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

Kaveh Khajavi, MD, FACS, Alessandria Y. Shen, MSPH, Tony Hutchison, MSN, ACNP

Georgia Spine and Neurosurgery Center

Atlanta, Georgia

GEORGIA SPINE & NEUROSURGERY CENTER

Minimally Invasive Maximum Results

INSTITUTE FOR NEUROSURGICAL & SPINAL RESEARCH

THE INSPIRE FOUNDATION

Disclosures

- FDA off-label usage
  - rh-BMP2 (INFUSE, Medtronic Sofamor Danek)
  - CoRoent PEEK cage stand-alone (NuVasive, Inc.)
- NuVasive, Inc.
  - Consultant
  - Honoraria
  - Travel

Introduction

- 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

Comorbidities

- Hypertension 58.3%
- GERD 35.0%
- High cholesterol 31.7%
- Diabetes 21.7%
- Depression 13.3%

Mean 3.15 per patient

Obesity not considered a comorbidity.

Conservative Treatments

- Physical Therapy 91.7%
- Pain Mgmt./EIS 66.7%
- Exercise Program 46.7%
- Chiropractic 35.0%
- Other 20.0%

Methods

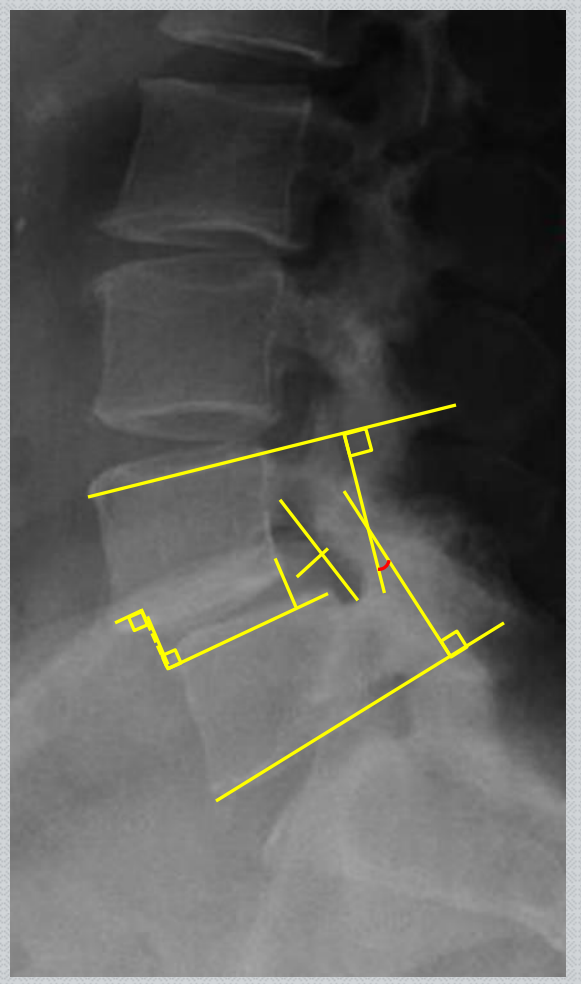
Treatment Summary

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

Methods

Analysis

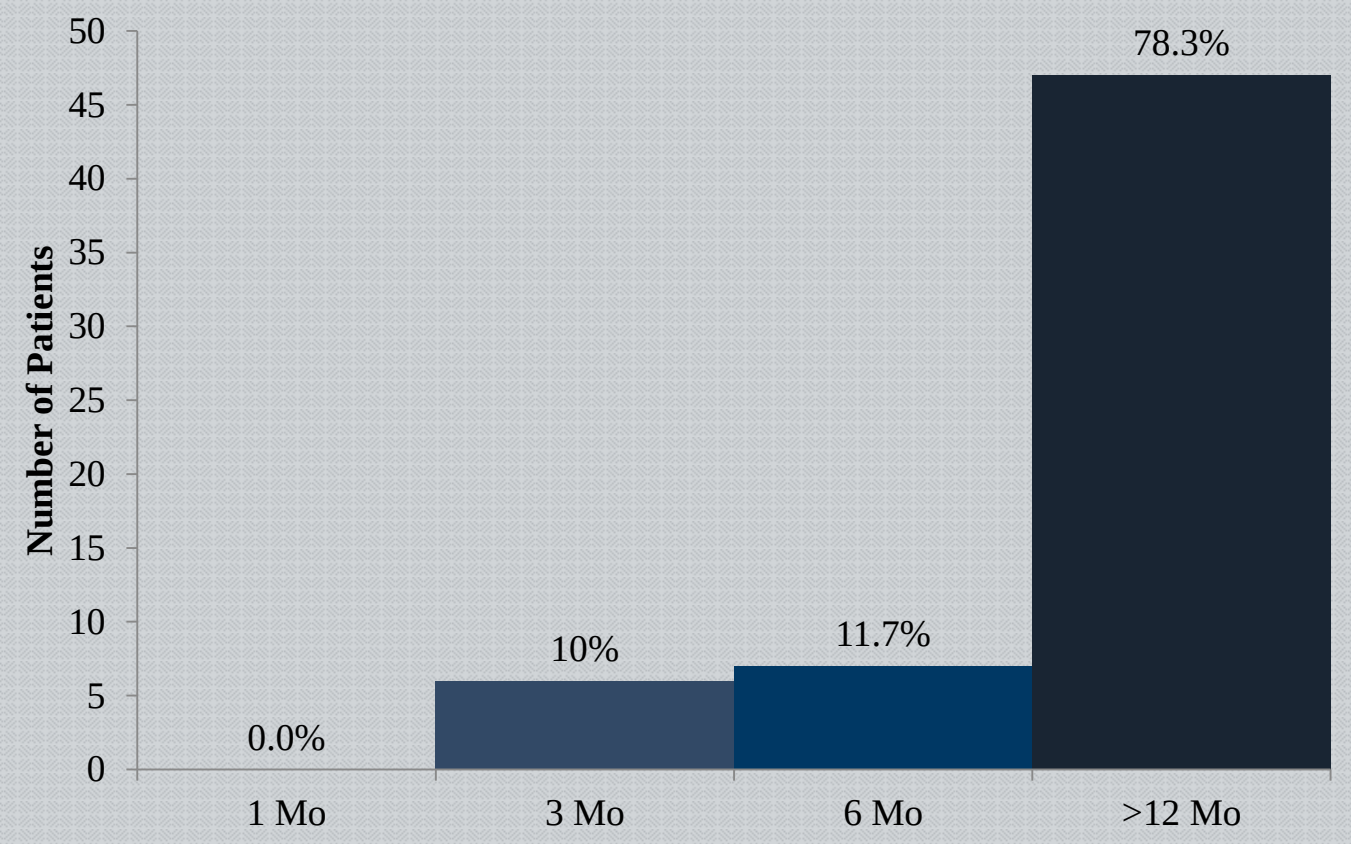
- Clinical Outcomes
  - ODI
  - VAS (back & leg)
  - SF-36 (PCS & MCS)
- Radiographic Measurements
  - Disc height
  - Foraminal height & width
  - Segmental lordosis
  - Slip percent & grade
- Analysis
  - One-way ANOVA
  - Significance accepted for $p \leq 0.05$



