Outpatient Minimally Invasive TLIFs with Stand-Alone Expandable Interbody Devices

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Education & Training

- Seattle University, School of Law, J.D., May 2011
- University of Washington, School of Business, MBA, 1997
- University of Washington, Dept. of Neurological Surgery, Chief Resident & Acting Instructor 1983
- National Hospital, Queen Square, London, England, Fellowship in Neuroradiology, 1980
- Yale University, School of Medicine, M.D., 1977
- Harvard College, A.B., 1973

Professional Experience - Abbreviated

- Founder, Managing Partner & Neurosurgeon, Neospine, 1983- Present
- Special Consultant for Spine Surgery, Symbion and Surgery Partners, 2008 - Present
- Chief Medical Officer, angelMD, 2014 – present
- Aqueduct Technologies, Board of Directors, 2013 - present
- Founder and Board Chairman, Neospine, LLC, 2001 – 2008
- U.S. Radiosurgery, Board of Directors, 2008 - 2012
- Ranier Technology Ltd., Scientific Advisory Board, 2006 - 2015
Disclosures

Consultant

- LDR, MIS Interspinous Fusion Device, Outpatient Arthroplasties
- Medtronic, Streamlined Design Systems
- Nuvasive, Health Care Policy
- Synthes, Outpatient Spine Surgery Strategies
- Spineology
- Wenzel, MIS TLIF
- Stryker
Back Pain

- Back pain is the leading cause of disability in Americans under 45 years old. More than 26 million Americans between the ages of 20-64 experience frequent back pain.

- Nearly two-thirds of Americans experience low back pain, but 37 percent do not seek professional help for pain relief.

- Back pain is the #1 cause of healthcare expenditures in the U.S.
  - Direct cost of over $80 billion for diagnosis, treatment, and rehabilitation.

National Center for Health Statistics Report
Cause of Back Pain

- Break in bony ring of vertebra
- Forward slippage
- Spondylolisthesis
- Normal disc
- Degenerative disc
- Bulging disc
- Herniated disc
- Thinning disc
Improved Surgical Treatment

Transforaminal Lumbar Interbody Fusion (TLIF)

- Refinement of the PLIF procedure
- Generally less traumatic to the spine
- Safer for the nerves
- Allows for minimal access and endoscopic techniques
- Disc space repair with bone graft and cages, screws, rods

We currently use many state-of-the-art cage technologies including those made of bone, titanium, polymer, and even bioresorbable materials.
Outpatient TLIF & ASC Benefits

• Improved Clinical Outcomes
  o Less blood loss
  o Lower infection rate
  o Less reported patient pain
  o Quicker ambulation and return to work

• Overall lower costs for minimally invasive procedures

Source: Accelero Health Partners 2015
ASC & Spine Surgery

Medicare added new spine codes to its final 2015 Ambulatory Surgery Center (ASC) payment rules. Those codes are:

- 22612 Lumbar spine fusion
- 22614 Spine fusion extra segment
- 63030 Low back disk surgery
- 63042 Laminotomy single lumbar
- 63044 Laminotomy, additional lumbar
- 63047 Removal of spinal lamina - lumbar
- 63056 Decompress spinal cord

Source: Centers for Medicare and Medicaid Services
# Minimally Invasive Current Processes

- **Tubular Retractors**

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimizes surgical dissection and exposure</td>
<td>Increased length of surgery</td>
</tr>
<tr>
<td>Allows for smaller incision, particularly among obese</td>
<td>Sometimes less ability to thoroughly decompress spine</td>
</tr>
<tr>
<td>Hardware and fusion can be performed</td>
<td>Limited bone graft for spinal fusion</td>
</tr>
</tbody>
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![Tubular Retractor System](image)

Titanium MIS Retractor System with 14, 16, 18mm Tubular Retractors & Dilators
### Pedicle Screws

<table>
<thead>
<tr>
<th>Advantages</th>
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<tr>
<td>- Rigidly stabilizes ventral and dorsal aspects of spine</td>
<td>- Caudal or medial penetration can result in dural or neural injury</td>
</tr>
<tr>
<td>- Allows for fewer normal motion segments to achieve stabilization of abnormal level</td>
<td>- Requires extensive tissue dissection</td>
</tr>
<tr>
<td>- ~60-90% fusion rate</td>
<td>- Rigid fixation accelerates ASD</td>
</tr>
<tr>
<td>- 1 in 1000 breakage rate</td>
<td>- 5-10% require removal due to pain</td>
</tr>
<tr>
<td>- 1 in 1000 nerve root damage</td>
<td>- Noted paraspinal muscle damage with postoperative muscle fibrosis</td>
</tr>
<tr>
<td>- 2-3% infection risk</td>
<td>- Increased muscle and facet joint denervation</td>
</tr>
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</table>

