New Modalities in Spinal Surgery

An Assessment of Value Based upon
Incremental Effectiveness

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Overview

• Measuring Outcomes in Spine Surgery
• Overview of Common Disorders of the Spine
  – Nerve Compression
  – Instability
  – Pain
• Utility of Established Interventions
  – Review of Outcomes
• New Technologies and Modalities
  – Vertebral Augmentation
  – Interspinous Devices
  – Motion preservation
  • Lumbar
  • Cervical
  – Dynamic Stabilization
  – Disc Regeneration
• Measuring the Incremental Value of New Technologies in the spine

Sorting the Wheat from the Chaff

An Evidence-based approach to the
management of disorders of the spine

Goals of Outcomes Research in Spine Surgery

• Quality Assurance
  – Surgeon Accountability
• Patient Information
• Clinical Research
  – Measure Effect of Treatment
  – Assess Efficacy of Treatment
  – Manage change in Treatment
• Demonstrate value to Purchasers of Healthcare
Evolution of Value-driven Healthcare

Healthcare Revolutions
Arnold Relman: NEJM 319, 1988

• Era of Expansion:
  – 1966-Medicare/Medicaid Legislation
  – Increase of expenditure on healthcare from 4% to 14% GDP over 2 decades

• Era of Containment:
  – Development of DRGs, Managed Health Plans

• Era of Accountability:
  – Value=Quality/Cost

Evidence for Quality of Care

• Process Variables
  – Antibiotic Dosing
  – DVT Prophylaxis
  – Documentation

• Utilization Variables
  – Rates of surgery
  – Rates of imaging

• Complications
  – Unscheduled return to OR
  – Revision within 180 days
  – Infection

• Patient-centered Variables
  – HRQoL
  – Satisfaction

• Context of Healthcare expenditures
Patient-centered Measure of Value

- In a healthcare economy with limited resources, it is important to demonstrate the impact of interventions on health-related quality of life.
- Goals of healthcare are to add years to life, and to add life to years (WHO, 1984).
- Comparison of alternative healthcare options creates a challenge in our measurement systems.
  - What is the impact of CABG compared with treatment of diabetes.

Spectrum of Spinal Disorders

- Neural Compromise
- Instability
- Deformity
- Tumor
- Infection
- Axial back pain

SPORT Study
Surgical Care for Lumbar Intervertebral Disc Herniation

- SPORT study
  - Weinstein, et al., JAMA 2006

**Figure 3:** Mean Outcome of Baseline and Each Follow-up Visit Through 2 Years

<table>
<thead>
<tr>
<th></th>
<th>95% CI</th>
<th>95% CI</th>
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<tbody>
<tr>
<td>Total Cost: Surgical</td>
<td>$16,729</td>
<td>$15,956</td>
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<tr>
<td>Total Cost: Mem-Op</td>
<td>$6,366</td>
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<td>Cost &amp; (Surgery+OP)</td>
<td>$10,304</td>
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<td>QALY: Surgical</td>
<td>0.60</td>
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<td>QALY: Mem-Op</td>
<td>0.69</td>
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<td>QALY &amp; (Surgery+OP)</td>
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<td>0.09</td>
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<td>IERR (cost/QALY)</td>
<td>$39,766</td>
<td>$35,092</td>
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Surgical versus Nonsurgical Therapy for Lumbar Spinal Stenosis

- 654 pts enrolled
  - 289 pts randomized
  - 365 pts observational
- Significantly improved outcomes for surgical care group at all time points from 3mos to 2 years compared with non-operative group

Spinal Stenosis and Degenerative Spondylolisthesis

- 654 pts enrolled
  - 289 pts randomized
  - 365 pts observational
- Significantly improved outcomes for surgical care group at all time points from 3mos to 2 years compared with non-operative group
Surgical versus Nonsurgical Treatment for Lumbar Degenerative Spondylolisthesis

- Randomization of patients with degenerative spondylolisthesis/spinal stenosis to operative vs. non-operative care
- Observation cohort
- Operative care:
  - Limited decompression
  - Open or Endoscopic
- Non-operative care
  - PT, ESI, Pain medications
  - Journal to track care

The Utility of Surgical Care for Degenerative Conditions of the Hip and Spine

- Matched cohort analysis of consecutive patients undergoing surgery for hip osteoarthritis compared with degenerative spinal disorders (Lumbar disc herniation, spinal stenosis)
- Utility of surgery measured by change in SF-12 scores at one year follow-up
Conclusions

- Patients with lumbar degenerative conditions have more severe MCS compromise (anxiety and depression) than patients with hip osteoarthritis.
- The utility of operative intervention is similar for each measured by improvement of physical and mental health domains.
- The Incremental Cost-Effectiveness of care for hip osteoarthritis and lumbar degenerative conditions is similar.

