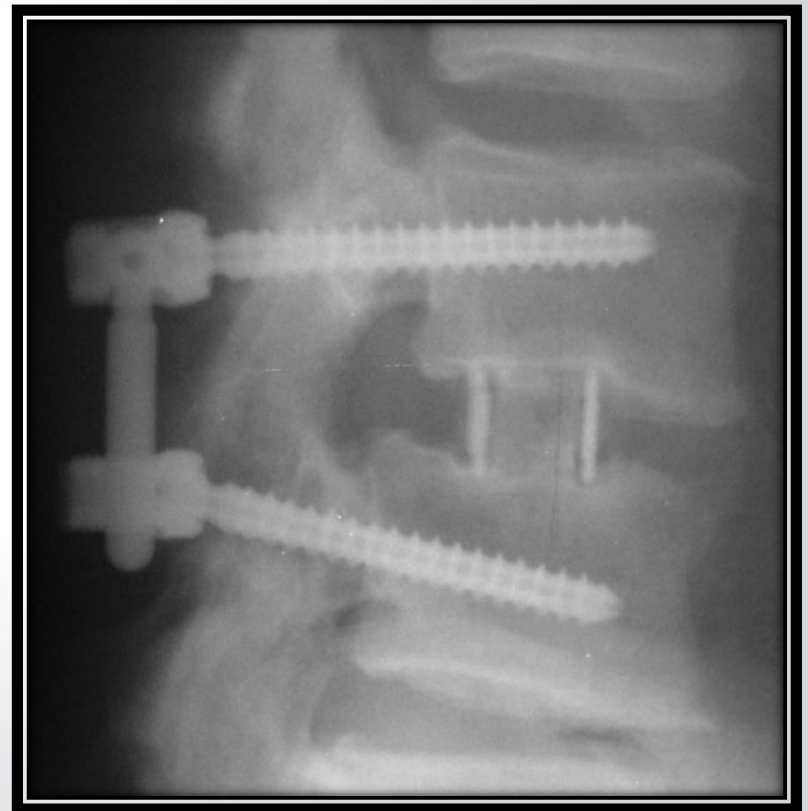


Outcomes of MIS Spinal Fusion: XLIF @ 12 and 24 Months

SMISS

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Conflicts: Past and Present

- AOI Medical
- Alphatec
- Bacterin
- Bioset
- EuroSurgical, SA
- Exactech**
- Facet Solutions
- HealthPoint Capital
- Nuvasive**
- Orthofix
- Pioneer Surgical
- Scient'X, SA
- Spineology
- Theken Spine
- TranS1
- US Spine
- Vertebron
- Wright Medical Technologies

*** products directly referenced in this lecture*

caveat emptor

A single surgeon prospective series of 710 consecutive patients undergoing extreme lateral interbody fusion (XLIF) for degenerative conditions.

Patients were followed with serial exams and radiographs at 2 weeks, 6 weeks, 3 months, 6 months, 12 months, and 24 months.

This report represents the largest analysis of patient outcomes associated with XLIF at 1 and 2 years after surgery.

Total Experience: XLIF Demographics

- 710 pts
- 238 F; 272 M
- 242 smokers
- Age 62.2 yrs (22 – 89)
- Height 66.2"/168.1cm
- Weight 194.9 lbs/88.6 kgs
- BMI 31.2 (17.0-61.8)
- LOS 1.21 days
- Hgb change 1.36 g
- 884 levels
- 1 Level 566
- 2 Level 116
- 3/4 Level 28
- Pedicle Screws 594
- Facet Screws 13
- Mesh 34
- Tab alone 64
- Stand Alone 5

