

Adjacent Segment Disease following Lumbar Spinal Fusion

Dr Bill Sears

Neurosurgical Society of Australasia Annual Scientific Meeting

Adelaide, September 1st 2017

Disclosures

- Consultant:
 - Paradigm Spine
 - Medtronic
- Royalties:
 - Medtronic: *Interbody fusion implant*
 - Paradigm Spine: *Dynamic stabiliser*



Patient from control arm of
Coflex® FDA IDE trial
(Images courtesy of Paradigm Spine)

... fusion disease... or natural history?

Prevalence

SPINE Volume 33, Number 15, pp 1701–1707
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Lumbar Adjacent Segment Degeneration and Disease After Arthrodesis and Total Disc Arthroplasty

James S. Harrop, MD,* Jim A. Youssef, MD,† Mitch Maltenfort, PhD,* Peggy Vorwald, BS,†
Pascal Jabbour, MD,* Christopher M. Bono, MD,‡ Neil Goldfarb, BS,§
Alexander R. Vaccaro, MD,* and Alan S. Hilibrand*

- ASDegen **34% (314/926)**
- ASDis **14% (173/1216)**

Adjacent Segment Disease Following Posterior Lumbar Interbody Fusion: *A Retrospective Review of 1000 PLIFs*

William Sears

Royal North Shore & Dalcross Adventist Hospitals
Sydney, Australia

NASS 2010 & EuroSpine 2010 & *Spine J* 2011



Study Population

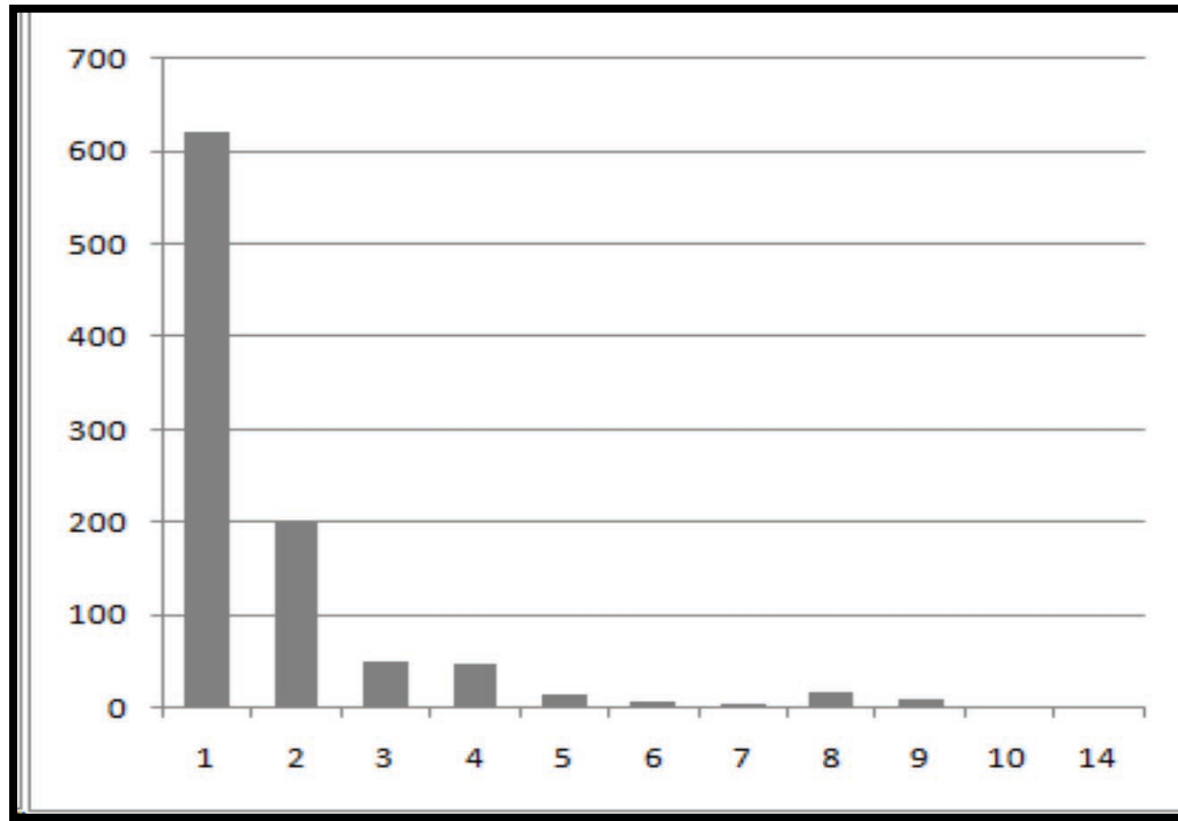
- **912 patients, 1000 consecutive PLIF procedures**
 - October 1993 – November 2009
 - Mean age: 63 yrs (range: 14-92)
- Inclusion criteria:
 - Lumbar degenerative pathology
 - Failed conservative management
- **Follow-up:**
 - **91 % patients, 92 % procedures**

Surgical Technique

- Posterior lumbar interbody fusion (PLIF)
 - **Open technique**
 - Insert & rotate interbody spacers
 - Pedicle screw instrumentation
- **Attempted restoration of coronal & sagittal balance**



Levels fused



Results

- Prevalence:
 - 130 / 1000 procedures – 13% (*mean f/u: 63 months*)
 - 12 laminectomy
 - 118 further fusions
- Annual incidence (*all patients*) – 2.5% (*95%CI: 1.9-3.1*)
- Mean time to further surgery – 43 months (*range: 2.3 – 162*)

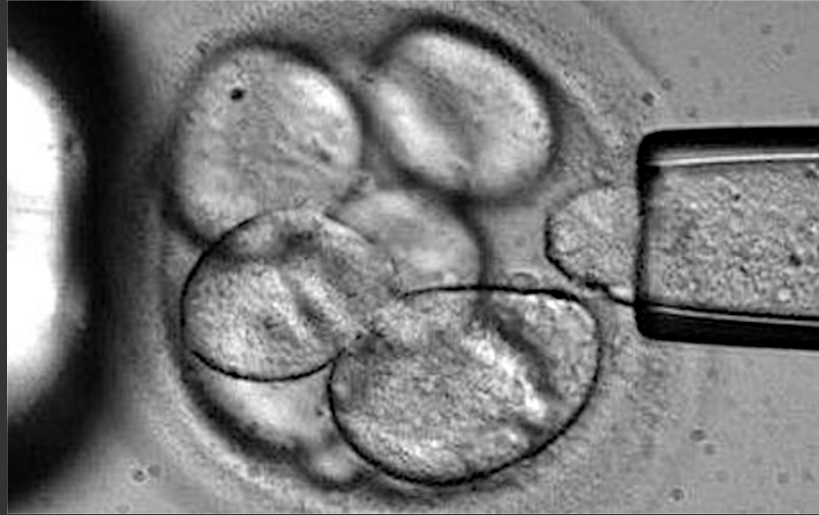
ASD relevance?

- 1,288,496 primary posterior lumbar fusion operations in the U.S. (1998 – 2008)

Pumberger M et al, *JBJS(Br)* 2012

→ 125,000 – 250,000 further surgeries for ASDis in the U.S. by 2018

... fusion disease... or natural history?



Pre-programmed
biological response?

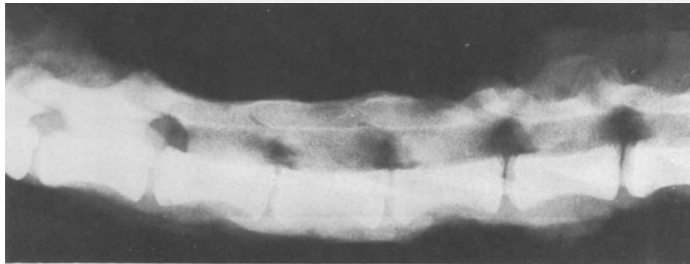
Genetics

The Effect of Spinal Fusion on Intervertebral Disc Composition: An Experimental Study¹

T. K. F. TAYLOR, D.PHIL.(OXON.), F.R.C.S., F.R.C.S.(EDIN.), F.R.A.C.S.;
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Raymond Purves Research Laboratories (University of Sydney), The Royal North Shore Hospital of Sydney, St. Leonards, N.S.W. 2065, Australia

Submitted for publication November 19, 1975



Genetics

- Battie et al. *Spine* 1995
 - 115 pairs human male monozygotic twins
 - DDD on MRI
 - Explained by:
 - Genetic factors – primarily
 - Environmental factors – complex contribution (incl. occupation)
- Sambrook et al. *Arthritis Rheum.* 1999
 - 86 monozygotic & 154 dizygotic twins
 - DDD on MRI
 - **Genetic inheritance: ~ 74% contribution**

Genetics

- Livshits et al. *Ann Rheum Dis.* 2011
 - Cross-sectional study 2256 women
 - 371 monozygotic & 698 dizygotic twins
 - **Odds ratio for LBP:**
 - **Monozygotic 6**
 - **Dizygotic 2.2**
 - Correlation between LBP and DDD ($p < 0.001$)

Genetics

- Gologorsky & Chi. *Neurosurg.* 2014
 - **Lumbar DDD probably polygenic**
 - Many genetic variants → small/moderate contributions
- Rajasekaran et al. *Spine* 2016
 - 71 single-nucleotide polymorphisms of 41 candidate genes correlated to 6 MRI markers of DDD in 809 patients
 - Studies of genetic associations prone to variability
 - **Difficult to consider one set of genes responsible**

Environment

Demographic & Environmental factors

- Age
- Gender
- Occupation
- Smoking

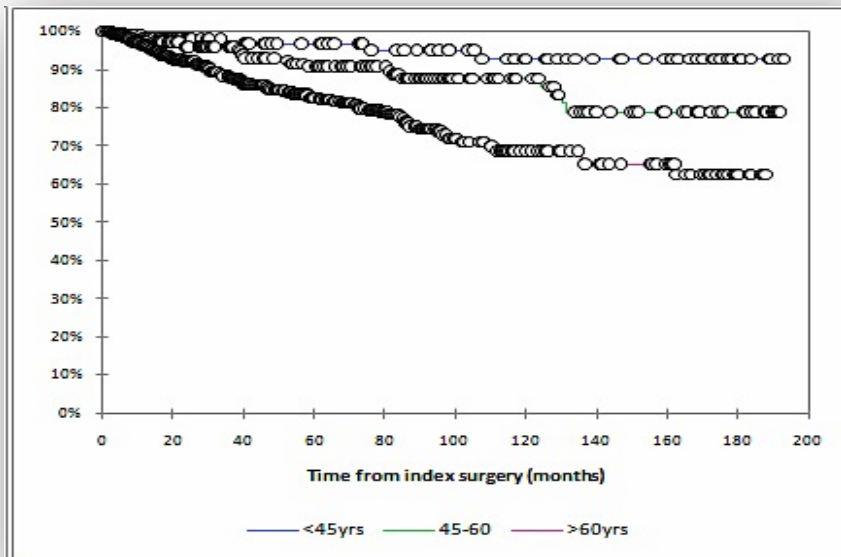
Demographic & Environmental factors

- Age

- A risk factor in most studies

- Age > 60 yrs → 2.5x risk of ASD Lee JC et al. *Spine* 2014

- Retrospective cohort study (n=1000) Sears et al. *Spine J* 2011



Cox proportional-hazards regression analysis

Covariate	Relative Risk (95%CI)	P value
< 45yrs	x 0.25 (0.10 to 0.63)	0.003
45-60yrs	x 0.55 (0.34 to 0.87)	0.01

Demographic & Environmental factors

- Age
- Gender
 - ASD – **no** (7 studies)

Demographic & Environmental factors

- Age
- Gender
- Occupation
 - 45 ♂ monozygotic twin study DDD. Battie et al. *Lancet* 2002
 - **modest effect**

Demographic & Environmental factors

- Age
- Gender
- Occupation
 - 45 ♂ monozygotic twin study DDD. Battie et al. *Lancet* 2002
 - modest effect
 - 115 ♂ monozygotic twin study DDD. Battie et al. *Spine* 1995
 - 7% upper lumbar
 - **2 % lower lumbar → 9% with age → 43% with familial aggregation**

Demographic & Environmental factors



- **Smoking**

- Monozygotic twin study → DDD

Järvinen & Aho. *Semin Arthritis Rheum* 1994

- **ASD**

- Retrospective (n=89). Mok et al

→ **Yes**

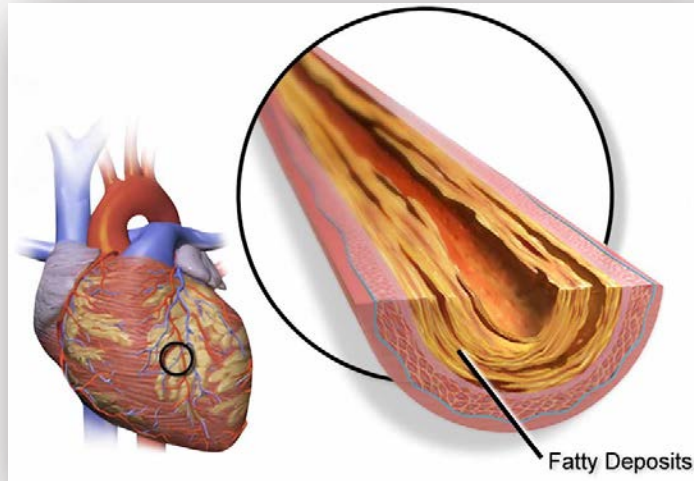
- Case control (n=51) & retrospective (n=137). Djurasovic et al & Alentado et al

→ **No**

Co-morbidities

- Diabetes
 - No clear evidence
- Depression
 - Retrospective ASD study. (n=137) Alentado et al *Spine* 2016
 - **O.R.: 5.35**, p=0.03

Co-morbidities



Study. (n=137) Alentado et al *Spine* 2016

- Cardio-vascular disease
 - Alentado et al → **Yes** (p=0.02)
 - Lee et al. *J Korean Neurosurg Soc.* 2017 **Hypertension ↔ DDD**

Co-morbidities

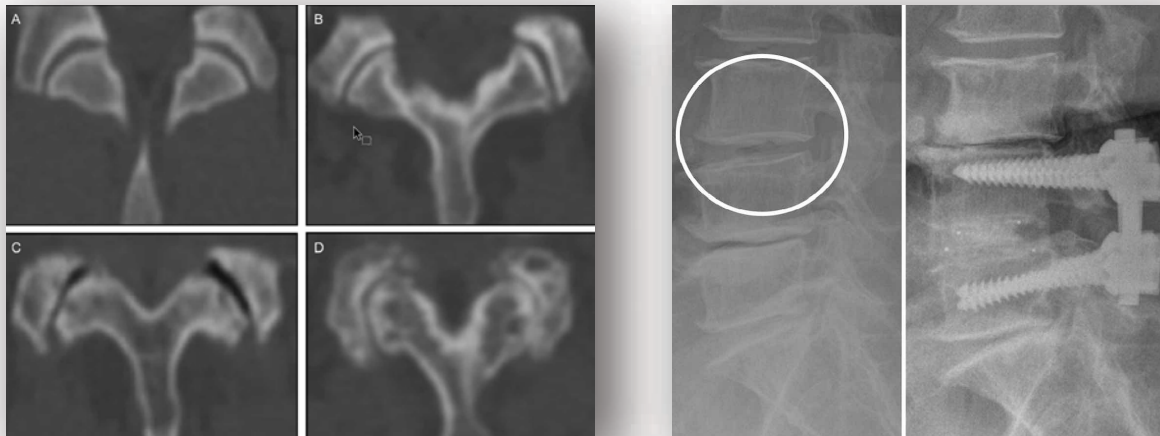


(n=137) Alentado et al *Spine* 2016

- Obesity
 - Nakashima et al & Alentado et al → **No** (*for ASD*)
 - Hangai et al & Lee et al → **Yes** (*for DDD*)
 - 1:1 pair analysis (n=100) ASD vs. No ASD Kim JY et al. *Spine J* 2016
→ **OR: 1.36, p=0.008**

Pre-existing ASD

- **Yes**
 - Retrospective, n=62 Han et al *J Neurosurg Spine* 2016
 - **Pfirrmann grade > 3 → 8.75x risk of ASD (p=0.005)**
 - Retrospective 1:1 pair analysis, n=100 Kim JY et al *Spine J* 2016
 - **Pre-op Facet joint degen → ASD (OR: 3.1, p=0.011)**
 - **Pre-op DDD → ASD (OR: 2.8, p=0.003)**



Pre-existing ASD

- **No**
 - Case-control retrospective, n=51 Djurasovic et al *Orthopedics* 2008

Biomechanical effects of fusion

- Range-of-motion
- Intradiscal pressures
- Facet joint loads
- Neutral zone

- Evidence:
 - *Ex vivo*
 - *In vivo*

Biomechanical effects of fusion

- *Ex vivo* study methodologies
 - Test protocol ?

Biomechanical effects of fusion

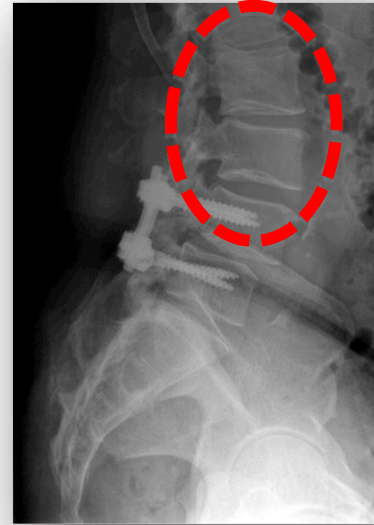
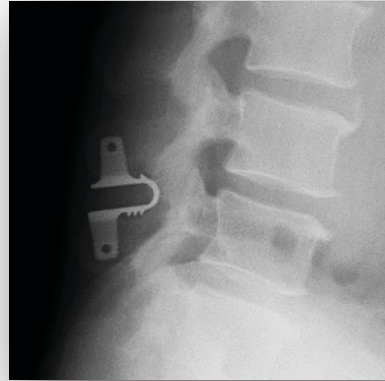
- *Ex vivo* study methodologies
 - Test protocol
 - Flexibility (load control)
 - Stiffness (displacement control)
 - Hybrid

Biomechanical effects of fusion

- *Ex vivo* study methodologies
 - Test protocol
 - Flexibility (load control)
 - Stiffness (displacement control)
 - Hybrid
 - **Systematic review of *in vivo* post fusion kinetics**

Malakoutian et al. *Eur Spine J* 2015

 - 5/6 studies reported ↓ ROM post fusion



The Coflex[®] vs. Fusion IDE Trial – An *in vivo* Biomechanical Study of Adjacent Segment Motion following Fusion

W.R. Sears¹, R.J. Davis², J.D. Auerbach³

¹Wentworth Spine Clinic, Sydney, Australia, ²Greater Baltimore Neurosurgical Associates, Baltimore, MD, USA, ³Albert Einstein College of Medicine, Bronx, NY, USA

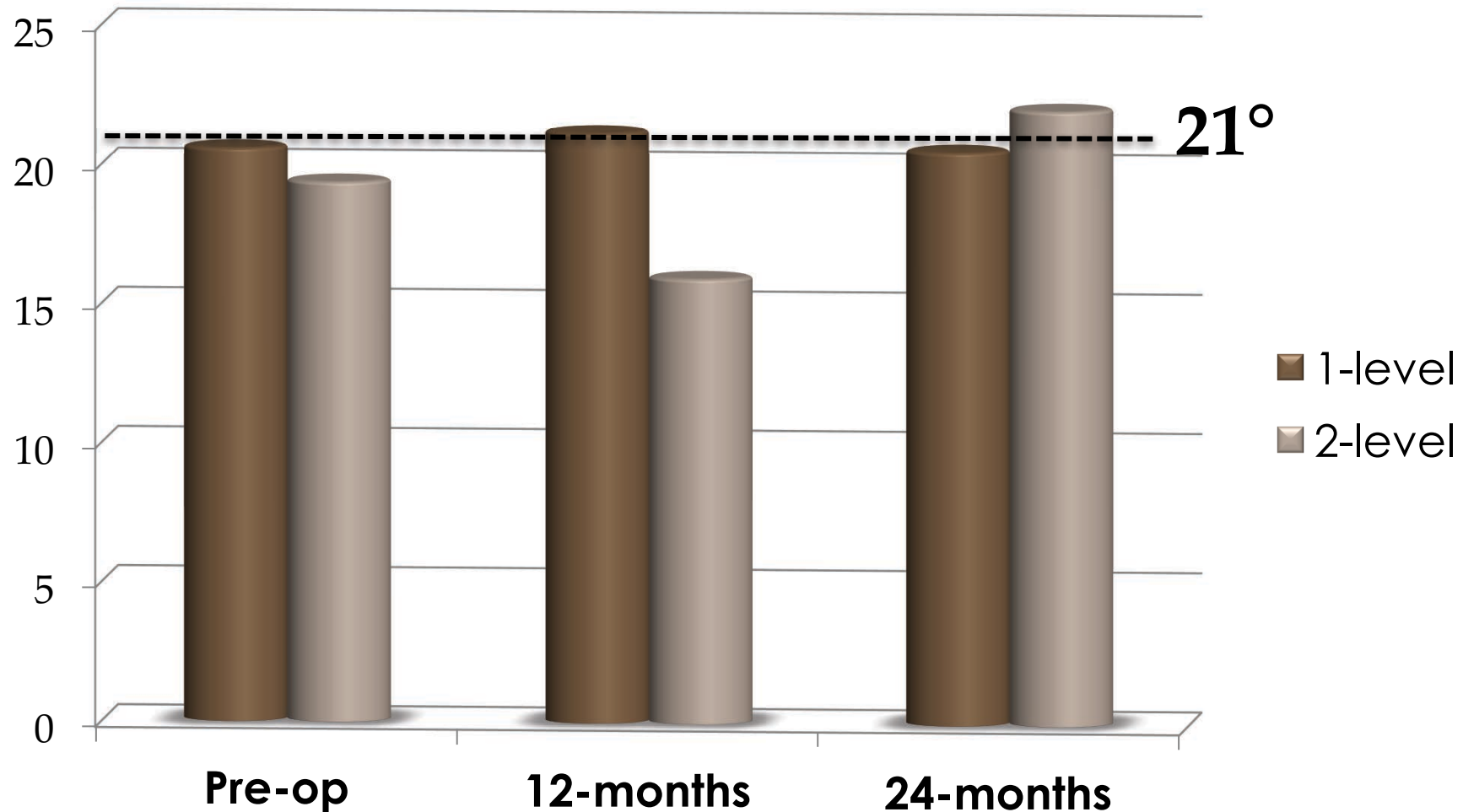
NASS 27th Annual Meeting (2012)

Dallas, October 2012



Wentworth
Spine Clinic

Total lumbar range of motion (L1-S1 in degrees, fusion patients)