Spectrum of Spinal Disorders

- Neural Compromise
- Instability
- Deformity
- Tumor
- Infection
- Axial back pain

Instability

- Traumatic
  - Fracture
  - Dislocation
- Developmental
  - Spondylolisthesis
Operative Management of High Grade Spondylolisthesis  
UCSF-NASS 2005

- Retrospective study design
- 20 consecutive patients with high grade spondylolisthesis (>grade 2)
- Outcomes recorded using SRS Instrument

Conclusions

- 17/20 patients reported measurable improvement of pain
- 16/20 patients reported measurable improvement of function
- 18/20 patients were somewhat or very satisfied with results of surgery
- 2/20 patients neither satisfied or dissatisfied
- No correlation between outcome and reduction of spondylolisthesis

Spectrum of Spinal Disorders

- Neural Compromise
- Instability
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Adult Degenerative Scoliosis

- Degenerative scoliosis is characterized by:
  - Adult onset of deformity (de novo)
  - Degenerative changes within the deformity:
    - Stenosis
    - Spondylolisthesis
    - Rotatory subluxation
    - Lumbar hypolordosis
    - Osteoporosis

Study Purpose

- Determine the Results of Operative Management for Degenerative Scoliosis
- Identify Surgical Strategies that are predictive of Outcome
- Provide information for an evidence-based approach to operative care of adult scoliosis

Material and Methods

- Retrospective study design from a single spine center
- Predictor Variables:
  - Patient demographics
  - Curve characteristics
  - Surgical Strategy
- Outcome variables
  - Radiographic parameters
  - Self-assessment: SF-36, SRS-29

Results

- 27 patients identified with greater than 2 years of clinical follow-up
  - 18 female, 9 male
- Average Age: 63.3yrs (range 40-81)
- Clinical follow-up: 54.9mos (range 24-129)
- Radiographic follow-up: 34.9mos (range 1-97)
Results

- Post-op SRS-29 scores:

  - Pain
  - Mental Health
  - Overall Satisfaction
Results

- 89% report improvement of pain after surgery
- 67% report improvement of function after surgery
- 92% would definitely or probably repeat choose surgery again

Spectrum of Spinal Disorders

- Neural Compromise
- Instability
- Deformity
- **Tumor**
- **Infection**
- Axial back pain

- 68yo male with a solitary metastatic thyroid tumor involving T11
  - 5 years after thyroidectomy and radiation to his primary tumor
DR

- 21yo female, college sophomore
- Developed low back pain, insidious onset
- Work-up demonstrated a chordoma at L4, intraosseous, low grade
Survival and Adequacy of Initial Resection

• Tomita, et al. Spine 2001
• Berven, et al. Spine 2001
  – Survival in chordoma is dependent upon adequacy of the original resection

Operative Care vs. Radiation for Spinal Metastasis with Neural Compromise

• 101 pts randomized to operative vs non-operative care for metastatic tumor affecting the spine and spinal cord
  – Able to walk at final follow-up:
    • 42/50 (84%) surgical group
    • 29/51 (57%) radiation group
  – Regained ability to walk after treatment
    • 10/16 (62%)
    • 3/16 (19%)

Lancet 2005

What are the new modalities that may improve outcome in established spinal procedures?

• Neural Compromise
• Instability
• Deformity
• Tumor
• Infection
• Axial back pain
Spinal Stenosis Treatments

Non-Operative Care
- Epidural injections
- Physical therapy
- NSAIDs other drugs
- Lifestyle modification

Surgical Decompression
- Laminectomy
- Laminectomy with fusion
- Laminotomy/facetectomy

- Minimally Invasive Techniques

X-STOP IMPLANT DESIGN

- Interspinous and supraspinous ligament is retained
- Not fixed to bony structures
- Placed posterior to neural structures, i.e., risk of neural injury is minimized

CANAL DIMENSIONS

Axial MRI slices of extended cadaver specimens showed
- Canal area: 118%
- Canal diameter: 110%
- Subarticular diameter: 150%

- No significant change at adjacent levels

Pre-Implant Post-Implant

FORAMEN DIMENSIONS

Para-sagittal MRI slices of extended cadaver specimens showed
- Foramen area: 125%
- Foramen width: 141%

- No significant changes at adjacent levels

Pre-Implant Post-Implant
Case Presentation

92 yo male with severe COPD
L3-4 stenosis
L4 Compression fracture
IDE Pivotal Trial Design (cont.)