- CAPLOX II
- Nuvasive
- Easyspine
- Solera
Minimally Invasive Current Processes

- **Mini Open Cortical Screws**

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<thead>
<tr>
<th>Advantages</th>
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<tr>
<td>• Improved trajectory that avoids spinal canal injury</td>
<td>• Technically challenging</td>
</tr>
<tr>
<td>• Reduces overall stress of the cortical bone</td>
<td>• Screw misplacement ranges from 6-40%</td>
</tr>
<tr>
<td>• Improved results in the sacral region (more cancellous bone)</td>
<td>• Potential injury:</td>
</tr>
<tr>
<td>• Use of K wires not required</td>
<td>• Spinal canal penetration</td>
</tr>
<tr>
<td></td>
<td>• Neural elements caused by medially misdirected screws</td>
</tr>
<tr>
<td></td>
<td>• Vascular injuries by laterally misdirected screws</td>
</tr>
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</table>

- Spineology Capture
- Medtronic Cortical Screws
- Depuy Viper
Minimally Invasive Current Processes

- Interspinous Process Clamps

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<tr>
<td>• Achieves rigid spinal fixation</td>
<td></td>
</tr>
<tr>
<td>• Reduces stress at adjacent levels</td>
<td></td>
</tr>
<tr>
<td>• Advantage with Stenosis or Grade I Spondylolisthesis</td>
<td></td>
</tr>
<tr>
<td>• May require supplemental fixation</td>
<td></td>
</tr>
<tr>
<td>• Higher reoperation rates (short-term use vs long-term use)</td>
<td></td>
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Images of interspinous process devices:
- Aspen
- Coflex
- InterBRIDGE Interspinous Fixation System
- Promise-F Minimal Invasive Lumbar Fusion System
Minimally Invasive Current Processes

• Interbody Implants

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<tr>
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<tr>
<td>• Direct neurological decompression</td>
<td>• Requires Supplemental Fixation</td>
</tr>
<tr>
<td>• Correction of coronal and sagittal plane deformity</td>
<td>Contraindicated for:</td>
</tr>
<tr>
<td>• Restoration of foraminal height</td>
<td>• Severe osteoporosis</td>
</tr>
<tr>
<td>• &gt;90% fusion rate</td>
<td>Anomalous neural anatomy; i.e. conjoined nerve root</td>
</tr>
<tr>
<td></td>
<td>• Severe fixed kyphosis</td>
</tr>
<tr>
<td></td>
<td>• Irreducible high-grade spondylolisthesis</td>
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Contraindicated for:
- Severe osteoporosis
- Anomalous neural anatomy; i.e. conjoined nerve root
- Severe fixed kyphosis
- Irreducible high-grade spondylolisthesis

Globus Caliber
BENVENUE Luna
Nuvasive XLIF
Medtronic Capstone
Minimally Invasive Current Processes

- Expandable **Stand-Alone** Interbody Implants

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<td>• &gt;90% fusion rate</td>
<td>• Severe fixed kyphosis</td>
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<td>• Typical incision length 2”</td>
<td>• Irreducible high-grade spondylolisthesis</td>
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<tr>
<td>• No supplemental fixation needed</td>
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Contraindicated for:
- Severe osteoporosis
- Anomalous neural anatomy; i.e. conjoined nerve root
- Severe fixed kyphosis
- Irreducible high-grade spondylolisthesis
ASC Adequate Patient Selection for Stand-Alone Interbody Fusion

• First Surgery at the Index Level

• Eligible Diagnosis:
  o Degenerative disc disease (DDD)
  o Grade I spondylolisthesis
  o Unilateral, bilateral, or central disc herniation

• Chronically-ill patients:
  o Is not immunologically suppressed or receiving steroid for chronic conditions
  o Has a stable HbA1C <7.0 for diagnosis of diabetes or insulin-dependent diabetes
Case Study Summary: XLIF

45-year-old, Caucasian female, who presented with iatrogenic facet disruption at L3-L4, disc degeneration at L3-L4, and iatrogenic pars defect at L3–left. The patient underwent an XLIF at L3-L4 with percutaneous pedicle screw instrumentation left side L3-L4.
Case Study Summary: ALIF

This is a 32-year-old female who presents with a 13-year history of progressive low back pain. Lumbar radiculitis; severe DDD at L5-S1; failure to respond to conservative measures. L5-S1 ALIF with PEEK cage and anterior plate. Posterior L5-S1 fusion L5-S1 with Aspen interspinous posterior instrumentation.
A 68-year-old woman showing spondylolytic spondylolisthesis at L4-5. MRI (A and B) and myelography (C) showing spondylolisthesis and stenosis at L4-5. Surgery performed was OLIF and percutaneous pedicle screws without posterior decompression.
Case Study Summary: VariLift

9 Current Stand-Alone Cases

Average VAS Pain Score

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<tr>
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<th>Preop</th>
<th>6 mo Post Op</th>
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<tr>
<td>Score</td>
<td>9</td>
<td>2</td>
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Average Patient Age: 54 (4 Male/5 Female)

Initial Diagnosis:
- Degenerative Disc Disease
- Spondylosis w/Radiculopathy
- Recurrent Disc Herniation

Surgical Intervention: TLIF
AVG Surgical Time: 123 minutes
AVG EBL: <50ml (minimal)

LOS: <23 hours

At 6 months: Fusion almost complete or In progress
Supplemental Fixation vs Stand-Alone

Grade I Spondylolisthesis at L4-L5

2 week follow-up

Grade I spondylolisthesis and severe disc space narrowing at L4-5

6 month follow-up with solid fusion
References


