Flexion “sitting” and extension standing with table support ?
- CT Scan
  - Useful if “red flags” / Fxs

Putto et al
Patient Selection for Lumbosacral Fusion Imaging

- Bone Scanning
  - R/O facet arthropathy
  - Injections may help PT etc..

Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine.
Part 13: Injection therapies, low-back pain, and lumbar fusion

Radiofrequency Denervation of the Lumbar Zygapophysial Joints: 10-Year Prospective Clinical Audit

- Facet injections / RFA
  - RFA provides long-term pain relief in appropriately selected patients
  - Patient selection based on response to a course of two facet injections
**Patient Selection for Lumbosacral Fusion Imaging**

- MRI / Discography
  - Disc morphology on MRI
    - Collapse
    - Loss of hydration (loss of T2WI signal)
  - $\pm$ HIZ
  - $\pm$ Modic end plate changes

- Can discography “replace” MRI?
  - Ito et al 1998 / Zucherman et al 1998 (-)
  - Schneiderman et al 1996 / Bernard et al 1990 (+)

**Discography and MRI**

- Ito et al. 1998 - + discography (concordant) does not correlate with MRI findings of radial tears (HIZ) (similar to Zucherman et al)
- Schneiderman et al. 1996 – discography dye leak does correlate with MRI changes and some correlation of HIZ with concordant pain
Patient Selection for Lumbosacral Fusion Tests

- Provocative Discography
  - Typical / Concordant pain (not dye leak)
    - Walsh et al 1990 (disco in pts. Without LBP) vs. Holt’s study
  - Multiple levels tested (control levels)
  - Only one or two levels positive
  - Hundreds of studies on sensitivity and specificity

- Discography and Fusion Outcomes

Discography

- Colhoun et al 1988 – prospectively performed discography on patients (+ DDD) and then operated on the patients irrespective of response
  - 89% vs 52% good response (pseudo excluded / 137 pts)
- Pace et al. 1996, Hess et al. 1992 etc… discography does not correlate with outcome (retro / P-L)
- Response to discography has been correlated with abnormal pain drawings
  - Block et al. 1996 – psychologic overlay is predictive of a positive response
- Carragee et al 1999
  - Pts. without LBP but with iliac crest grafting had concordant pain with disco (buttock pain – however not LBP)
**Discography**

So do we use discography?

- NASS (1995) – technique is useful for further evaluation of abnormal discs to assess the extent of abnormality or correlation of this abnormality with clinical symptoms. Discography can be utilized as a preoperative test when fusion is considered.
  - “in order to determine how a diagnostic test alters the outcome of treatment it is necessary to define the diagnosis, the type of surgery, and the outcome evaluation method in ways that have not been done until this day”
Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 5: magnetic resonance imaging and discography for patient selection for lumbar fusion.

John E. Brickey, M.D., Todd D. Cappelli, M.D., Andrew T. DeLuc, M.D., Michael W. Grogan, M.D., Lundy G. Kay, M.D., Paul R. Mercier, M.D., Paul P. Mina, M.D., William C. Weller, M.D., Jeffrey P. Wirth, M.D., Jeffrey G. Weller, M.D., and Mark B. Hase, M.D.

Department of Neurosurgery, University of Wisconsin, Madison, Wisconsin, Department of Neurosurgery, University of Maryland, Baltimore, Maryland, Department of Neurosurgery, University of Pittsburgh, Pittsburgh, Pennsylvania, Department of Neurosurgery, University of California, Los Angeles, California, Department of Neurosurgery, University of Tennessee, University of California, Los Angeles, California, University of Alabama at Birmingham, Alabama, and Department of Neurosurgery, University of Wisconsin, Madison, Wisconsin.

Keywords: lumbar spine, fusion, magnetic resonance imaging, discography, patient selection.

Recommendations:

There is insufficient evidence to recommend a treatment standard.

Rationale:

The surgical treatment of patients with degenerative disease of the lumbar spine is often performed based on the results of diagnostic imaging. The presence of a disc herniation on MRI may not correlate with the patient's symptoms. Discography has been used as a diagnostic tool to determine the presence of a disc herniation. However, the results of discography have been inconsistent and have not been consistently correlated with patient outcomes.

In conclusion, the use of discography as a diagnostic tool for lumbar fusion surgery is not recommended due to the lack of evidence for its effectiveness.

Conclusion:

The use of discography for lumbar fusion surgery is not recommended. Further research is needed to determine the role of discography in the evaluation of patients with degenerative disease of the lumbar spine.