- Primary outcome measure
  - ZCQ (Zurich Claudication Questionnaire)
    - Validated (Stucki - Spine 1996; Pratt - Spine 2002)
    - 3 subdomains
      - Symptom Severity (Pain)
      - Physical Function
      - Patient Satisfaction

- Secondary outcomes measures
  - SF-36 (Quality of Life)
  - Radiographic measurements

Symptom Severity (Pain)

- ZCQ percent change from baseline
- Immediate and maintained clinical and statistically significant improvement
  (p < 0.001)

Figure 3: The mean percent change in the Symptom Severity scores relative to each patient’s baseline score. At each time point, the mean percent change of the X-STOP patient’s score was significantly greater than that of the control patient’s score (p < 0.001). There were no significant differences between time points for either the X-STOP (p = 0.18) or control groups (p = 0.903). The percent change for each patient at each time point was calculated as the change from baseline relative to the baseline score, i.e., (baseline score - score)/baseline score.
What are the new modalities that may improve outcome in established spinal procedures?

- **Neural Compromise**
- **Instability**
- **Deformity**
- **Tumor**
- **Infection**
- Axial back pain

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### Physical Function

- ZCQ percent change from baseline
- Immediate and maintained clinical and statistically significant improvement (p < 0.001)

![Graph showing mean percent change in Physical Function score relative to baseline](image)

Figure 1. The mean percentage change of the Physical Function score relative to each patient’s baseline score. At each time point, the mean percent change of the X-STOP patient’s score was significantly greater than that of the control patient’s score (P < 0.001). There were no significant differences between time points for either the X-STOP (P > 0.05) or control groups (P > 0.05). The percent change for each patient at each time point was calculated as the change from baseline relative to the baseline score, i.e., (Baseline score – score)/Baseline score.

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### Comparison to Laminectomy

- 6 patients in X-STOP IPD procedure group and 24 in Non-op group underwent decompressive laminectomy
  - Laminectomy results were comparable to remainder of X-STOP IPD procedure group
  - Results were similar to “historic” laminectomy group (Katz – Spine 1999)
- Randomized trial of X-stop compared to laminectomy demonstrated similar clinical outcomes, but 20% revision rate for x-stop at one year

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### Fusion Rates

- **Osteobiologics**
  - Recombinant Bone Morphogenetic Proteins
    - BMP-2 (Infuse)
    - BMP-7 (OP-1)
    - BMP-14 (MP-52)
Osteoinductive Materials

Bone Formation by Autoinduction

MARSHALL R. UREST
Department of Surgery, University of California Center for Health Sciences, Los Angeles 90024
12 NOVEMBER 1965

Serial CT Review

Study Results

<table>
<thead>
<tr>
<th></th>
<th>rhBMP-2</th>
<th>Autograft</th>
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<tbody>
<tr>
<td>Mean op time</td>
<td>96min</td>
<td>120min</td>
</tr>
<tr>
<td>Mean blood loss</td>
<td>109.8cc</td>
<td>153.1cc</td>
</tr>
<tr>
<td>Avg. hospital stay</td>
<td>3.1 d</td>
<td>3.3 d</td>
</tr>
<tr>
<td>Return to work</td>
<td>116d</td>
<td>170.5d</td>
</tr>
<tr>
<td>Fusion rate (24mo)</td>
<td>94.5%</td>
<td>88.7%</td>
</tr>
<tr>
<td>Bone graft site pain (24mo)</td>
<td>0%</td>
<td>32%</td>
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</tbody>
</table>
Comparison of BMP-2 vs ICBG in a single-level instrumented posterolateral fusion
FDA IDE study
Fusion rates 73% vs 88% (p=0.051)
No difference in clinical outcomes at any timepoint

What are the new modalities that may improve outcome in established spinal procedures?
- Neural Compromise
- Instability
- Deformity
- Tumor/Fracture
- Infection
- Axial back pain

Kyphoplasty as a Minimally Invasive Technique for the Management of Spinal Tumors

KYH
- 86yo female lives independently
- Progressive back pain and progressive kyphotic deformity after fall in 12/00
- History of severe osteoporosis, remote history of breast cancer
Minimally Invasive Fracture Reduction

Overview of Treatment Steps

1) The balloon is inserted into the fractured vertebral body.