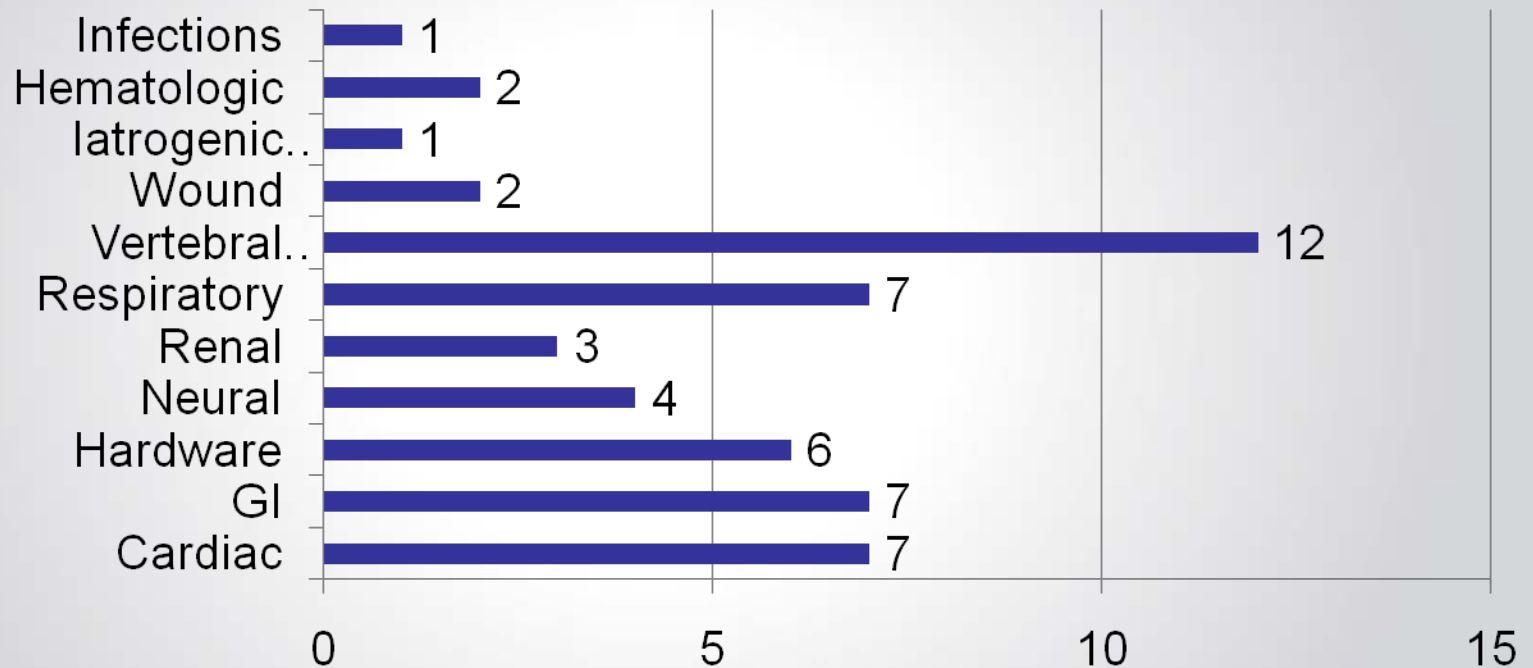
Total Experience: XLIF Outcomes @ 12 and 24 Months

	Preop	Post	3 mos	6 mos	12 mos	24 mos
<i>Pts</i>			541	468	319	104
VAS	8.8		3.2	2.8	2.6	2.2
Disk Height (mm)	6.2	10.4	9.9	9.4	9.2	9.2
Slip (mm)	4.5	0.8	0.8	1.0	0.9	0.8
Scoliosis	16.4	12.1	13.1	11.7	13.4	8.4
Lenke			2.0	1.4	1.2	1.1

Are Outcomes affected by Complications or Reoperations?

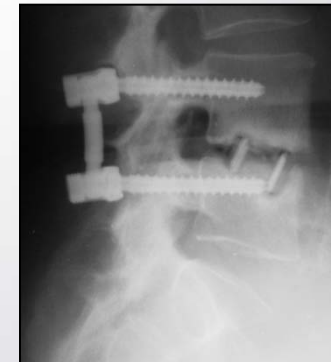
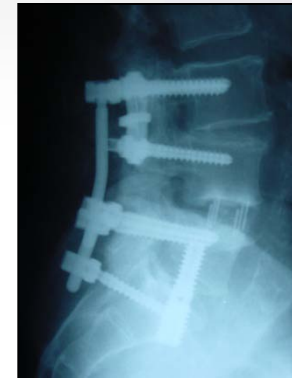
Total Experience: XLIF

Complications – 52 (7.3%)



Reoperations – 50 (7.0%)

- AxiaLIF 7
- XLIF 15
 - additional level
- ALIF 2
 - Pseudarthrosis (revised elsewhere)
 - Another pending (by report)
- Laminectomy 11
 - Residual stenosis (8)
 - HNP (1)
 - Endplate fx (1)
- Vertebroplasty 7
- Posterior Instrumentation 6
 - Vertebral body fracture
 - Rod fracture revision



Neural Complications: An Area of Controversy

- Motor deficits 4 (0.6%)
 - Quadriceps weakness (3)
 - Tib ant weakness (1)
 - Self-limited: near complete resolution in 12 weeks in all cases
 - All cases involved L4-5 level (428 total L4-5 cases = 60.3%)
- After 4th motor deficit case, we began premedicating with **Decadron**
 - (10mg IVP prior to skin incision)
 - No further deficits.