References:


Patient Selection for Lumbosacral Fusion Imaging

MRI / Discography

1) MRI specific for degenerative changes but overly sensitive (oversensitive)

2) “equivocal MR imaging findings”
   “clearly pathologic levels”

Surgery decided disco used to treat / test adjacent levels

Several segments degenerated on MRI and pain likely to be discogenic LBP

Uncertainty if pain discogenic and one level suspected on MRI

Uncertainty if pain discogenic and multiple levels suspected on MRI
Discography
(How I use discography)

• Discography utilized to “rule out” patients as surgical candidates
  – History consistent with mechanical LBP
  – No psychosocial issues
  – Positive MRI findings (one / two levels)
  – Obtain disco and if control levels positive then no fusion
    • MRI “oversensitive”
    • What if disco negative?
• Rarely to include adjacent level
Discography

Patient Selection for Lumbosacral Fusion

Non-surgical Management (IDD)
Patient Selection for Lumbosacral Fusion Nonsurgical Care

- Six point plan (all can be quantitated) QTF 1997
  - Augmentation of physical well being (education)
    - Weight loss
    - Smoking cessation
  - Behavioral therapy
  - Aerobic exercise
  - Stretching exercises
  - Strengthening exercises
  - Pain regimen (therapy)
    - NSAIDS, MR, ESI, Narcs
**Patient Selection for Lumbosacral Fusion**

**Nonsurgical Care**

- Behavioral therapy (RCT x 10 7 + results)
  - Operant conditioning
  - Cognitive treatment (coping strategies / imagery)
  - Progressive muscle relaxation
- Exercise therapy (RCT x 16 8 + results)
  - Stretching
  - Strengthening
  - Aerobic conditioning
  - Weight loss

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**Patient Selection for Lumbosacral Fusion**

**Nonsurgical Care**

- Pain regiment
  - NSAIDS (RCT x 6 2 + effect)
  - Muscle relaxants (RCT x 1 + effect)
  - Antidepressants (RCT x 3 – effect)
  - ESI (RCT x 7 only 1 + effect)
  - Facet injections / RFA (RCT x 4 2 + effect)
- Smoking cessation
  - Fusion rates
Patient Selection for Lumbosacral Fusion
Nonsurgical Care

• Orthoses
  – Corset with or without support (RCT x 3 1 + result)

Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine.
Part 14: brace therapy as an adjunct to or substitute for lumbar fusion

Patient Selection for Lumbosacral Fusion
Nonsurgical Care

• TENS (RCT x 4 1 + result)
• Acupuncture (no RCTs / no class 3 evidence)
Outcome Measures
(functional and economic)

Patient Selection for Lumbosacral Fusion
Functional Outcome Measures
(not fusion alone)

- SF-36 (SF-12)
- Visual Analogue Scale (VAS)
- NASS Low Back Outcome Instrument
- Low-Back Outcome Score (Greenough et al)
- Roland-Morris Disability Questionaire (Deyo et al 1986)
- Oswestry Disability Index (ODI)
**Patient Selection for Lumbosacral Fusion**

**Economic Outcome Measures**

- Return to work rates
- Termination of disability compensation
- Long term care costs

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**Patient Selection for Lumbosacral Fusion**

**“IDD”**

**Surgical Management**

- Fusion / Stabilization
- IDET (revisited “again”)
  - Barendse et al 2001 (RCT - benefit)
  - Pauza et al 2004 (RCT ± benefit)
    - + VAS/ODI
    - - SF-36
  - Freeman et al 2005 (RCT - benefit)
  - Assietti et al J Neurosurg Spine 2010
- Nucleoplasty
Patient Selection for Lumbosacral Fusion
“IDD”

Intradiscal electrothermal therapy for symptomatic internal disc disruption: 24-month results and predictors of clinical success

Clinical article

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Surgical vs Nonsurgical Management

- Studies on non-surgical management “easier” to perform / regulate
- Only two “good” randomized surgical studies (Class I / Class III)
  - Fritzell et al Spine 2001
  - Brox et al Spine 2003

“Carefully selected”
Should this course be considered “conventional”?
Surgical vs Nonsurgical Management

Fritzell et al - Poor control (non-surgical) group (similar in second paper 2002)

“Patients in the non-surgical were treated with different kinds of physical therapy” (PT supplemented with TENS/Acupuncture/Injections/Cognitive therapy)

Brox et al - Underpowered study but clearly better control group

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Patient Selection for Lumbosacral Fusion "IDD"

- Surgical Strategies (fusion)
  - Elimination of motion “through the disc”
  - Complete disc obliteration?
Patient Selection for Lumbosacral Fusion “IDD”

• Surgical Techniques
  – Posterolateral Fusion / Pedicle Fixation
  – ALIF (+ posterior fixation)
  – PLIF / TLIF (+ posterior fixation)
  – “360”

Patient Selection For Lumbosacral Fusion “IDD”

