A Prospective Evaluation of Minimally Disruptive Lateral Interbody Fusion in the Treatment of Degenerative Spondylolisthesis: Mid-Term Clinical and Radiographic Outcomes

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Disclosures

- FDA off-label usage
  - rh-BMP2 (INFUSE, Medtronic Sofamor Danek)
  - CoRoent PEEK cage stand-alone (NuVasive, Inc.)
- NuVasive, Inc.
  - Consultant
  - Honoraria
  - Travel
Degenerative spondylolisthesis is a common cause of LBP & disability in older adults, and surgical treatment can be beneficial.

Modern minimally-disruptive lateral lumbar IBF techniques may minimize the morbidity of conventional surgical approaches.

Long-term clinical and radiographic outcomes, as well as patient satisfaction, are less well understood.
Methods

Study Overview

- Study Design
  - Prospective registry (ProSTOS, PhDx)
  - Retrospective review

- Inclusion Criteria
  - Consecutive patients treated 2006-2011
  - Grade 1 or 2 spondylolisthesis
  - Treated with 1- or 2-level MI lateral IBF
  - Available for long-term follow-up
Methods

Patient Sample

- Sample size \( n = 60 \)
- Characteristics
  - Age (years) \( 64.5 \) (range 48 – 81)
  - BMI \( 29.1 \) (range 20.3 – 39.8)
  - Female 75%
  - Tobacco use 40%
- Primary type
  - Degenerative 46 (77%)
  - PLS Instability 14 (23%)
## Methods

### Patient Sample

<table>
<thead>
<tr>
<th>Comorbidities</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Hypertension</td>
<td>58.3%</td>
</tr>
<tr>
<td>• GERD</td>
<td>35.0%</td>
</tr>
<tr>
<td>• High cholesterol</td>
<td>31.7%</td>
</tr>
<tr>
<td>• Diabetes</td>
<td>21.7%</td>
</tr>
<tr>
<td>• Depression</td>
<td>13.3%</td>
</tr>
</tbody>
</table>

Mean 3.15 per patient

<table>
<thead>
<tr>
<th>Conservative Treatments</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Physical Therapy</td>
<td>91.7%</td>
</tr>
<tr>
<td>• Pain Mgmt./EIS</td>
<td>66.7%</td>
</tr>
<tr>
<td>• Exercise Program</td>
<td>46.7%</td>
</tr>
<tr>
<td>• Chiropractic</td>
<td>35.0%</td>
</tr>
<tr>
<td>• Other</td>
<td>20.0%</td>
</tr>
</tbody>
</table>

Obesity not considered a comorbidity.
Methods

Treatment Summary

- Fusion
  - Total disc levels treated (11 two-levels)  71
- Posterior
  - Decompression  26 (43%)
  - Supplemental posterior percutaneous pedicle screw / rod fixation  57 (95%)
- rh-BMP2 used in all cases
Methods

Analysis

- Clinical Outcomes
  - ODI
  - VAS (back & leg)
  - SF-36 (PCS & MCS)

- Radiographic Measurements
  - Disc height
  - Foraminal height & width
  - Segmental lordosis
  - Slip percent & grade

- Analysis
  - One-way ANOVA
  - Significance accepted for $p \leq 0.05$
Results

Last Follow-Up

- Mean follow-up: 17.4 months
Results

Surgical Summary

**OR Time**
- <2 hrs: 5%
- 2-3 hrs: 25%
- 3-4 hrs: 37%
- >4 hrs: 33%

**Length of Stay**
- 1 day: 77%
- 2 days: 15%
- >2 days: 7%

**EBL**
- 0-25cc: 12%
- 26-50cc: 37%
- 51-100cc: 47%
- >100cc: 5%

**Means**
- OR Time: 206 minutes
- EBL: 83 mL
- LOS: 1.29 days
Results

Adverse Events

- Complications 3 (5.0%)
  - Myocardial infarction 1
  - Urinary retention 1
  - Delayed DF weakness 1

- Side Effects 5 (8.3%)
  - Thigh sensory 3
  - Hip flexion weakness 2

All resolved (10d-6 mo)
Results
Radiographic

Disc Height

Last Follow-Up
71.2% Improvement

Segmental Lordosis

Last Follow-Up
27.8% Improvement
Results
Radiographic

Last Follow-Up
69.1% Improvement

Last Follow-Up
68.0% Improvement
Results
Radiographic

Foraminal Height

Foraminal Width

Foraminal Cross-Sectional Area

Improvement at Last Follow-Up

Height: 19.7%
Width: 18.0%
Area: 39.6%
Results
Clinical

ODI

12 MO
52.5% Improvement
(p<0.001)

Pre-op 1 Mo 3 Mo 6 Mo 12 Mo

43.2 37.0 26.0 24.1 20.5
Results
Clinical

VAS LBP

12 MO
73.7% Improvement
(p<0.001)

VAS Leg

12 MO
66.2% Improvement
(p<0.001)
Results

Clinical

SF-36 PCS

12 MO
41.7% Improvement
(p<0.001)

SF-36 MCS

12 MO
19.2% Improvement
(p=0.003)
Results
Patient Satisfaction

How satisfied are you with your surgical outcome?