Results

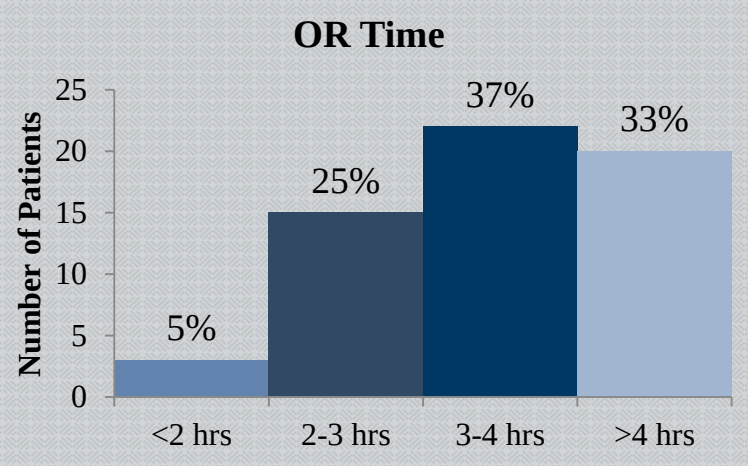
Last Follow-Up

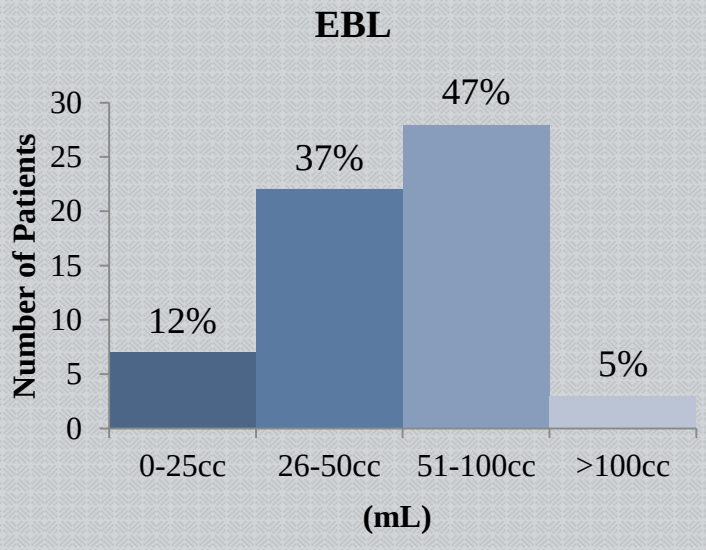
- Mean follow-up: 17.4 months

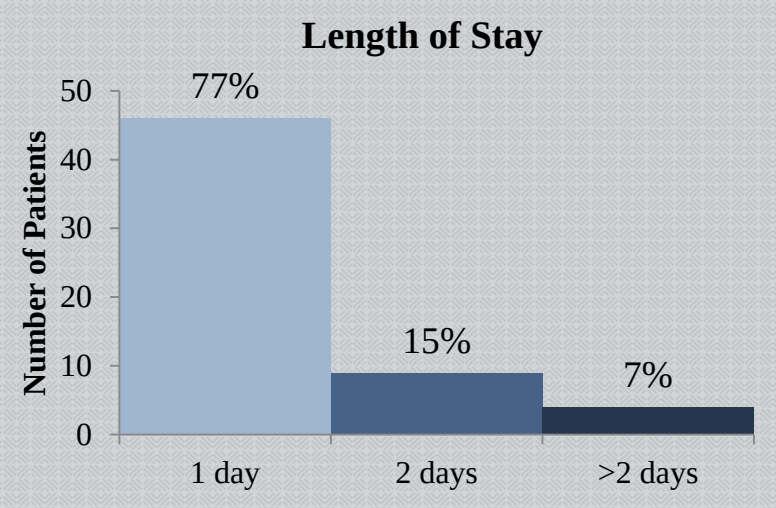


Results

Surgical Summary







Means

OR Time: 206 minutes

EBL: 83 mL

LOS: 1.29 days

Results

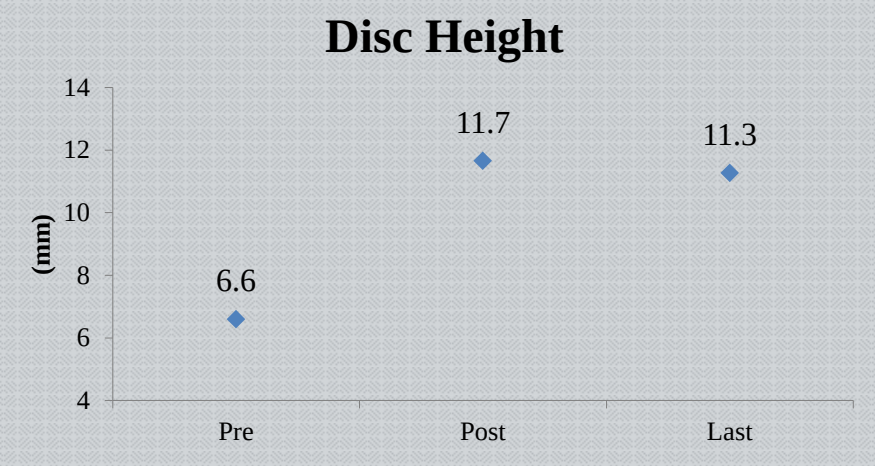
Adverse Events

- 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)

