MIS Procedure: Potential Clinical Benefits

• Blood loss was significantly lower for MIS fusion\(^1\text{-}^2\)
• MIS lumbar fusion associated with less postoperative pain (in two of three prospective studies)\(^2\)
• Rates of complications showed favoring trend towards MIS\(^3\)
• Fusion rates comparable for open and MIS approaches\(^4\)
**MIS Procedure: Potential Economical Benefits**

- MIS procedure has been shown to reduce length of stay (ranging from 4 to 9 days versus 7 to 13) \(^1\)\(^-\)\(^2\)
- MIS lumbar fusion has been shown to reduce hospital costs \(^3\)

**Noteworthy Inhibitor:**
- Operating room time was higher for MIS lumbar fusion \(^1\)\(^-\)\(^2\)
  *New procedure with new technology presents learning curve*

Length of Hospital Stay: MIS vs. Open \(^1\)\(^-\)\(^2\)
The Lateral Access Market continues to exhibit strong, double digit growth.
Lateral Approach: Potential Clinical Benefits

- Decreases tissue disruption when compared with open approaches to lumbar fusion \(^1,2\)
- Lateral interbody fusion may reduce intraoperative blood loss when compared to open interbody fusion \(^3\)
- An Access surgeon may not be needed
- Lateral approach allows for better access to concave side in patients with secondary DDD deformity
Lateral Approach: Potential Clinical Benefits

- Less traumatic soft tissue and muscle damage
- Limits or reduces potential risk for vascular injuries
- A.L.L is kept intact during procedure
  (In comparison to an Anterior Lumbar Interbody Fusion)
- Can reach multiple levels through one incision
- Does not disrupt posterior musculature or ligamentous structure
  (In comparison to a Posterior or Transforaminal Lumbar Interbody Fusion)
Lateral Approach: Potential Economic Benefits

• Mean Hospital Length of Stay ranged from 1.24 days to 5 days in reviewed studies ³
• DePuy Spine’s system platform may be used with hospital’s existing neuromonitoring system ⁴
  (This could potentially reduce procedural costs by using integrated equipment)

Noteworthy Inhibitor:

• The potential for nerve damage ³
• Use of “Reverse” table positioning to access the spine laterally
1. Peng CW, Yue WM, Poh SY, Yeo W, Tan SB. Clinical and radiological outcomes of minimally invasive versus open transforaminal lumbar interbody fusion. Spine (Phila PA 1976) 2009; 34:1385-9

2. Shunwu F, Xing Z, Fengdong Z, Xiangqian F. Minimally invasive transforaminal lumbar interbody fusion for the treatment of degenerative lumbar diseases. Spine (Phila Pa 1976);35: 1615-20

3. McGirt MJ, Parker S, Lerner J, Engelhart L, Wang MY. Comparative analysis of surgical site infection after minimally invasive open posterior/transforaminal lumbar interbody fusion: analysis of hospital billing and discharge data from 5328 patients. Neurosurgery. 2010;67(2):(908).

4. Wu RH, Fraser JF, Hartl R. Minimal Access Versus Open Transforaminal Lumbar Interbody Fusion: Meta-Analysis of Fusion Rates. Spine (Phila Pa 1976)

5. Wang MY, Lerner JH, Lesko J, McGirt MJ. Acute Hospitalization Costs Following Minimally Invasive Versus Open Lumbar Interbody Fusion: Data From a US National Database With 6106 Patients. www.neurosurgery-online.com; August 2010; 67; 544.
DePuy Spine Inc.

- Provides solutions designed to improve efficiency and treatment flexibility for a better patient experience

- High quality products with a track record of successful performance

- Ensuring medical education with high quality product or technical support to meet the challenge of constant change and innovation
Integrated products designed to work together for complete procedural solutions:
- Microdiscectomy & Decompression
- Degenerative Procedures
  - TLIF, Lateral, ALIF, and PLIF
- Complex Procedures
  - Trauma, Adult and AIS Deformity, Tumor
- Mini-Open Procedures

Versatile Systems capable of adapting to varying surgeon needs & approaches
- Adaptable systems across product lines
- Intuitive products that are easy to use without a significant change to the surgeon’s technique
Meeting the Challenges of the Dynamic Spine Market

• Invest in R&D to identify solutions to fill unmet needs

• Provide leadership in the spine community to meet some of the most important issues of our time

• Harnessing the resources, portfolio and commitment to continue to provide the right products for the right patient at the right time
DePuy Spine’s Focus on MIS

**Standard open approach to fusion may result in**:¹

**MIS approach to fusion can**:

- **Significant muscle trauma and blood loss**
- **Elevated post-op pain**
- **Increased hospital LOS**
- **Lower blood loss**²⁻⁴
- **Lower OR, lab, and pharmacy costs**⁶
- **Mitigate post-op infection**⁵
- **Reduce hospital LOS**²⁻⁴
- **Reduce post-op pain (less morphine, rapid time to ambulations)**²⁻⁴

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¹. Hu SS. Blood loss in adult spinal surgery. *Eur Spine J.* 2004;13 Suppl 1:S3-S5.
². Peng CW, Yue WM, Poh SY, Yeo W, Tan SB. Clinical and radiological outcomes of minimally invasive versus open transforaminal lumbar interbody fusion. *Spine (Phila Pa 1976).* 2009;34:1385-1389.
³. Schizas C, Tzimieris N, Tsiors E, Kosmopoulos V. Minimally invasive versus open transforaminal lumbar interbody fusion: evaluating initial experience. *Int Orthop.* 2009;33:1683-1688.
⁴. Shunwu F, Xing Z, Fengdong Z, Xiangqian F. Minimally invasive transforaminal lumbar interbody fusion for the treatment of degenerative lumbar diseases. *Spine (Phila Pa 1976).* 35:1015-1020.
⁵. McGirt NJ, Parker S, Lerner J, Engelhart L, Wang MY. Comparative analysis of surgical site infection after minimally invasive open posterior/transforaminal lumbar interbody fusion: analysis of hospital billing and discharge data from 5328 patients. *Neurosurgery.* 2010;67(2):908.
⁶. Acute Hospitalization Costs Following Minimally Invasive Versus Open Lumbar Interbody Fusion: Data From a US National Database With 6106 Patients. Data on file. DS, Inc.
DePuy Spine MIS Timeline

2005

2006

2007

2008

2009

2010

2011

Pipeline L.S
Lateral Cage System

Viper 2.

Viper

3D MIS Correction Set

Concorde Bullet
F2 Transfacet Pedicular System

Spotlight

Expedium Spine System

Bullet Viper

Semi-Constrained Screw
MIS Product Offerings

Access

Posterior Fixation

Vertebral Body Augmentation

Interbody Instrumentation

SPOTLIGHT

PIPEDLINE

PIPEDLINE L.S

VIPER.

