North Carolina Spine Society
2017 Annual Meeting
Saturday Handouts

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Charlotte, NC

This continuing medical education activity is jointly provided by the North Carolina Spine Society and Southern Regional Area Health Education Center
Development of an ERAS program for lumbar spinal fusion

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Disclosures
Consultant: Depuy Spine
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JoiMax
K2M
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Quality Medical Publishing
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Spinicity
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VS.
What is ERAS?
Enhancing Recovery After Surgery

- AKA Fast-track or ERP
- Developed by Kehlet in Denmark in colonic surgery
- Has gained world-wide acceptance
- Has spread across medical disciplines
- Originally described in Open Surgery but same advantages seem to apply for Laparoscopy

Enhanced Recovery After Surgery aka: ERAS®

Key features:
- Patient focus
- Team approach
- Multi-modal
- Surgical journey
- “Fast tracking”
- Iterative improvement
Japanese Relevance

ERAS Results

<table>
<thead>
<tr>
<th>Type of Operation</th>
<th>Duration of stay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carotid endarterectomy</td>
<td>1-2 days</td>
</tr>
<tr>
<td>Lung lobectomy</td>
<td>1-2 days</td>
</tr>
<tr>
<td>Prostatectomy</td>
<td>1-2 days</td>
</tr>
<tr>
<td>Colectomy</td>
<td>1-3 days</td>
</tr>
<tr>
<td>Aortic Aneurysm</td>
<td>3-4 days</td>
</tr>
</tbody>
</table>

Why do we need a spine ERAS program?

- Patients are terrified of spine surgery
- Recovery from surgery is long & painful
- Both procedural & nationwide costs are especially high
- There is tremendous variability in practice
- There is tremendous variability in outcomes
- There is a lot of room for improvement
The Morbidity of Open Surgery

- Pain
- Disability

Inciting Event  Surgical Intervention  Muscle Healing  Bony Fusion

The “Cost” of Surgery

- Preop
- POD #1
- “Healthy”

Inciting Event  Surgical Intervention  Muscle Healing  Bony Fusion
Minimally Invasive Surgery

Get in and out with minimal disruption!

ObamaCare: Greater access, higher quality, at lower cost

Is this possible?

Technically, no…

The only possibility is through:

1. New technology
2. Systems approach

1. New Technology

Access
Visualization
Localization
Manipulation
What is the Zeitgeist?

- Cost concerns & and payor denials
- Affordability for the individual
- Reproducibility across surgeon providers
- Consistency in good results
- Complications monitoring and reduction
- A ballooning “extreme aged” population
- Patient-driven vs. Systems-driven care
Figure 2.3
Changes in the Population Pyramid

1950

2007

2050 (Projection)


“80 is the new 60”

Oldest college grad.

LIVE LIFE
Pass It On.
THE COMMUNITY IS A BETTER LIFE
To Nola Ocha

Senior Highs

Population 80 and over by county
**U.S. Census Data**

Number of U.S. Centenarians

- Number of Centenarians: 27
Do MIS approaches allow us to operate on older, sicker, fatter people?

Six Components

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Advantages</th>
<th>Disadvantages</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awake Anesthesia</td>
<td>8 mm incision</td>
<td>Limited decompression capability</td>
<td>Off-label</td>
</tr>
<tr>
<td>Perioperative Fixation</td>
<td>Allows for a formal discectomy</td>
<td>Capital equipment costs</td>
<td></td>
</tr>
<tr>
<td>Endoscopic Visualization</td>
<td>Clear visualization</td>
<td>Learning curve</td>
<td></td>
</tr>
<tr>
<td>Long Acting Na+ Blockers</td>
<td>Limited anesthetic side effects</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteobiologics for Fusion</td>
<td>Mentos normal hemostasis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expandable Interbody</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Awake Anesthesia

- Patient neuromonitoring
- Limited anesthetic side effects
- Mentos normal hemostasis
- Capital equipment costs
- Limited working time
- Airway not secured
- Close airway monitoring needed

On-Label

- Patient neuromonitoring
- Limited anesthetic side effects
- Mentos normal hemostasis
- Capital equipment costs
- Limited working time
- Airway not secured
- Close airway monitoring needed

Off-label

- Patient neuromonitoring
- Limited anesthetic side effects
- Mentos normal hemostasis
- Capital equipment costs
- Limited working time
- Airway not secured
- Close airway monitoring needed
Case Illustration

Operative time was 115 minutes with a total blood loss of 65 cc. The total hospital was 22 hours.