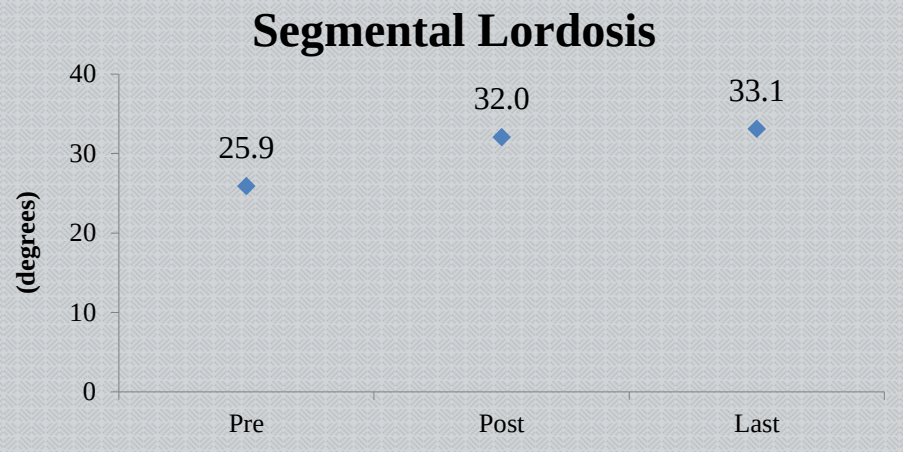
Results

Radiographic



Last Follow-Up

71.2% Improvement

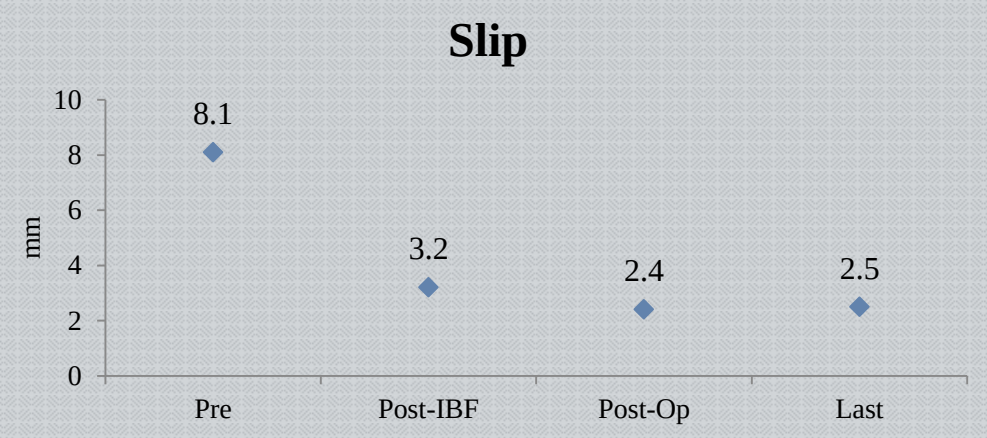


Last Follow-Up

27.8% Improvement

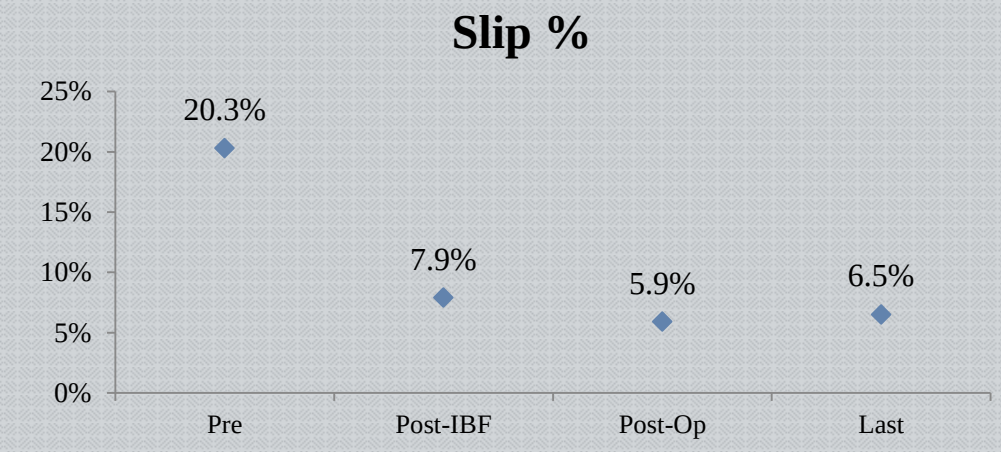
Results

Radiographic



Last Follow-Up

69.1% Improvement

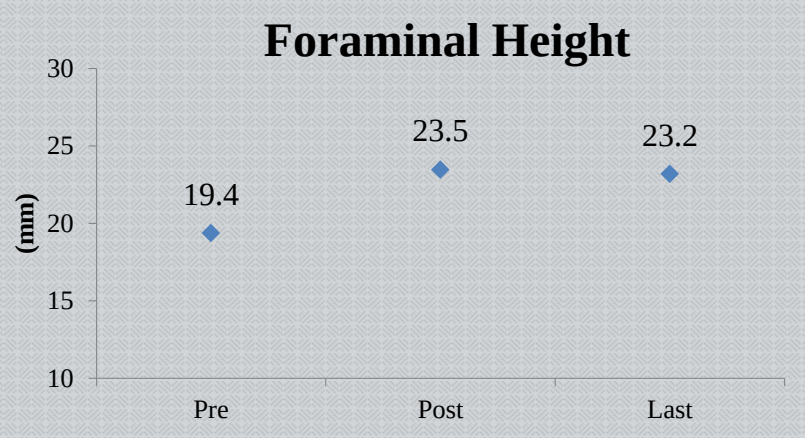