• Posterolateral Fusion / Pedicle Fixation
  – Zuckerman et al 1992 (89% fusion / only 60% relief)
  – Zdeblick 1993 (92% good outcome with instrumentation)
  – Cowan et al (NASS) 1994 (85% fusion / 67% success)
  – Wetzel et al 1994 (48% fusion / 46% improvement)
  – Boden et al 2002 (rhBMP-2 100% fusion)
  – Fritzell et al 2002 (Comparison study – PL fusion, PL fusion with pedicle fixation, PL fusion with interbody graft and pedicle screws
  – Overall 40-90% fusion / 40-90% clinical success
**Patient Selection For Lumbosacral Fusion “IDD”**

- **PLIF (alone – allo / auto bone)**
  - Schechter et al 1991 (95% fusion / 58% clinical success)
  - Brantigan et al 1994 (allograft 56% fusion / 60% clinical success)
  - Lee et al 1995 (94% fusion / 96% clinical success)
  - Overall 50-95% fusion / 60-95% clinical success

- **ALIF (alone)**
  - Loguidice et al 1988 (autogenous bone 80% fusion / 80% clinical success)
  - Newman et al 1992 (86% fusion / 89% clinical success)
  - Gill et al 1992 (85% fusion / 75% clinical success / 50% clinical success if - MRI / + discog)
  - Knox et al 1993 (70% fusion / 50% clinical success)
  - Burkus et al 2002 (rhBMP-2 with threaded dowels)
  - Overall ALIF with bone (allograft / autograft) 70-95% fusion / 50-90% clinical success
Patient Selection
For Lumbosacral Fusion
“IDD”

• Cages Alone (PLIF / ALIF)
  – Brantigan et al 1993 (100% fusion vs 54% allograft fusion / 70% clinical success)
  – Brodke et al 1993 – Cage (ALIF) similar in stability to PLIF / pedicle screw
  – Kuslich et al 1994 (91% fusion / 91% success)
  – Ray et al 1997 (96% fusion / 65% success)
  – Burkus et al 2002 (rhBMP-2 95% fusion)
  – Overall 50-100% fusion / 60-90% success

Patient Selection
For Lumbosacral Fusion
“IDD”

• Anterior / Posterior (prevent graft resorption, “rocking”, pseudoarthrosis)
  – Kozak et al 1990 (allo + pedicle screws, 80% clinical success even with two levels)
  – O’Brien et al 1986 (86% improved)
  – Losar et al 1994 (99% fusion / 80% clinical improvement, only 38% return to work) / similar to Albert et al 1994
  – Barnes et al 2001 (95% fusion / 70% success)
  – Overall 60-90% clinical success / 90% fusion
Patient Selection
For Lumbosacral Fusion
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Patient Selection
For Lumbosacral Fusion
“IDD”

Surgical Options
“IDD”

“The doctors are just getting a second opinion on the financial aspects of your treatment.”
Patient Selection For Lumbosacral Fusion “IDD”

So what is the answer?
P-L surgery, PLIF, ALIF, 360°, or just conservative therapy?

Patient Selection for Lumbosacral Fusion

Guidelines: PLF adds no benefit after ALIF or after ALIF with posterior instrumentation.
**Patient Selection**

*For Lumbosacral Fusion*

• After careful **selection** of patients
  – Mechanical LBP
  – MRI changes in the disc c/w degenerative changes
  – Discography to r/o patients

**Do the fusion / stabilization that is the “safest” and most efficacious in your hands**

Problem-based decision making

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**Patient Selection**

*for Lumbosacral Fusion*

**Conclusions**

• Low Back Pain is Often an Illness Not a Disease
  – Abnormal illness behavior cannot be treated by a spine operation not even a perfectly executed fusion using the “ultimate spine fixation device” Many patients eventually develop a lifestyle based on suffering and despondency thus becoming “low back losers”
  – Spine surgeons often need to know more about psychological factors in low back pain than they need to know about biomechanics of the lumbar spine or the characteristics of different implants
Remember old saying:

“Although the technology for fusion may be very cool,

a bad treatment plan makes you just another fool!”

Thank You
What Should Evidence-Based Medicine Mean?

Evidence-based medicine is a process by which the literature may be evaluated in a comprehensive and systematic fashion in order to answer clinical questions with varying levels of certainty. In short, evidence-based medicine combines a critical evaluation of the literature with physician judgment and patient values to arrive at a “best guess” solution for a particular problem. When there is high-quality medical evidence to support a particular treatment strategy, then the “best-guess” is likely to actually be the best treatment strategy for that particular patient with that particular disorder. If the medical evidence is questionable, then the “best guess” may simply be a treatment strategy that truly represents a well-intentioned and informed guess.