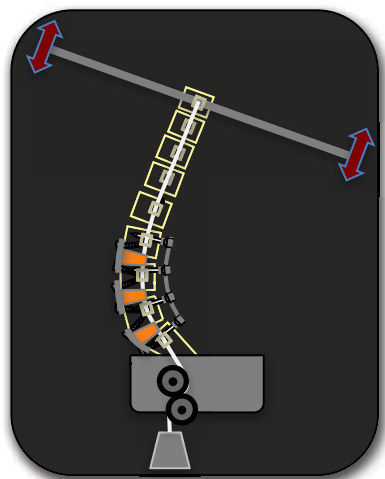


Displacement control – *in vivo*



Fusion variables: Biomechanical effects and ASD risk

- Length of fusion
- Fusion alignment
 - Sagittal plane
 - Coronal plane
- Fusion rigidity



**PROGRESSIVE INCREASE IN MECHANICAL BURDEN
ON ADJACENT LEVELS
AFTER 1-, 2- & 3-LEVEL LUMBAR FUSIONS:
an *in vitro* Study**

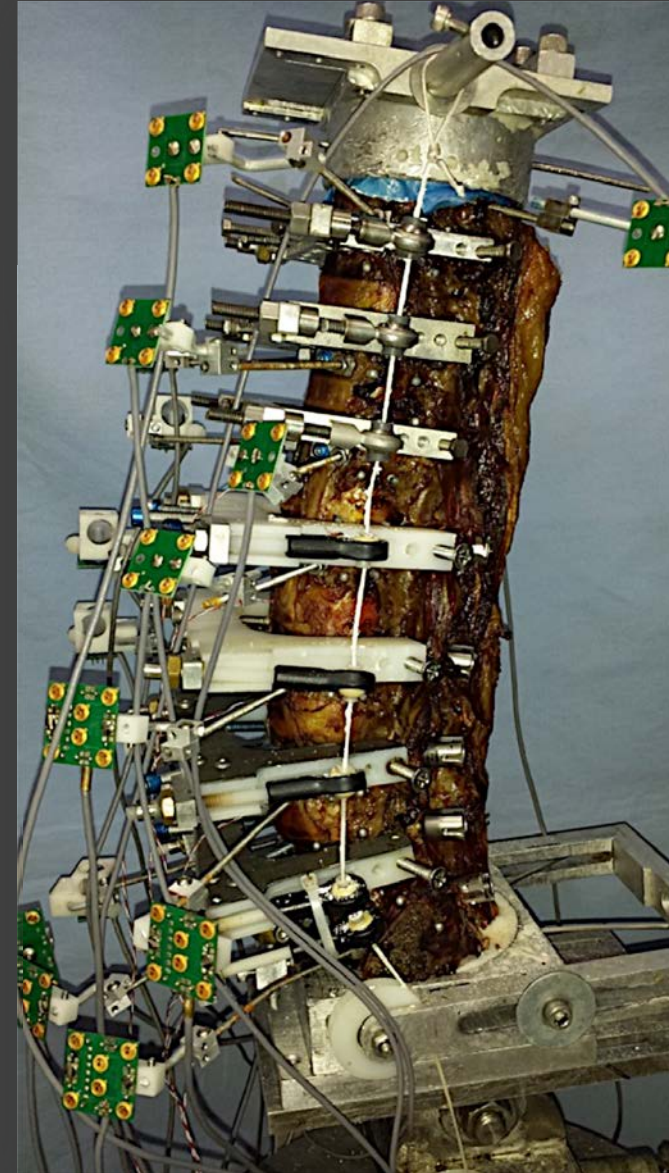
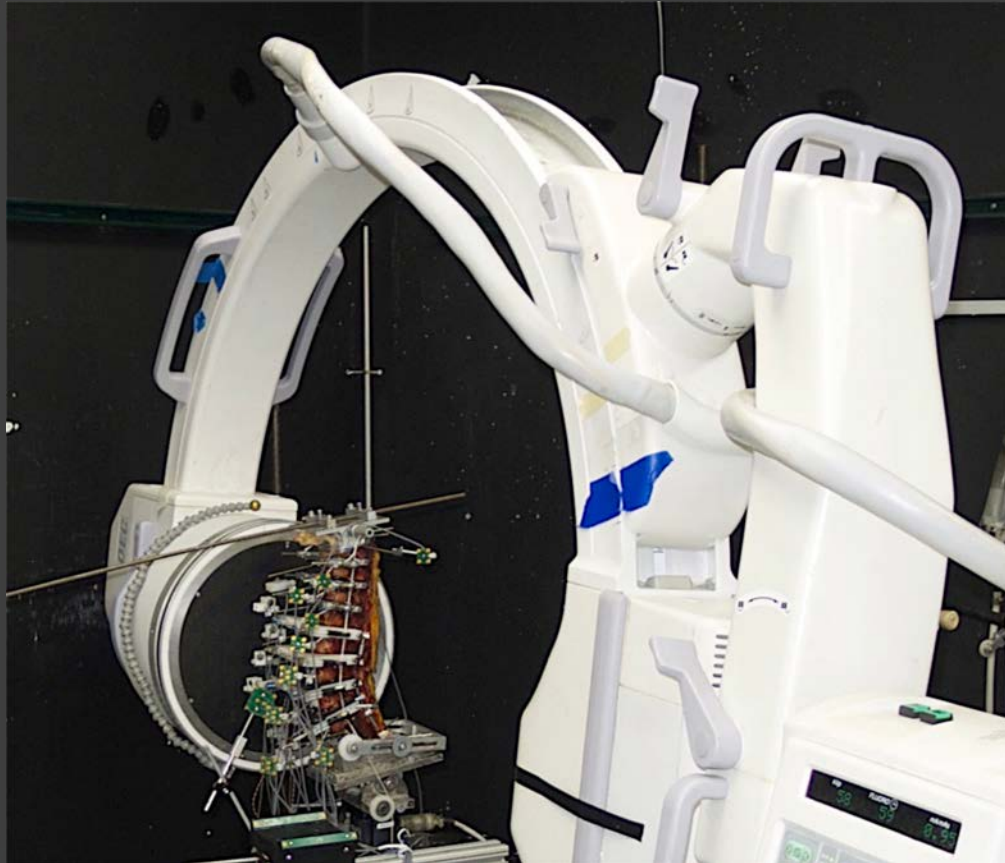
William Sears* Ryan Sullivan# Leonard Voronov# Robert Havey# Gerard Carandang#
Muturi Muriuki# Saeed Khayatzadeh# Avinash Patwardhan#

*Wentworth Spine Clinic, Sydney, Australia; #Orthopedic Biomechanics Lab, Edward Hines Jr. VA Hospital, Chicago, USA

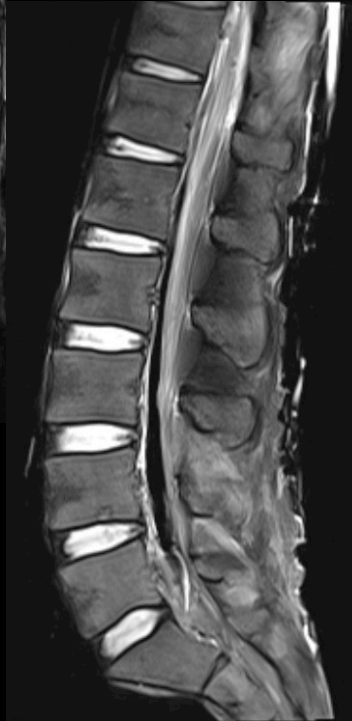
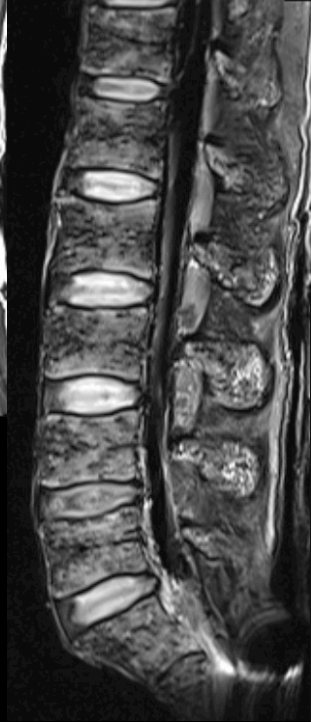
ISASS, SanDiego, Ca.

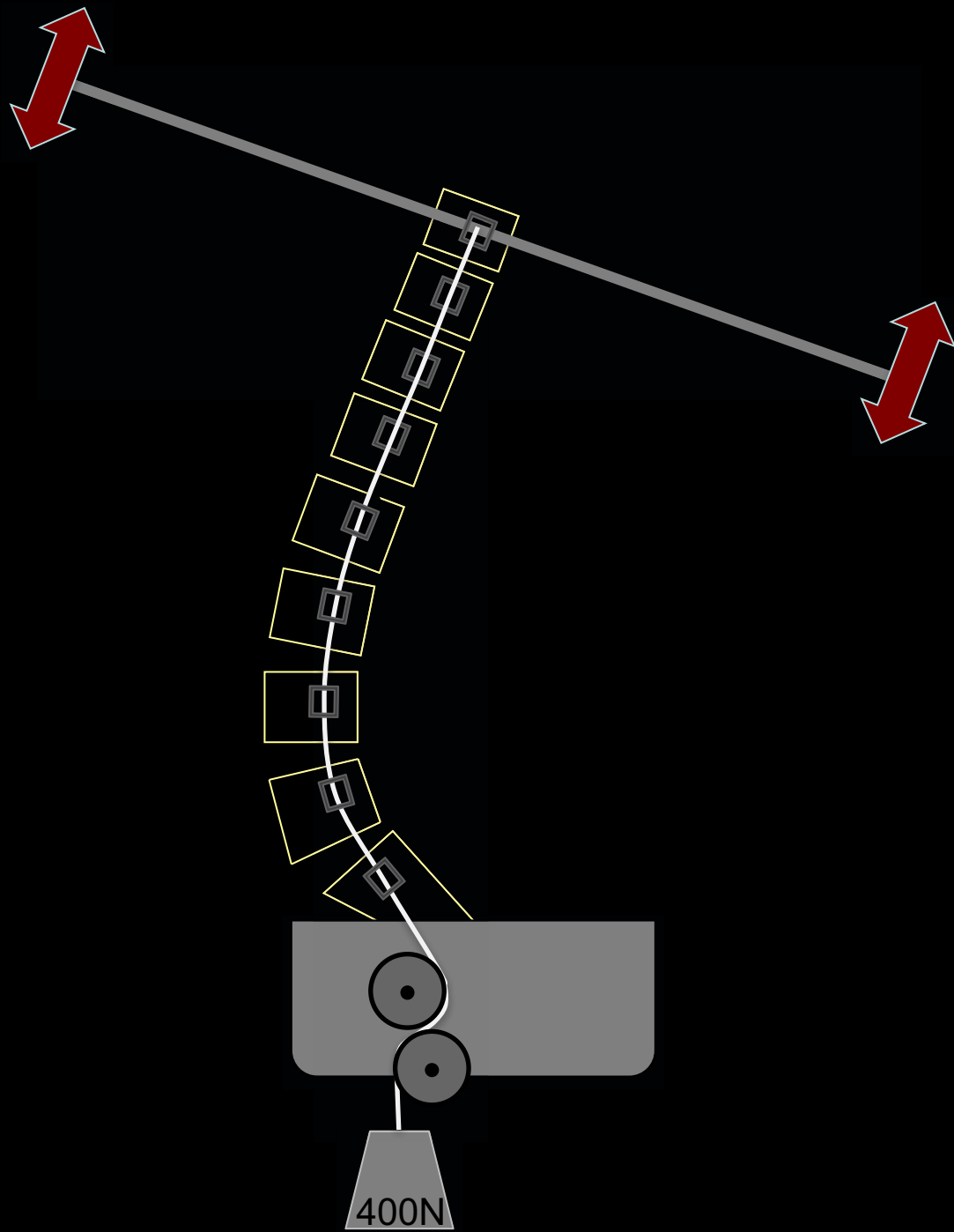
April 2015

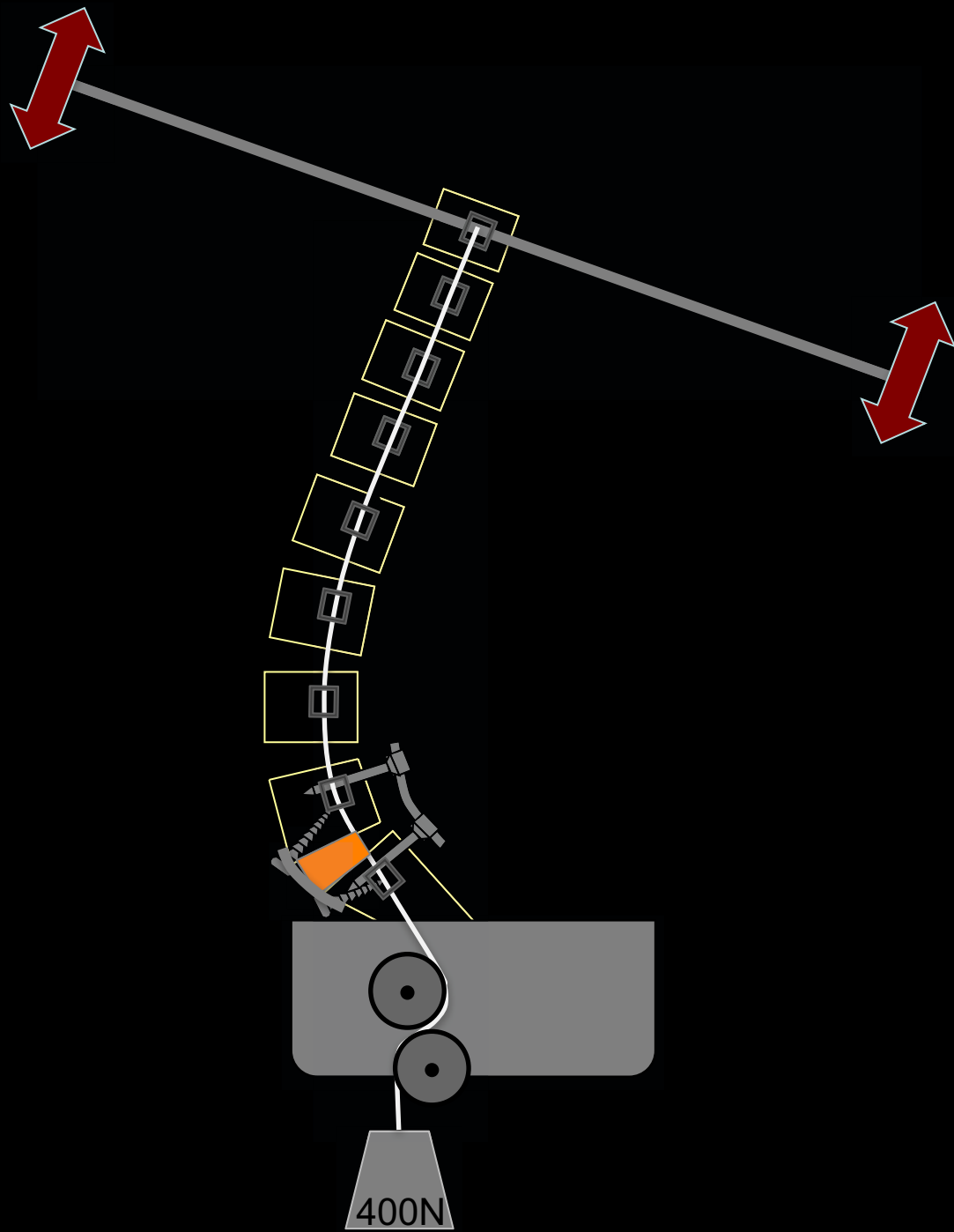
Test Setup

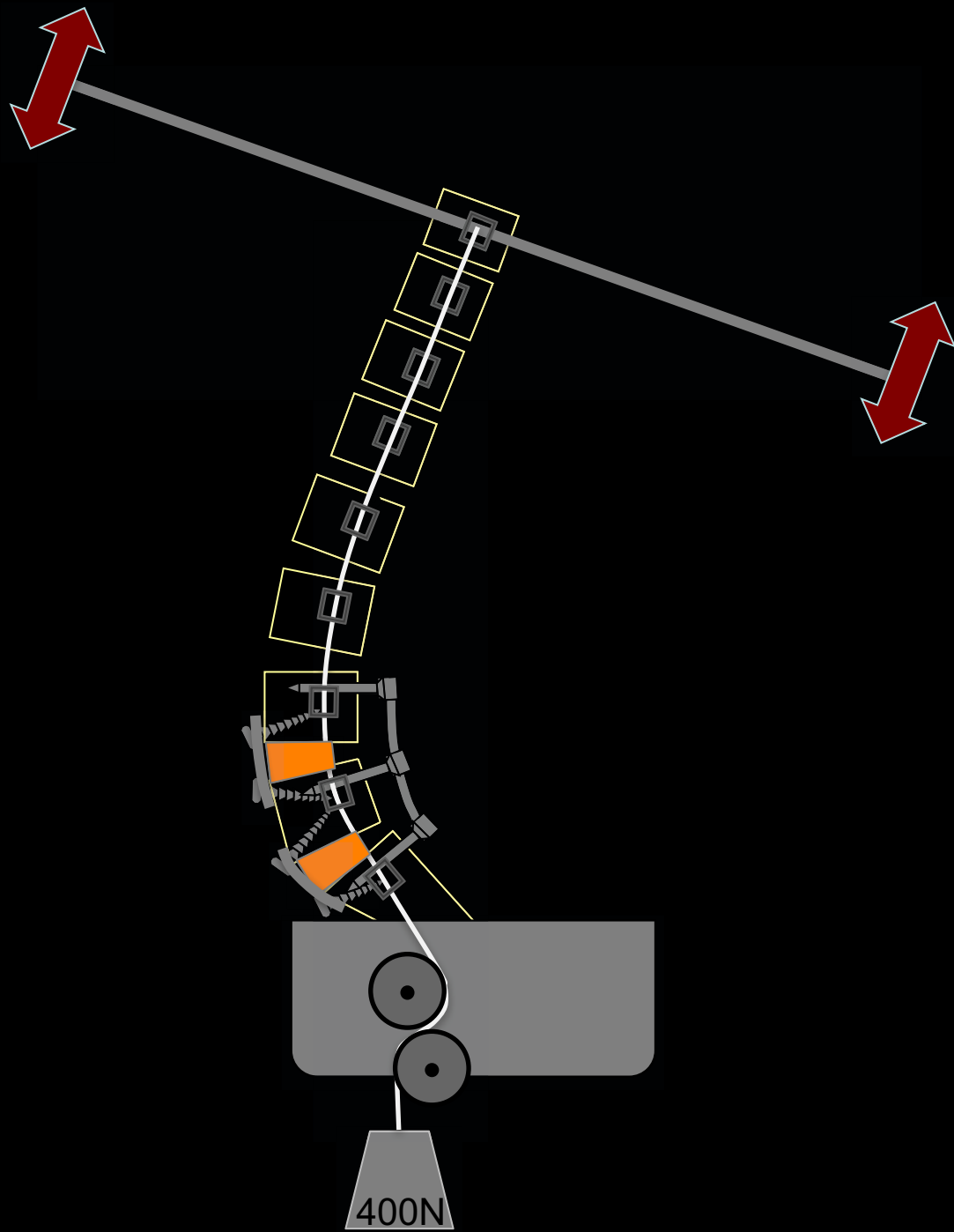


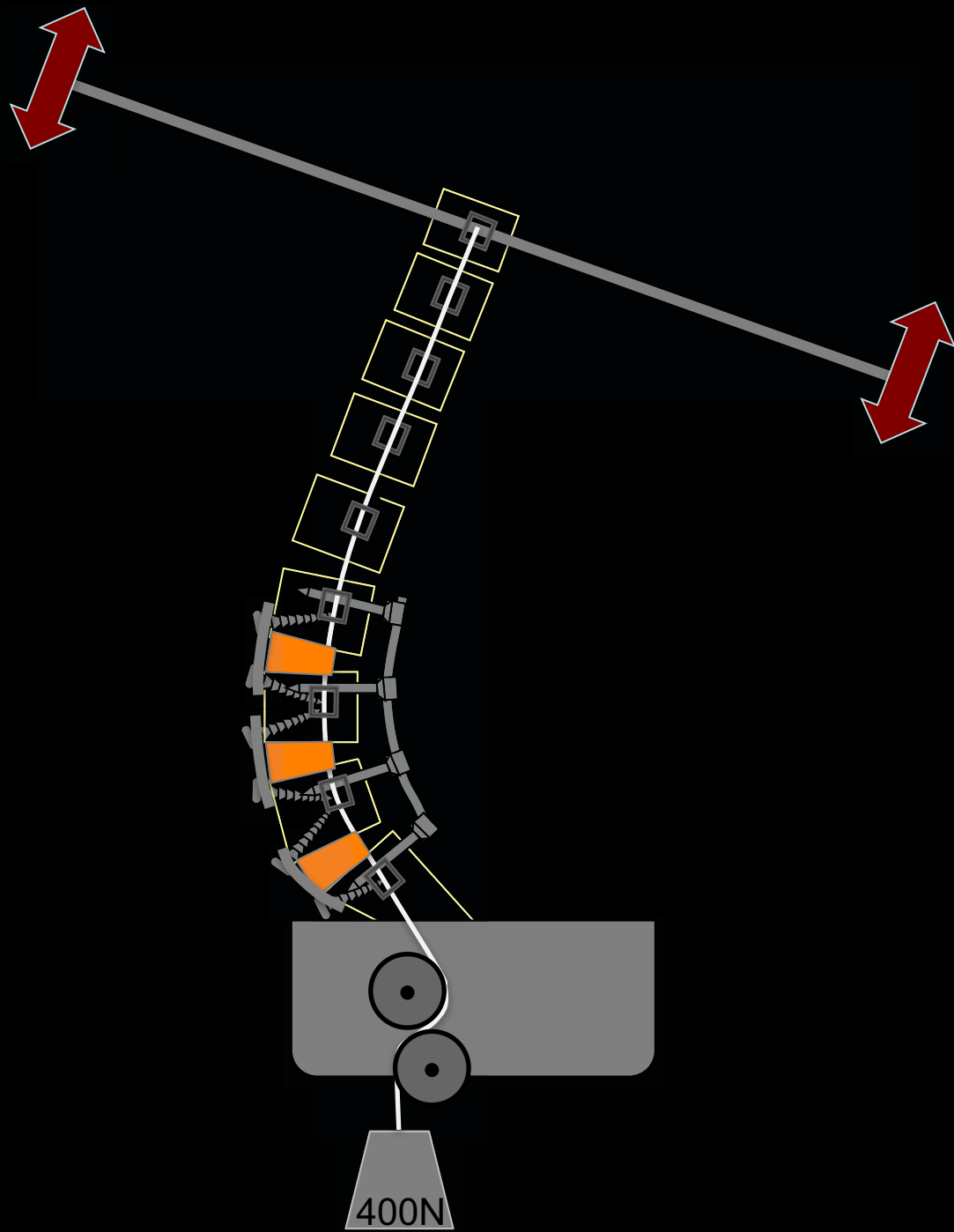
Mean age: 45years
(range: 30-51)