The Protective Effect of Decadron

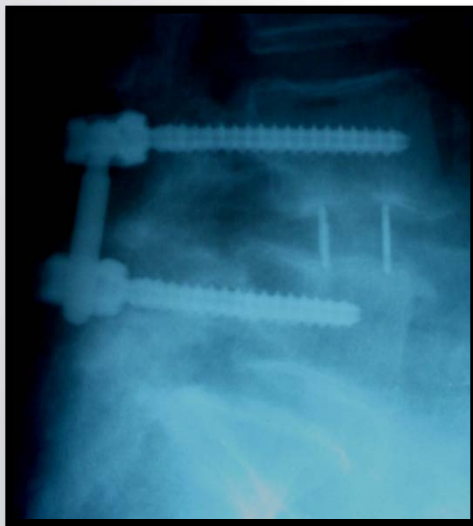
Premedication with Decadron has been shown to have a statistically significant effect on the incidence of motor deficits after XLIF.

- 4/191 (L4-5 XLIF) without Decadron (2.1%)
- 0/237(L4-5 XLIF) with Decadron (0.0%)

Since the use of Decadron, no additional neural deficit developed, a statistically significant difference ($p=0.0245$).

What about *Thigh Pain* after XLIF?

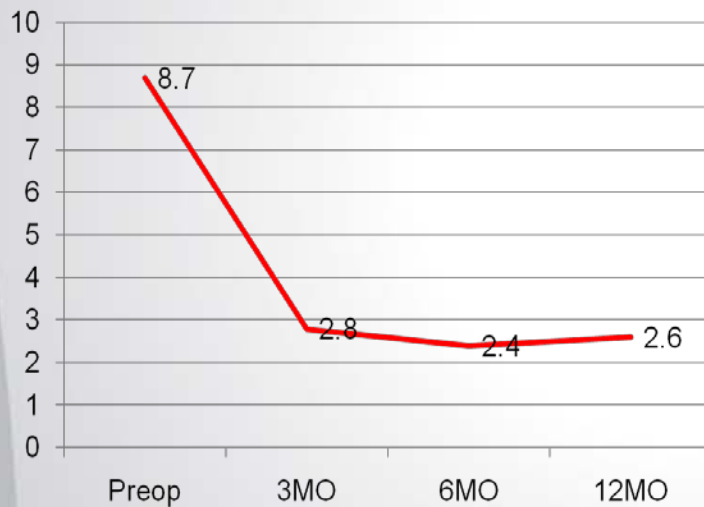
There has been much discussion about the incidence of thigh pain after XLIF. It has been our experience that thigh pain – which we believe to be related to a combination of psoas trauma and irritation of the lumbar plexus – is nearly universal in our patients, but appears to be transient.



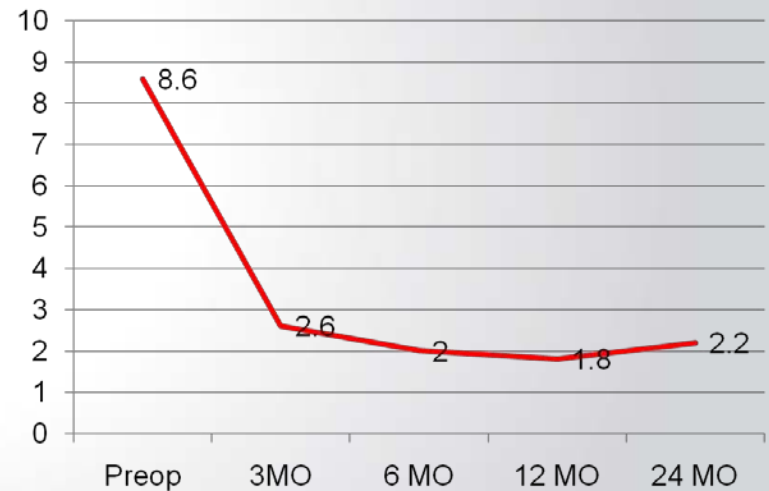
Of our 319 patients who have returned for 1 year follow-up exams, none noted the persistence of this postoperative thigh pain one year after surgery.