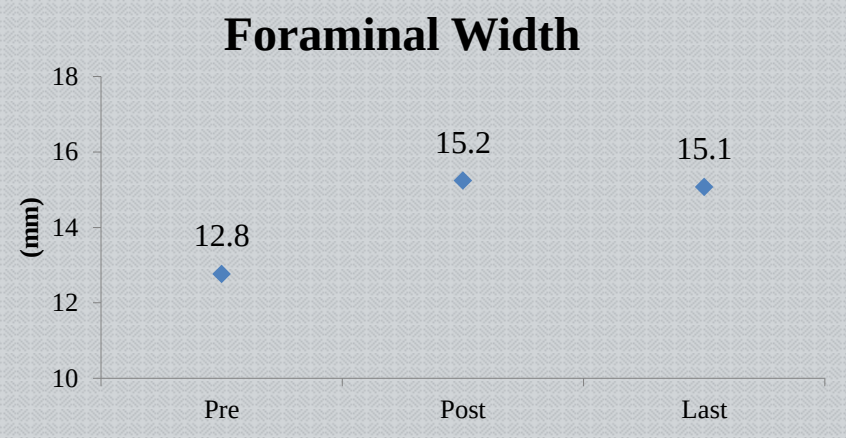
Last Follow-Up

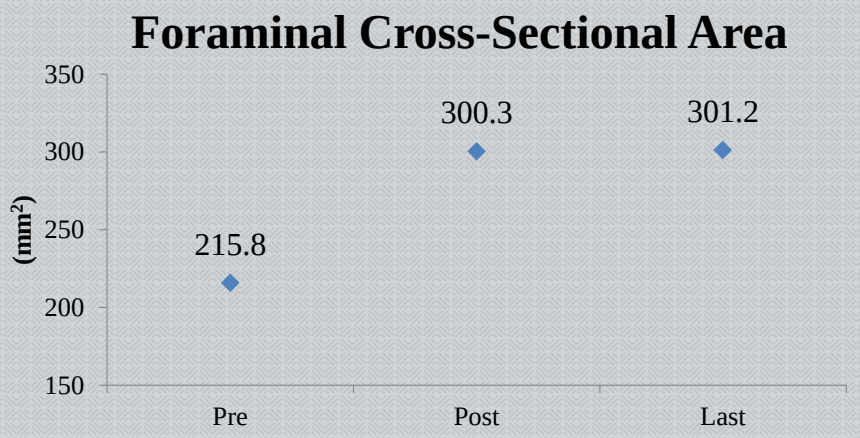
68.0% Improvement

Results

Radiographic







Improvement at Last Follow-Up

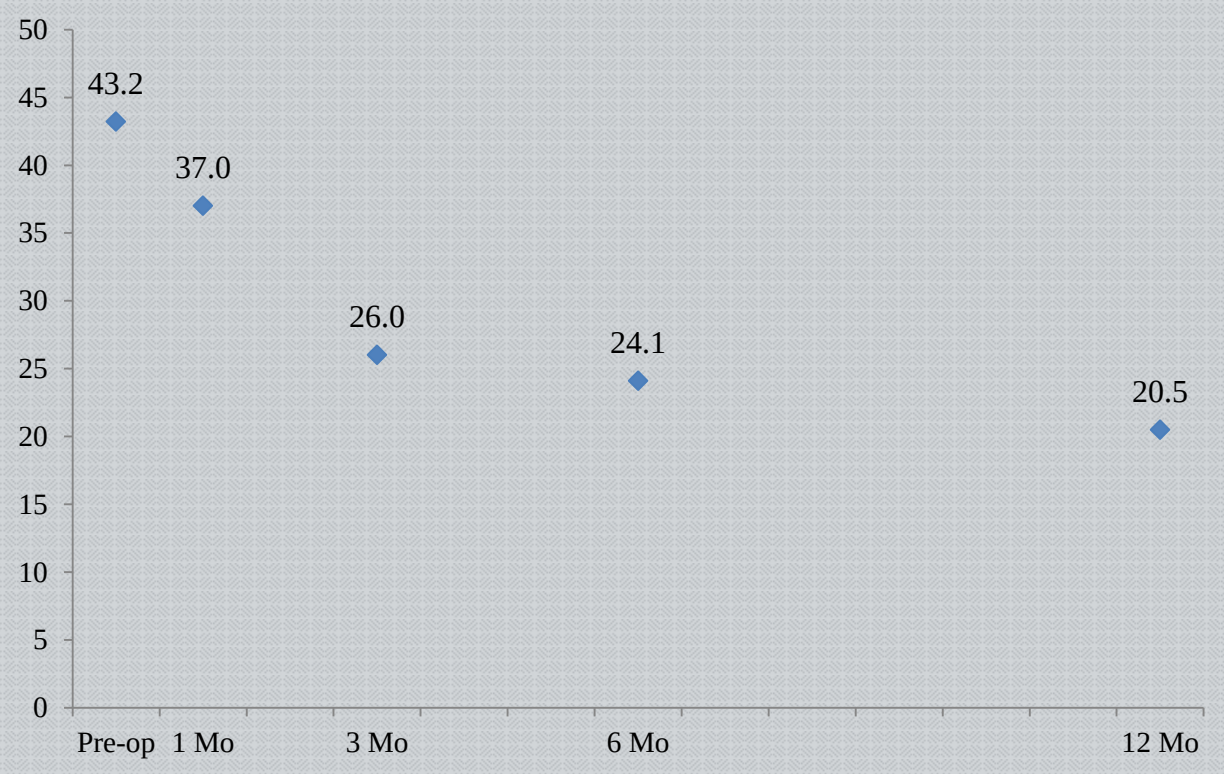
Height: 19.7%

Width: 18.0%

Area: 39.6%

Results

Clinical



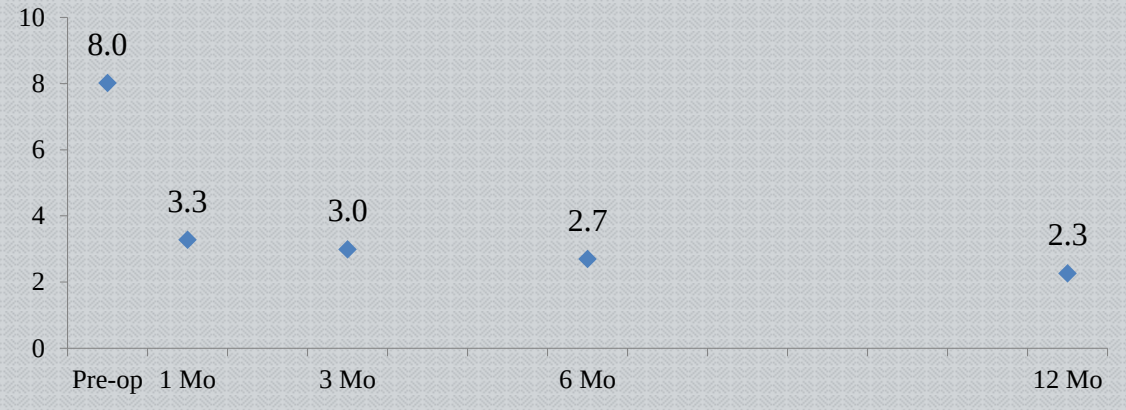
12 MO

52.5% Improvement

($p<0.001$)