Targeting and Access

Kambin’s Triangle Approach

Discectomy/Decompression

Endplate Preparation
Cage Placement & Fixation

The Methods Employed Could be Termed:

- Endoscopic Lumbar Fusion
- Percutaneous Lumbar Fusion
- “Awake” Lumbar Fusion
- ERAS® Lumbar Fusion
2. The power of endoscopy

* 8 mm space
What about lumbar stenosis?
3. Genetically Engineered Proteins
25 Years of Progress

1977  2002

There is a great deal of debate regarding BMP-2:
1. Safety
2. Cancer risk
3. Retrograde ejaculation
4. Heterotopic bone formation
5. Cost

What no one disagrees about is that
IT WORKS

YODA Study

Conclusion: At 24 months, rhBMP-2 increases fusion rates, reduces pain by a clinically insignificant amount, and increases early postoperative pain compared with ICBG. Evidence of increased cancer incidence is inconclusive.
4. *In situ* Interbody Assembly

**Entrance through Kambin’s Triangle allows access through a traditional discectomy approach.**

5. Percutaneous Fixation

**SIZE MATTERS**

<table>
<thead>
<tr>
<th></th>
<th>Screw A</th>
<th>Screw B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter</td>
<td>0.7 cm</td>
<td>1.3 cm</td>
</tr>
<tr>
<td>Skin Incision</td>
<td>1.1 cm</td>
<td>2.1 cm</td>
</tr>
<tr>
<td>Area of exposure</td>
<td>0.39 cm²</td>
<td>1.34 cm²</td>
</tr>
<tr>
<td>Volume in 4” depth</td>
<td>15.7 cm³</td>
<td>54.3 cm³</td>
</tr>
</tbody>
</table>
A 62 year-old male with intractable back (7/10) and right leg (4/10) pain that was associated with standing and walking, relieved with recumbency.
Results

- Mean age of 62.2±9.0 (range 52-78)
- 60% had a Grade I spondylolisthesis
- Mean operative time was 113.5±6.3 min
- Mean blood loss was 65±38 cc (30-190)
- Hospital length of stay was 1.2±1.3 nights
- No intraop complications
- No conversions to open surgery
- One case of cage migration
- Two cases of infection
Results

• ODI 42±11.8 to 13.3±15.1
• SF-36 PCS 47.6±3.8 to 49.7±5.4
• SF-36 MCS 47±3.9 to 46.7±3.4
• EQ5D 10.7±9.5 to 14.2±1.6

Study & Technique Flaws

• Small sample size
• Longer follow-up needed
• Off-label use of products
• Capital equipment investment
• Generalizability
• Teachability
• Limits of decompression
• Difficulty with treating L5/S1

MIS vs. open TLIF Charges: University of Miami

• 74 patients treated over 14 months
• 59 1-level (75% MIS)
• 15 2-level (53% MIS)
• Patients underwent open surgery if neural symptoms were bilateral
But are there real advantages?

VS.

Open  MIS

MIS TLIF Charges - Miami

$70,159  $78,444  $87,454  $108,843

P=0.027  P=0.071

Comparative Effectiveness
Reducing but Sustained Improvement

EQ-5D - MIS vs Open TLIF

Effects on Cost

<table>
<thead>
<tr>
<th>MIS TLIF</th>
<th>Open TLIF</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>$10,942 ± 9102</td>
<td>$10,416 ± 22,727</td>
<td>0.06</td>
</tr>
<tr>
<td>$16,563 ± 10,594</td>
<td>$17,918 ± 20,140</td>
<td>0.63</td>
</tr>
</tbody>
</table>

$9,259 savings per case
Single Level Fusion(s)

- Open surgery: 4.3 days, 420 cc, $39,444
- Minimally invasive: 3.1 days, 265 cc, $35,159
- Awake fusion: 1.2 days, 68 cc, $19,561

Cost is related to access

- National costs must be calculated considering procedural prevalence
- What will happen if there is no insurance or governmental coverage?
- Can patients afford surgery?
- How much can an average patient afford?

If we can do this awake, then it proves that:

1. We have taken MIS to a point where soft tissue damage is truly minimal
2. We avoid many of the risks and complications of anesthesia
3. We can now treat the ballooning extreme elderly population
4. Surgery becomes affordable to the average patient without insurance
Caveats

1. This will not treat all pathologies
2. Patient selection is critical
3. The patient must be compliant/cooperative
4. What will the fusion rate be?
5. Long term data is needed
6. Is this reproducible?

The Future of Medicine

What to do with this?
Conclusions

1. Even less invasive approaches for fusion are possible leveraging new technologies
2. Used in select patients, excellent improvement rates in pain and disability are possible with a rapid recovery
3. Long term follow-up on larger clinical series are necessary
4. Non-technical elements will need to be incorporated (Diet, Psych, Meds, etc.)
Expandable Interbody Spacers: A Paradigm Shift in the Restoration of Disc Space Geometry?

Sergio Mendoza-Lattes, MD
Associate Professor, Department of Orthopaedic Surgery
Duke University Medical Center

I have the following relevant financial relationships with the manufacturers of any commercial products and/or providers of commercial services discussed in this CME activity.

Globus Medical - Consultant

AND

My content will include reference to commercial products; however, generic and alternative products will be discussed whenever possible.