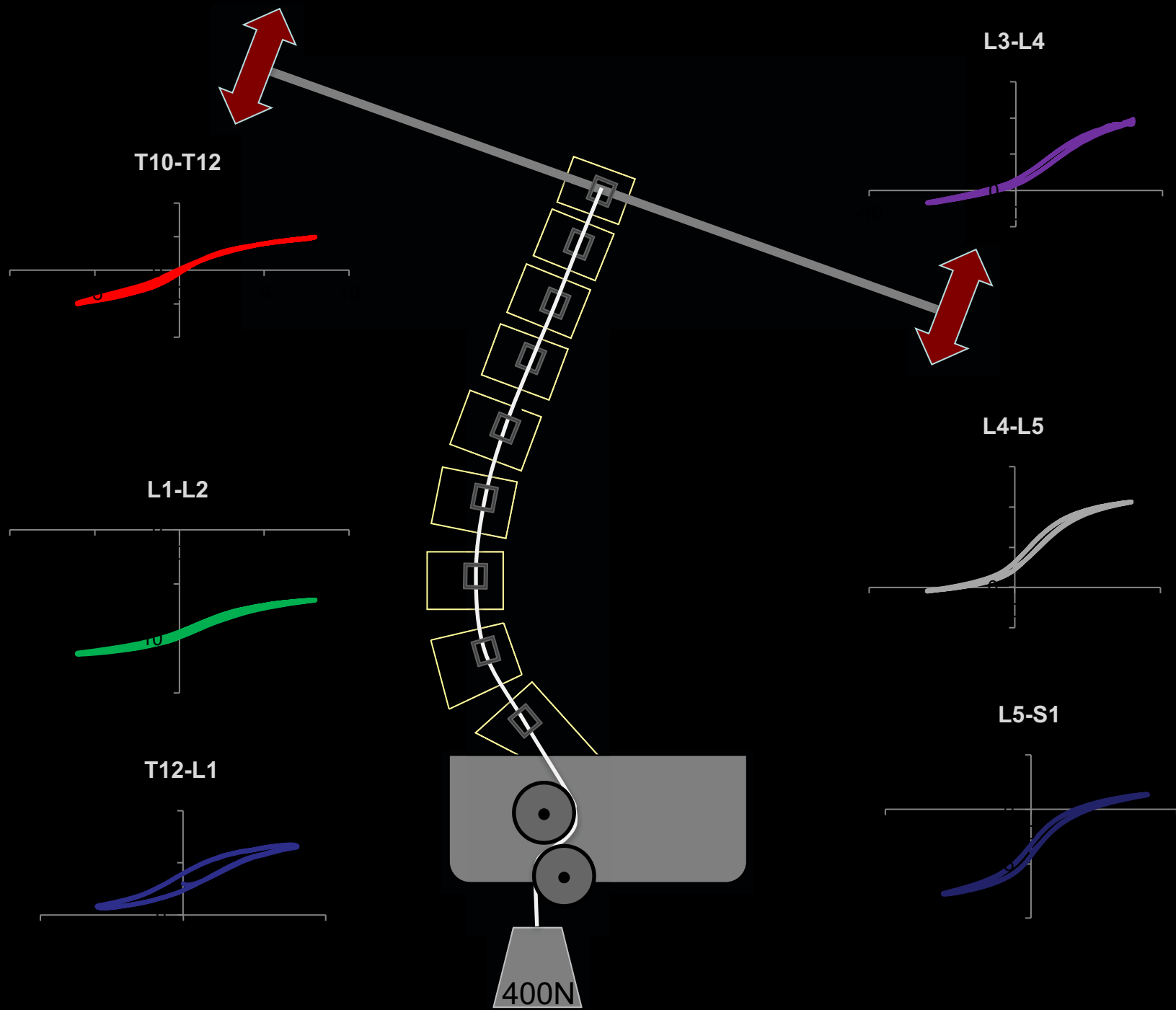






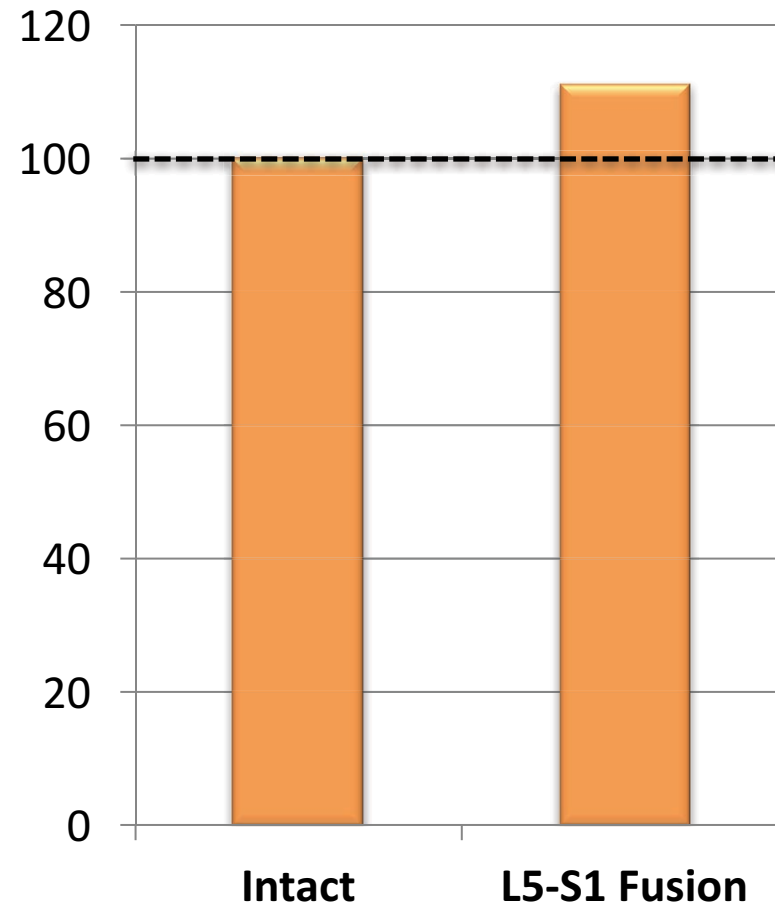






Mean pooled Range of Motion @ L4/5

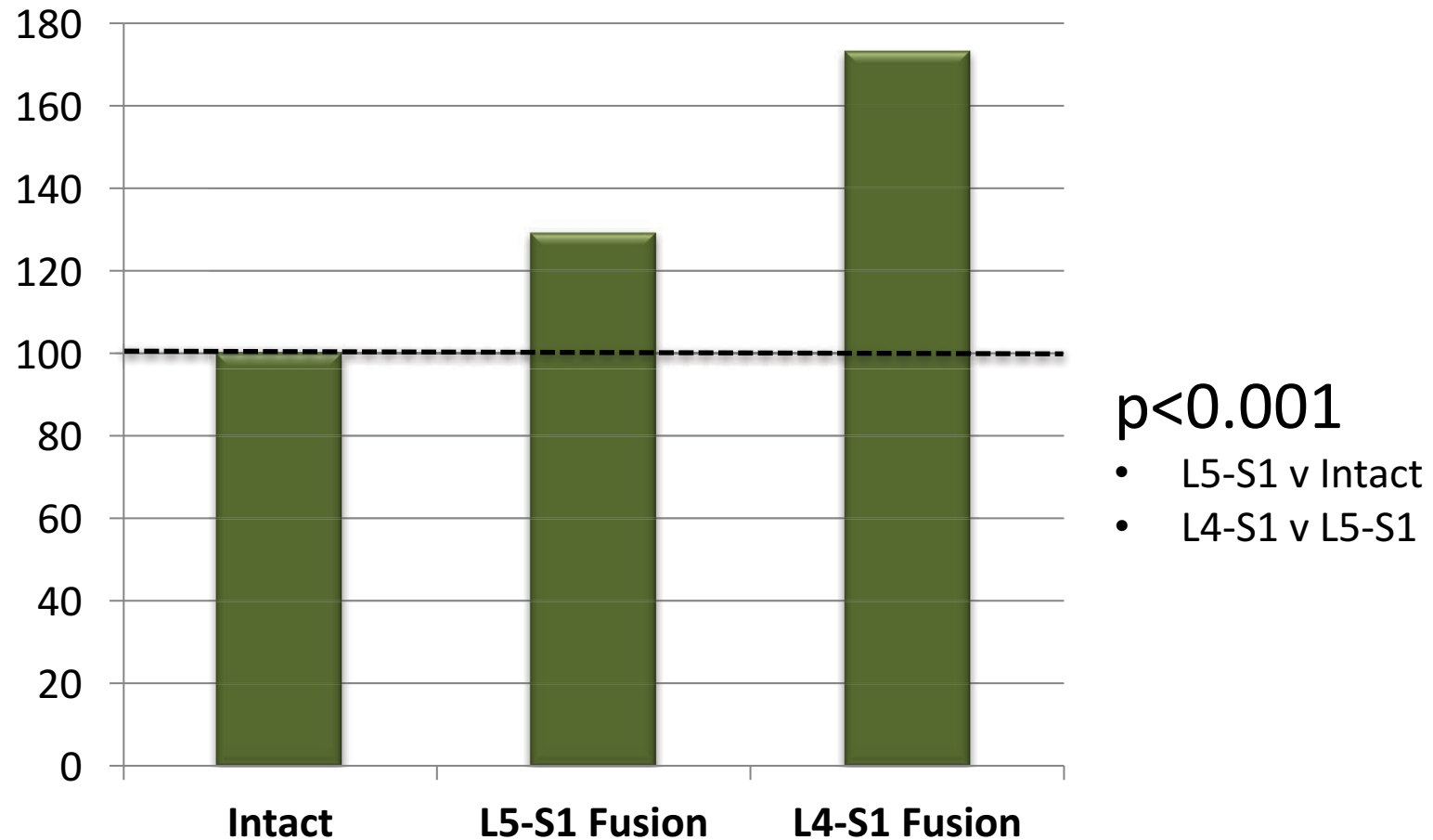
%age of intact, Displacement control



p=0.04

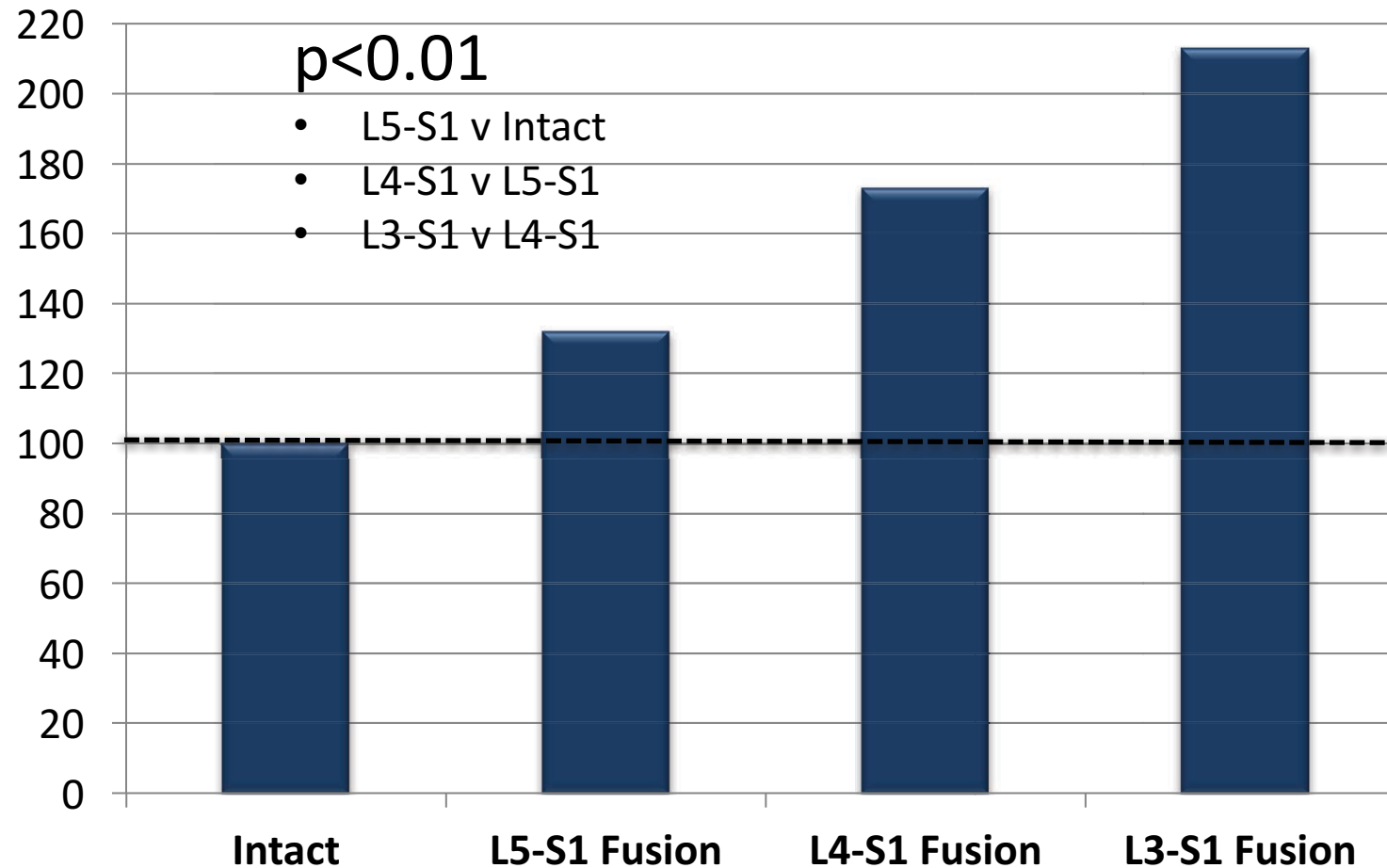
Mean pooled Range of Motion @ L3/4

%age of intact, Displacement control



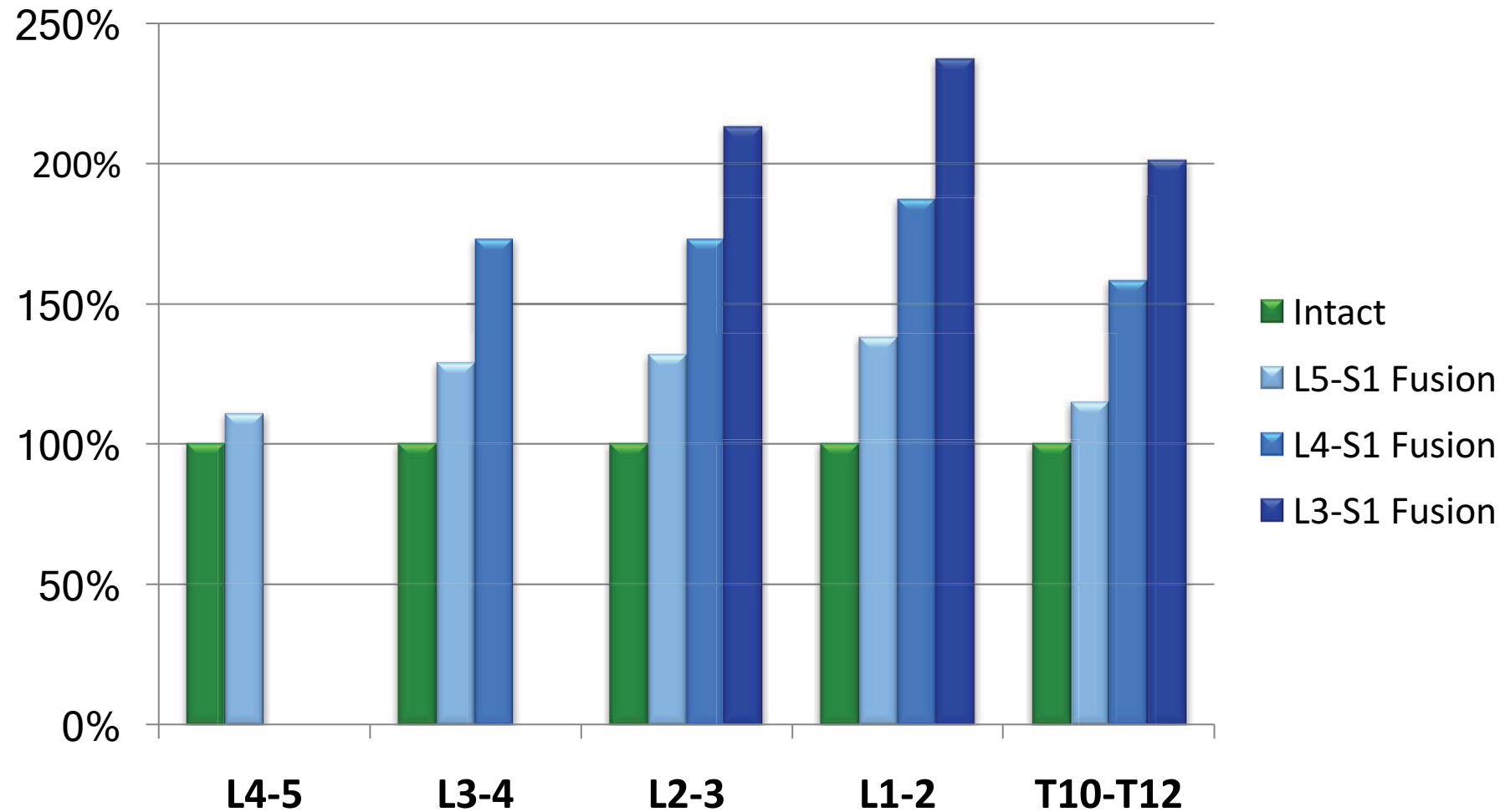
Mean pooled Range of Motion @ L2/3

%age of intact, Displacement control



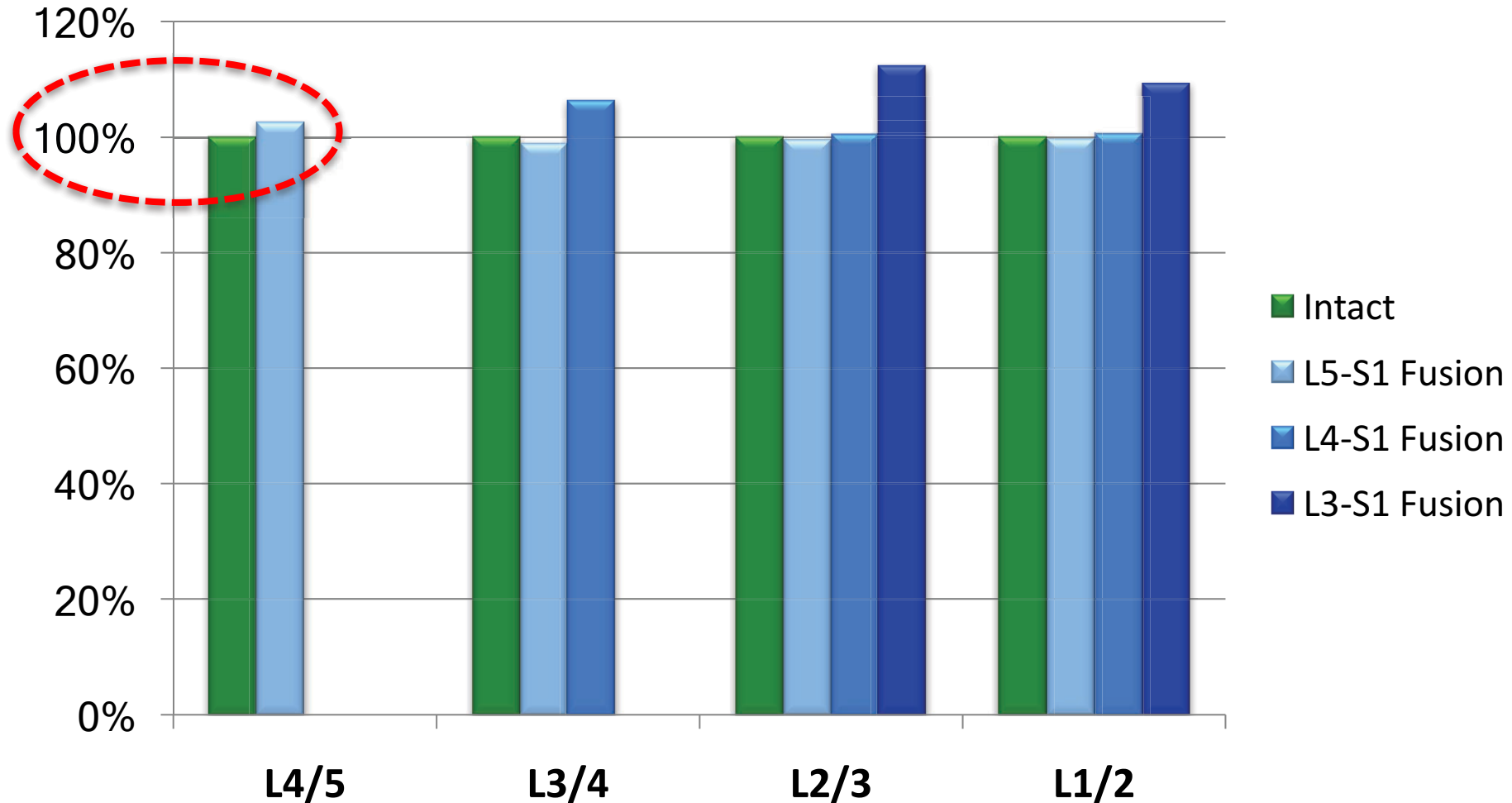
Mean Segmental Ranges of Motion

(Displacement Control, Flex/ext, %age of intact)