Results

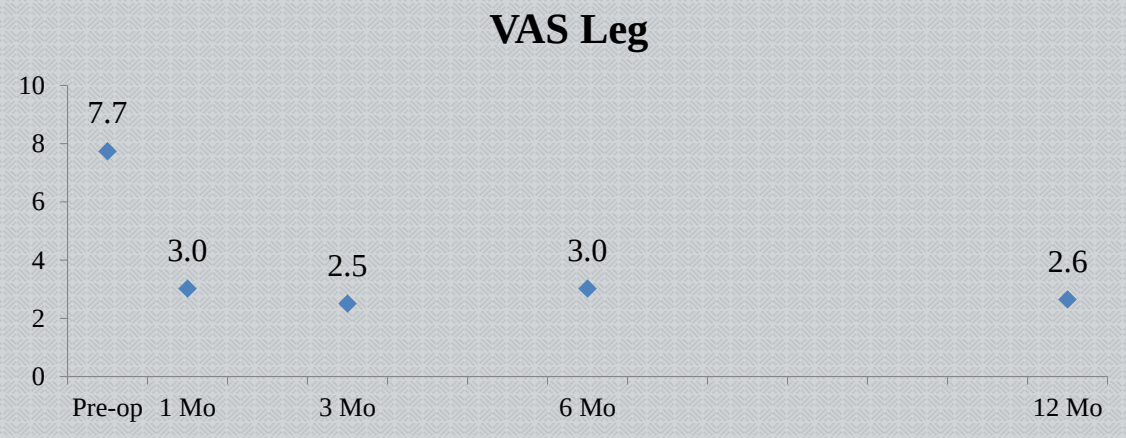
Clinical



12 MO

73.7% Improvement

(p<0.001)



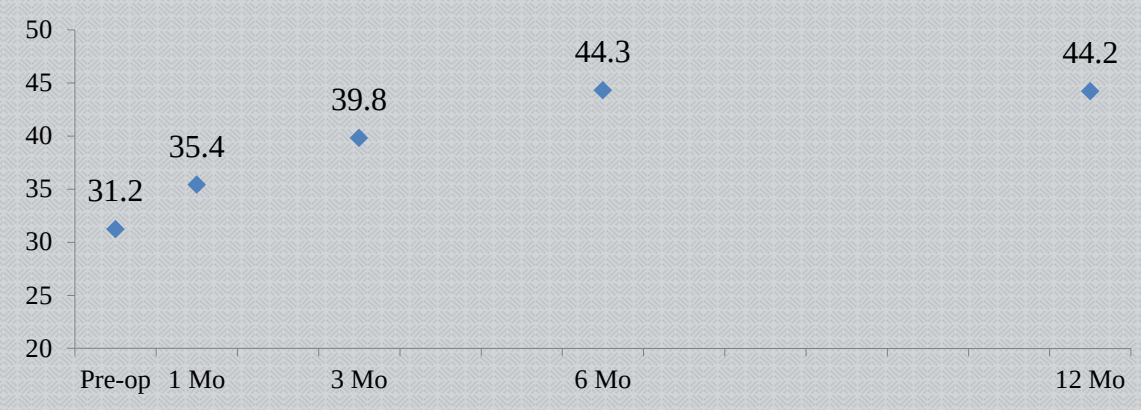
12 MO

66.2% Improvement

(p<0.001)

Results

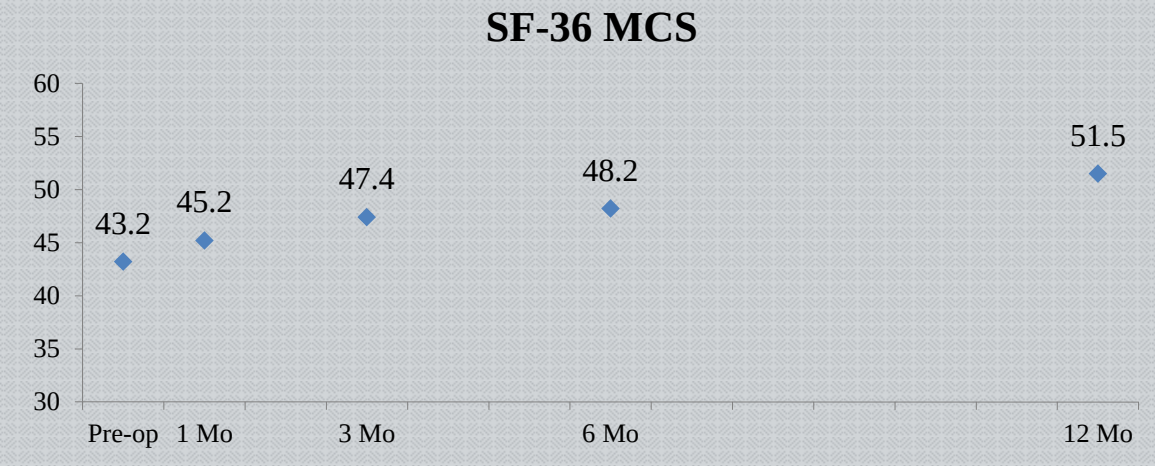
Clinical



12 MO

41.7% Improvement

($p<0.001$)



12 MO

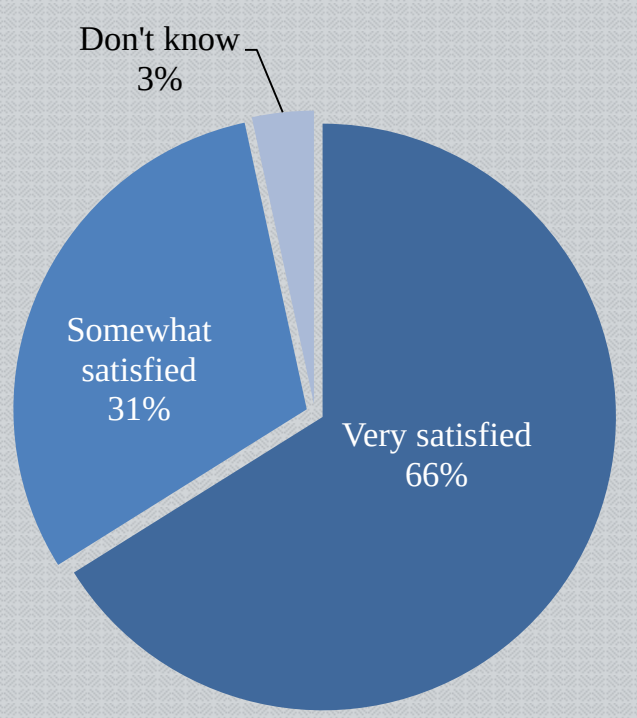
19.2% Improvement

($p=0.003$)