VIPER

VIPER.

3D MIS Correction Set

F2 Transfacet Pedicular System

CONFIDENCE

COUGAR L.S

CONCORDE BULLET
• Minimally invasive retraction system
  • Designed for TLIF & PLIF procedures as well as decompression
• Offers flexibility in order to adjust to a variety of conditions
• Complements supporting MIS instruments
Features & Benefits

Micro Adjustability
• Cephalad-Caudal expansion- allows up to a 2 level procedure
• Medial-Lateral expansion
• Telescoping blades allows for blade depth adjustment & prevents muscle creep
• Ratchet Grooves & Release Buttons for intraoperative adjustments

Minimal Trauma with Maximum Access
• Curved Racks to increase visualization
• 19 mm Inner Diameter to minimize muscle trauma

Universal Attachments
• Universal Connection slots compatible with other systems
• Adjustable Light Source
• Rigid Arm

Click here for Competitive Selling Strategies.
An access device for Lateral Minimally Invasive procedures

Independent blades for controlled distal expansion

Innovative 3 blade design provides clear visibility

• Telescoping feature allows for intraoperative blade depth adjustment to conform to anatomy and prevent muscle creep

• Toeing capability allows for expansion in the working area rather than at the skin level

Radiolucent retractor top allows for visualization during lateral cage placement
Features & Benefits

Three piece instrument allows for simple assembly

**Two universal attachment slots posterior and anterior to provide fixation**
- Rigid Arm attachment to hold the retractor in place

**Blade depth tower to measure the depth of the instrument**

**Anterior blade option to prevent muscle creep through the anterior side of the retractor**
• **Premier tubular access system**
  • Allows surgeons to perform MIS procedures safely and reliably

• **360 degrees of illumination to eliminate shadows**

• **Integrated light source**
  • Can be used as either an enhancement or replacement to an alternative light source

• **Reusable**
  • Results in cost saving
Features & Benefits

Set of 58 Microdiscectomy

- Provides optimal functionality

Five port diameters

- 12mm, 15mm, 18mm, 21mm, and 24mm
- Able to accommodate a variety of surgical preferences & procedures

Straight and anatomic configurations

- Contoured to fit the cervical, thoracic, and lumbar spine
- Reduces muscle creep
**Updated Retractors**

- Self-dilating or Wiltse Plane
- Adjustable, full P/L access
- “Belt & Suspenders” to back up lateral
- Multi-pathology applications

**MIS P/L Fusion Instruments**

- Quick and easy decortication
- Designed for port/ retractor use
- Cannulated for guidewire insertion

*Pending F.D.A. submission*
MIS Product Offerings

**Access**
- SPOTLIGHT
- PIPLNE
- PIPLNE L5

**Vertebral Body Augmentation**
- Conﬁdence

**Posterior Fixation**
- VIPER 3D MIS Correction Set
- VIPER F2 Transfacet Pedicular System

**Interbody Instrumentation**
- COUGAR L5
- CONCORDE BULLET
• Minimally Invasive Screw and Rod system
• Free hand Rod insertion
• Streamlined work flow during surgical procedures
• Introduced to enhance the ability to treat trauma and lumbar degenerative cases
• Innovative X-tab screws with built in reduction
• Longer rod options with straight or kyphosed available
• Intraoperative adaptability
Features & Benefits

Designed to make Lumber Degenerative cases easier

- Simple, strong screw extensions
- Better compression & distraction than VIPER® Minimally Invasive Pedicle system
- Improved Pedicle Preparation instruments from original VIPER®

Complex MIS Cases become possible

- Large extension slots allow unlimited rod possibilities
- Specialized multi-level rod holder
- Powerful and intuitive rod reduction options
- Intraoperative adaptability

Click here for Competitive Selling Strategies.
Extended Tab Screws

- A novel Minimally Invasive screw
- A device with an integrated extension and no assembly needed
- Built-in threaded reduction
- Low profile which helps to reduce crowding from L5 to S1
Additional instrumentation to treat complex pathologies less invasively

- Set of instruments & implants designed for complex pathologies
- Built upon and fully compatible with VIPER®2 Minimally Invasive Pedicle system
- Brings the benefits of Minimally Invasive Surgery to more patients

3D MIS Correction Set
Three Dimensional Correction of the Spine

Potential Clinical Applications
- Adult Degenerative Deformity
- Idiopathic Scoliosis
- High grade Spondylolithesis
- Multi-level Trauma

Click here for Competitive Selling Strategies.
F2 Transfacet Pedicular System

- **Transfacet Pedicular screw for rigid fixation**
  - Trajectory of the screw enters through the facet joint and into the pedicle
  - Innovative technology to improve the technique and ability of facet screws
  - Fixation in the pedicle to help ensure the screws hold over time

- **Commonly used for simple degenerative cases**

- **One midline incision for bilateral facet fixation & compression**

- **Alternative for Screw/ Rod system**
  - Two facet screws versus the use of four screws, two rods and four set screws
Features & Benefits

**Aiding in ease & time of MIS procedure**
- Reducing the amount of devices implanted
- Streamlined set of instruments in simple tray
- **Sterile-packed Implants**

**Proper anatomic implant to fit varying patient anatomy**
- Variety of sizes available
- Separate screw and washer to customize the device needed
- Largest washer on the market
- Mobile washer allows ease of insertion
- Innovative polyaxial washer fixates on facet for maximum stabilization & improved compression
MIS Product Offerings

Access

Posterior Fixation

Vertebral Body Augmentation

Interbody Instrumentation
• Designed for MIS posterior lumbar placement
  • TLIF and PLIF Procedures

• Only CFRP MIS Implant System on market

• Patented 35° angle and unique lordotic option for oblique (TLIF) Placement

• Sturdy Self-distracting bullet tip
Features & Benefits

**Innovative Self-distracting “bullet tip”**
- Easier to insert
- Significantly lowers maximum insertion force

**Pyramidal Teeth**
- Improved resistance to migration
- Significantly less movement towards anterior

**Available in a variety of sizing options**
- Matches patient anatomy
- Lordotic options available
- 1mm height increments

*Data on file*
Lateral Cage System

Carbon Fiber Reinforced Polymer material

- Two times the strength of pure PEEK*

Bulleted nose for streamlined insertion

Pyramidal Teeth provide resistance to migration

Radiolucent Cage with tantalum wire markers

- Allows visualization of cage during placement

*Data on file
### Lateral Cage System

- **Degrees of lordosis available to restore sagittal plane alignment**
- **Offers a variety of sizing options to fit a variety of patient anatomy**

| Dimensions | Parallel Cages | Lordotic Cages (7.5°) |
|------------|----------------|-----------------------|
| Height     | 6mm – 16mm (Even sizes only) | 7mm – 16mm (Even sizes only) |
| Width      | 15mm, 18mm, 21mm | 15mm, 18mm, 21mm |
| Length     | 30mm – 55mm (5mm increments) | 30mm – 55mm (5mm increments) |
MIS Product Offerings