I do/ do not intend to discuss any unapproved or investigative use of commercial products or devices.

Why use Interbody Cages?

1) Fusion rates – load bearing construct.
2) Disc space geometry
   Sagittal alignment
   Coronal alignment
3) Foraminal capacity
Circumferential Fusion Improves Outcome in Comparison with Instrumented Posterolateral Fusion: Long-term Results of a Randomized Clinical Trial. Tina S. Videbaek, MD, Finn B. Christensen, MD, PhD, Ebbe Sejersen, MPH, Ebbe L. Hansen, MD, DMSc, Kristian Vag, MD, Peter Holing, MD, PhD, Janz Mikkelsen, MD, Sune I. Balskov, MD, and Todd L. Burggra, MD, DMSc, SPINE Volume 31, Number 25, pp 2875–2880, 2006

Posterior instrumentation vs. ALIF

PRC trial, 93% f/u
73 vs. 73 cases; 5 – 9 year follow-up.
• Superior clinical results with ALIF.
• ODI: 40 vs. 28 (p<0.004)
• SF-36 PCS: 33 vs. 39 (p<0.005)

A Meta-Analysis of Circumferential Fusion Versus Instrumented Posterolateral Fusion in the Lumbar Spine. Han Xuejun, MD, Zhu Yue, MD, Cui Cui, MS, and Wu Yajun, MS, SPINE Volume 34, Number 17, pp E618–E625, 2009

Posterior instrumentation vs. ALIF.
• Comparable clinical results <2 years.
• Higher fusion rates with ALIF (OR 2.11)
• Lower re-operation rates with ALIF (OR 0.44)


Posterior instrumentation vs. PLIF-TLIF:
• Comparable clinical results < 2 years.
• Significantly higher union rates with PLIF-TLIF (OR 2.60)
• Significantly less re-operations with PLIF-TLIF (OR 0.20)

**ALIF vs. TLIF:**

Metanalysis – 9 retrospective studies:
- Comparable clinical results at 2 years.
- ALIF presents superior disc space restoration, segmental and global lordosis restoration.

**ALIF** vs. **TLIF**:

ALIF is superior in:
- Foraminal height (18.5% vs. 0.4%)
- Segment lordosis (8.3 vs. 0.1)
- Global lordosis (6.2 vs. 2.1)


Expandable PLIF / TLIF
Prospective data collection
1) 31 ePLIF (age = 62; BMI=32; # of levels 1.74)
2) 36 ALIF (age = 43; BMI = 29.4; # of levels 1.2)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Pre-op</th>
<th>Post-op</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ePLIF</td>
<td>13.6mm</td>
<td>14.8mm</td>
<td>0.033</td>
</tr>
<tr>
<td>ALIF</td>
<td>11.6mm</td>
<td>12.3mm</td>
<td></td>
</tr>
<tr>
<td>Anterior Height</td>
<td>(2.7 - 5.0)</td>
<td>(2.3 - 3.9)</td>
<td></td>
</tr>
<tr>
<td>Posterior Height</td>
<td>(4.2 - 5.7)</td>
<td>(3.2 - 5.3)</td>
<td></td>
</tr>
<tr>
<td>Intervertebral angulation</td>
<td>(-5.3° to 4.7°)</td>
<td>(-7.5° to 10.5°)</td>
<td></td>
</tr>
</tbody>
</table>

Absolute change in disc space angulation.

<table>
<thead>
<tr>
<th>Change in IA (degrees)</th>
<th>All</th>
<th>Posterior</th>
<th>Central</th>
<th>Anterior</th>
</tr>
</thead>
<tbody>
<tr>
<td>-2</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>-1</td>
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<td></td>
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<tr>
<td>0</td>
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<td>6</td>
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<td>7</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Ryan SP, Larson N, Bethany Harpole, B, Pugley A, Nash R: Disc Space and Foraminal Geometry Following Anterior vs. Posterior Lumbar Interbody Fusion with Expandable Cages: A Case Control Study. Submitted
Published average values of change in inter-body lordosis. Dependent values reflect net change in interbody lordosis. No correlation with the implant geometry is observed. Metanalysis includes 35 of 242 manuscripts.

Published average values of change in inter-body lordosis. Dependent values reflect net change in interbody lordosis. No correlation with the implant geometry is observed. Metanalysis includes 35 of 242 manuscripts.
Static vs. Expandable MIS-TLIF:
44 patients
16 static
28 expandable
Age 58 - 64
70% L4-L5

Also consider...

58yo female. BMI=32; Rheumatoid Arthritis (Infliximab) Neurogenic claudication BLE pain.
Post-Op day#2

6-months post-op
Back pain and left L5 radiculopathy – 4/5 EHL y TA

47yo female; LBP + BLE pain
BMI=38

47yo female; LBP + BLE pain
BMI=38

TLIF/PLIF vs. XLIF/DLIF:
Greater surface bearing area – epiphyseal rim.