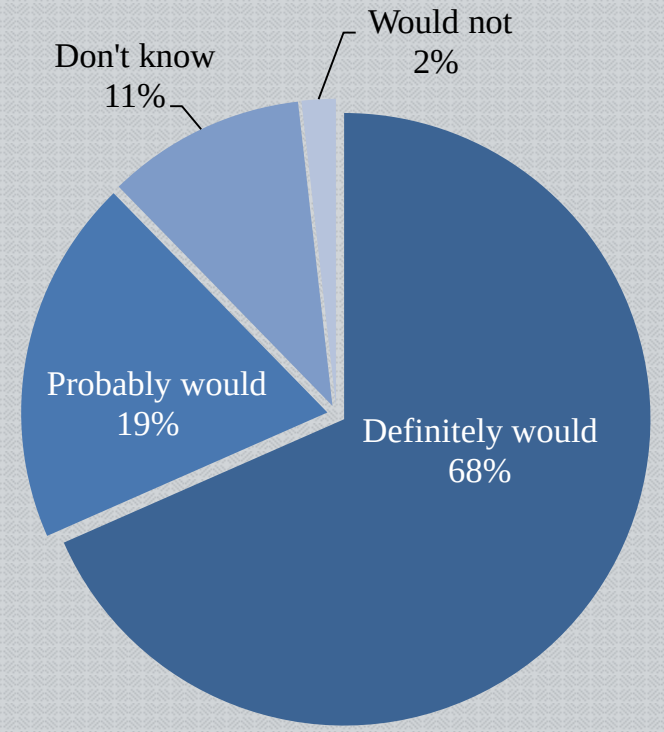
Results

Patient Satisfaction

How satisfied are you with your surgical outcome?



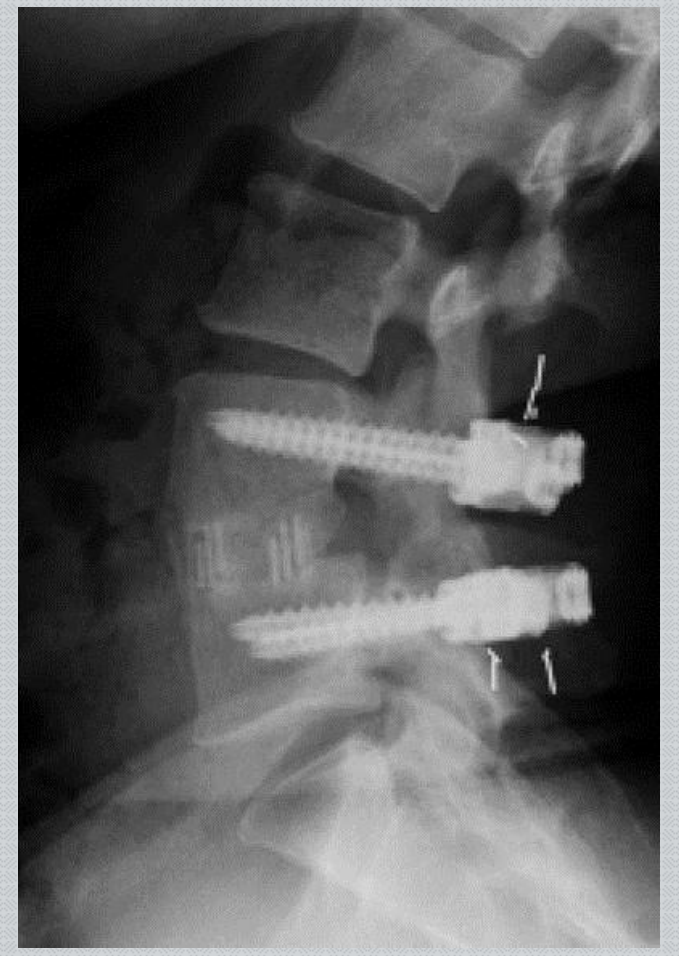
Given your current condition, would you elect to have the same surgery again?



Case Example

Patient 1

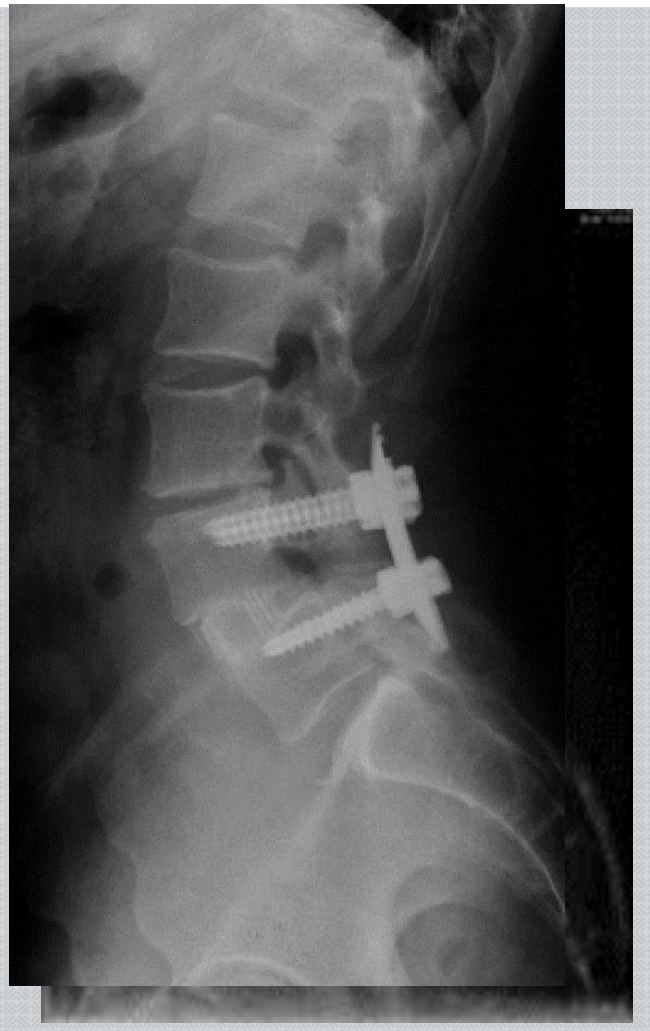
- History
  - 55 year-old female
  - Presented with LBP & right anterolateral leg pain
  - Previous L4-5 laminectomy
- Outcome (12 months PO)
  - VAS LBP: 8 → 3
  - VAS Leg: 10 → 2
  - ODI: 60 → 30
  - SF-36 PCS: 28.4 → 36.9
  - SF-36 MCS: 37.7 → 49.9



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
  - 77 year-old female
  - Presented with LBP & bilateral leg pain
  - No previous lumbar surgery
- Outcome (12 months PO)
  - VAS LBP: 8 → 1
  - VAS Leg: 6 → 1
  - ODI: 32 → 20
  - SF-36 PCS: 40.1 → 40.2
  - 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

  Jaeschke R, et al. *Cont Clin Trials*. 1989;10:407-15.