Access
- SPOTLIGHT
- PIPELINE
- PIPELINE L.S

Posterior Fixation
- VIPER
- Viper
- F2 Transfacet Pedicular System

Vertebral Body Augmentation
- Confidence

Interbody Instrumentation
- Cougar L.S
- Concorde Bullet
Ultra High Viscosity Cement

- **Reaches doughy consistency immediately after mixing**
  - Improves delivery control by enabling precise placement
  - Reduces wait time between mixing and placing the cement

- **8 to 10 minutes of working procedure time after mixing the cement**

- **Polymethylmethacrylate formula (PMMA)**
  - Radiopaque: 30% barium sulfate by weight
OSSEOFLEX™ Steerable Needle

Vertebral Body Augmentation

- Delivery device for a minimally invasive surgery with or without cavity creation
- Novel system to repair vertebral compression fractures
- Creates a void within the vertebral body
  Disrupts cancellous bone by steering & channeling through the bone
- Polymeric bone cement fills the void
**Features & Benefits: OSSEOFLEX™**

**Steerable and Curveable Needle**
- 100 degree angle feature
- Allows for direct and precise insertion

**Unique distal tip design**
- Drive through the bone easily
- Delivery port located on the side of the tip to prevent bone fragment & tissue from entering needle

**Can result in lower costs than kyphoplasty**

**Low cement extravasation rates**

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*Lerner J, Engelhart J, Kozma C, Slaton T. Cost minimization analysis: Vertebroplasty versus kyphoplasty for treatment of osteoporotic vertebral compression fractures. Poster presented at ISPOR 15th Annual Meeting, Atlanta, USA, May 18, 2010.*
Pathologies & Case Studies

Degenerative Disc Disease Cases
- Lateral Approach
- Spondylolthesis Lateral
- Spondylolthesis TLIF
- Spondylolthesis

Trauma Cases
- Thoracic Fractures
- Burst Lumbar Fractures
- Complex Fractures

Tumor Cases
- Spinal Tumor

Deformity Cases
- Scoliosis
- Stenosis with Facet Screws
Degenerative Disc Disease: Lateral Approach

Case Details & Pre-op Information

- 78 year old male
- 5 years post-trauma
- DDD L3 to L4 with significant Modic changes
- Plus analgesic discogram (100% pain relief)
- L3 to L4 was the only pain generator
- Foraminal stenosis
- Difficult to address with Transforaminal Lumber Interbody Fusion

* Dr. Kornelis Poelstra MD. PhD.
Degenerative Disc Disease: Lateral Approach

Approach for Treatment

- Lateral interbody Fusion at L3- MIS Lateral Platform L4 using DePuy MIS Lateral Platform
- Supported spine with VIPER™ 2 Spine System posteriorly
- Patient’s resulting hospital stay was 1 day

Two Months Post-Op
- 100% pain free
- Can mow the lawn for 90 minutes

* Dr. Kornelis Poelstra MD. PhD.
Degenerative Disc Disease: Spondylololithesis

Case Details & Pre-op Information

- 16 year old, skeletally mature female
- Two year history of back and leg pain
- Patient had a shortened trunk and a “duck waddle” gait
- Mild EHL weakness bilaterally
- Intermittently severe hamstring spasticity with L5 numbness
Degenerative Disc Disease: Spondylololithesis

Approach for Treatment

- 2 level Transforaminal Lumbar Interbody Fusion at L4 – 5 and L5-S1
- Spondylolithesis reduction using Extension Tab VIPER® Screw
Patient with Grade II Spondylolisthesis
• Deformity located at L5 – S1
• Lack of mobility of the spondy

Approach During Surgery
• Screws placed on the contralateral side
• Decompression & discectomy procedure was performed with the aid of the Spotlight port
• Reduced the deformity by using the distraction rack
• Interbody cage was placed to restore height alignment
• Achieved slight correction and secured L5 – S1 with Screw and Rod system

Degenerative Disc Disease: Spondylololithesis with TLIF

Case Details & Approach for Treatment
Degenerative Disc Disease: Spondylolisthesis Lateral

Case Details & Approach for Treatment

**Patient with Spondylolisthesis**
- 43 year old male
- Spondy located at L4 – L5

**Approach During Surgery**
- Positioned table to avoid interference from the iliac crest
- Restored disc height using the COUGAR® LS Interbody Cage
- Stabilized the area with VIPER® 2 X-Tab screws
- Spondy fully reduced
Pathologies & Case Studies

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- Spondylolisthesis

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- Complex Fractures

Tumor Cases
- Spinal Tumor

Deformity Cases
- Scoliosis
- Stenosis with Facet Screws
Trauma: Thoracic Fracture

Case Details & Pre-op Information

- 64 year old male
- T 12 Fracture caused by trauma
- Injuries caused by a cement wall falling on the patient

Patient sustained serious head injuries from trauma as well

- Surgery necessary to repair the spinal injury had to be put off for 6 weeks due to the head injury
- Possible autofusion of bones

Operative plan focused on reducing blood loss to manage head trauma in relation to anesthesia
Trauma: Thoracic Fracture

Approach for Treatment

Repair fracture by performing successful Decompression and reduction procedure

- Used both EXPEDIUM® & VIPER® in order to restore proper sagittal alignment, achieve ligamentotaxis & reduce the fracture

Initial goal was to distract the fracture → however the anterior portion of the fracture was already autofused

(Complication arose from postponing the surgery to ensure patients safety from the head injury)

- Achieve ligamentotaxis using the VIPER® 3D quick Stick Screws extensions
- Compress the Quick Sticks proximally in order to reduce fracture and achieve lordosis

Total Operating Time: Approximately 4 hours
Trauma: Burst Lumbar Fracture

Case Details & Pre-op Information

- 25 year old female
- L 2 Burst Fracture caused by trauma during a car accident
- 60% retropulsion into canal

Complications:

Patient was 8 months pregnant at time of injury

- Necessary to provide an internal brace
- External brace would be impossible given the patient’s pregnancy
- Other alternative to MIS procedure was bed rest until the patient gave birth (approximately 6 weeks)
- Would have to remain on narcotics for the 6 weeks

*Dr. Timothy VanFleet MD.*
Surgeon combined Viper 2 implants and regular Viper implants

- VIPER® 2 X-Tab Implants used at L3 & T11
- VIPER® with Closed Extensions used at T12 & L1
- Surgeon did not instrument on the injured level

Used extensions to attach the top loading derotation rack

- This allowed for distraction of the fracture while skipping the injured level
- Was able to successfully distract the fracture

Why MIS benefited patient...