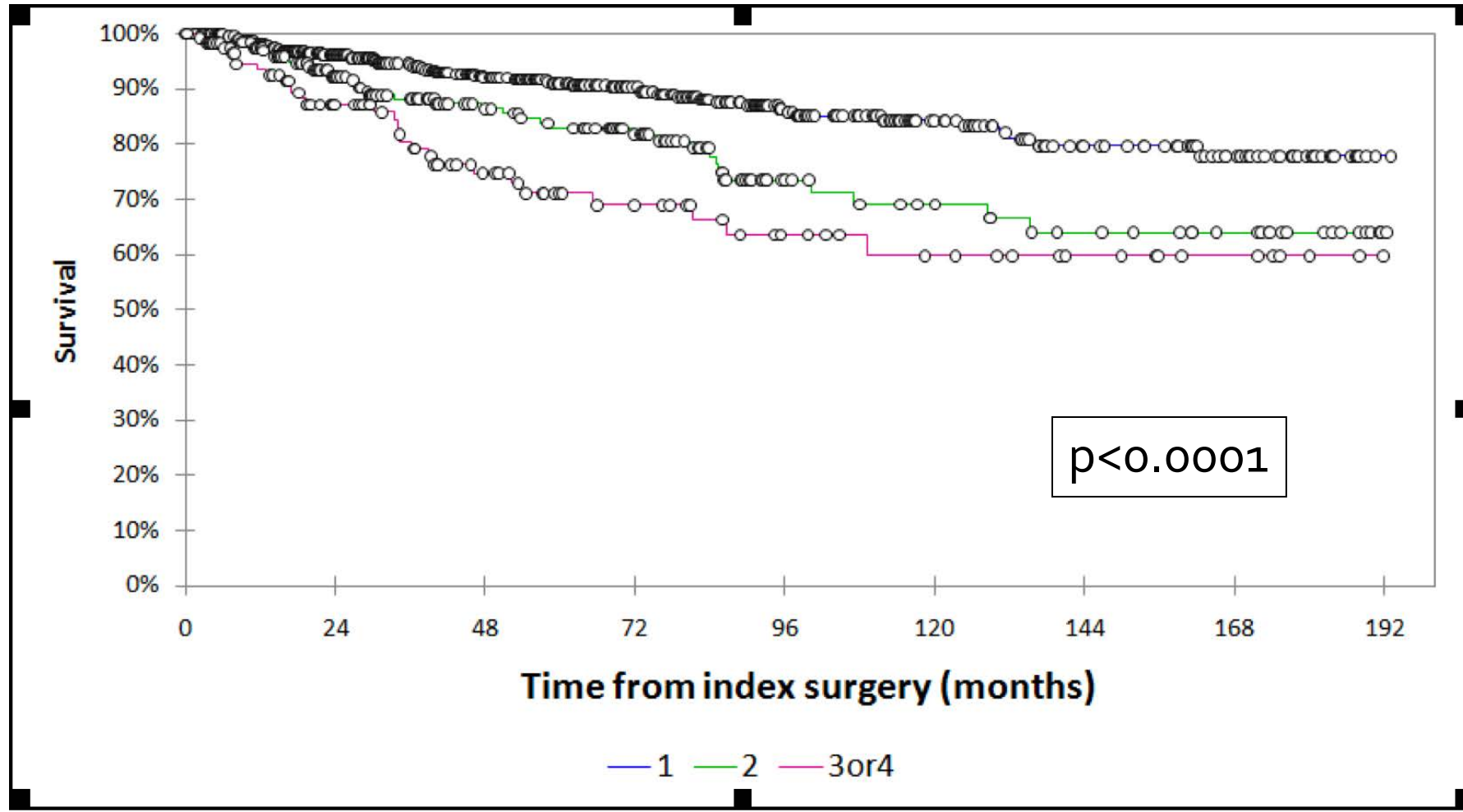
Mean Segmental Ranges of Motion

(Load Control, Flex/ext, %age of intact)



Kaplan Meier Survivorship Analysis. n=1000, Sears et al. *Spine J* 2011

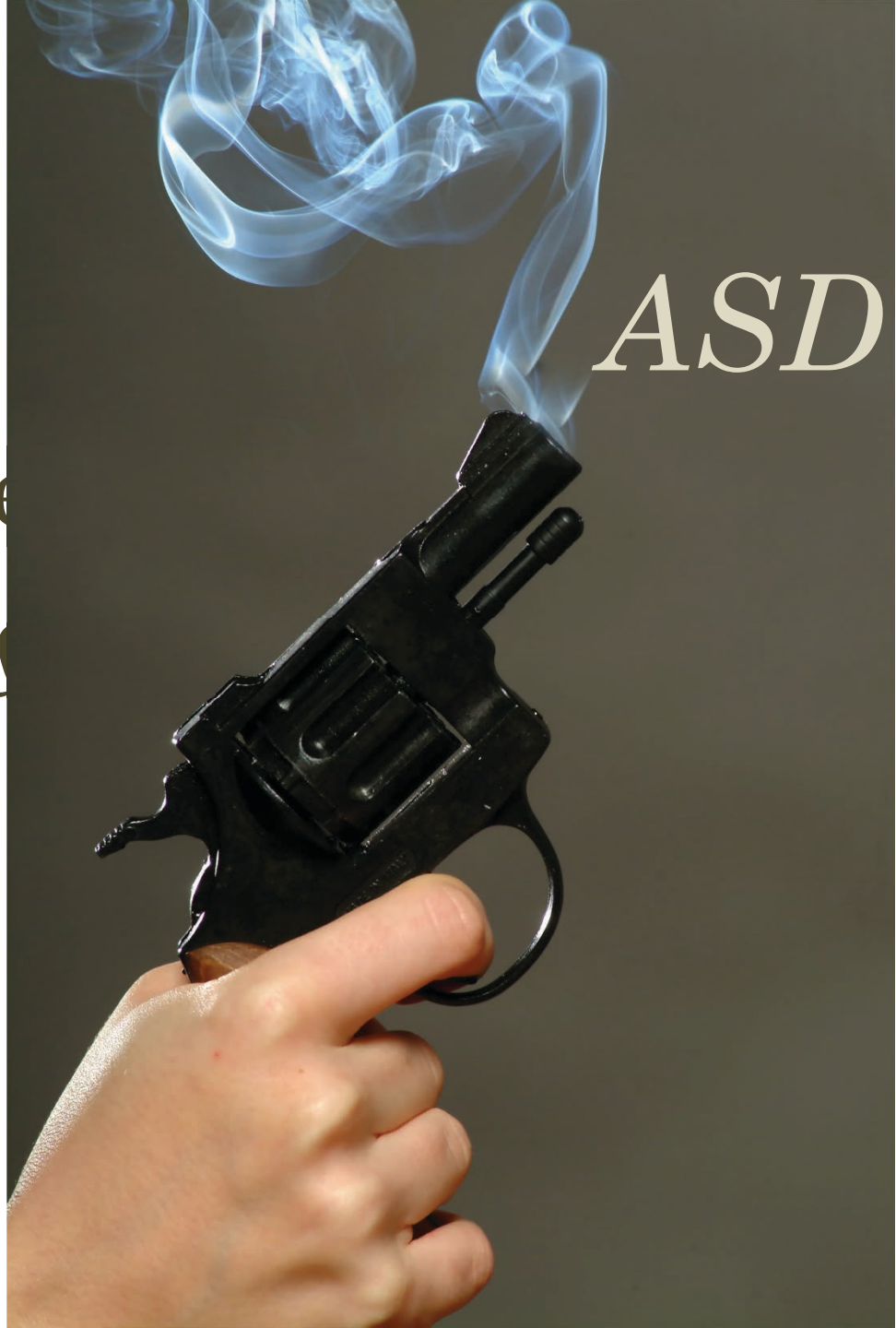
Number of Levels Fused: 1, 2, 3 & 4



Annual Incidence & Prevalence vs. Number of Levels Fused

<i>No. of Levels Fused</i>	Annual Incidence (95%CI)	Prevalence <i>5 year</i>	Prevalence <i>10 year</i>
Mixed (all patients)	2.5 % (1.9-3.1)	14 %	22 %
1	1.7 % (1.3-2.2)	9 %	16 %
2	3.6 % (2.1-5.2)	17 %	31 %
3 & 4	5.0 % (3.3-6.7)	29 %	40 %

↑ Range
in vitro &



ASD

Lumbar Spinal Fusion as a Risk Factor for Adjacent Segment Degeneration – Results of a Randomized Controlled Trial

W. Sears¹, G. Maislin², R. Davis³, T. Errico⁴, H. Bae⁵

1 Wentworth Spine Clinic, Sydney, Australia; 2 Biomedical Statistical Consulting, Wynnwood, PA; 3 Greater Baltimore Neurosurgical Associates, Baltimore, MD, United States; 4 NYU Hospital for Joint Diseases, New York, NY; 5 Cedars Sinai Spine Center, Los Angeles, CA

EuroSpine 2016, Berlin, September 7th 2016

Methodology

- Inter-laminar dynamic spacer US IDE RCT
- Secondary quantitative data analysis



Spine

SPINE Volume 38, Number 18, pp 1529-1539
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RANDOMIZED TRIAL

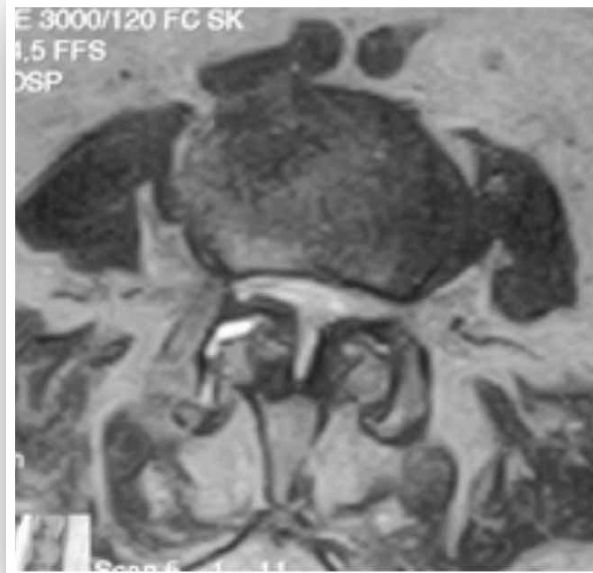
Decompression and Coflex Interlaminar Stabilization Compared With Decompression and Instrumented Spinal Fusion for Spinal Stenosis and Low-Grade Degenerative Spondylolisthesis

Two-Year Results From the Prospective, Randomized, Multicenter, Food and Drug Administration Investigational Device Exemption Trial

Reginald J. Davis, MD,* Thomas J. Errico, MD,† Hyun Bae, MD,‡ and Joshua D. Auerbach, MDS

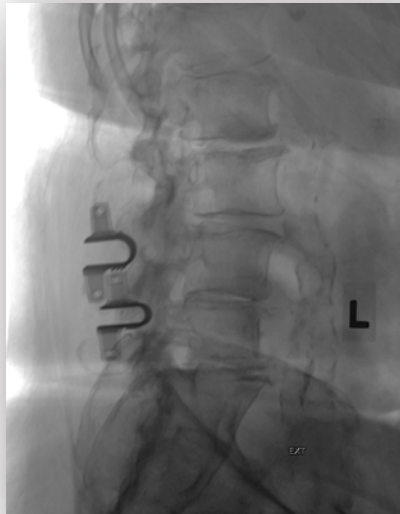
Methodology

- Inter-laminar dynamic spacer *vs.* posterolateral fusion



Methodology

- Inter-laminar dynamic spacer IDE RCT
 - **two-level arm**
 - 55 investigational & 27 fusion controls

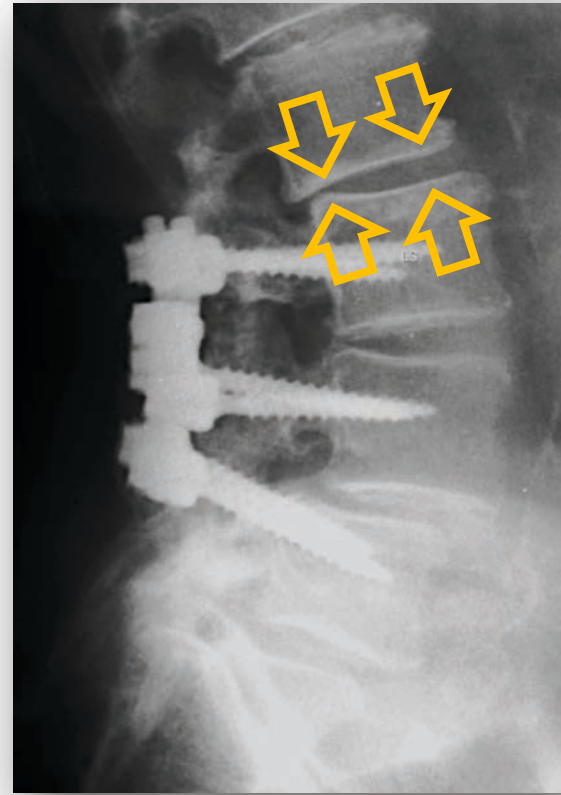


Methodology

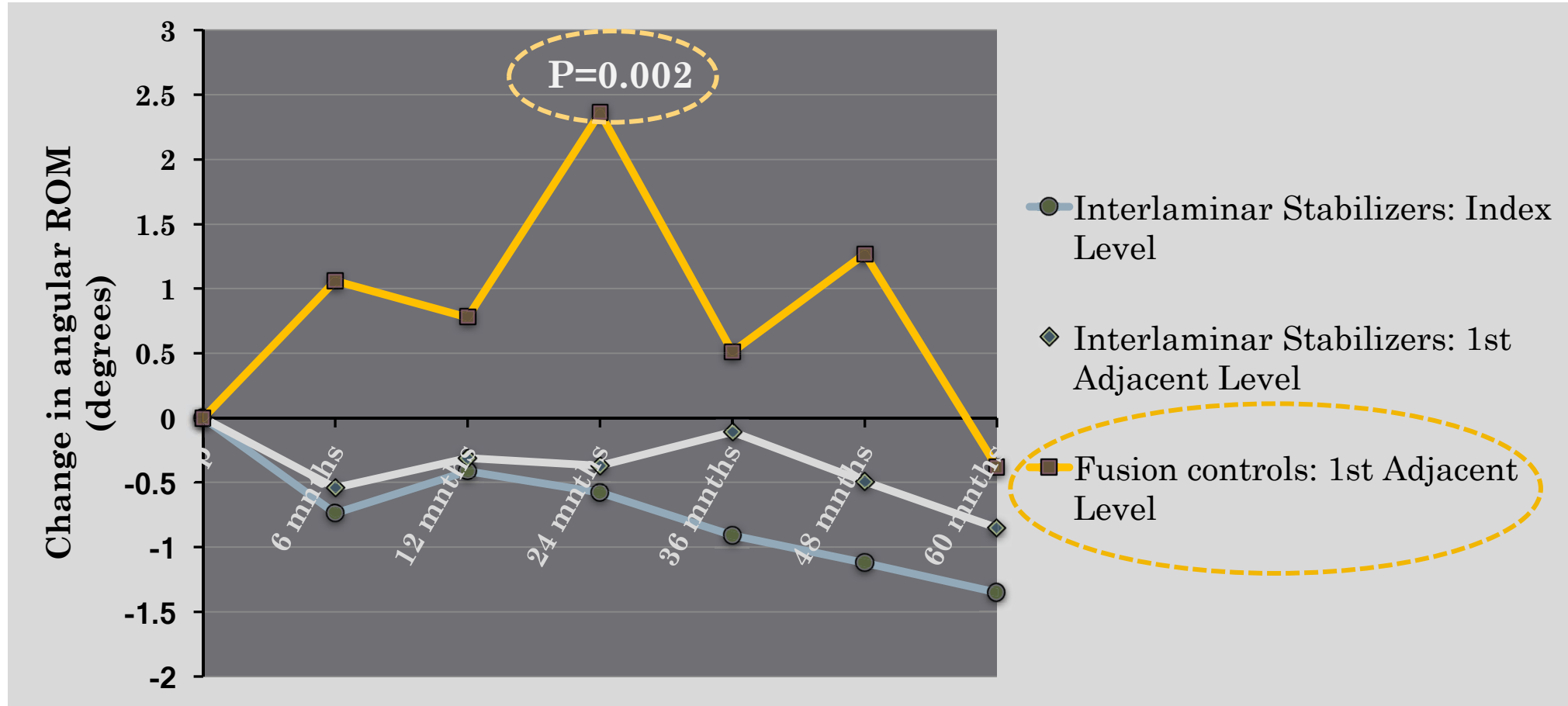
- Inter-laminar dynamic spacer IDE RCT
 - two-level arm
 - 55 investigational & 27 fusion controls
- Secondary radiographic analysis
 - Pre-op through 5-year post-op.
 - Index, 1st & 2nd adjacent segments
 - Quantitative Motion Analysis (Medical Metrics Inc, TX).
 - angular range-of-motion (ROM)
 - average disc-space heights

Methodology

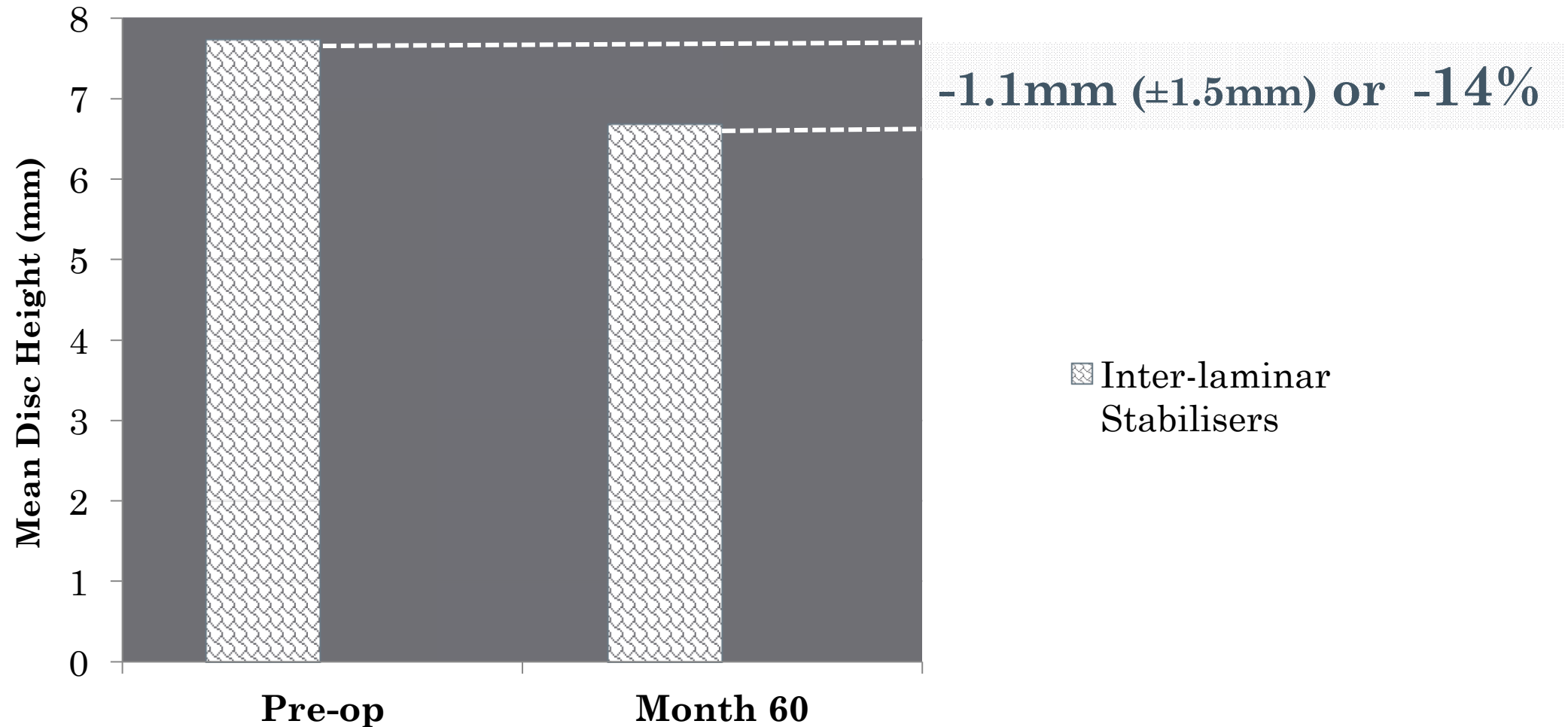
- Disc-space heights



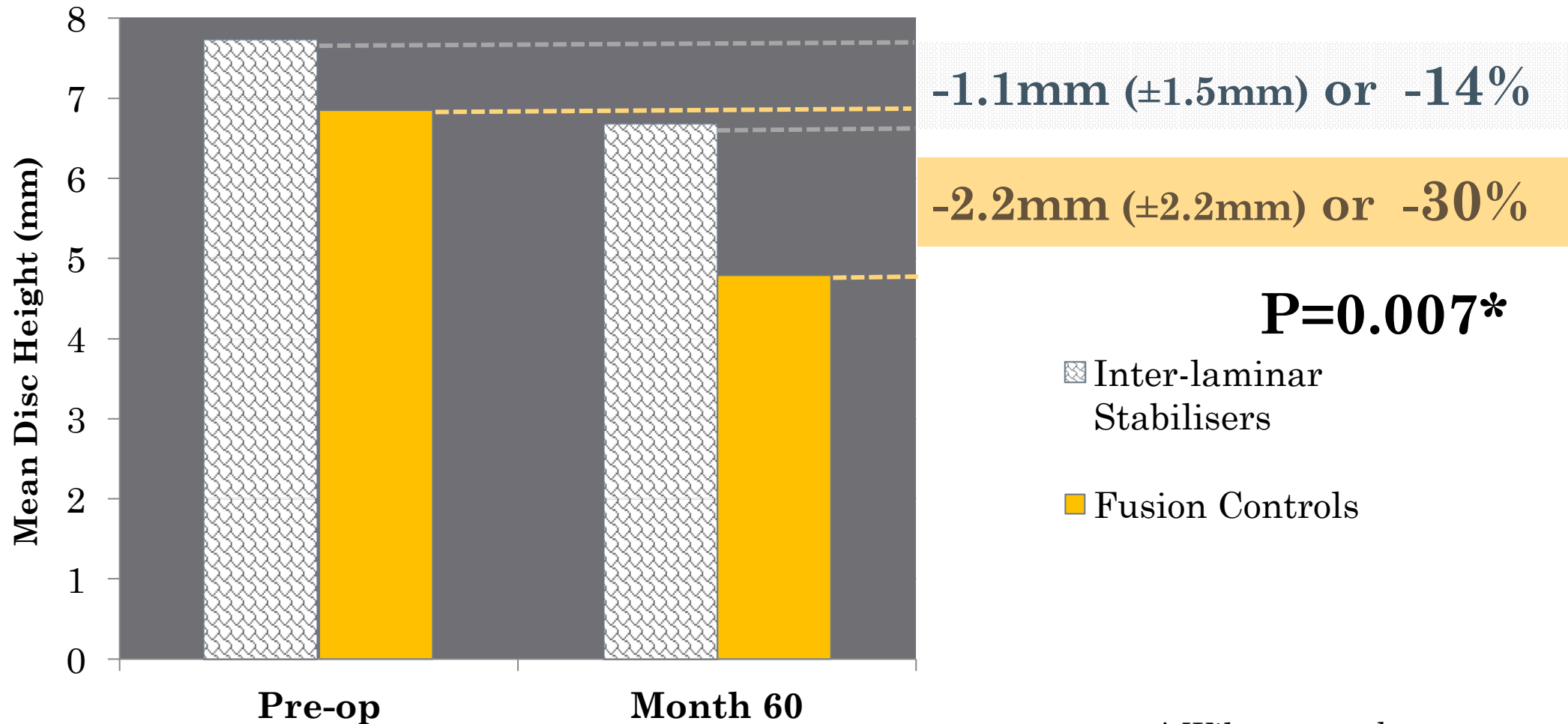
Results – Segmental angular ROM



Results – disc space height (1st adjacent level)