- 4 cases of TLIF cage migration
- 125 patients (144 levels)
- Risk factors for migration:
  - Bullet-shaped cage
  - Higher PDH
  - Undersized cages


Moving forward. Climbing higher.
Outcomes of Surgical Treatment for Metastatic Disease of the Spine

Vignesh Alamanda, MD

Coauthors – Myra M. Robinson, MSPH; Jeffrey S. Kneisl, MD, FACS; Joshua C. Patt, MD, MPH

Levine Cancer Institute
Carolina HealthCare Systems

Disclosure(s)

I have no conflicts of interest in relation to this program/presentation.

Outline

Does surgical intervention improve functional levels, specifically ambulatory status?

Revision Surgery – Predictive Factors and Survival Outcomes
Spinal Metastasis has been noted in up to 40% of cancer patients. More than more than 18,000 new cases are reported every year in North America alone. Prognostic prediction tools such as Tokuhashi scores exist but functional outcomes remain largely unknown.

Background

- Retrospective review of patients undergoing surgical treatment from Jan 2010-Dec 2015
- Patients were excluded if they had primary tumors of the spine, if they underwent non-surgical treatment or if they were younger than 18yo
- Minimum 6mos f/u
- 55 patients met criteria.

Patient Population

- 60% males; 72.7% Caucasians
- 49% smokers
- RCC most common cancer type – 27.3%
- 93% reported pain as one of their chief complaints upon initial presentation
- 82% ASIA E upon presentation
- 71% to Thoracic Spine
- 78.2% also had extra-spinal metastasis
- 76.4% received XRT
- 90.9% received chemotherapy

Key Statistics
Ambulatory Status

- Changes in ambulatory status can sometimes be the presenting sign of spinal metastasis and epidural compression.
- Can present as a slow, progressive onset or rapid neurologic emergency.
- Studies such as Patchell et al have found that the ability to walk has been improved with surgery + XRT vs XRT alone (122 days vs 13 days).

Ambulatory Status

<table>
<thead>
<tr>
<th></th>
<th>Input</th>
<th>Pre-op</th>
<th>Post-op</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambulatory Status</td>
<td>a %</td>
<td>a %</td>
<td>a %</td>
<td>a %</td>
</tr>
<tr>
<td>Ambulation</td>
<td>30 96.9</td>
<td>30 97.3</td>
<td>33 96.1</td>
<td>35 93.6</td>
</tr>
<tr>
<td>Weakness / Paralysis</td>
<td>5 91.7</td>
<td>7 12.7</td>
<td>2 50.0</td>
<td>20 84.6</td>
</tr>
</tbody>
</table>

- Ambulation improves in the immediate postoperative period.
- Gains in ambulation unable to be sustained long term.

Survival Statistics

- Median time to Spinal Metastasis from cancer diagnosis, excluding concurrent diagnosis → 2.5 yrs (95% CI: 1.1-3.8 years).
- Median overall time till death from surgical intervention → 1.6 yrs (95% CI: 1.2, 2.0 years).
Revision Surgery

- 55 Patients: 12 patients (21.8%) underwent revision surgery.

- Key difference between the two groups:
  - Higher smoking use in the revision group (75% vs. 42%; p=0.055)
  - RCC was the most common type in both the revision and the non-revision group. Relatively radioresistant and with intermediate prognosis.

Reasons for Revisions

<table>
<thead>
<tr>
<th>Revision Reason</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumor Progression</td>
<td>8</td>
<td>66.7</td>
</tr>
<tr>
<td>Non-union</td>
<td>2</td>
<td>16.66</td>
</tr>
<tr>
<td>Wound dehiscence</td>
<td>1</td>
<td>8.33</td>
</tr>
<tr>
<td>Construct Failure</td>
<td>1</td>
<td>8.33</td>
</tr>
</tbody>
</table>
Smoking and Revision Surgery

Multivariate analysis showed that current or past smoking use increases odds of undergoing revision surgery by 3.5 times (p < 0.10).

Smoking and Spine surgery

- Smoking has been found to have a negative impact in many disease pathologies—both oncological and non-oncological entities, including decreasing rate of union.
- Delayed union can allow for development of hardware failure and necessitate a revision.
- Smoking has also been implicated in wound healing complications.

Survival Comparison

- Revision group: median overall survival 3.0 years
- Non-revision group: median overall survival 1.5 years
- Approached statistical significance (p = 0.105)
Revision Surgery


Key Differences
- Revision rate larger (10.7% vs 21.8%)
- 64.5% of patient re-operated during same admission in the Quraishi et al study, 0% in this study
- Similar mean survival outcomes in the revision group
- Similar reasons necessitating a revision in both groups.