- Minimized time under anesthesia
- Minimized unborn baby’s exposure to narcotics

Total Operating Time: Approximately 1.5 hours
Estimated Blood Loss: 50 ccs
Trauma: Complex Thoraco-Lumbar Fractures

- 61 year old male at 320 lbs
- Patient with Ankylosing Spondylitis
- Struck by a motor vehicle as a pedestrian
- Vertebral bones T6 through T11 were disconnected from upper & lower spine

Highly unstable Extension Distraction injury at T5-6 & T11-12

Additional Injuries sustained

- Left humerus fracture
- Left tibial plateau fracture
- Multiple left sided rib fractures
- Splenic & Liver Lacerations
- Pulmonary Contusion (left sided test tube)
- Intra-Cranial Bleed resulting in 30% of skull being removed to reduce compression

Spontaneously able to move bilateral upper & lower extremities
Trauma: Complex Thoraco-Lumbar Fractures

Approach for Treatment

- Imperative that surgeons stabilized the vertebral detachment

  *Complications and extensive injuries made performing open surgery very risky*

- Time spent in surgery needed to be as short as possible

- Essential to minimize blood loss

- Necessary to reduce post-op period as the patient would be immobile for quite some time

  *Used VIPER® Rod and Screw System for fixation & decompression*

- Estimated Blood Loss: 200 ml

- OR-Time: 120 minutes

*Dr. Kornelis Poelstra MD. PhD. & Steven C. Ludwig MD.*
Trauma: Complex Thoraco-Lumbar Fractures

Post-Op Progress: 4 months after operation
Pathologies & Case Studies

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- Lateral Approach
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- Complex Fractures

Tumor Cases
- Spinal Tumor

Deformity Cases
- Scoliosis
- Stenosis with Facet Screws
Deformity: Scoliosis

Case Details & Pre-op Information

- 16 year old, skeletally mature female with severe spinal curve
- Curve had progressed from 45° to 58°
- Patient had significant Thoracic Rib prominence
- Moderate sagittal in balance

Complication: Patient’s religious beliefs prevented blood transfusions
(discouraged open surgery)

*Dr. Kornelis Poelstra MD. PhD. & Steven C. Ludwig MD.*
Deformity: Scoliosis

Post-Op Progress

- Coronal curve reduced to approximately 17
- Sagittal balance mostly restored
- Returned to school after 3 weeks
- No complaints of muscle pain
- Approximately 200 ccs of blood loss
- Operating time was approximately 5 hours
- Hospital Stay was 3 days

5 Months Post Operation

- Patient resumed normally activities
- No signs of further progression in the curvature
- Correction had been maintained
Deformity: Scoliosis with VIPER®3D

Case Details & Pre-op Information

- Adolescent, skeletally mature female diagnosed with scoliosis
- 60° right convex curve
Deformity: Scoliosis with VIPER®3D

Approach for Treatment

Muscle Sparing Approach to correction procedure
- Navigated down to the facet joints for posterolateral fusion

Instrument from T4 – L2 in order to correct
- Optimal fixation & correction
- Placement of VIPER Uniplanar screws bilaterally at apex of the curve
- Implants aid in reduction, translation and derotation of the correction procedure

Surgeon performed a series of compression & distractions maneuvers
- Utilized VIPER®3D Compression/ Distraction Rack

*Dr. Matthew Geck MD.*
Deformity: Scoliosis with VIPER®3D

Post-Op Information

Correction of curvature completed successfully
- Decreased muscle disruption
- Patient was mobilized quickly
- Minimized blood loss
- Minimized potential threat of inflection

Total Operating Time: Approximately 6 hours
Estimated Blood Loss: 100 ccs
Patient mobile later that night
Deformity: Stenosis with Facet Screws

Case Details & Pre-op Information

- 69 year old female
- Stenosis at L5 – S1
- Grade I Spondylolithesis
- A Cyst located on the median to left, lower facet joint

Patient had strong bone quality and build
**Deformity: Stenosis with Facet Screws**

**Approach for Treatment**

*Mini laminectomy on the left side of the spinous process for cage insertion*
- Ensuring that the facet is preserved

*Implant instruments to correct the deformities*
- Implants placed at L5 – S1: Concorde 9 x 23 and VIPER F₂® Transfacet Pedicular Screws
- Implants placed at L4 – L5: Concorde 10 x 23 and Viper F2 Screws
Pathologies & Case Studies

Degenerative Disc Disease Cases
- Lateral Approach
- Spondylolysis Lateral
- Spondylolysis TLIF
- Spondylolysis

Trauma Cases
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- Burst Lumbar Fractures
- Complex Fractures

Tumor Cases
- Spinal Tumor

Deformity Cases
- Scoliosis
- Stenosis with Facet Screws
Spinal Tumor

Case Details & Pre-op Information

- 39 year old male
- Present with 6 months of history with back pain
  (Increasing and associated with lower-extremity paresthesia)
- Vertebral fractures on T4 – 5
- Right lung mass appeared on radiography
- Biopsy of the lung mass indicated primary lung adenocarcinoma.
- Intermediate paresthesia
- Mild- lower-extremity weakness
Spinal Tumor

Approach for Treatment

Minimally Invasive Laminectomy & Vertebrectomy of T4 – 5

- Decompression of the spinal cord by fusion of thoracic spine with T1 – 8
- Costotransversectomy performed for metastatic tumor
  (Procedure performed through PIPELINE® Expandable Retractor)
- Placement of expandable cage for vertebral body replacement at T4 -5 anterior & middle columns
- Placement of percutaneous pedicle screw system

*MedScape. Potential of Minimally Invasive Spine Surgery in Complex Spinal Disorders: Spinal Oncology*
Minimally Invasive Surgery

Thank you!
Clinical and Radiological Outcomes of Minimally Invasive Versus Open Transforaminal Lumbar Interbody Fusion

Chin Wearn Benedict Pong, MD, Wai Man Yau, MD, Song Yong Poh, MD, William Yew Moh, MD, and Seang Beng Tan, MD

Study Design. Prospective study.
Objective. Comparison of clinical and radiologic outcomes of minimally invasive (MIS) versus open transforaminal lumbar interbody fusion (TLIF).
Summary of Background Data. Open TLIF has been performed for many years with good results. MIS TLIF techniques have recently been introduced with the aim of smaller wounds and faster recovery.
Methods. From October 2004 to June 2006, 20 MIS TLIF were matched paired with 29 Open TLIF. Patient demographics and operative data were collected. Clinical assessment in terms of North American Spinal Surgeons Association, Oswestry Disability Index, Short Form-36, and Visual Analogue scores were performed before surgery, 6 months and 2 years after surgery. Fusion rates based on bridging were assessed at 2 years.