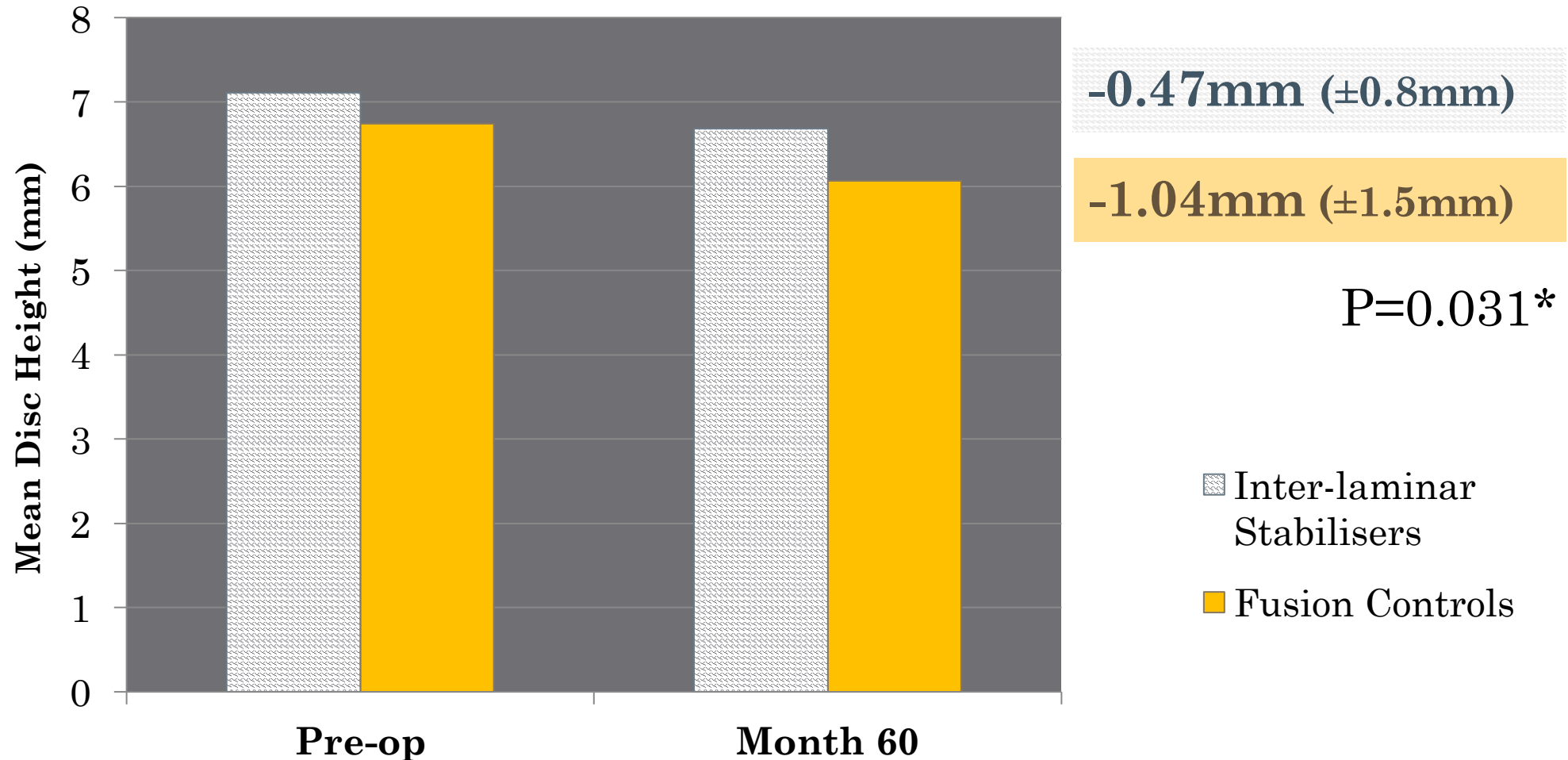


Results – disc space height (1st adjacent level)



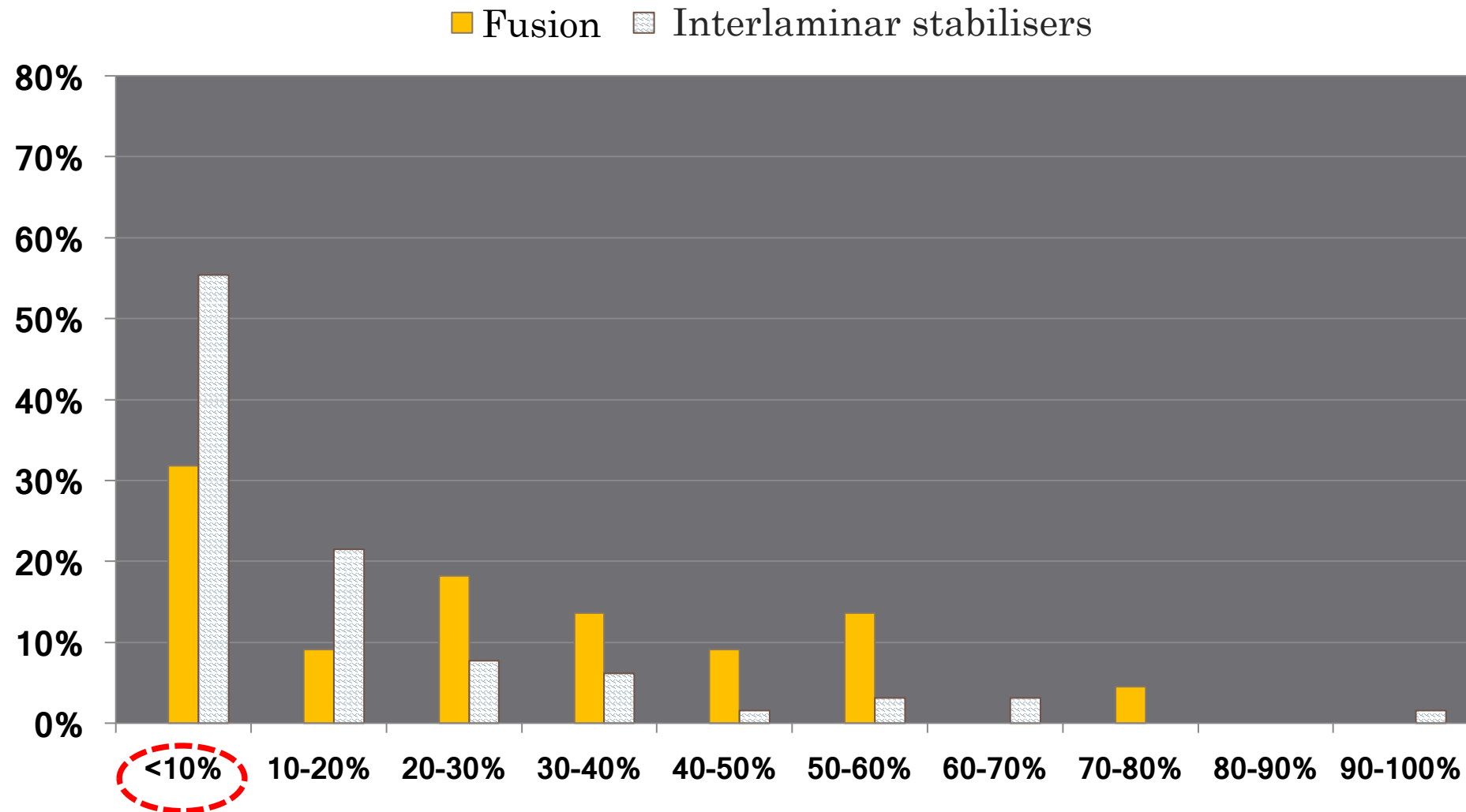
* Wilcoxon rank sum

Disc space heights (2nd adjacent level)



* Wilcoxon rank sum

Frequency distribution of Percentage Reductions in relative disc-space height @ 60-months – 1st adjacent level Fusion *vs.* ILS



Fusion variables: Biomechanical effects and ASD risk

- Length of fusion
- Fusion alignment
 - Sagittal plane
 - Coronal plane
- Fusion rigidity

Sagittal plane fusion alignment and ASD risk

- Retrospective *in vivo* studies – post-op sagittal alignment & ASD
 - Kumar et al. Eur Spine J 2001
 - Djurasovic et al. Orthopedics 2008
 - Min et al. J Spinal Disord Tech 2008
 - Bae et al. Neurosurgery 2010
 - Korovessis et al. Spine 2010
 - Nakashima et al. Spine 2015

Iatrogenic/surgical factors and ASD risk

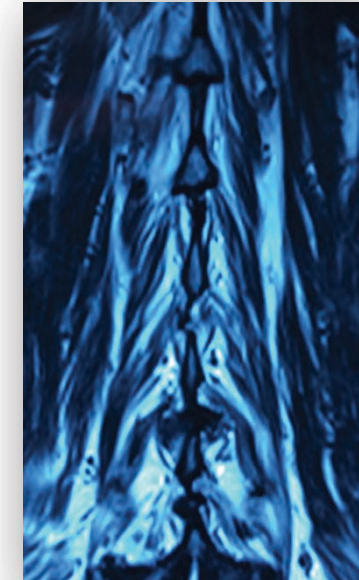
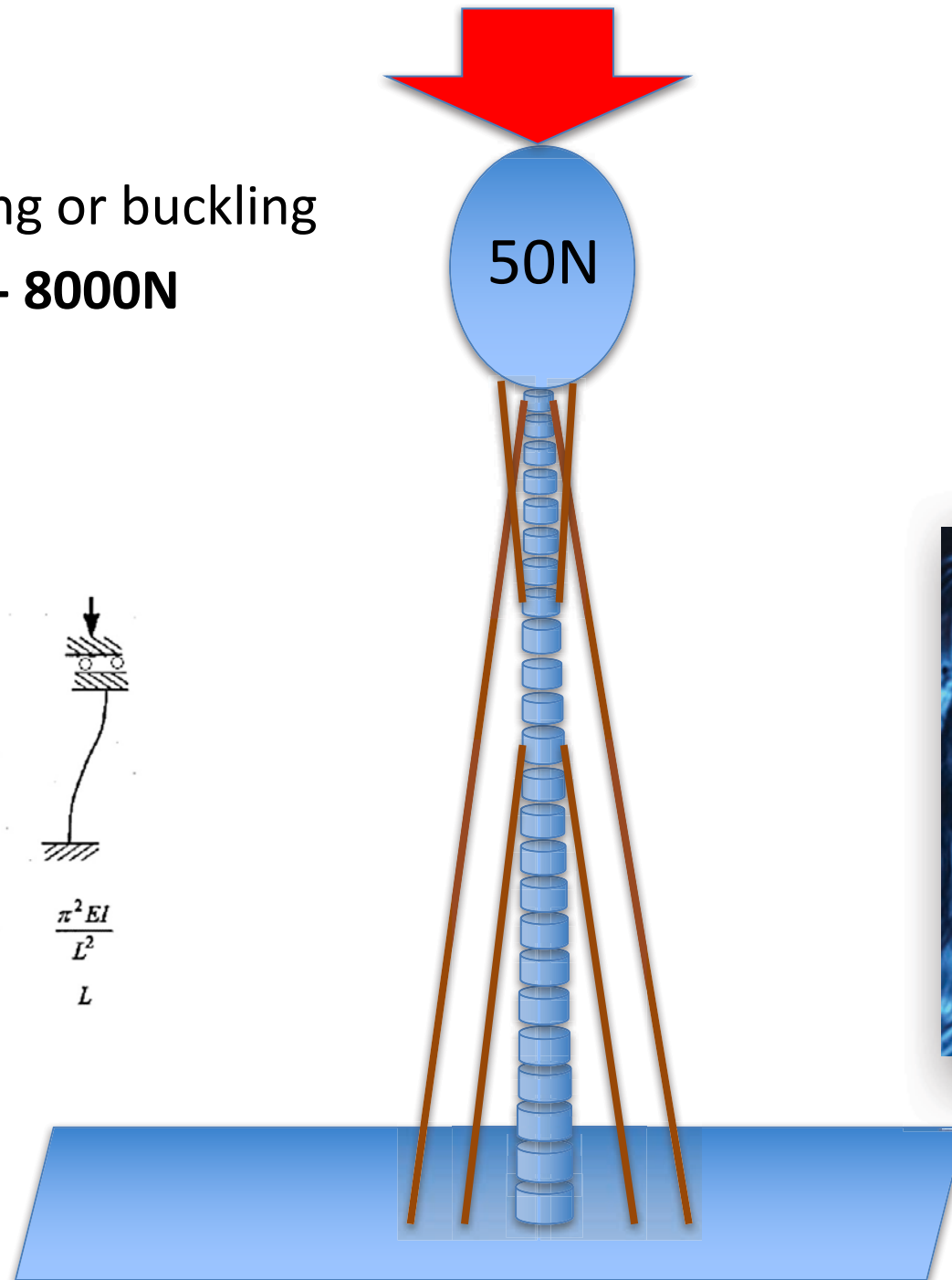
- Surgical approach
 - Muscle damage
 - Ligament damage
 - Rostral laminectomy
 - Facet joint damage

Load tolerance to bending or buckling

- Intact spine: **3000 - 8000N**
- Cadaver spine: **20N**

Buckling Loads

Buckling Load	$\frac{\pi^2 EI}{L^2}$	$\frac{4\pi^2 EI}{L^2}$	$\frac{2.045\pi^2 EI}{L^2}$	$\frac{\pi^2 EI}{4L^2}$	$\frac{\pi^2 EI}{L^2}$
Effective Length	L	$0.5L$	$0.699L$	$2L$	L



Iatrogenic/surgical factors and ASD risk

- Surgical approach
 - Muscle damage – *in vivo* evidence:
 - ↑ **flex/ext ROM at suprajacent segment ALIF vs. PLF**
 - 7.7° vs. 11.6° (p<0.05)
 - Retrospective study (n=28) Kim HJ et al *Clin Invest Med.* 2009
 - ↑ **fatty degen & muscle atrophy in ASD patients**
 - Retrospective logistic regression (n=100) Min et al. *Asian Spine J* 2009

Iatrogenic/surgical factors and ASD risk

- Surgical approach
 - M.I.S. – *in vivo* evidence:
 - Varied muscle damage reports
 - Systematic review of ASD. Li et al. *PlosOne* 2017
 - 9 trials, 770 patients but low-moderate quality evidence
 - **↓ ASD incidence in MIS vs. open**

Iatrogenic/surgical factors and ASD risk

- Surgical approach
 - Muscle damage
 - Ligament damage
 - Rostral laminectomy
 - Facet joint damage

<u>Cox proportional-hazards regression analysis</u>		
Covariate	Relative Risk ^(95%CI)	P value
Adjacent level laminectomy	x 2.4 (1.09 to 5.17)	0.03

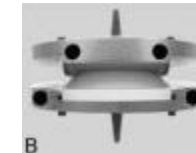
Sears et al. *Spine J* 2011

If ASD a disease... why?

Can we mitigate the effects of fusion?

Adjacent Segment Disease Mitigation strategies

- Index level... *motion preservation*
 - **Disc arthroplasty**
 - Nucleus replacement
 - TDR
 - **Posterior dynamic stabilizers**
 - Interspinous
 - Pedicle screw based



ASD: Disc arthroplasty *vs.* fusion...

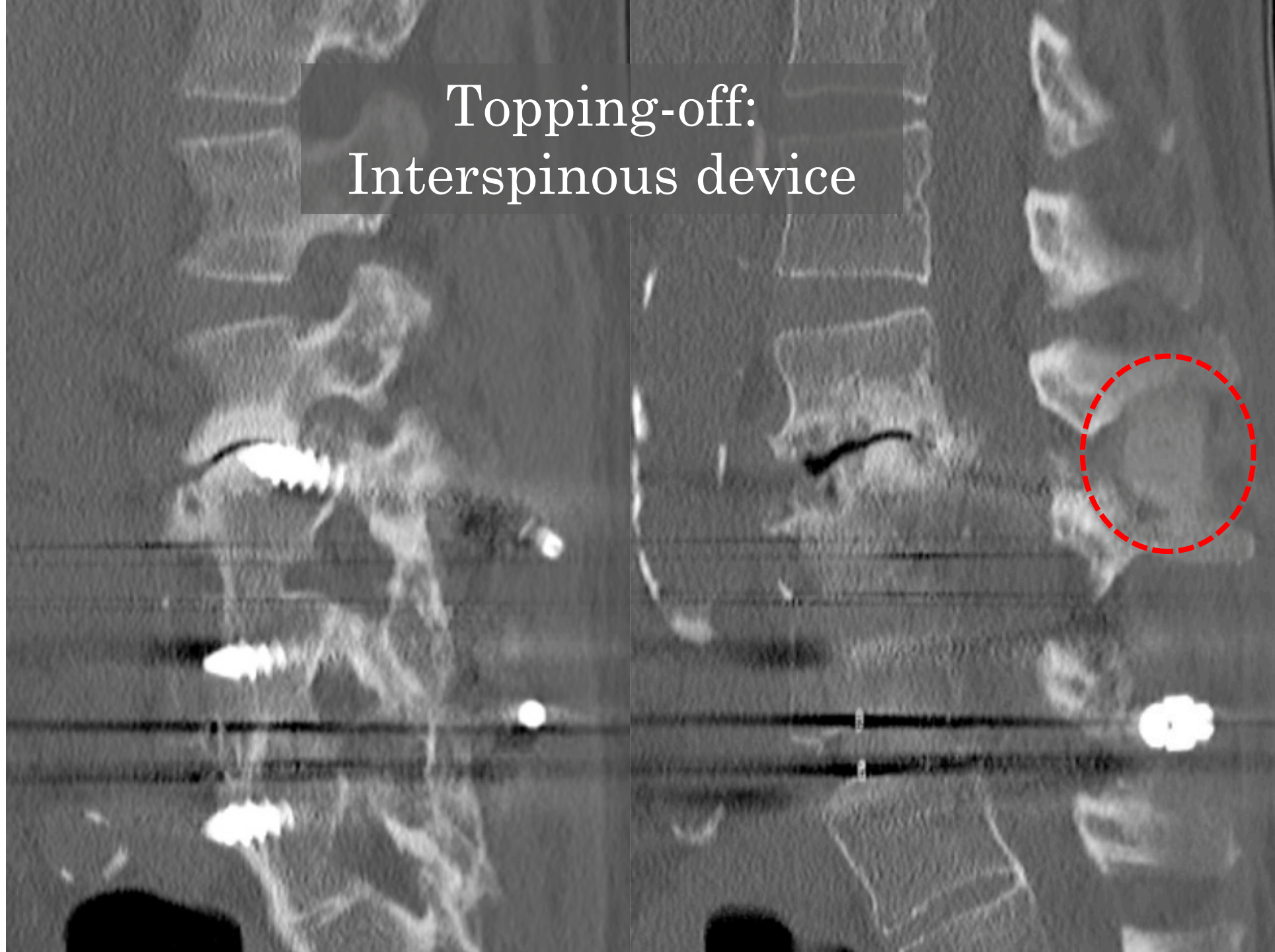
- Systematic review – Wang et al *Spine* **2012**
 - Combined 2 RCTs (Berg et al & Guyer et al), n=285 @ 2-5 years
 - **Clinical ASD in 1.2% TDR *vs.* 7.0% fusions (5.9x, p=0.02)**
- Cochrane systematic review – Jacobs et al *Spine* **2013**
 - “Long term benefits such as ASD not properly assessed”
- Systematic review/meta-analysis – Ren et al *Eur J Orthop Surg Traumatol.* **2014**
 - 13 studies, n=1270
 - < 5-years: No difference in clin. ASD (p=0.10)
 - > 5-years: **Signif. ↓ASD reoperation rate for TDR (p<0.0001)**

Adjacent Segment Disease Mitigation strategies

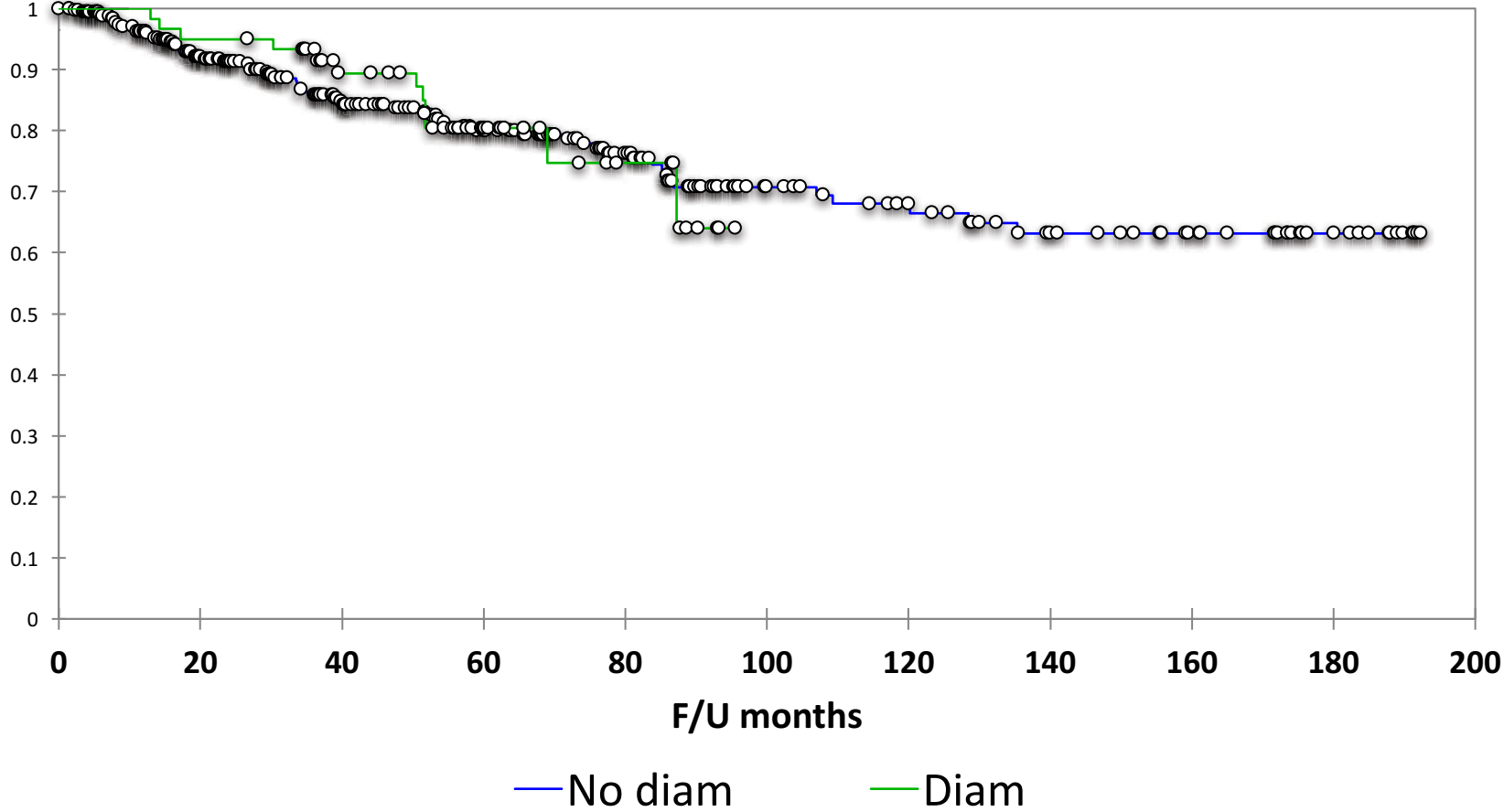
- Index level... *motion preservation*
 - Disc arthroplasty
 - Nucleus replacement
 - TDR
 - Posterior dynamic stabilizers
 - Interspinous
 - Pedicle screw based
- Adjacent level... *'topping off'*
 - *Does is it work?*