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

- MCID in lumbar spine surgery

  Copay AG, et al. *Spine J*. 2008;8:968-74.

  - 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

  Glassman et al. *J Bone Joint Surg Am*. 2008;90:1839-47.

  - 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

Clinical Outcome	Patients Reaching MCID (%)	Patients Reaching SCB (%)
VAS LBP	91.5%	94.7%
VAS LP	81.7%	84.6%
ODI	83.3%	83.7%
SF-36 PCS	85.7%	66.7%

Discussion

Previous Studies

- Our results compared favorably with other published studies
  - Rodgers WB, et al., *SAS Jour* 2010;4:63-6.
  - Oliveira L, et al., *Spine* 2010;35(26S):S331-S337.
  - Ozgur BM, et al., *SAS Jour* 2010; 4:41-46.
  - Marchi L, et al., *Scientific World Jour* 2012; Epub Apr 2012.
- 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)

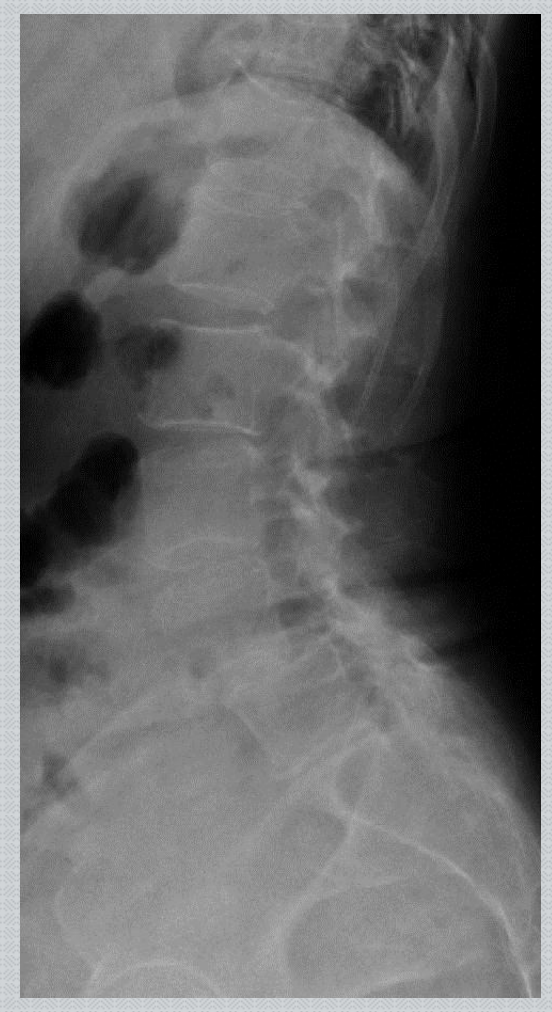
Conclusions

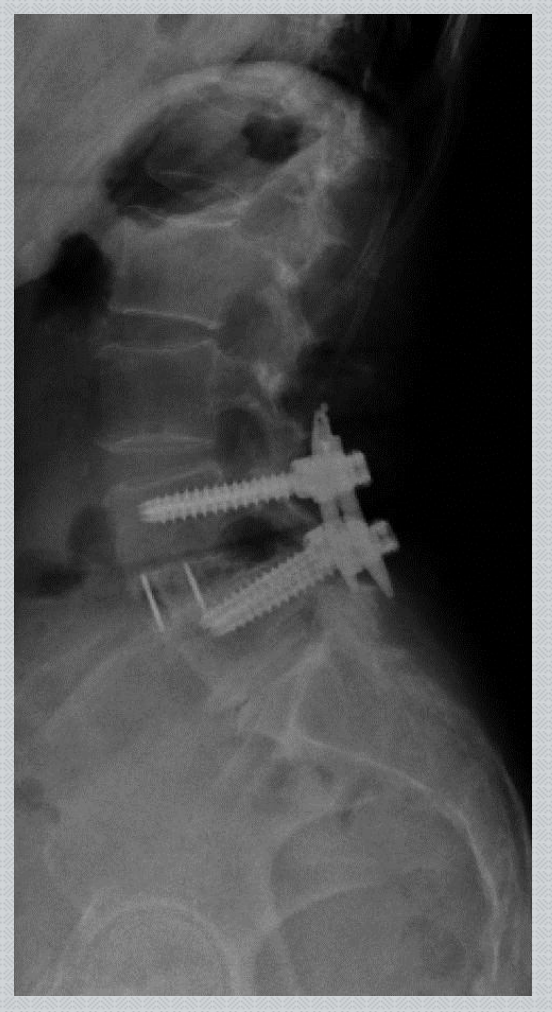
- Compared to conventional approaches, the minimally disruptive lateral approach for IBF resulted in:
  - Few complications with shortened postoperative recovery
  - Excellent mid-term clinical outcomes, with significant and maintained improvements on pain, disability, and QOL
  - Radiographic measures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