Results. The mean age for MIS and Open procedures was 54.1 and 52.5 years, respectively. There were 24 males and 5 males in both groups. Mean operative time (MIS: 106.6 minutes, Open: 126.4 minutes, P<0.05) and postoperative time (MIS: 216.4 minutes, Open: 176.5 minutes, P<0.05) were less in MIS cases. There was less blood loss in MIS (156 mL) versus Open (861 mL) procedures (P<0.05). The total morphine used for MIS cases (7.2 mg) was less compared to that of Open cases (15.9 mg). Postoperative hospitalization was shorter compared to Open (6.7 days, P<0.05). Both MIS and Open groups showed significant improvement in Oswestry Disability Index (P<0.05). Back pain and lower limb symptoms (North American Spinal Surgeons Association, Visual Analogue Scale) were reduced (P<0.05). Quality of life scores (Short Form-36, P<0.05) at 6 months and 2 years, but there was no significant difference between the 2 groups. Eighty percent of MIS and 90% of Open TLIF levels achieved grade 1 fusion (P<0.05).

Conclusion. MIS TLIF has similar good long-term clinical outcomes and fusion rates of Open TLIF with the additional benefits of less initial postoperative pain, early rehabilitation, shorter hospitalization, and faster complication.

Key words: lumbar fusion, minimally invasive technique, clinical outcomes. Spine 2006;31:1335-1340

Various interbody arthrodesis techniques have been described with the aim of improving fusion rates, restoring normal disc space height, and maintaining vertebral alignment.

Open transforaminal lumbar interbody fusion (TLIF) has been performed for many years with good results. However, it may avoid the risks of retraction and peritonealization structures that are associated with anterior lumbar interbody fusion techniques. Compared to posterior lumbar interbody fusion, the TLIF procedure allows access to the disc space via a less-invasive approach after removal of the facetectomy. This allows mobilization of the thecal sac and less risk of retraction injury to the nerve roots. The main challenges of TLIF are the extensive soft tissue dissection that is necessary to expose the anatomic landmarks for pedicle screw insertion, achieve a proper lateral-to-medial screw trajectory, and for resection of the facet complex. Multiple authors have documented the harmful effects of this extensive muscle dissection and retraction that normally occurs.

The significant intrathecal muscle and soft tissue injury that occurs during the surgical approach can result in increased postoperative pain, lengthened recovery time, and impaired spinal function.

Minimally invasive techniques for transforaminal lumbar interbody fusion (TLIF) are being introduced that have demonstrated the potential of smaller wounds, less tissue trauma, and faster recovery. The purpose of this study is to compare the clinical results of minimally invasive versus open transforaminal lumbar interbody fusion.

Materials and Methods
From 2004 to 2006, 29 patients with MIS TLIF and 29 patients with Open TLIF performed at the Singapore General Hospital were matched paired based on age, sex, and level operated. The indications for surgery were as follows: 1-grade or 2 spondylolisthesis and/or 2 degenerative discs presenting with mechanical low back pain and radicular symptoms. Relative contraindications for MIS include patients with severely collapsed disc space, which does not move on flexion/extension as well as revision/repeat surgery in which there is significant scar tissue present at the bony lesion where the compromised exiting nerve root and postoperative bone graft and cage introduction are. All patients had preoperative evaluation with static and dynamic plain lumbar spine radiography, MRI imaging, and/or CT myelography and had failed conservative management (minimum 6 weeks) before surgery. The minimum follow-up was 24 months (range, 24 months to 4 years).

The MIS TLIF patients were from our established experience. The Open TLIF patients were from a new institution. The North American Spine Society (NASS) scores for back pain/leg pain, Oswestry Disability Index (ODI), Visual Analogue (VAS) scores for back pain and leg pain, and Short Form-36 (SF-36) scores were evaluated by independent assessors before surgery and at 6 months and 2 years after surgery. Fusion rates based on the Bridwell classification (Table 1) were assessed at 2 years. All data were collected prospectively and this is a retrospective series.

Statistical analysis was performed with the use of SPSS version 10.0. Student t test and analysis of variance were used to determine statistical significance. Significance was defined as P<0.05.

Technique for MIS TLIF
The TLIF procedure was performed on the less symptomatic side. If both legs were symptomatic, the approach was from the side of more severe pathology. Autograft bone graft was first harvested from the iliac crest through a separate incision from the TLIF incision.

Fluoroscopy was used to determine the operative level. A paramarginal incision was made approximately 3 to 5 cm lateral to the midline, extending between the central and contralateral pedicle at the disc level of interest. Soft tissue dissection was then performed through the incision down to the facets complex to the desired working diameter usually 24 to 26 mm was achieved.

A facetectomy was then performed using a high-speed drill from the anterolateral to the posterolateral and central aspect of the disc. At most levels (except for L5/S1), it is not common to visualize any of the neural elements at this stage. A standard discectomy is next performed to access the lumbar disc. The paramarginal incision was then placed anteriorly and contralaterally to the anulus to the intervertebral space followed by an interbody cage. Fluoroscopy was used to ensure proper positioning of the cage. The rest of the implantation and fusion were then performed.

The lateral margins of the lamina and flavum was then excised to expose the interlaminar or epidural space, and nerve root. If needed, the caudal root could be “waxed” separately (and the patient tilted laterally) so that a more extensive decompression could be carried out by the discectomy and decompression of the central canal from bone and the central canal and the nerve root.

Once the interbody fusion and adequate decompression had been carried out, the tubular retractor was removed and an interlaminar percutaneous pedicle screw–rod construct was placed through the same approach. Under fluoroscopic guidance, a Jambhiri needle was inserted into the pedicle. A K-wire is then passed through the Jambhiri trocar into the pedicle. Using cannulated instruments, a bone tap followed by a cannulated reamer was used to prepare the pedicle. A second cannulated reamer was inserted to the pedicle. On the pedicle side, the spine was placed in a similar fashion and a rod was then placed percutaneously to connect the screws. Compression was applied to the construct before final tightening.

Fluoroscopic time (range, 51.5-93.8 minutes) was longer for the mis group (P<0.05) and for the Open Group (24.9 vs. 33.0 minutes). Each group consisted of 25 patients who were operated at L4, 25 at L3, 1 at L4, and 1 patient with 2 levels operated (L3 and L4). Fluoroscopic operative time was significantly longer for MIS compared to Open cases. However, blood loss was significantly less in MIS compared to Open procedures (Table 2). None of the MIS TLIF patients suffered any complications related to the surgery.