2) The balloon is inflated, reducing the fracture and elevating the endplates.

3) The balloon is deflated and withdrawn, leaving a cavity within the vertebra.
Cost Effectiveness of Kyphoplasty for Vertebral Compression Fractures
ISSLS 2006

• Improvement
  – Average improvement in HRQL 2 yrs .16
    • (95% CI = .03)
    • (Range -.146 to .423)
  – Average improvement in QALYs 2 yrs by method of Brazier was .32 QALY
    • (95% CI = .05)
• Average Cost per QALY at 2 yrs
  – Inpatient - $23,292
  – Outpatient - $11,856

Spectrum of Spinal Disorders

• Neural Compromise
• Instability
• Deformity
• Tumor
• Infection
• Axial back pain
  – Pain of Spinal Origin, in the absence of nerve impingement (stenosis), instability, deformity, tumor or infection
Diagnostics

- The accurate identification of a pain generator is critical for the success of operative intervention on a painful motion segment.

Radiographic Evaluation

- Plain Radiography
- MRI
- Myelography
- SPECT
- NMR

Provocative Testing Techniques

- Discography
  - Provocative
  - Functional Anesthetic
- Facet Joint Injection
- Epidural Steroid Injection
- Selective Nerve Root Blocks

Treatments

- Disc Arthroplasty
- Disc Regeneration
• 31yo male restaurant owner
• Pain to lumbosacral spine worst with forward flexion and lifting, improved with sitting with lumbar cushion
• Left L5 radicular pain, positive tension signs
• Unable to lift boxes from floor
• Persistent pain despite activity modification, bracing, PT, pain medications
Absence of an Effect Size in the Outcomes of Disc Arthroplasty compared with alternatives

Radiographic Outcomes
Flexion / Extension
Excellent results seen in both groups.

PRESTIGE® Disc showed statistically significant differences at 6 weeks, 3 months, and 12 months.

Neck Disability Index (NDI)

PRESTIGE® Disc statistically significant difference at 6 weeks and 3 months.

Arm Pain

Fusion

PRESTIGE® Disc

77.5% improvement

40

55

70

PRESTIGE® Disc

78.0% improvement

26

Strategies for Regeneration of the Intervertebral Disc

- Injection of Growth Factors
- Mesenchymal Stem Cell-based Therapy
Intervertebral Disc Degeneration

- Measurable Changes in Disc Degeneration
  - Histological
    - Disc Height/Volume
    - Cellularity and cell viability
    - Architecture
    - Aggrecan/Type II Collagen Expression
  - Biomechanical
    - Load Displacement
    - Bending Stiffness/Strength
    - Neutral Zone

Intervertebral Disc Regeneration

- Stimulation of IVD by Growth Factors

  Canine IVD Tissue Culture Model:
  Nucleus, transition zone and anulus responded to growth factors with marked increase in PG and collagen production
  - TGF-B
  - EGF
  - PFG
  - IGF-1

Goals of Intervertebral Disc Regeneration

- Restoration of:
  - Intervertebral Disc Height/Volume
  - Viable and active cells in the nucleus pulposis
  - Architecture of inner/outer annulus
  - Biomechanical Properties

Growth Factor Injections
TGF-B Injected Discs

Saline Control
4 weeks

TBG-B injected
4 weeks

MPC and Intervertebral Disc Regeneration

5ul injection
MPC in HA Gel
Estimate 2-8x10^3 cells injected
Results: Cellularity

Blank gel

0 days – gel w/ cells
28 days – gel w/ cells

Injected Mesenchymal Stem Cells in Disc
• Vertebral augmentation for fractures and tumors is cost-effective.

- Prospective study and measurement of outcomes in spinal surgery is important in the assessment of efficacy and in the measurement of change.
- New technologies in the spine may add significant costs to spine care and value of these interventions is dependent upon the incremental difference in outcomes.
- Interspinous distraction may have advantage over decompression in select patients, but advantages over laminectomy remain questionable.
- Biologics improve fusion rates, but the cost-effectiveness of this difference is unproven.
- Vertebral augmentation for fractures and tumors is cost-effective.
- Disc arthroplasty results are similar to fusion in the lumbar spine, and may show incremental benefit in the cervical spine.
- New technologies in diagnostics and tissue regeneration may have the greatest promise in improving outcomes of care for pain of spinal origin.