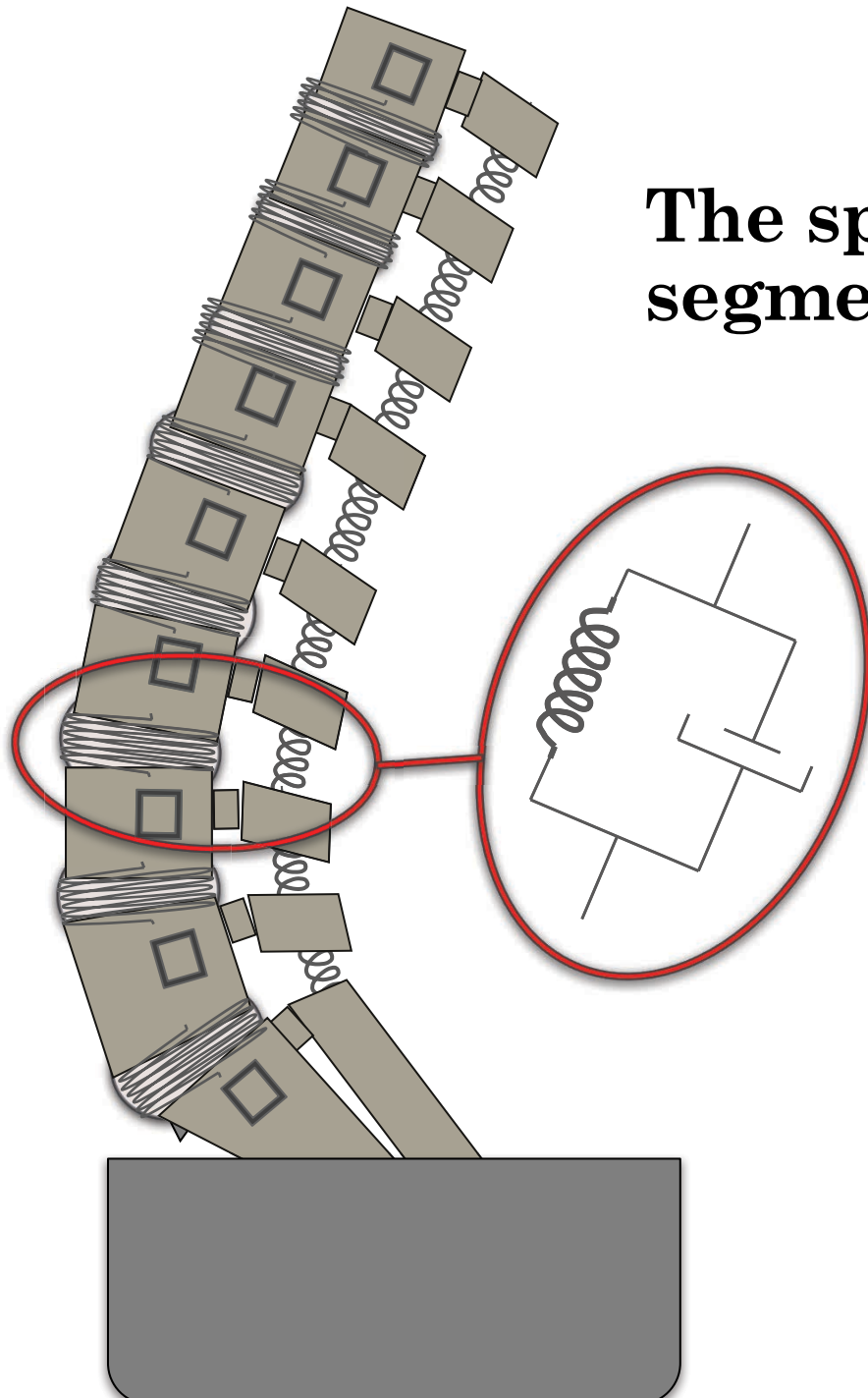
Topping-off:
Interspinous device



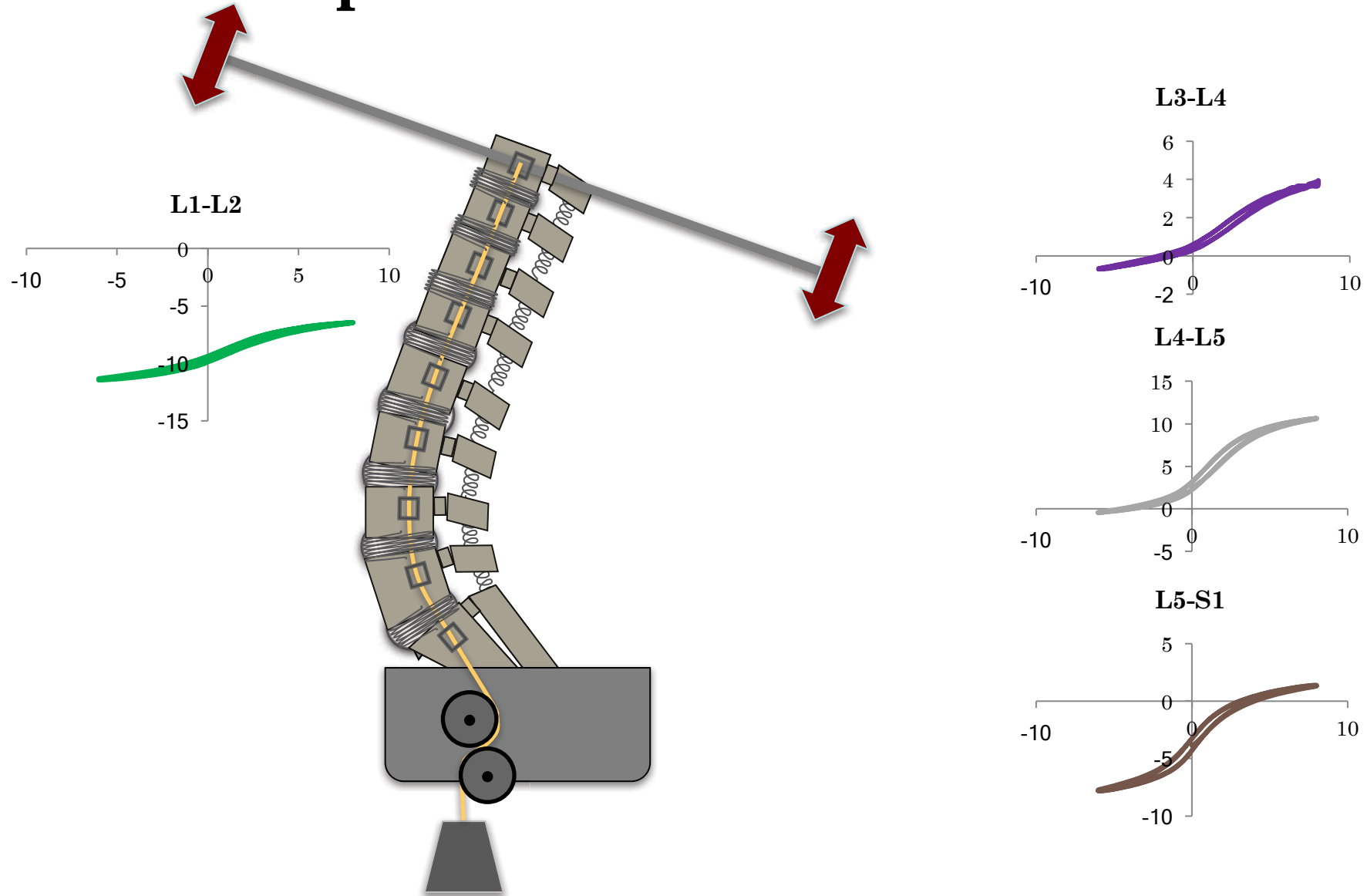
Further surgery for ASD after 'Topping-off' with interspinous spacers



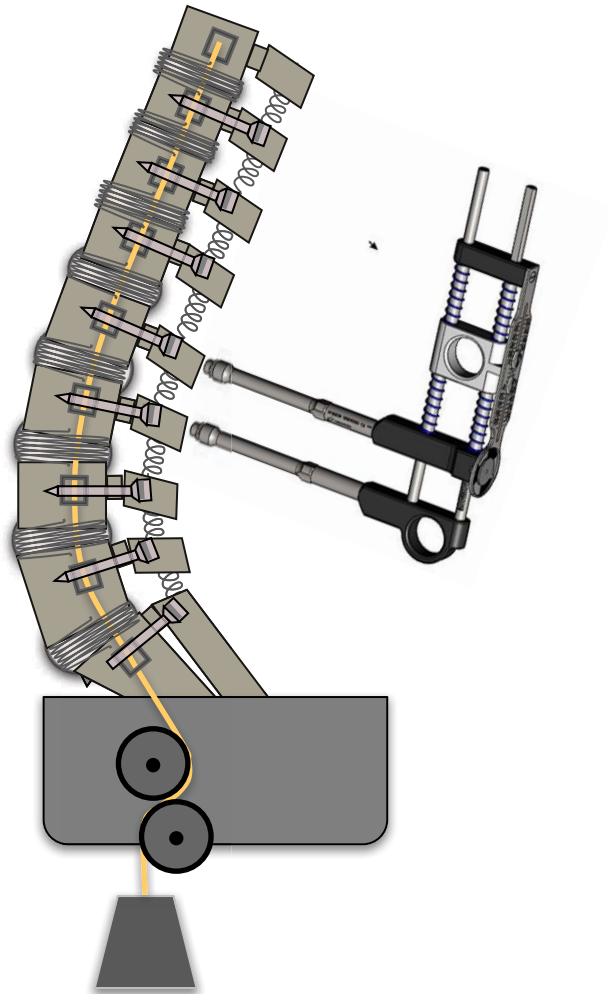
**The spine: a tower of damped,
segmental 'spring' elements**



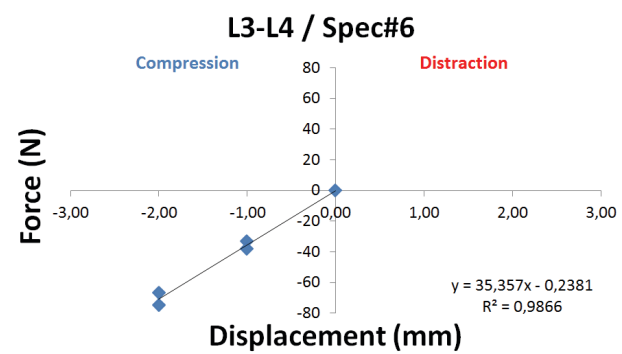
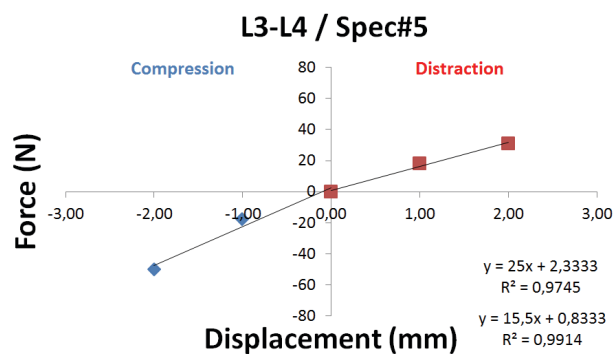
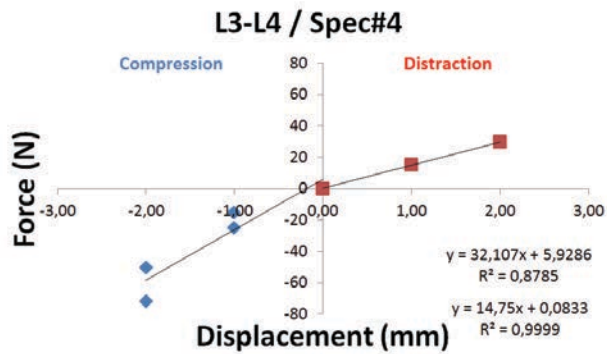
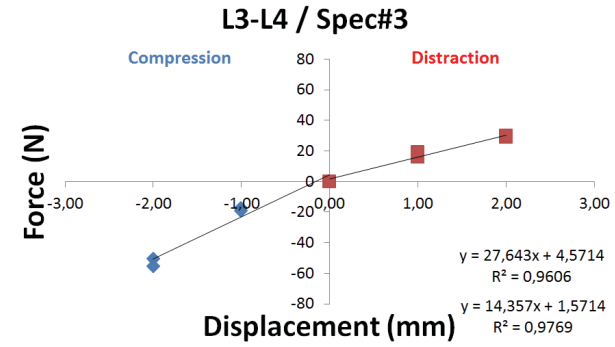
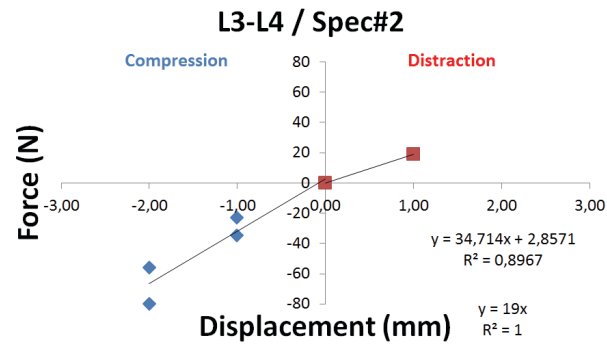
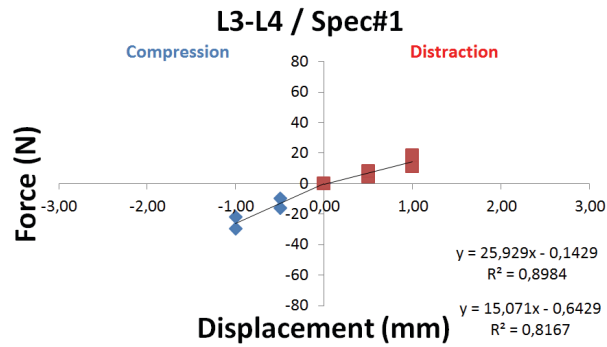
Overall spinal & individual segmental load displacement curves – *in vitro*

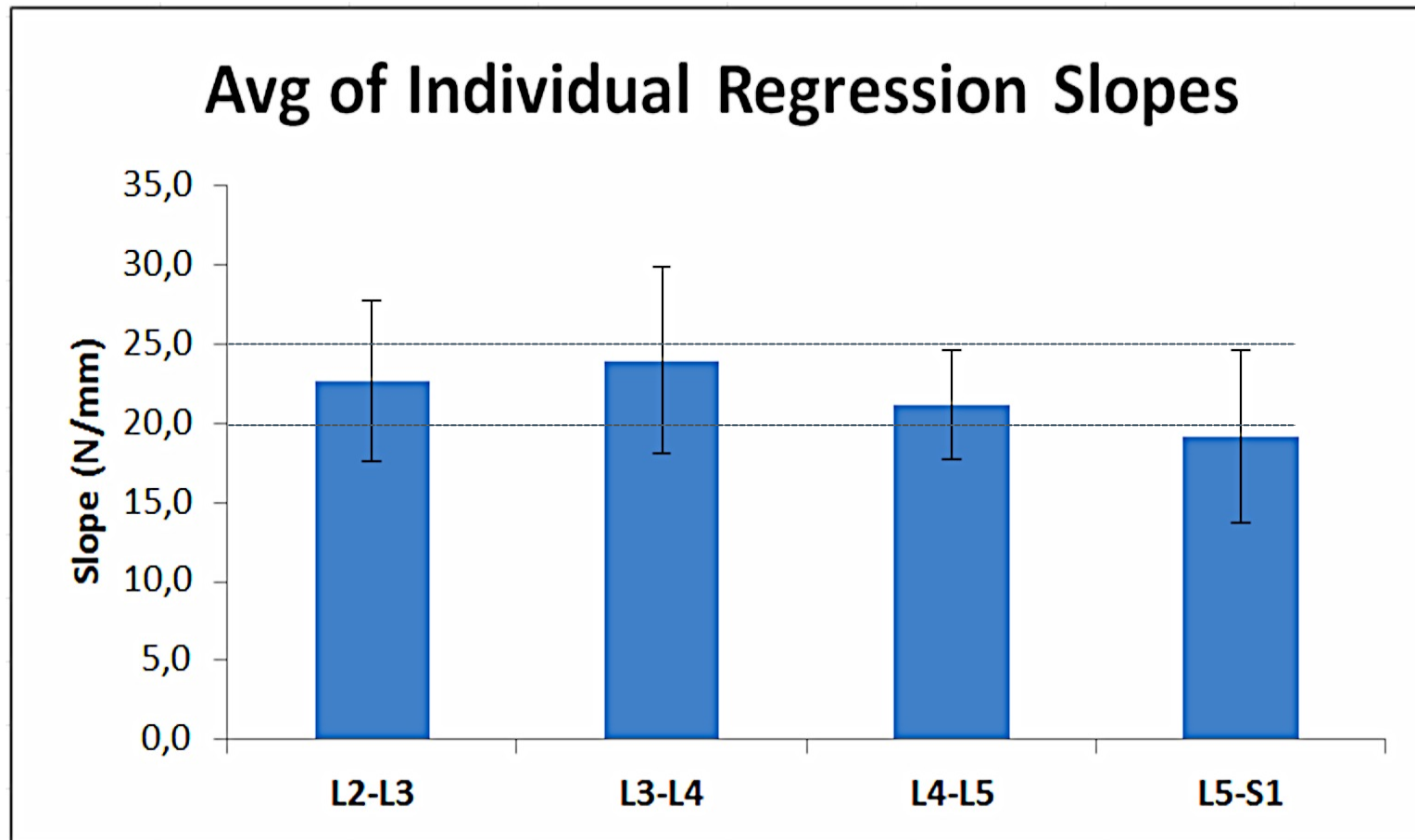


Measuring segmental stiffness



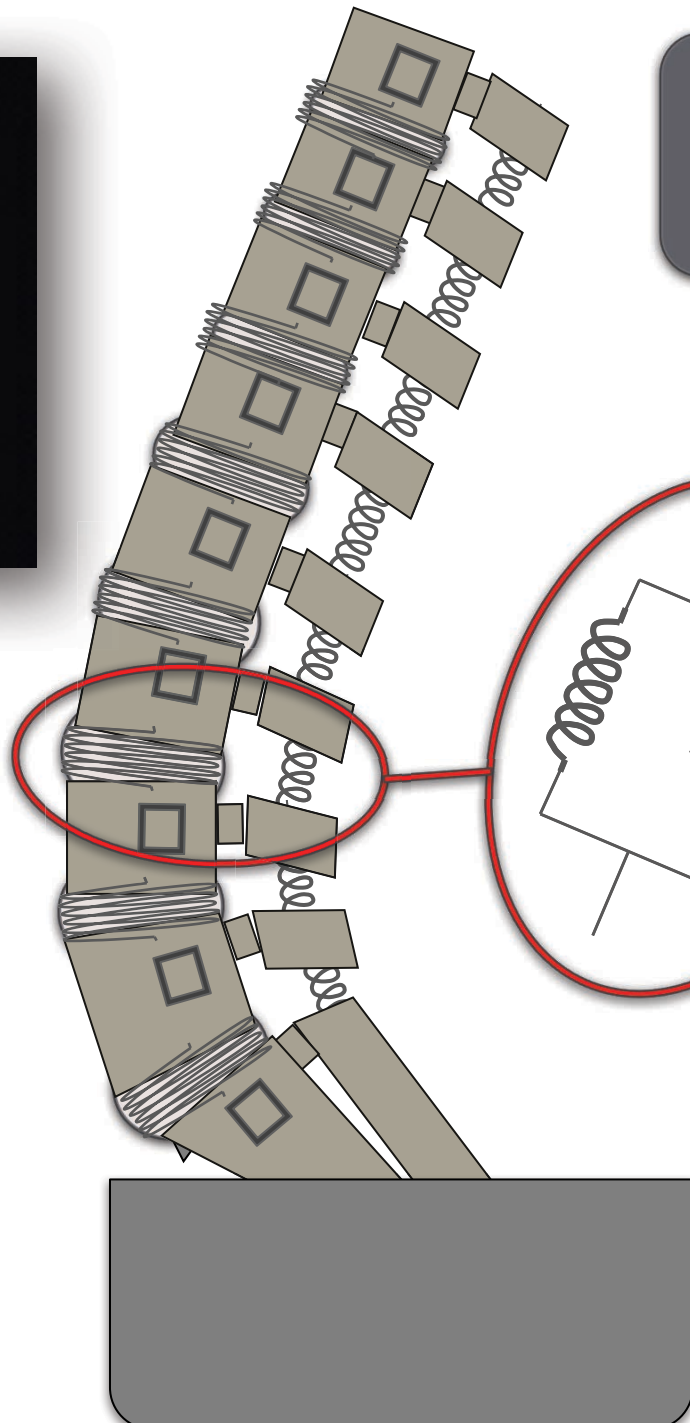
L3-L4 Regression Slope per Specimen







Kirkaldy-Willis &
Farfan.
*Clin Orthop Relat
Res* 1982.