Table 1. Radiological Evaluation Using the Bridwell Anterior Fusion Grading System

| Grade | Description |
|-------|-------------|
| I     | Fixed with screwing and transverse plate |
| II     | graft intact, not fully radiolucid and incorporated, but no lucency present |
| III    | Graft intact, potential lucency present at top and bottom of graft |
| IV     | Fusion absent with collapse/separation of vertebra |

Table 2. Perioperative Parameters

| Parameter | MIS (n=29) | Open (n=29) |
|-----------|------------|-------------|
| Fluoroscopic time (range) | 51.5-93.8 | 24.9-33.0 |
| Blood loss | 15.1±3.9 | 31.7±10.3 |
| Duration of surgery (min) | 286±106 | 286±112 |
| Length of hospital stay (days) | 4.8±2.3 | 5.2±2.4 |

From the Singapore General Hospital, Outram Road, Singapore. Acknowledgment date: September 5, 2009. First revision date: December 1, 2009. Final acceptance date: January 9, 2010. Deauthorizing statement: The authors state that there is no conflict of interest for this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript. Address correspondence to Wai-Man Yau, MD, Department of Orthopaedic Surgery, Singapore General Hospital, Outram Road, Singapore 168894; Email: wmyau@sgh.com.sg

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Minimally Invasive Transforaminal Lumbar Interbody Fusion for the Treatment of Degenerative Lumbar Diseases

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Objective. To determine whether minimally invasive transfemoral lumbar interbody fusion (TLIF) using the tubular retractor system reduces the postoperative morbidity inherent in conventional open surgery.

Summary of Background Data. Posterior lumbar fusion using the transforaminal approach has been reported and described well. Supporters have claimed that minimally invasive techniques reduce soft-tissue trauma, blood loss, postoperative pain, infection, and length of hospital stay, as compared with reports describing the traditional open procedure. However, there are several studies of minimally invasive TLIF, especially studies that directly compared minimally invasive and open approaches in a single center.

Methods. Between May 2005 and December 2006, a total of 92 patients underwent 1-level TLIF by 1 surgeon in 1 hospital of 2.7% underwent minimally invasive TLIF using the tubular retractor system, and the other 36 underwent the traditional open procedure. The operative duration, blood loss, complications, and recovery time were recorded. The clinical outcomes were evaluated by the Oswestry Disability Index and the Visual Analog Scale. The total surgery time was significantly lower in the minimally invasive group than those in the traditional surgery group. In addition, better outcomes were achieved in the minimally invasive group in terms of overall clinical and radiographic outcomes.

Results. The minimally invasive group was found to have reduced blood loss, fewer transfusions, less postoperative pain, lower serum creatinine levels on the third postoperative day, a shorter time to ambulation, and a hospital stay of 4 days. The Oswestry Disability Index scores of the minimally invasive group were significantly lower in the minimally invasive group during follow-up. However, the open group had a shorter operative duration. The complications in the 2 groups were similar, but 2 cases of screw misplacement occurred in the minimally invasive group.

Conclusion. Minimally invasive TLIF as a management of 1-level degenerative lumbar diseases is superior to the traditional open procedure in terms of postoperative back pain, total blood loss, need for transfusion, time to ambulation, length of hospital stay, soft-tissue injury, and functional recovery. However, this procedure takes longer operative duration and requires close attention to the risk of technical complications. Long-term studies involving a larger sample size are needed to validate the long-term efficacy of minimally invasive TLIF.

Key words: minimally invasive, traditional open, transforaminal lumbar interbody fusion, tubular retractor system

Figure 1. Tubular retractor used in the minimally invasive TLIF approach.

### Table 1. Patient Information

| Minimally Invasive Group | Traditional Open Group | P |
|--------------------------|------------------------|---|
| No. cases                | 32                     | 30 | 0.496 |
| Gender (M/F)             | 19/13                  | 16/14 | 0.12 |
| Age (yr)                 | 53.4 ± 7.2             | 53.0 ± 8.4 | 0.888 |
| Mean height (cm)         | 172.2 ± 7.9            | 172.0 ± 8.1 | 0.321 |
| Mean weight (kg)         | 65.2 ± 12.9            | 64.2 ± 12.2 | 0.736 |
| Mean BMI                 | 21.9 ± 4.7             | 20.9 ± 4.5 | 0.157 |
| Index diagnosis          | 6.4                    | 6.4 | 1.000 |
| Disk herniation          | 13                     | 13 | 1.000 |
| Unilateral lumbar disc   | 3                      | 3 | 1.000 |
| Herniation              | 5                      | 5 | 1.000 |
| Separation of posterior | 5                      | 5 | 1.000 |
| ring epiphysis            | 3                      | 3 | 1.000 |
| Lumbar spondylolisthesis | 2                      | 2 | 1.000 |
| Chi-square test           | 0.332                  | 0.332 | 1.000 |

Figure 2. Incision about 2.4 cm long.

### Minimally Invasive Technique

In the minimally invasive TLIF group, after induction of general anesthesia, the patient was positioned prone on a radiolucent operating table. Lateral and anteroposterior c-arm fluoroscopic images were obtained to ensure the disc segment, and the pedicle positions were marked on the body surface. Twelve posterior incisions were planned by connecting a line between the outer portions of the superior and inferior pedicles (approximately 3.0 cm on midline) (Figure 2). After skin and subcutaneous incision, a plane was developed on the lateral border of the paraspinal muscles by using progressively larger dilator tubes. Finally, the tubular retractor was expanded to provide an operative field of a diameter of 2.5 to 4.0 cm and achieve pedicle-to-plate exposure. For patients with unilateral nerve root compression, TLIF was performed on the symptomatic side to ensure adequate foraminal decompression.

On the basis of anatomic landmarks and monitoring by C-arm fluoroscopy, the pedicle screws were placed and the pedicle screws were inserted. Furthermore, the pedicle screws and rod contralateral to the decompressed side were connected. Then, sequential distraction of the intervertebral space was achieved by gradually distracting the contralateral pedicle screw and rod system. On the decompressed side, adequate decompression was achieved by cutting the inferior portion of the lamina, hypertrophied superior and inferior articular processes, and ligaments flavum. The intervertebral space and endplate were prepared. Adequate spongy bone was obtained from the iliac crest. Before placing the titanium cages, the anterior disc space was packed with spongy bone. Then, the cages were grasped and the pedicle screws were medially compressed and encased, to restore lumbar lordosis and maintain the restored disc height. Before closing the incision, two 100 ml saline drainage tubes were placed in the double incision. In L5-S1 cases, subcutaneous suctioning was always performed from the same incision to immaculate, and an aspirate drill was used to obtain spongy bone. In L4-L5 cases, incision of approximately 1 cm was made at the donor site.