Future Directions

- Large, multicenter trials
- However, inconsistencies in surgical indications may limit direct comparison of large groups of patients from multiple surgeons

Summary

- Ambulation status improved compared to preoperative levels. However, unable to be sustained long term
- Revision surgery associated with smoking use
- Tumor progression remains the most common reason for necessitating revision
- Revision surgery should be considered in patients with indications for it as it does not appear to detrimentally affect survival.
References

Single-position extreme lateral interbody fusion and percutaneous pedicle screw fixation allows for adequate correction of spinal sagittal imbalance

J. Alex Thomas, M.D.
Atlantic Neurosurgical and Spine Specialists
Wilmington, N.C.

Introduction

- Placement of bilateral pedicle screw fixation (PSF) in the lateral decubitus (LD) position after extreme lateral interbody fusion (XLIF) is safe, efficient and reproducible.
- Benefits of “single-position” surgery
  - Eliminate “flip time” to prone position
  - Decreased risks to patient
  - More cost effective?
- Perceived limitation: adequate correction of segmental and lumbar lordosis (SL and LL) may not be achieved in the LD position.

Aims & Objectives

- Compare pre- and postoperative spinopelvic parameters of patients who underwent XLIF followed by placement of bilateral PSF in either LD or prone position.
- Is prone positioning after XLIF necessary to adequately correct spinal sagittal imbalance?
Methods

• Prospective cohort study
• Consecutive patients who since October 2015 underwent either extreme lateral interbody fusion (XLIF) or lateral anterior lumbar interbody fusion (L-ALIF) with bilateral PSF placed in either LD or prone position.
  -- Some screws in prone group placed using Mazor robotic guidance
• No rod manipulation
• Pelvic incidence (PI), lumbar lordosis (LL), segmental lordosis (SL), ΔLL, ΔSL, PI-LL mismatch calculated for all patients
• Student’s T-test used as appropriate.

Results

<table>
<thead>
<tr>
<th></th>
<th>LD</th>
<th>Prone</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td># patients</td>
<td>72</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>62.2</td>
<td>66.0</td>
<td>.16</td>
</tr>
<tr>
<td>BMI</td>
<td>28.8</td>
<td>28.1</td>
<td>.50</td>
</tr>
<tr>
<td># levels</td>
<td>86</td>
<td>30</td>
<td>.10</td>
</tr>
<tr>
<td>Avg. # levels</td>
<td>1.2</td>
<td>2.3</td>
<td>.01</td>
</tr>
<tr>
<td>Total # screws</td>
<td>322</td>
<td>90</td>
<td>.01</td>
</tr>
<tr>
<td>Avg. # screws</td>
<td>4.3</td>
<td>6.9</td>
<td>.01</td>
</tr>
<tr>
<td>Avg total case time (min)</td>
<td>88.7</td>
<td>130.7</td>
<td>.00</td>
</tr>
<tr>
<td>Total time for screws (min)</td>
<td>25.9</td>
<td>48.1</td>
<td>.04</td>
</tr>
<tr>
<td>Time per screw (min)</td>
<td>5.7</td>
<td>6.2</td>
<td>.10</td>
</tr>
<tr>
<td>Fluoro time per screw (sec)</td>
<td>16.5</td>
<td>13.3</td>
<td>.00</td>
</tr>
<tr>
<td>EBL (cc)</td>
<td>65.2</td>
<td>146.4</td>
<td>.10</td>
</tr>
<tr>
<td>LOS (days)</td>
<td>1.2</td>
<td>3.3</td>
<td>.02</td>
</tr>
</tbody>
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Results

<table>
<thead>
<tr>
<th></th>
<th>LD</th>
<th>prone</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SL, preop</td>
<td>-52.1</td>
<td>-46.5</td>
<td>.01</td>
</tr>
<tr>
<td>SL, postop</td>
<td>-6.1</td>
<td>-6.2</td>
<td>.93</td>
</tr>
<tr>
<td>ΔSL</td>
<td>4.6</td>
<td>5.9</td>
<td>.64</td>
</tr>
<tr>
<td>ΔLL</td>
<td>3.9</td>
<td>11.2</td>
<td>.05</td>
</tr>
<tr>
<td>ΔLL/# levels</td>
<td>3.2</td>
<td>5.7</td>
<td>.15</td>
</tr>
<tr>
<td>PI-LL, preop</td>
<td>6.8</td>
<td>10.1</td>
<td>.27</td>
</tr>
<tr>
<td>PI-LL, postop</td>
<td>2.9</td>
<td>1.7</td>
<td>.49</td>
</tr>
</tbody>
</table>

Complications:
- Breech rate: 4.3% for LD position versus 8.8% in prone position
- Shin et al., 2015: 7.8%
- Wiesner et al., 2000: 6.6%
- 2 patients required reoperation in LD position group for malpositioned screws (only 1 had new radicular pain.)
- There were no infections.