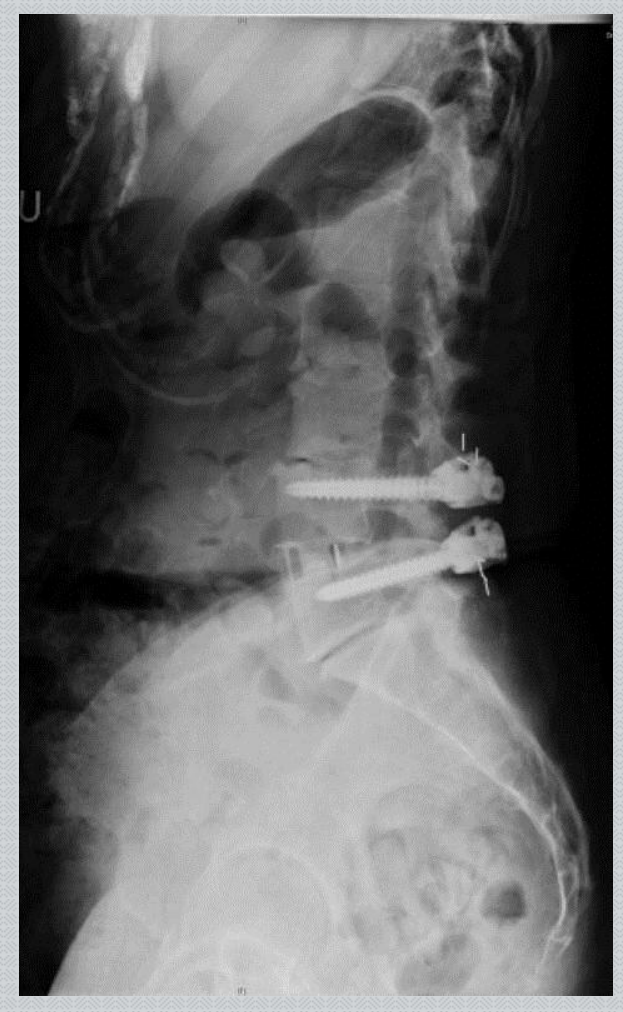
Thank you!

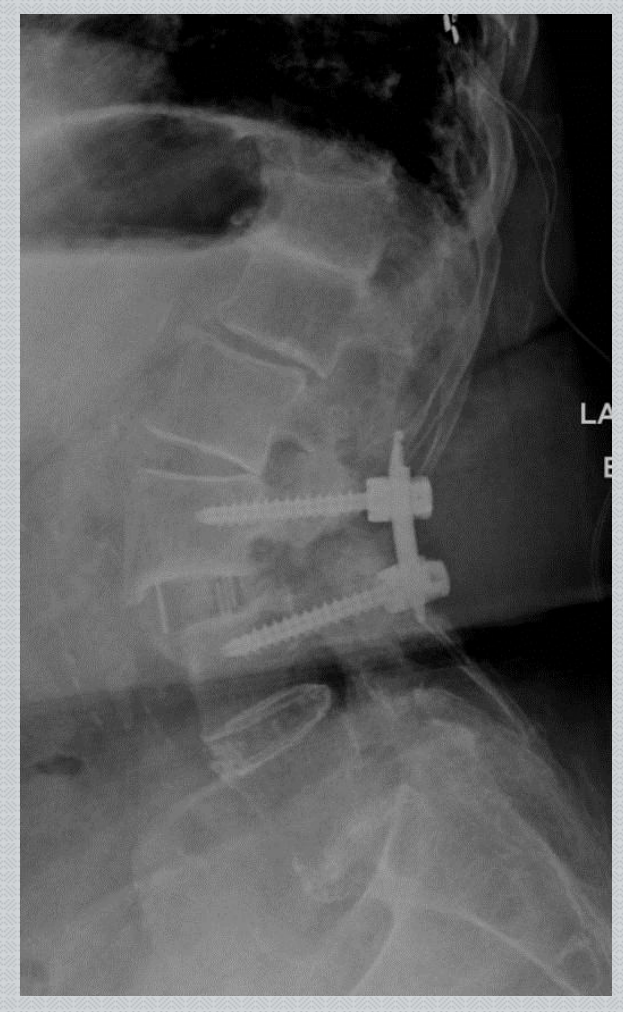

GEORGIA SPINE
& NEUROSURGERY CENTER
Minimally Invasive
Maximum Results

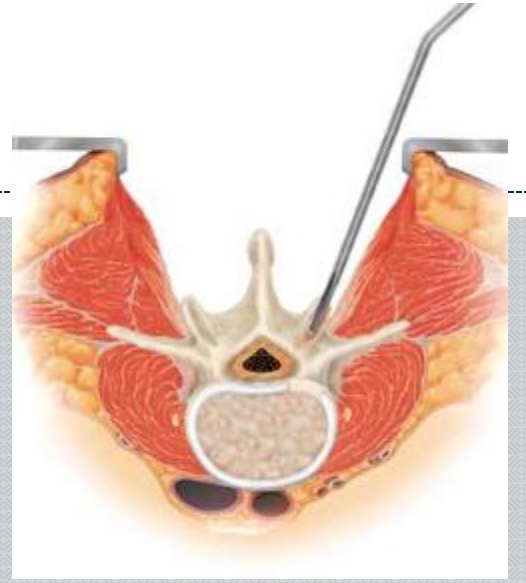

INSTITUTE FOR NEUROSURGICAL & SPINAL RESEARCH
THE INSPIRE FOUNDATION









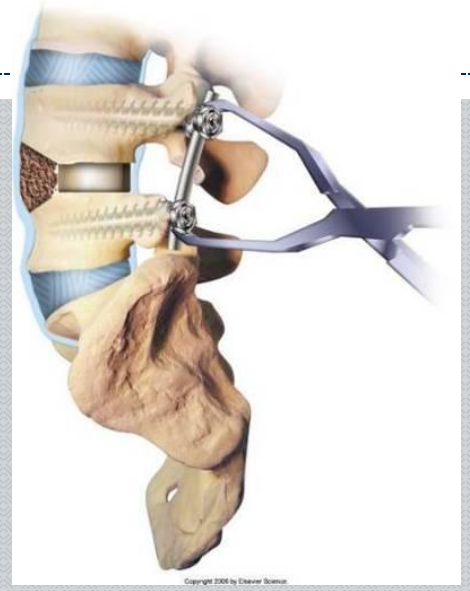


- ↑ operative time, pain, blood loss

- **Damage to back muscles may result in long term pain & disability**

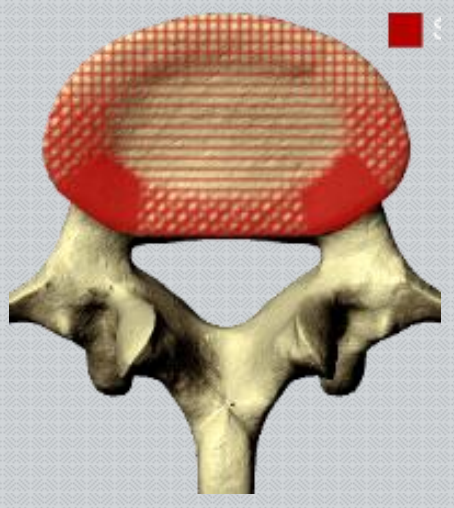
Disadvantages of Traditional TLIF / PLIF

- 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