### Assessment of Results and Follow-up

The data collected from both groups prospectively were age, gender, preoperative diagnoses, clinical and radiographic results after surgery, surgical time, blood loss, pain, and complications. Before surgery, and on the third and seventh postoperative days, all patients were reevaluated with MRI. In L5-S1 cases, pain on average of 1 cm was made at the donor site.
390 Association of Surgical Resection and Survival in Patients With Metastatic Primary Osseous Spinal Neoplasms From the Surveillance, Epidemiology, and End Results (SEER) Database.
Katherine N. Chishuma, MD; Debraj Mukherjee, MD; Ziya Y. Gokaslan, MD; Otar Arozoein, MD; Joseph S. Cheung, MD; MS; Matthew J. McGirr, MD

INTRODUCTION: While surgical resection has been shown to improve the short-term local disease control, its overall impact on survival is associated with improved overall survival in patients with metastatic primary osseous spinal neoplasms. We reviewed survival data from a US cancer registry spanning 30 years to determine if surgical resection was independently associated with overall survival.

METHODS: The SEER registry (1973-2003) was queried to identify cases of histologically confirmed primary spinal chordoma, chondrosarcoma, and Ewing's sarcoma of the mobile spine and pelvis via ICD-O-2 coding. Patient with systemic metastases were excluded. Age, sex, race, tumor location, and primary treatments were identified. Extents of local tumor invasion was classified as confined within vertebrae vs. extension beyond vertebrae to surrounding tissues. The association of surgical resection with overall survival was assessed via Cox proportional hazards regression analysis adjusting for age, radiotherapy, and tumor invasion.

RESULTS: Eight hundred and twenty-seven patients were identified with metastatic primary osseous spinal neoplasms (295 chordomas, 282 chondrosarcomas, 156 osteosarcomas, and 33 Ewing's sarcomas). One hundred thirty-five patients (16%) died in the intraoperative period. Overall median survival was 30 months (range: 1-324 months). Patients with metastatic spinal neoplasms were independently associated with significantly improved survival for chordoma (Hazard Ratio [HR]: 0.59; 95% confidence interval [CI]: 0.47-0.76), chondrosarcoma (HR: 0.52; 95%CI: 0.38-0.72), and Ewing's sarcoma (HR: 0.58; 95%CI: 0.37-0.93), but not statistically significant for osteosarcoma (HR: 0.89; 95%CI: 0.55-1.45).

CONCLUSION: In our analysis of a 30-year US population based cancer registry (SEER), patients undergoing surgical resection for primary spinal chordoma, chondrosarcoma, Ewing's sarcoma, or osteosarcoma demonstrated prolonged overall survival independent of patient age, extent of local invasion, or location. Surgical resection may play a role in prolonging survival in the multi-modality treatment of patients with these malignant primary osseous spinal neoplasms.

901 Cost-Utility Analysis of a Single Institution's Experience With Antibiotic Impregnated Shunt Systems for Adult Hydrocephalus
Sara Hanson Barber, Scott Becker, Chtsia Adogho BS, MPH; Daniele Rigamonti, MD; Matthew J. McGirr, MD

INTRODUCTION: Cerebrospinal fluid (CSF) shunt infection remains a major cause of morbidity and mortality in the treatment of hydrocephalus and is associated with significant medical costs. Several studies have demonstrated the efficacy of antibiotic impregnated shunt (AIS) systems in reducing CSF shunt infections; however, providers remain reluctant to adopt AIS catheters into practice due to their increased upfront cost. We set out to determine if the use of AIS catheters in adults undergoing hydrocephalus has been cost-effective at our institution.

METHODS: All adult patients undergoing shunt insertion over a 7 year period (2003-2010) at a single institution were retrospectively reviewed (2004-2009). In a retrospective chart review of antibiotic impregnated shunt (AIS) catheters was made. Prior to 2006, standard non-impregnated shunt catheters were utilized. We retrospectively assess the 3-year incidence of shunt infection and reviewed accounting and billing records to determine shunt infection-related medical costs for patients undergoing AIS vs standard shunt surgery.

RESULTS: Pre-handled (250 AIS, 250 non-AIS) shunt surgeries were performed for normal pressure hydrocephalus in 378 (78%), pseudotumor cerebi in 83 (16%), and various obstructive and communicating hydrocephalus etiologies in 46 (8%) patients. The incidence of shunt infection was decreased in the AIS (1.2%) vs non-AIS (4.0%) cohort, P = 0.052. Overall, the mean cost per shunt infection was $40,737. Per 250 shunts placed, the total infection related-cost was reduced from $312,467 to $285,424 after the conversion to AIS catheters. Table 1. AIS catheters associated with direct cost savings of $47,193 per 100 shunt surgeries performed.

CONCLUSION: In a retrospective cohort study of 800 CSF shunt surgeries performed for adult hydrocephalus, our categorical conversion to AIS was associated with a significant reduction in infection-related costs within the first year after surgery. Our study demonstrates that cost-related data may aid in determining whether or not to convert all patients to AIS catheters. However, these findings may not be generalizable to non-cerebrospinal surgery.
Minimal Access Versus Open Transforaminal Lumbar Interbody Fusion

Meta-Analysis of Fusion Rates

Ray H. Wei, BS, Justin F. Fraser, MD, and Roger Hadd, MD

Study Design. A quantitative meta-analysis was conducted to determine fusion rates after open or minimally invasive mini-open transforaminal lumbar interbody fusion (TLIF) procedures for single or multiple level degenerative disc disease with spondylosis and degenerative disc disease.

Objectives. The primary aim of this study was to establish benchmarks fusion rates for open TLIF and minimally invasive TLIF (mTLIF) based on published studies. A secondary aim was to review complication rates for both approaches.

Summary of Background Data. Lumbar fusion for the treatment of degenerative disease has evolved from a purely posterior instrumented approach to a combination of anterior and posterior technique with instrumentation. The increasingly popular transforaminal approach has advanced to incorporate minimally invasive surgical technique. There currently exist no controlled comparisons between open TLIF and mTLIF.

Methods. A Medline search was performed to identify studies reporting fusion rate on open TLIF or mTLIF with instrumentation. A database including patient demographic information and complication rates was created. Fusion and complication rates were pooled according to whether TLIF was performed with open or minimally invasive instruments. Publication bias was assessed using Egger's test, and adjustments were performed using Duval and Tweedie's Trim and Fill algorithm.

Results. Twenty-three articles were identified that fit inclusion criteria. In each of the 23 studies, TLIF was performed with pedicle screw fixation and fusion was evaluated using radiographic or computed tomography scan at minimum 6-month follow-up. The studies included 10,317 patients, 48% of which were female. The mean age of all patients was 60.7 years (range, 38-64 years) and mean follow-up interval for assessment of fusion was 26.6 months (range, 6-46 months). The usage of recombinant bone morphogenetic protein (rBMP) was noted in 5% of the mTLIF group (53.2%). Mean fusion rate from 16 studies (761 patients of open TLIF) was 90.0%, whereas mean fusion rate from 8 studies (312 patients of mTLIF) was 82.0% and 7.6% for open and mTLIF, respectively.