Conclusions
- Placement of bilateral PSF in the LD position allowed for adequate correction of SL, LL and PI-LL mismatch.
- The majority of patients in single position group were within 10 degrees of PI-LL mismatch at baseline.
- Surgeons already doing surgery in LD position should consider “single-position” PSF.
Assessment of Robotic Guided Instrumentation: Accuracy, Learning Curve, and Revisions

North Carolina Spine Society
August 19, 2017
Todd M. Chapman, Jr.; John A. Ruder; R. Alden Milam; P. Bradley Segebarth; Leo R. Spector; Bruce V. Darden, II; Alfred L. Rhyne; Eric B. Laxer

Disclosures
• Neither I nor any member of my immediate family has a financial relationship or interest with any proprietary entity producing health care goods or services related to the content of this CME activity.
• My content will include reference to commercial products; however, generic and alternative products will be discussed whenever possible.
• I do not intend to discuss any unapproved or investigative use of commercial products or devices.

Advantages of Pedicle Screws
• Fixation
  – Immediate fixation
  – 3 dimensional control of vertebral level
  – Reduction of deformity
• Fusion
  – Higher fusion rates
• Outcomes
  – Improved with pedicle screw fixation
Biomechanical Considerations

- Goel et al. (Spine 1991)
  - 70% reduction in flexion/extension motion
  - 65% reduction in lateral bending/axial motion
- Lill et al. (J Spinal Disorders, 2000)
  - Pedicle screws backed out ½ turn (180 degrees) – pull out strength decreased 50%
- Barber et al. (J Spinal Disorders, 1998)
  - Convergent screws
    - Avoid adjacent facet joints
    - Allows for longer screws
    - 28.6% higher resistance to pullout compared to parallel screws

Depth of Insertion

- Pedicles – 60% of fixation strength – lumbar spine
- Increase in depth – from 50-80% of vertebral body – increased fixation – 30%
- Penetration of screws >80% vertebral body – 10 - 30% anterior body penetration
- Sacral bicortical fixation – increases fixation strength 90%
  (concerns: iliac vessels, L5 nerve root!)

Accuracy Matters…

- Kosmopoulos et al. (Spine 2007)
  - Freehand technique 90.3% accurate
  - Navigation group 95.2% accurate
- Tian and Xu (Int Orthop 2009)
  - CT-based navigation 90.76% accurate
  - Two-dimensional fluoroscopy 85.48% accurate
Mazor Accuracy

- Devito et al. (Spine J 2010)
  - 3271 implants in 14 centers
  - 98.3% accurate
  - 49% percutaneous implants
- Kantelhardt et al. (Eur Spine J 2011)
  - 94.5% robot assisted screws accurate
  - 91.4% conventionally placed screws accurate
  - 34 sec flouro per screw for robot vs 77 sec per screw conventional

OrthoCarolina Experience

- Mazor robot acquired and implemented in July 2015
- All surgeons participated in Mazor approved training prior to utilizing

Purpose

- Retrospectively review the accuracy, flouroscopy time, and acceptance of implants utilizing the Mazor robot
- Two institutions, 7 fellowship trained spine surgeons
Methods

- Type of surgery
  - Open – traditional pedicle screws
  - MIS – cortical screws, percutanous pedicle screws
- Failed registrations, aborted instrumentations, time of fluoroscopy
- Revision instrumentation/infections requiring operative treatment

Results

- Total Cases: 139
- Total Screws Implanted: 575
- Total Screws Not Implanted/Revised: 66
- Average fluoroscopy time per screw: 31 seconds
- Average time per level: 8 minutes
Results

Breakdown of all Non-executed screws

Conclusions

- Experience Matters!
  - Fluoroscopy time
  - Time per level
  - Aborted screws
- Percutaneous/MIS Cases
  - Less soft tissue interference
  - Increased utilization
Discussion

- Rate of implementation
- Primary vs revision cases
- Effect on education

Resources

Introduction

• Pedicle screw fixation in the cervicothoracic spine is challenging.
• Numerous anatomical challenges for proper placement exist.
  – Robotic and navigational systems are costly, not completely reliable
  – Conventional fluoroscopic imaging involves significant radiation exposure to the surgeon and patient.
  – An accurate and inexpensive alternative is needed.

• Patient-specific drill templates using 3-D printed drill templates may overcome these challenges
• 3-D printed drill templates are designed preoperatively through computed tomographic (CT) imaging and CAD based software to pre-plan optimal screw trajectories for each independent level.
• Patient specific drill templates may improve accuracy of pedicle screw placement
Study Purpose

The purpose of this biomechanical, cadaveric study was to assess the feasibility and accuracy of a pedicle screw placement using novel patient-specific drill templates in the cervico-thoracic spine.