- Very satisfied: 66%
- Somewhat satisfied: 31%
- Don't know: 3%

Given your current condition, would you elect to have the same surgery again?

- Definitely would: 68%
- Probably would: 19%
- Wouldn't: 2%
- Don't know: 11%
Case Example
Patient 1

- **History**
  - 55 year-old female
  - Presented with LBP & right anterolateral leg pain
  - Previous L4-5 laminectomy

- **Outcome (12 months PO)**
  - VAS LBP: 8 → 3
  - VAS Leg: 10 → 2
  - ODI: 60 → 30
  - SF-36 PCS: 28.4 → 36.9
  - SF-36 MCS: 37.7 → 49.9
Case Example
Patient 2

History
- 58 year-old male
- Presented with LBP & bilateral leg pain
- Previous L4-S1 decompression (x3)

Outcome (12 months PO)
- VAS LBP: 9 → 1
- VAS Leg: 9 → 1
- ODI: 32 → 0
- SF-36 PCS: 31.7 → 55.2
- SF-36 MCS: 34.5 → 40.2
Case Example
Patient 3

• History
  o 77 year-old female
  o Presented with LBP & bilateral leg pain
  o No previous lumbar surgery

• Outcome (12 months PO)
  o VAS LBP: 8 → 1
  o VAS Leg: 6 → 1
  o ODI: 32 → 20
  o SF-36 PCS: 40.1 → 40.2
  o SF-36 MCS: 29.2 → 35.9
Discussion
Clinical Outcomes

- Statistically significant changes do not necessarily translate to significant improvement in clinical practice, and vice versa
- Problems with patient-reported outcomes
  - Actual state of health v. expectations
  - Recall bias
  - External factors
- Determinations of “successful outcome”
  - Minimal clinically important difference (MCID)
  - Substantial clinical benefit (SCB)
Discussion

MCID

- Operational definition
  - Minimal amount of patient reported change, and
  - Value significant enough to change patient management

- MCID in lumbar spine surgery
  - ODI: net 12.8 points
  - VAS LBP: net 1.2 points
  - VAS Leg: net 1.6 points
  - SF-36 PCS: net 4.9 points
Discussion
Substantial Clinical Benefit

- Magnitude of health-related quality-of-life improvement that a patient recognizes as a substantial benefit

- SCB in lumbar arthrodesis
  - ODI: 36.8% improvement, net 18.8 points, or final <31.3 points
  - VAS LBP: 41.4% improvement, net 2.5 points, or final <3.5 points
  - VAS Leg: 38.8% improvement, net 2.5 points, or final <3.5 points
  - SF-36 PCS: 19.4% improvement, net 6.2 points, or final ≥ 35.1 points
## Discussion

**MCID & SCB**

<table>
<thead>
<tr>
<th>Clinical Outcome</th>
<th>Patients Reaching MCID (%)</th>
<th>Patients Reaching SCB (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS LBP</td>
<td>91.5%</td>
<td>94.7%</td>
</tr>
<tr>
<td>VAS LP</td>
<td>81.7%</td>
<td>84.6%</td>
</tr>
<tr>
<td>ODI</td>
<td>83.3%</td>
<td>83.7%</td>
</tr>
<tr>
<td>SF-36 PCS</td>
<td>85.7%</td>
<td>66.7%</td>
</tr>
</tbody>
</table>
Discussion

Previous Studies

- Our results compared favorably with other published studies

- Comparable published papers on open approaches were difficult to find

- Lauber et al., Clinical and Radiologic 2-4 Year Results of Transforaminal Lumbar Interbody Fusion in Degenerative and Isthmic Spondylolisthesis Grades 1 and 2, *Spine* 2006; 31:1693-98.
  - Slip reduction: 23% to 15% (35% improvement)
  - ODI: 28 to 20 at 12 months (29% reduction)
  - VAS: 8.1 to 5.2 (36% reduction)
Conclusions

- Compared to conventional approaches, the minimally disruptive lateral approach for IBF resulted in:
  - Few complications with shortened postoperative recovery
  - Excellent mid-term clinical outcomes, with significant and maintained improvements on pain, disability, and QOL
  - Radiographic measures significantly improved and maintained over mid-term follow-up
- Lateral MIS fusion appears to be a safe and effective treatment for spondylolisthesis.
Thank you!
Damage to back muscles may result in long term pain & disability

↑ operative time, pain, blood loss
Disadvantages of Traditional TLIF / PLIF

- Limited access to the disc space
  - Suboptimal disc removal, implant size
  - Risk of nerve root injury, CSF leak
- Cage in weakest part of endplate
- Very difficult to restore lordosis
  - May result in flat back
- Painful, prolonged muscle retraction, ↑ blood loss
- Damage to paraspinal muscles may lead to chronic pain and disability
Alternatives

- Minimally Invasive TLIF / PLIF
  - Technically difficult
  - Does not address all the issues

- ALIF
  - Avoids most of the disadvantages of a posterior approach
  - More complete discectomy
  - Better correction of spinal alignment
  - But risks injury to vascular / peritoneal contents, retrograde ejaculation, usually requires an approach surgeon
Introduction
MI Lateral IBF

- Lateral ALIF
  - Lumbar fusion through small flank incision
- Truly minimally invasive
  - Less post-operative pain and morbidity
  - Avoids problems of posterior approaches