VAS for Pain Outcomes

Patients with 12 Month Follow-Up (319)



Patients with 24 Month Follow-Up (104)



Are Outcomes Predictable?

Predicting Reoperations by Postop Disc Height

- Loss of disc height (both relative and absolute) at 6 months postop is a statistically significant predictor of reoperation for residual symptoms.
- Greater than 5mm disc height loss from postop to 6 months is predictive of needing a reoperation ($p < 0.0001$).
- Patients who lose more than 50% of surgically gained disc height by 6 months required reoperation significantly more often ($p < 0.0001$).
- In addition, patients who lost less than 1mm of disc height from postop to six months underwent reoperation significantly ($p = 0.0034$) less frequently.
- A loss of less than 10% of disc height from postop to 6 months is predictive of not needing a reoperation.

Are Outcomes Predictable?

Complications

The occurrence of complications was **not** found to be a statistically significant factor in XLIF outcomes, neither at 12 nor 24 months.

(p=0.2282; p=0.6022)

Below are VAS scores of XLIF patients who had complications.

Preop	3MO	6 MO	12 MO	24 MO
50	42	41	29	8
8.7	4.3	3.4	2.6	2.1

Reoperations

The occurrence of reoperations was **not** found to be a statistically significant factor in XLIF outcomes, neither at 12 nor 24 months.

Below are VAS scores of XLIF patients who had reoperations.

Preop	3MO	6 MO	12 MO	24 MO
52	38	34	23	9
8.9	4.0	3.2	2.4	1.7

Are 12 Month Outcomes Predictable?

For the purpose of this analysis, VAS success was considered an improvement of at least 2 points (an IDE standard).

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VAS Success:
12 MO: **94.5%**

Factors of VAS Success		
AGE*	Age was a significant factor in success	p=0.0283
Comorbidity	Smoking was not a factor but trended towards significance.	p=0.0502
Prior Fusion	Prior fusion was not a factor in success.	
Preop VAS	Patients with a higher preop VAS were shown to have a better chance of VAS success.	p=0.0065
L4-5 Treated	Inclusion of the L4-5 level did not affect VAS success	
Satisfaction	Satisfaction directly correlated with VAS success.	p=0.0002
“Elect Again”	“Elect Again” directly correlated with VAS success	p=0.007

*Age was a factor in success, although those who were successes were, on average, older: 62.7yrs vs 55.9 yrs

Are 24 Month Outcomes Predictable?

For the purpose of this analysis, VAS success was considered an improvement of at least 2 points (an IDE standard).

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VAS Success:
24 MO: **97.4%**

Factors of VAS Success

Factors of VAS Success		
AGE*	Age did not affect VAS success at 24 months.	
Comorbidity	Patients with COPD were less likely to have VAS success at 24 months.	p=0.0114
Prior Fusion	Prior fusion was not a factor in success.	
Preop VAS	At 24 months, preop VAS approached significance.	p=0.0548
L4-5 Treated	Inclusion of the L4-5 level did not affect VAS success	
Satisfaction	Satisfaction directly correlated with VAS success.	p=0.0002
“Elect Again”	“Elect Again” directly correlated with VAS success	p=0.007

XLIF : 319 pts @ 1 Year Follow-Up Rate Satisfaction

To date, 319 patients treated with XLIF have presented for one year follow-up.

- **88.1%** of patients were satisfied or very satisfied with their outcome.
- **90.2%** definitely or likely would have the surgery again.
- **79.9%** of cases were judged good or excellent outcome by surgeon.

Conclusion

Our data shows satisfactory intermediate term clinical outcomes in our series of 319 XLIF patients at 12 months. VAS scores improved, disk height was restored and maintained, and slip was adequately reduced. Patient and surgeon satisfaction scores at 12 months are encouraging.

Early data shows maintenance of these outcomes in 104 patients at 24 months. More follow-up will be mandatory to determine long-term outcomes.

Statistical Significance

Of particular interest is the statistical analysis of our data, showing that certain aspects of a patient's demographics, or radiographic outcomes from their surgery, are predictive of the success of the procedure. We believe that this is the first time such factors have been delineated and their effects on outcomes in XLIF quantified.

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JEFFERSON CITY, MO



Thank you