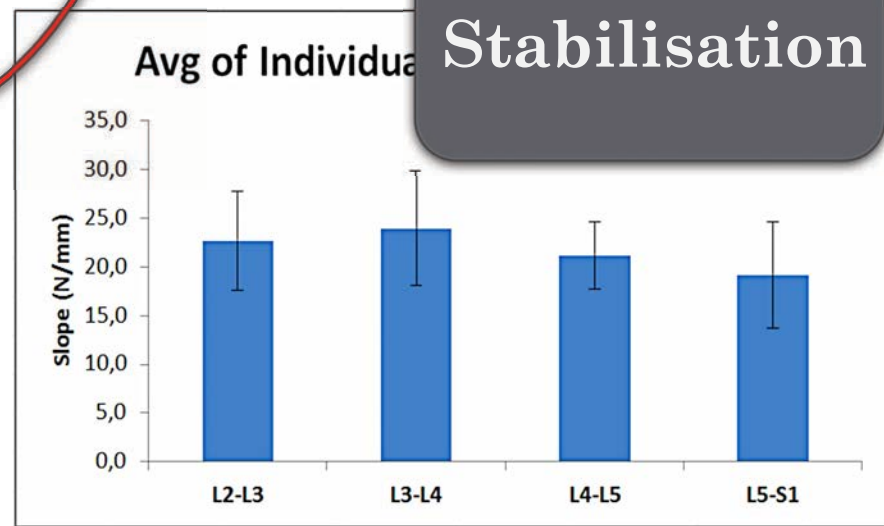
Dysfunction

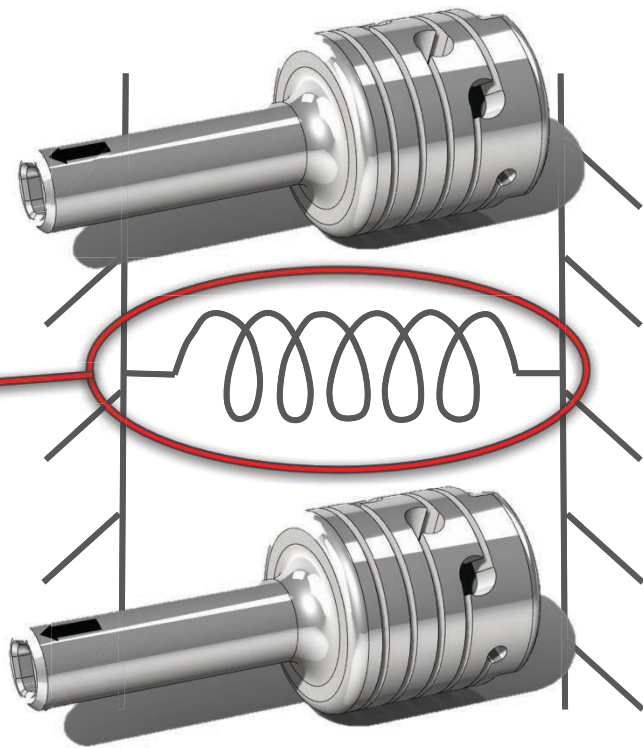
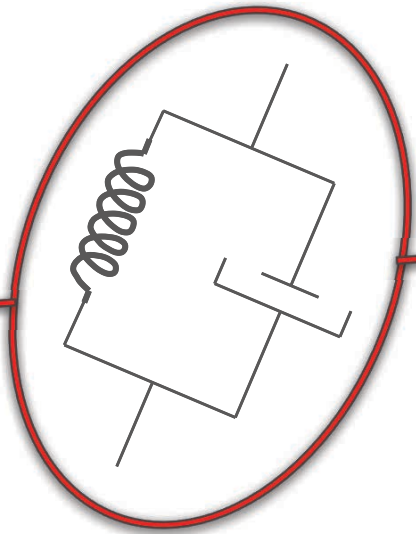
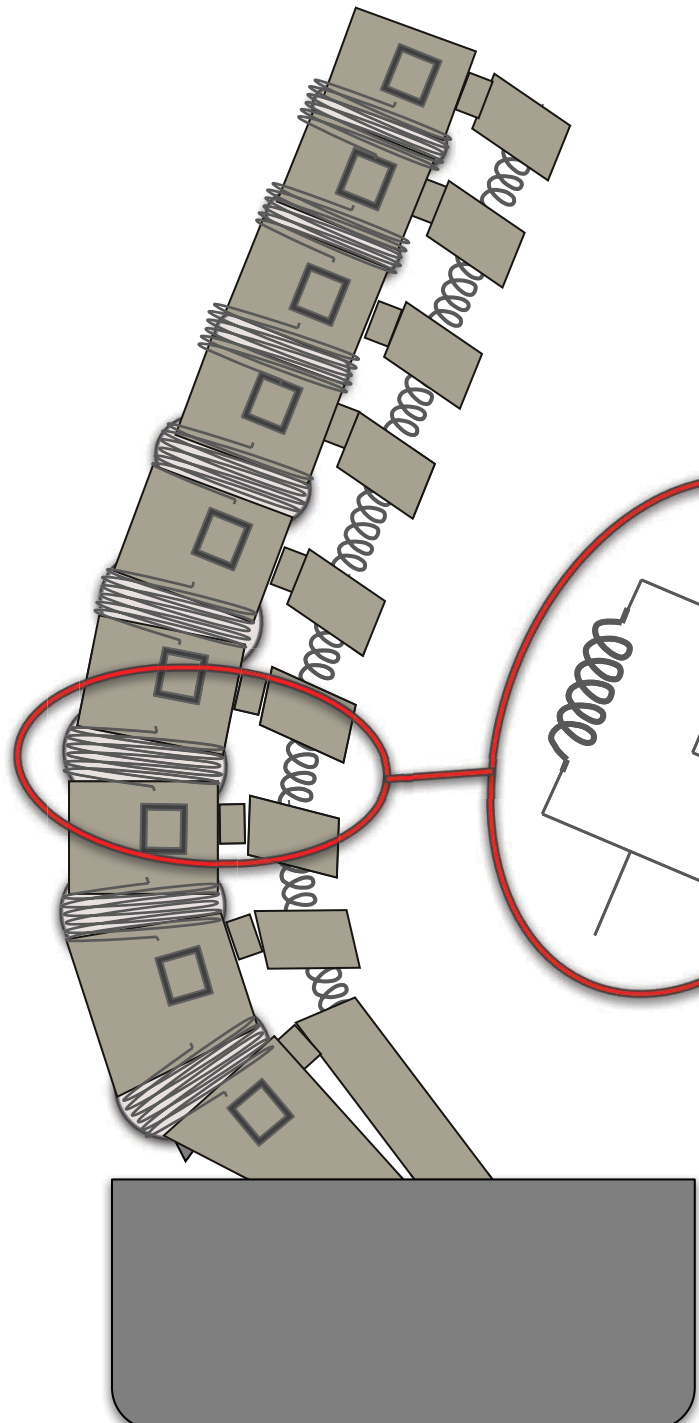


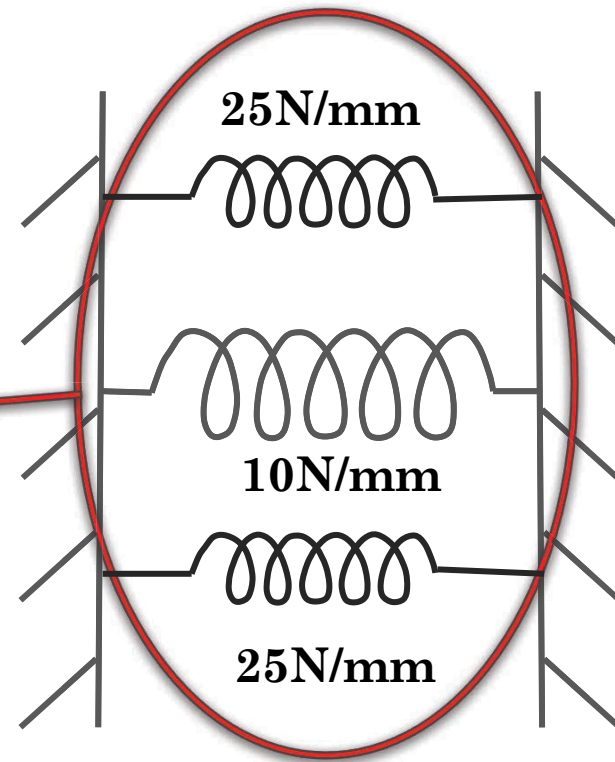
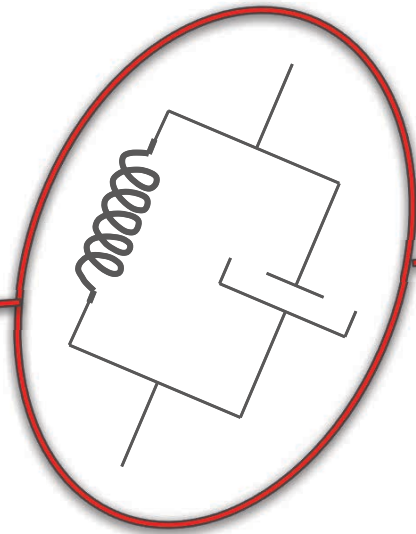
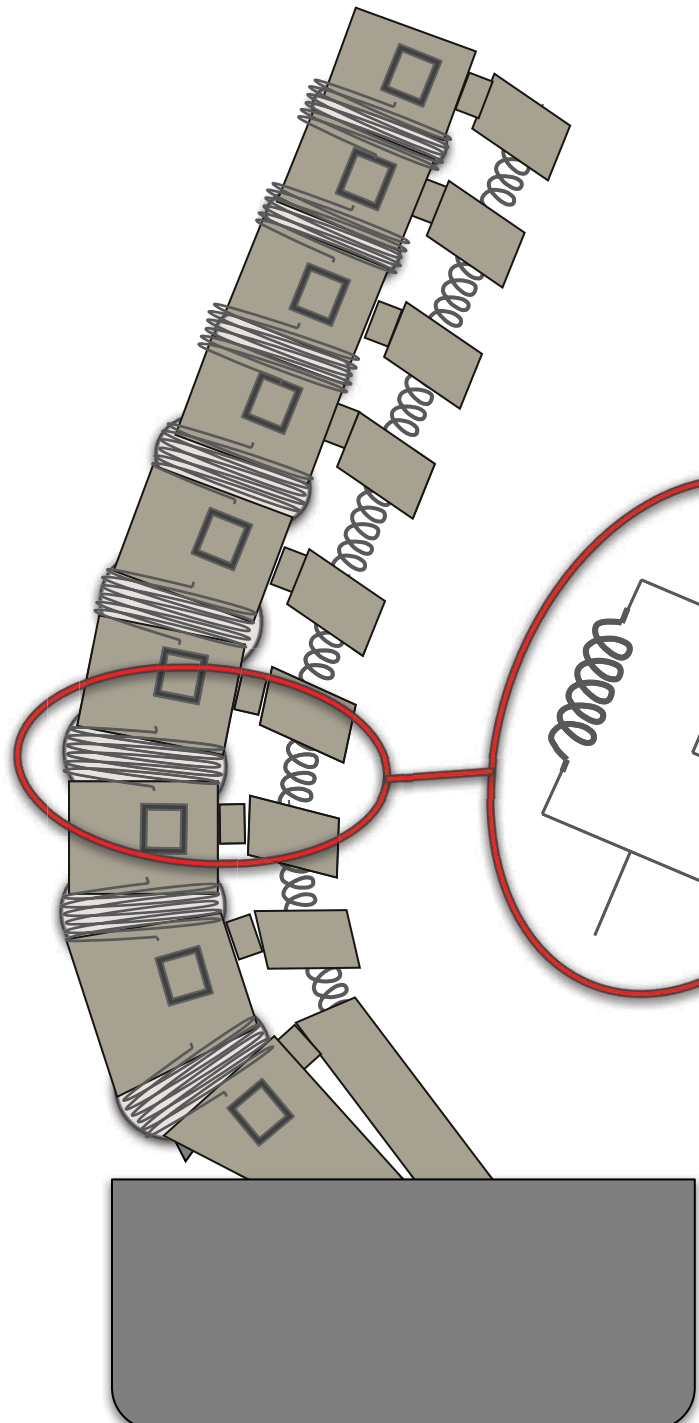
Instability



Stabilisation





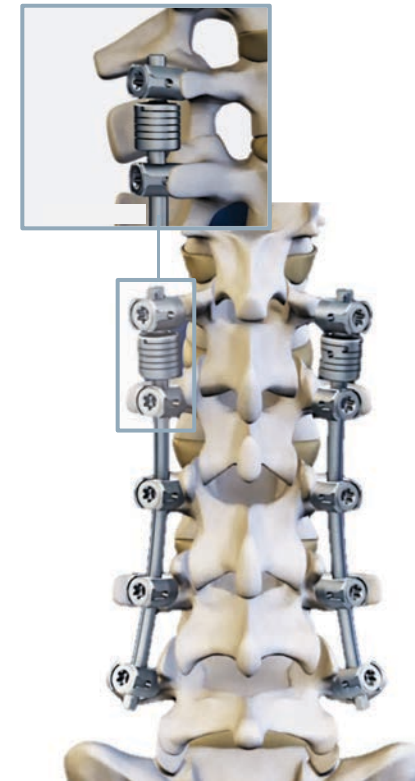


New total segment stiffness:

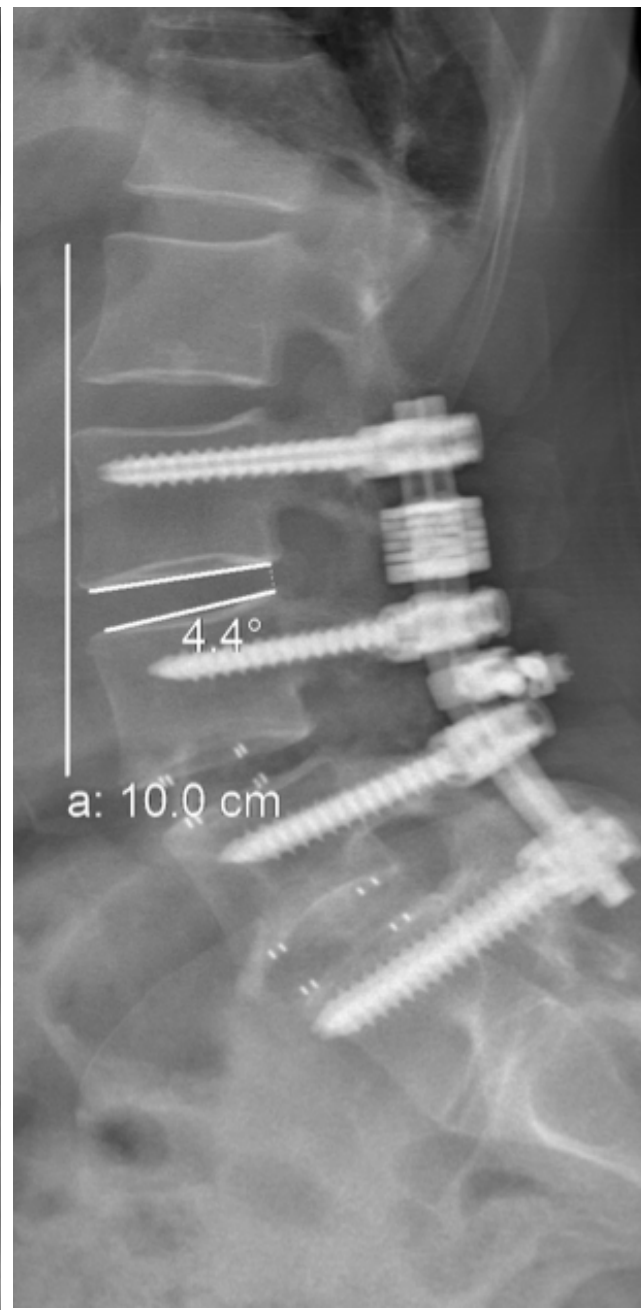
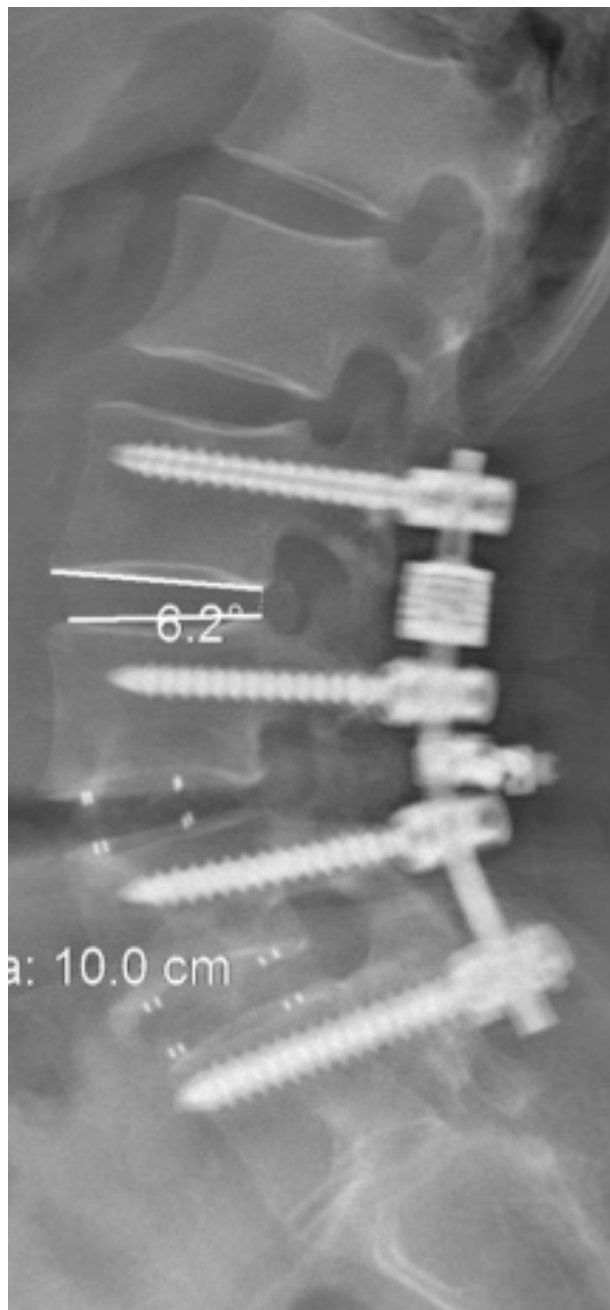
$$10 + 25 + 25 = \mathbf{60N/mm}$$

Adjacent Segment Disease Mitigation strategies

- Index level... *motion preservation*
 - Disc arthroplasty
 - Nucleus replacement
 - TDR
 - Posterior dynamic stabilizers
 - Interspinous
 - Pedicle screw based
- Adjacent level... *'topping off'*
 - *Does this work?*



78 F



Comparative demographics

Historical controls vs. FSD 'topping off' (Sep 2011-Present)

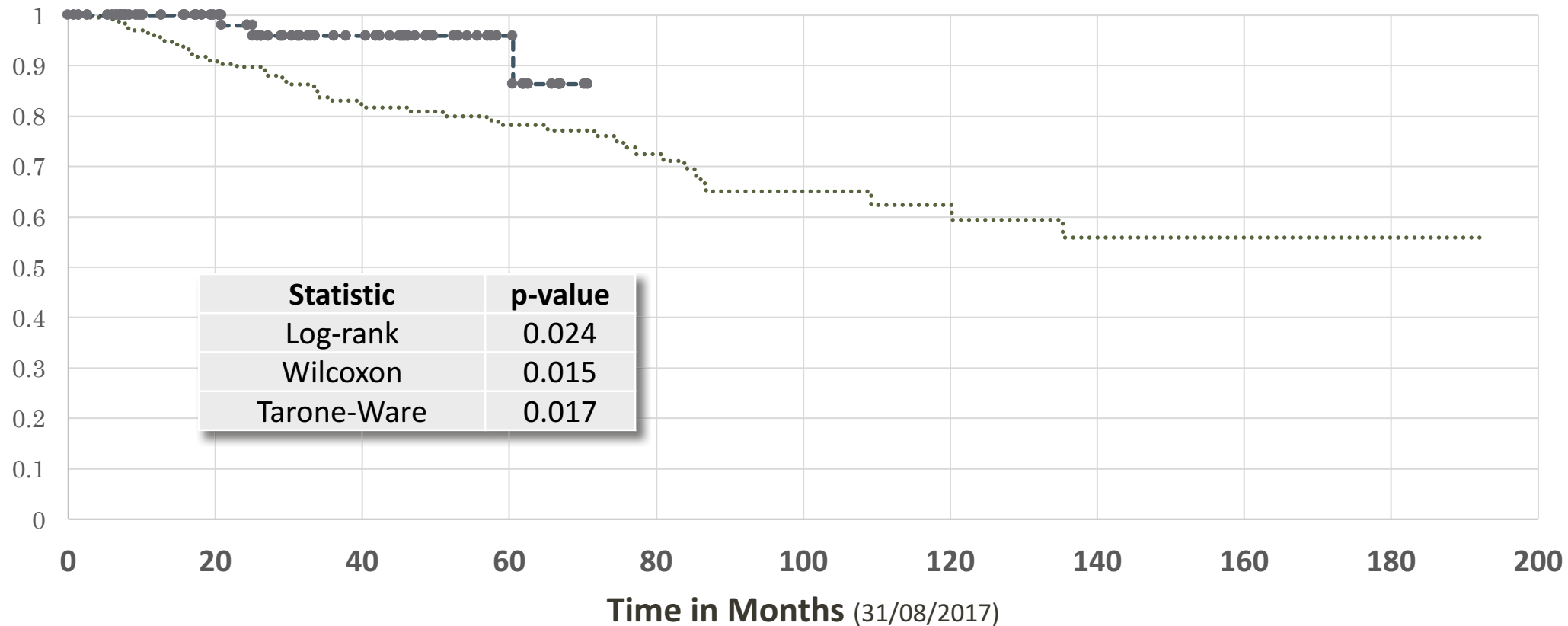
Post 2-, 3- & 4-level fusions, 60+years

	Historical Controls	FSD Topping-off
n	253	76
Age	73yrs (± 6.5)	72yrs (± 6.4)
BMI	28 (± 6)	28 (± 5)
male : female (%)	39 : 61	32 : 44
Previous surgeries (mean \pm SD)	1.0 (± 1.1)	1.6 (± 0.8)
No. of levels fused: 2	72%	42%
3	17%	34%
4	11%	24%

Kaplan Meier Survivorship Analysis

Pedicle screw based couplers vs. Historical controls

2-4 level fusions, aged 60+yrs, PJK patients excluded

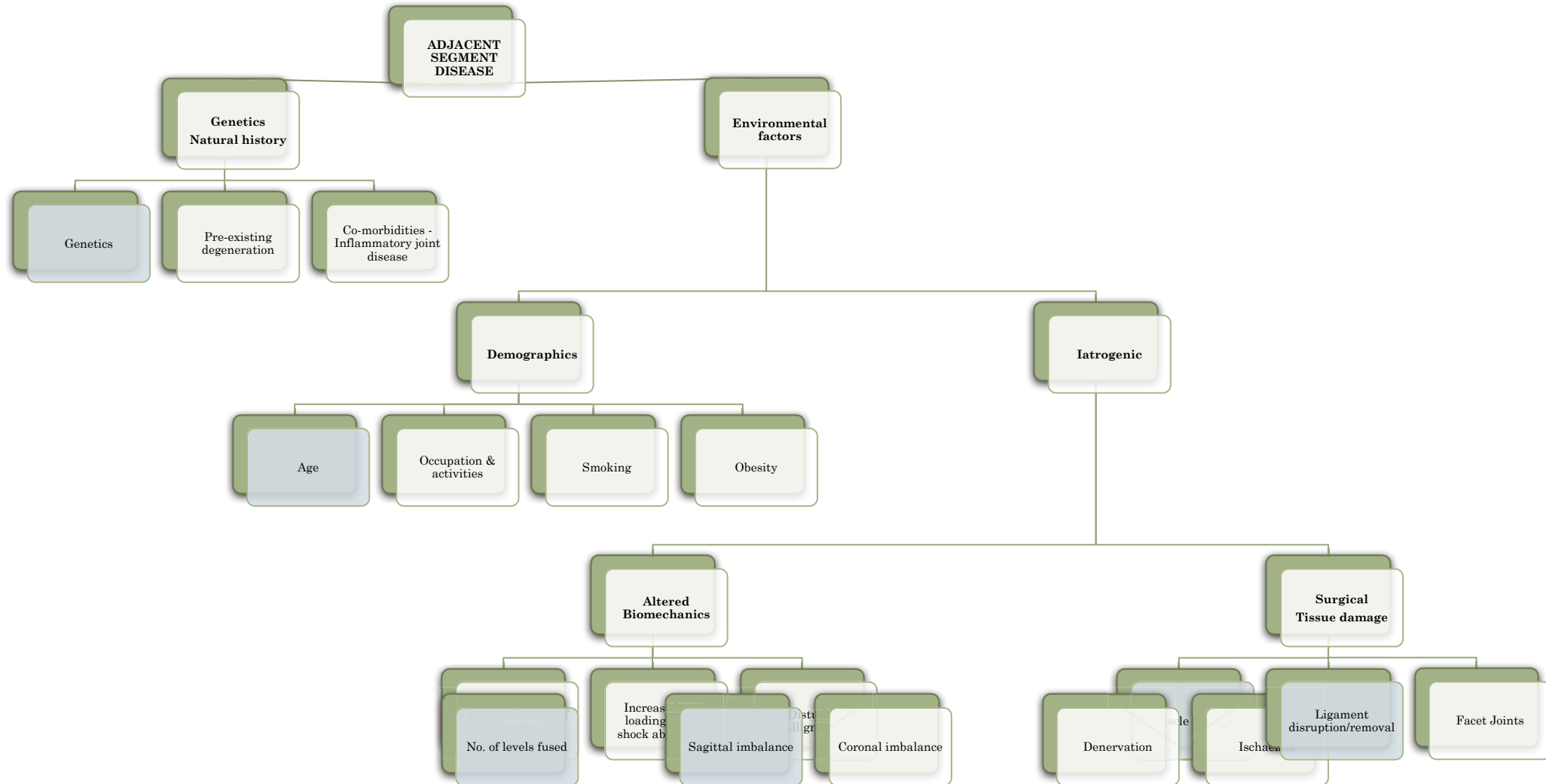


..... Historical controls
(n=253)