Methods

• Two fresh cadaveric human cervical spines initially imaged by CT scan from C1 to T12
• Bone images exported in DICOM format to 3D imaging software (Ziostation, Ziosoft)
• Screw trajectories planned 3-dimensionally
  – Location, drill-guide and screw-guide templates printed for each screw trajectory

Methods

• Screw insertion
  – 3.5 mm screws inserted in each pedicle at each level
  – One exception: at C2 in one cadaver whose anatomy required laminar screw placement
  – accomplished without fluoroscopy for all seventy-six sites
• CT scanning post-implantation used to confirm accuracy
Methods

- Calibrated post-insertion screw accuracy quantitatively analyzed
- Screw deviation from center of pedicle in each anatomic plane evaluated

Post-op Computed Tomography
Methods

• Independent radiologist qualitatively assessed screw placements for safety

Miyamoto and Uno grading system

<table>
<thead>
<tr>
<th>Grade</th>
<th>Breach Distance</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0 mm</td>
<td>Screw completely within pedicle</td>
</tr>
<tr>
<td>1</td>
<td>&lt; 2 mm</td>
<td>Small breach of pedicle wall</td>
</tr>
<tr>
<td>2</td>
<td>&gt; 2 mm</td>
<td>Substantial breach with no neurological damage</td>
</tr>
<tr>
<td>3</td>
<td>Complication</td>
<td>Pedicle fracture, anterior breach with neurological or vascular compromise, lateral/medial breach with neurological sequelae</td>
</tr>
</tbody>
</table>

Methods

• Statistical Analysis
  – Data not-normally distributed
  – Kruskal-Wallis tests
  – Multivariable generalized estimating equations with Tukey adjusted least square means tests were used
    • to assess adjusted screw deviation
    • independent effects of region (cervical, thoracic), side, and placement grade

Results

Frequency and Percentage of Miyamoto and Uno Grade by Region

<table>
<thead>
<tr>
<th>Screw Site</th>
<th>Grade</th>
<th>N (%)</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>18 (64%)</td>
<td>89%</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>7 (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>3 (11%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>47 (98%)</td>
<td></td>
</tr>
<tr>
<td>Thoracic</td>
<td>1</td>
<td>1 (2%)</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>0 (0%)</td>
<td></td>
</tr>
</tbody>
</table>

Grade 0  Grade 1  Grade 2
Results

• No significant differences in screw deviation between region (p=.44), side (p=.12) or placement Grade (p=.41) in the coronal plane.

• Significant differences between Grade (p=.002) and region (p<.001) in the sagittal plane existed.

• The significant effect of region remained in the multivariable analysis. The adjusted mean screw deviation in the cervical region was -0.49 mm compared to 2.37 mm in the thoracic region (p=.007).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coronal Offset</th>
<th>Sagittal Offset</th>
<th>P-value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miyamoto and Uno Grade</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 0</td>
<td>0.13 (-.17-.62)</td>
<td>0.94 (-2.21.48)</td>
<td>0.408</td>
</tr>
<tr>
<td>Grade 1</td>
<td>-0.59 (1.04-1.49)</td>
<td>-0.98 (1.24-5.35)</td>
<td>0.025</td>
</tr>
<tr>
<td>Grade 2</td>
<td>-0.65 (1.7-2.31)</td>
<td>-1.04 (1.63-3.96)</td>
<td>0.002</td>
</tr>
<tr>
<td>Region</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cervical</td>
<td>0.43 (-0.59-1.045)</td>
<td>-0.74 (1.06-2.23)</td>
<td>0.444</td>
</tr>
<tr>
<td>Thoracic</td>
<td>0.09 (-.245-.46)</td>
<td>1.305 (775-1.74)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Side</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>-0.015 (-.5-.58)</td>
<td>0.415 (-.4-1.48)</td>
<td>0.119</td>
</tr>
<tr>
<td>Right</td>
<td>0.285 (-1.7-.15)</td>
<td>0.915 (-.57-1.45)</td>
<td>.751</td>
</tr>
</tbody>
</table>

Discussion

• Our results of greater than 92% of successfully placed screws compare favorably with series using navigation techniques.

• Only 2 screws showed Grade 2 perforations, thus a possible “critical breach.”

• Study limitations:
  – No comparative group
  – Instrumentation for screw insertion not “medical grade”
Conclusion

- With no perforations into spinal canal and greater than 92% accuracy, this patient-specific screw guide system is an encouraging technology for cervical and thoracic screw placement.
- The speed and ease of use as well as the lack of need for fluoroscopy make the screw guide technique an alternative to navigation.
- Further comparative research is needed.

Thank You

Charlotte, NC, USA

Methods

- Calibrated post-insertion screw accuracy quantitatively analyzed.
- Screw deviation from center of pedicle in each anatomic plane.
Is there value in retrospective 90-day bundle payment models for lumbar spine procedures?

Susan Odum, PhD
Bryce Van Doren, MPA, MPH
Leo Spector, MD

The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of Centers for Medicare & Medicaid Services. The authors assume responsibility for the accuracy and completeness of the information in this document.