Conclusion. Fusion rates for both open and mTLIF are relatively high and in similar ranges. Complication rates are also similar, with a trend toward mTLIF having a lower rate. This analysis provides clear benchmarks for fusion rates and may guide mortality rates for spine surgeons.

Key words: minimally invasive spine surgery, transforaminal lumbar interbody fusion, fusion rate, meta-analysis. Spine 2010;35:2275-2281

Since its introduction in 1992 by Harms and Roland, a transforaminal lumbar interbody fusion (TLIF) has been increasingly used for the treatment of symptomatic lumbar degenerative disease.2-5 Compared with other interbody fusion techniques, TLIF is recognized to have advantages in safety and postoperative recovery, while achieving high rates of fusion.6,7 These advantages stem from its lateral approach requiring exposure of only one facet joint and foramen, which provides sufficient exposure of the disc space for graft placement with minimal neural retraction. The contralateral lamina, facet, and pedicles are spared.8,9 In addition, TLIF can be performed in the upper lumbar levels, whereas the bilateral posterolateral interbody fusion is more suited to lower lumbar levels.8

Numerous investigators have reported open TLIF fusion rates of more than 90%,2,6,5,6,11 Although successful in achieving high fusion rates, drawbacks to the conventional open approach include postoperative pain from muscle dissection, blood loss, and lengthy hospital stays. These drawbacks arise primarily from the extensive soft tissue dissection necessary in the open procedure.6,11 Minimally invasive spine approaches may resolve these disadvantages while maintaining the operative fusion goals of the procedure.4

A minimally invasive percutaneous posterior lumbar interbody fusion (PLIF) technique was developed and described in 2002 by Khosla et al with the purpose of eliminating paraspinal muscle injury and reducing soft tissue trauma without sacrificing effectiveness in spinal fusion. The first minimally invasive TLIF (mTLIF) was described in 2003 by Fesly et al.12 Whereas open TLIF requires direct vision of the intervertebral disc with significant muscular dissection, mTLIF limits tissue dissection by taking advantage of 2- or 3-dimensional neuroangiography for the placement of hardware. Despite numerous reports comparing patient outcomes, complications, and radiographic fusion rates between mTLIF and open TLIF procedures. With no class I evidence to compare them directly, we endeavored to perform a quantitative meta-analysis of the current literature consisting of observational data to develop benchmarks for fusion rates in mTLIF and open TLIF.12 A secondary aim was to review complication rates for the mTLIF and open TLIF approaches.

Materials and Methods

Search Strategy. A Medline search was conducted using combinations of the key terms "transforaminal lumbar interbody fusion" or "TLIF" and "mTLIF," "mini-open" or "mini-invasive" up to March 2008. A hand search of reference lists of obtained articles was also performed.

Inclusion/Exclusion Criteria. Only studies reporting fusion rates from either mTLIF or open TLIF were included. "Minimally invasive" was defined as a "mini-open" procedure that involved "mini-open" placement of the interbody cage through a tubular retractor system and mini-open or percutaneous placement of uni- or bi-pedicular screws. Studies comparing TLIF to an alternate fusion procedure such as PLIF or anterior lumbar fusion were included with only TLIF data extracted. Case reports, biomechanical and cadaveric studies, and articles in languages other than English were excluded. To avoid repeat patient data, each group or institution was limited to one study in the meta-analysis. In cases where a particular study did not publish all demographics, failure to specify whether multi- or uni-pedicular screws, infection, pseudarthrosis, instrumentation failure, suture drain, hematoma, pneumonia, postoperative stroke, and pulmonary emboli. An additional database was created from excluding studies containing the earlier information with an extra category providing justification for exclusion.

Statistical Analysis. Fusion and complication rates from the included studies were grouped according to whether TLIF was performed using mTLIF or open technique, because of uncontrollable differences between included studies, such as patient disease severity, definition of fusion, construct used, surgeon skill level, and specific techniques; it could not be assumed that the true effect of treatment, in this case fusion from either mTLIF or open TLIF, was the same for all studies within their respective groups. Thus, a fixed-effect model was not appropriate for the data.

Table 1. Demographics of Included Studies

| Study | Mean Age | N | Female | % | % Single-Level Fusion |
|-------|----------|---|--------|---|----------------------|
| mTLIF |          |   |        |   |                      |
| Wiens and et al10 | 48 | 50.5 | 82.5 | 97.4% |
| Schnelleck et al10 | 40 | 56.0 | 83.5 | 100.0% |
| Schmiedek et al10 | 40 | 67.5 | 83.5 | 100.0% |
| Jiang et al10 | 40 | 67.5 | 83.5 | 100.0% |
| Deutsch et al10 | 30 | 46.0 | 40.0 | 100.0% |
| Bergher et al10 | 30 | 46.0 | 40.0 | 100.0% |
| Mabrouk et al10 | 30 | 46.0 | 40.0 | 100.0% |
| Auer et al10 | 100 | 50.5 | 50.0 | 76.0% |
| Jasser et al10 | 80 | 67.5 | 50.0 | 86.0% |
| Rumpold et al10 | 30 | 50.5 | 50.0 | 83.0% |
| Total | 300 | 58.5 | 50.0 | 83.5% |

Open

| Study | Mean Age | N | Female | % | % Single-Level Fusion |
|-------|----------|---|--------|---|----------------------|
| Barltet et al10 | 37 | 45.5 | 83.5 | 100.0% |
| Houton et al10 | 32 | 42.5 | 43.5 | 100.0% |
| Hackett et al10 | 32 | 42.5 | 43.5 | 100.0% |
| Salois et al10 | 22 | 45.5 | 45.5 | 100.0% |
| Hall et al10 | 22 | 45.5 | 45.5 | 100.0% |
| Lussi et al10 | 39 | 40.5 | 50.0 | 82.0% |
| Laws et al10 | 60 | 49.5 | 49.5 | 90.0% |
| Wohlgen et al10 | 25 | 55.5 | 55.5 | 90.0% |
| Hase et al10 | 138 | 43.5 | 23.5 | 87.5% |
| Kobil et al10 | 22 | 47.5 | 27.5 | 35.0% |
| Murmann et al10 | 34 | 50.5 | 40.5 | 90.0% |
| Gnan et al10 | 23 | 48.5 | 50.5 | 90.0% |
| Peter et al10 | 100 | 60.5 | 30.0 | 90.0% |
| Tatschaki et al10 | 88 | 49.5 | 44.5 | 95.0% |
| Wassen et al10 | 22 | 50.5 | 50.0 | 85.0% |
| Nieswar et al10 | 30 | 50.5 | 50.0 | 100.0% |
| Total | 306 | 58.5 | 50.0 | 99.0% |

Weighted mean 58.5 83.5

mTLIF indicates minimally invasive transforaminal lumbar interbody fusion.