Disclosures

• Susan Marie Odum, PhD (Charlotte, NC) Submitted on: 04/04/2017 American Association of Hip and Knee Surgeons: Board or committee member; Journal of Arthroplasty: Editorial or governing board
• Bryce Van Doren, MPH (Charlotte, NC) Submitted on: 01/13/2017 None
• Leo R Spector, MD (Charlotte, NC) Submitted on: 04/04/2017 Stryker: Paid consultant, Paid presenter or speaker

Introduction

• As healthcare shifts from volume to value, alternative payment models are being explored.
• Bundled payment models
  – alternative to traditional fee for service (FFS) models
  – conceptually align with value-based goals of improved outcomes at lower costs.
Introduction

- In 2013, under the Affordable Care Act, the Centers for Medicaid and Medicare Services (CMS) implemented the Bundled Payments for Care Improvement (BPCI) initiative.
- At our private practice we implemented a retrospective Model 2 with a 90-day postoperative period for several orthopedic procedures including lumbar spine fusion surgery.

Purpose

- The purpose of study was to assess the value of the BPCI model 2 for lumbar spine fusion at our private practice.
- We compared post-acute event rates and expenditures between patients who had surgery within a traditional FFS payment model to those within a BPCI payment model.
Methods: Data Source

- Utilized deidentified CMS claims data to obtain post-acute event rates & expenditures for lumbar fusion patients:
  - DRG 459 w/MCC
  - DRG 460 no/CC
- Traditional FFS – 323 patients had sx between 2009-2012
- BPCI – 177 patients had sx in 2015 (year 1 of BPCI)

Methods: Outcomes

- Post acute events:
  - Inpatient Rehabilitation Facility (IRF)
  - Skilled Nursing Facility (SNF)
  - Home Health (HH)
  - 90-day readmission
- Expenditures
  - Acute (hospitalization)
  - Post-acute (90-days post-op)
  - Total = Acute + Post-acute

Methods: Statistical Analysis

- Fisher’s Exact test - differences in post-acute event rates between BPCI and FFS
- All $ converted to 2016 $ with CPI. Expenditure data was not normally distributed
- Wilcoxon tests - differences in median expenditures between BPCI and FFS
- Multivariable GEE (regression model) - adjusted differences in log total expenditures between payment models and assess independent effects of post acute events
### Results: Post Acute Event Rates

#### IRF Admission

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPCI</td>
<td>3 (2%)</td>
<td>174 (98%)</td>
<td>.13</td>
</tr>
<tr>
<td>Traditional FFS</td>
<td>15 (5%)</td>
<td>308 (95%)</td>
<td></td>
</tr>
</tbody>
</table>

**Multivariable GEE**

IRF admission significantly associated with a 45% increase in total expenditure (95% CI: 33%, 56%; p<.0001).

#### SNF Admission

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPCI</td>
<td>60 (34%)</td>
<td>117 (66%)</td>
<td>.36</td>
</tr>
<tr>
<td>Traditional FFS</td>
<td>96 (30%)</td>
<td>227 (70%)</td>
<td></td>
</tr>
</tbody>
</table>

**Multivariable GEE**

SNF admission significantly associated with a 28% increase in total expenditure (95% CI: 24%, 33%; p<.0001).

#### Home Health Utilization

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPCI</td>
<td>95 (54%)</td>
<td>82 (46%)</td>
<td>.0085</td>
</tr>
<tr>
<td>Traditional FFS</td>
<td>133 (41%)</td>
<td>190 (59%)</td>
<td></td>
</tr>
</tbody>
</table>

**Multivariable GEE**

HH utilization significantly associated with a 10% increase in total expenditure (95% CI: 6%, 14%; p<.0001).
Results: Post Acute Event Rates

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPCI</td>
<td>17</td>
<td>160</td>
<td>.16</td>
</tr>
<tr>
<td>Traditional FFS</td>
<td>46</td>
<td>277</td>
<td></td>
</tr>
</tbody>
</table>

Multivariable GEE
90-day readmission significantly associated with a 43% increase in total expenditures (95% CI: 34%, 51%; p<.0001)

Results: Expenditures

Multivariable GEE
After adjusting for post-acute events, BPCI associated with a 3% increase in total expenditure (95% CI: -3%, 4%; p=.90)

Discussion

- In spite of our efforts, BPCI payment model was not associated with lower expenditures and improved outcomes.
- Study limitations
  - Retrospective, small sample size
  - Groups drawn from different time periods
  - Single center, private group, not generalizable
  - Clinical data not available for risk stratification
  - Expenditures not true cost
Conclusion

- Overall, our private practice was successful with BPCI
- We believe using DRGs for lumbar fusion bundles is not ideal due to the relatively high variability and low volume
- Future lumbar spine bundles should be designed by CPT code rather than DRG
- We have discontinued this BPCI for lumbar fusion

Thank you

We would like to thank:
- AAOS
- OrthoCarolina spine surgeons
- OrthoCarolina Research Institute
- Quality improvement team
- BPCI team led by Tim Pysell, DrHA, MMSc, PA-C, AT, DFAAPA and Stephen Freshly, RN