-.-.- Topped off with flexible couplers
(n=76)

Conclusions

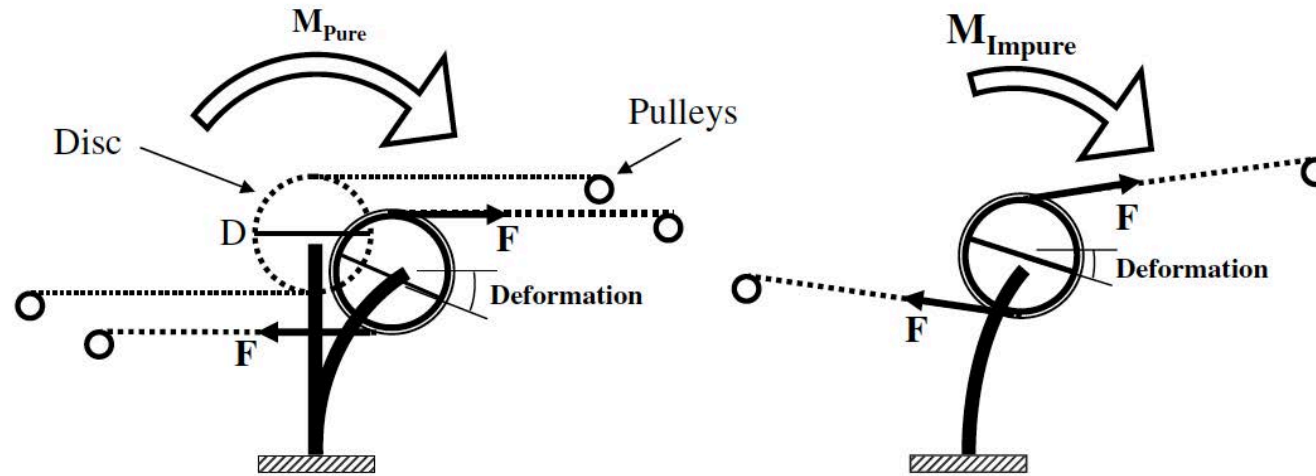
- ASD: a complex and likely multifactorial pathology





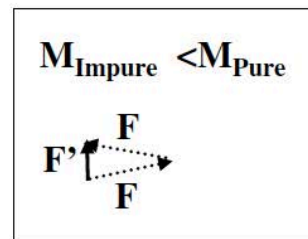


Pure moments



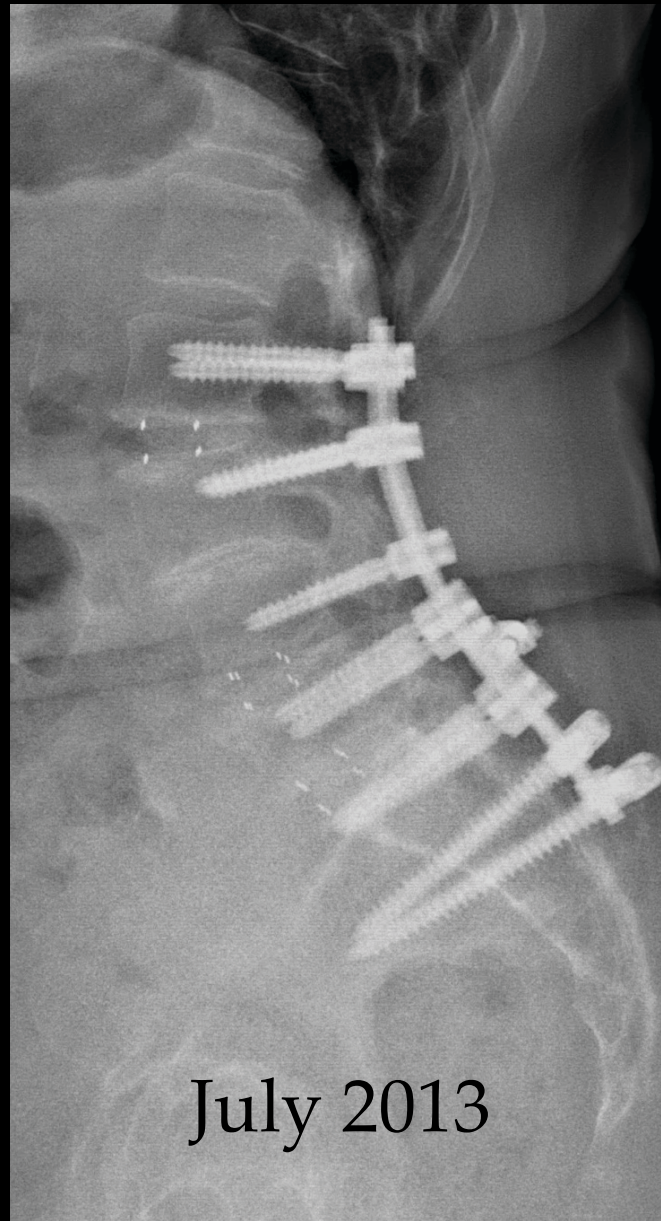
A. Pure moment (pulleys moved)

B. Impure moment (pulleys fixed)

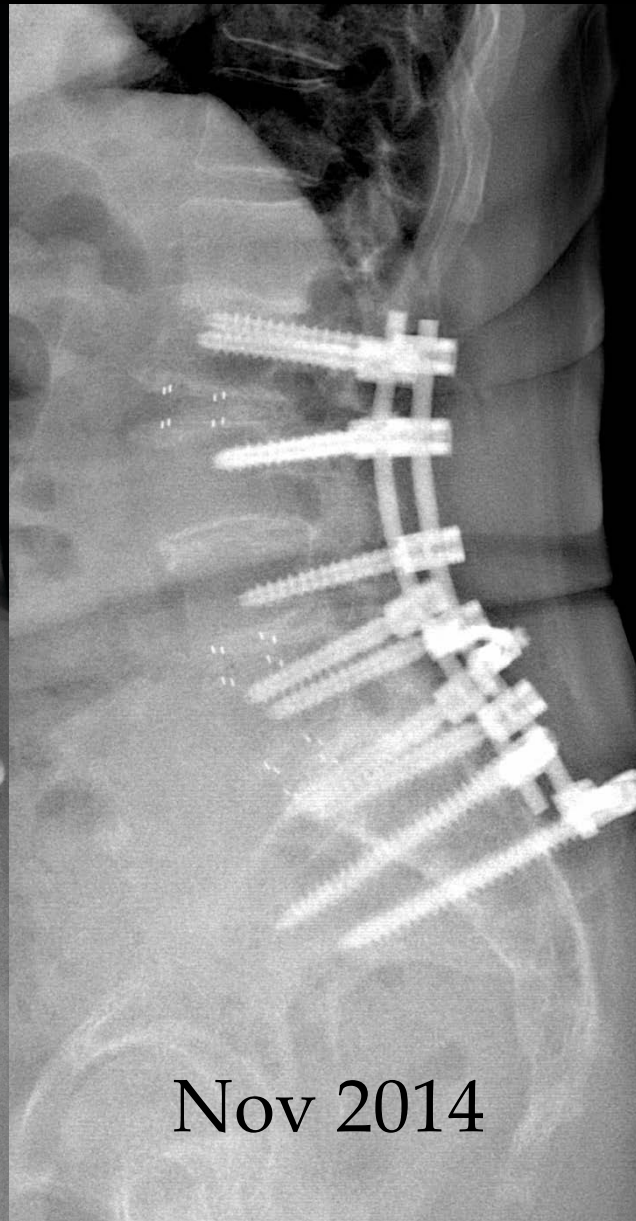


C. Resulting moment and force (pulleys fixed)

From: Panjabi *Clin Biomech* 2007

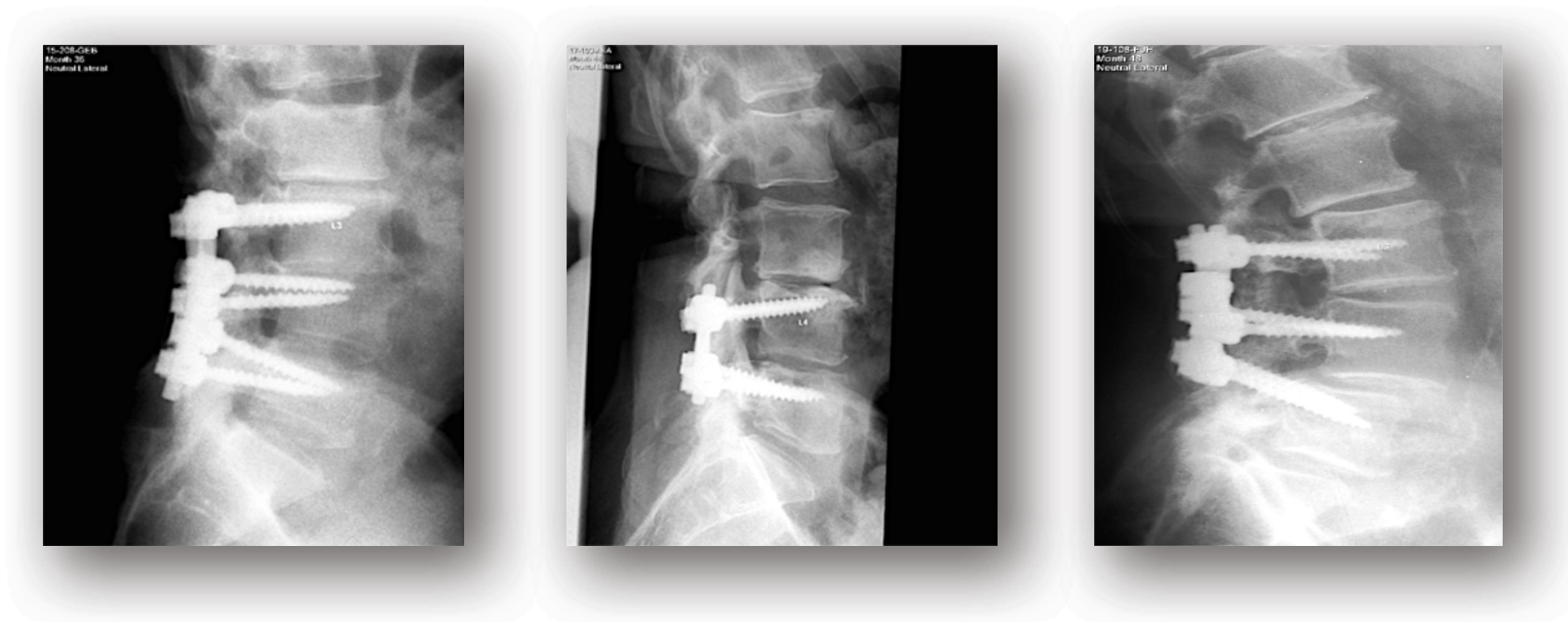


July 2013



Nov 2014

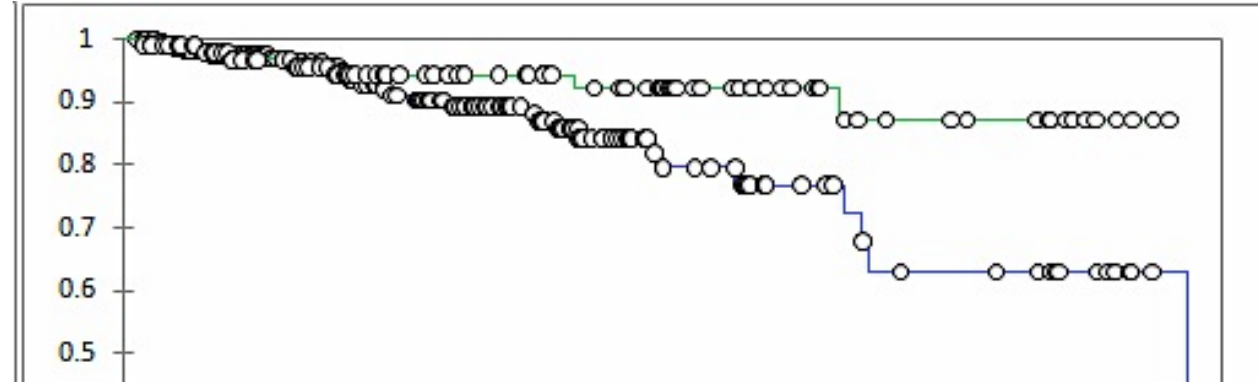
Adjacent segment disease



... fusion disease... or natural history?

Kaplan Meier Survivorship Analysis

Lytic (n=103) vs. Degenerative Spondylolistheses (n=221)



Spondy Type	Annual Incidence (95%CI)	5 year Prevalence	10 year Prevalence
Lytic	1.1 % (0.3-1.8)	6 %	8 %
Degen.	2.4 % (0.7-4.1)	11 %	27 %

p=0.04

Multivariate Risk Factor Analysis

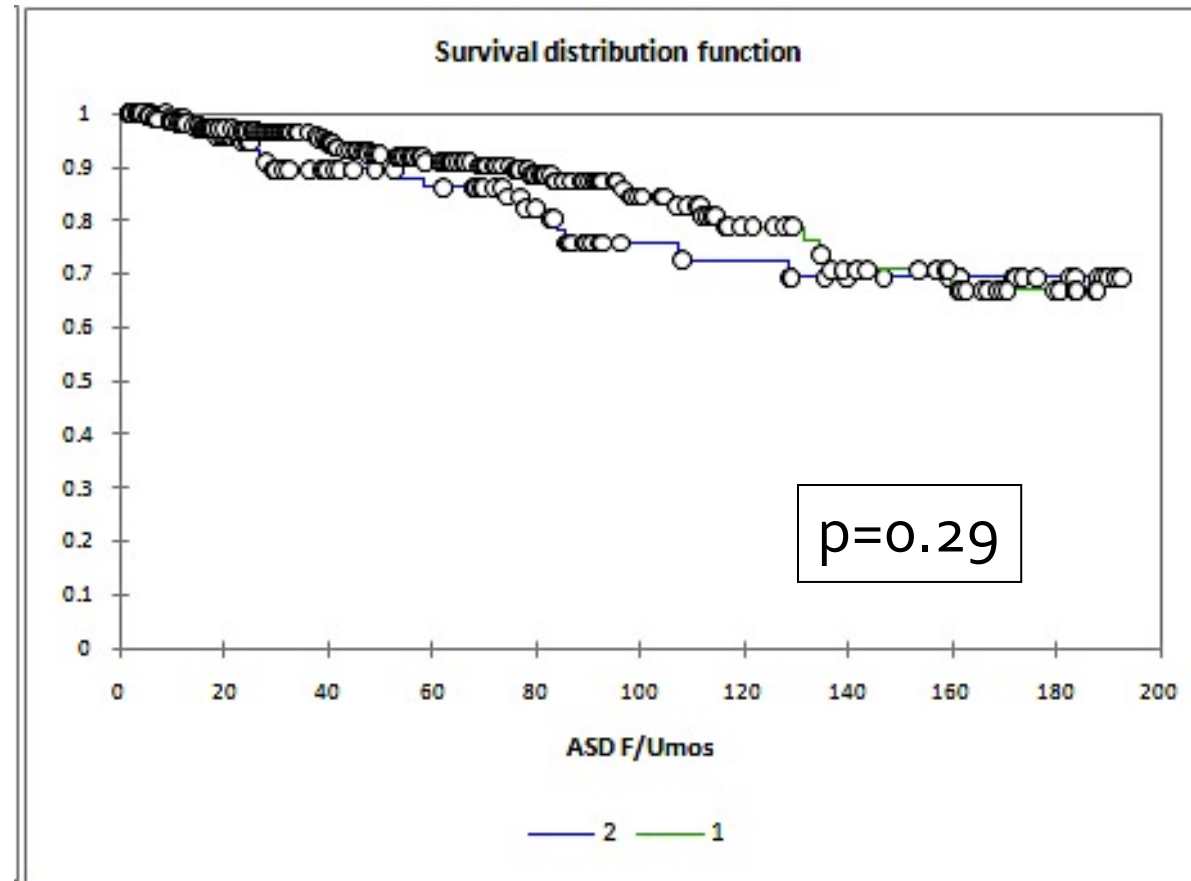
(Cox proportional-hazards regression model)

- Age –
 - < 45 (n=130)
 - 45-60 (n=199)
 - > 60-years (n=671)
- Number of levels fused –
 - 1-level (n=593)
 - 2-levels (n=216)
 - 3 or 4 levels (n=117) and 5+ levels (n=60)
- Sex – male or female
- Previous surgery – 0 - 6
- Laminectomy adjacent (to the index fused levels)
- Level of the Distal fused vertebra – L1, L2, L3, L4, L5 or S1
- Deformity – Nil, degen spondy, lytic spondy, scoliosis < 15degs, scoliosis > 15degs, kyphosis/flat-back

Covariate	b	SE	P	Exp(b)	95% CI of Exp(b)
Age = 45-60yrs	-0.587	0.24	0.012	0.55	0.34 to 0.87
Age = <45yrs	-1.364	0.47	0.003	0.25	0.10 to 0.63
Levels_fused = 3 or 4	1.121	0.24	<0.0001	3.0	1.89 to 4.86
Levels_fused = 2	0.775	0.21	0.0003	2.1	1.42 to 3.25
Lowest_lev = L5	0.498	0.19	0.007	1.7	1.15 to 2.41
Additional Laminectomy	0.870	0.40	0.03	2.4	1.09 to 5.17

Floating Fusions?

L4/5 vs L4-S1 (Degen spondylolistheses)



Aims

1. Determine

- Annual incidence
- Prevalence

of surgical intervention for **ASD** following **lumbar arthrodesis**

2. Examine

- Relative risk factors

Statistical analysis

- Kaplan-Meier survivorship analysis –
 - Prevalence & annual Incidence
- Cox proportional-hazards regression –
 - Multivariate analysis of risk factors
- Xlstat version 2009.6.03 & Medcalc version 11.2.1.0
- Significance set at $p < 0.05$

Discussion

- Methodology:
 - Single surgeon
 - Single technique
 - Personal indications
 - *Disadvantages*
 - Care required in applying to other surgeons/techniques
 - *Advantages*
 - Reduction in confounding variables
 - Facilitates multi-variant analysis
 - *Yields relative risk factors*
- End-point of further surgery may underestimate true incidence
- More work: Roles of pre-existing ASD, Balance, other surgeons/techniques

Conclusions:

Average annual incidence further surgery for ASD

- Cervical –

- Hilibrand *et al*, *JBJS* 1999 – **2.9%**

Radiculopathy and Myelopathy at Segments Adjacent to the Site of a Previous Anterior Cervical Arthrodesis*

BY ALAN S. HILIBRAND, M.D.†, GREGORY D. CARLSON, M.D.‡, MARK A. PALUMBO, M.D.§,
PAUL K. JONES, PH.D.‡, AND HENRY H. BOHLMAN, M.D.‡, CLEVELAND, OHIO

Investigation performed at the Department of Orthopaedic Surgery, University Hospitals Spine Institute, Case Western Reserve University School of Medicine, Cleveland

- Lumbar –

- Sears *et al*, *Spine J* 2011 – **2.5%** ... but incidence varies...



Adjacent Segment Disease following Lumbar Spinal Fusion

Dr Bill Sears

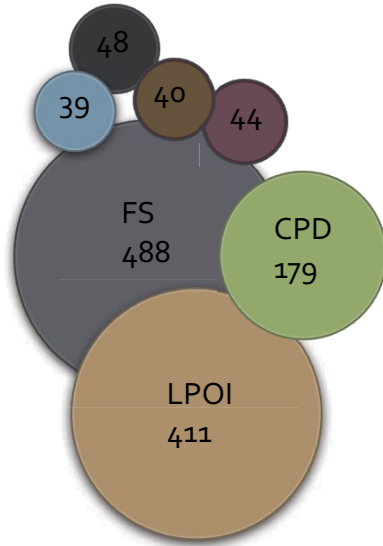
Neurosurgical Society of Australasia Annual Scientific Meeting

Adelaide, September 1st 2017

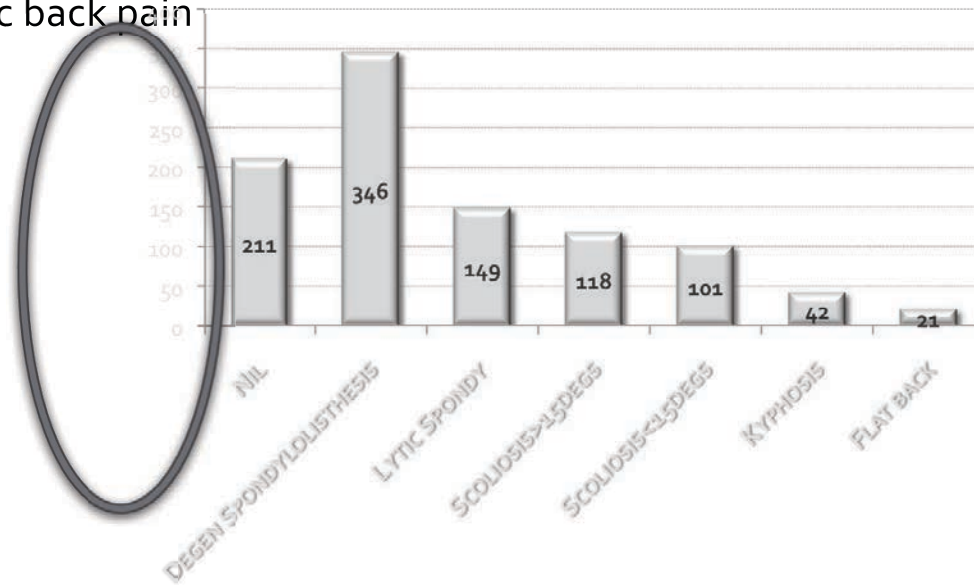
Methodology

- Retrospective cohort analysis
- End points:
 - Further surgical intervention - at adjacent level
 - Death / loss to F/U

Indications



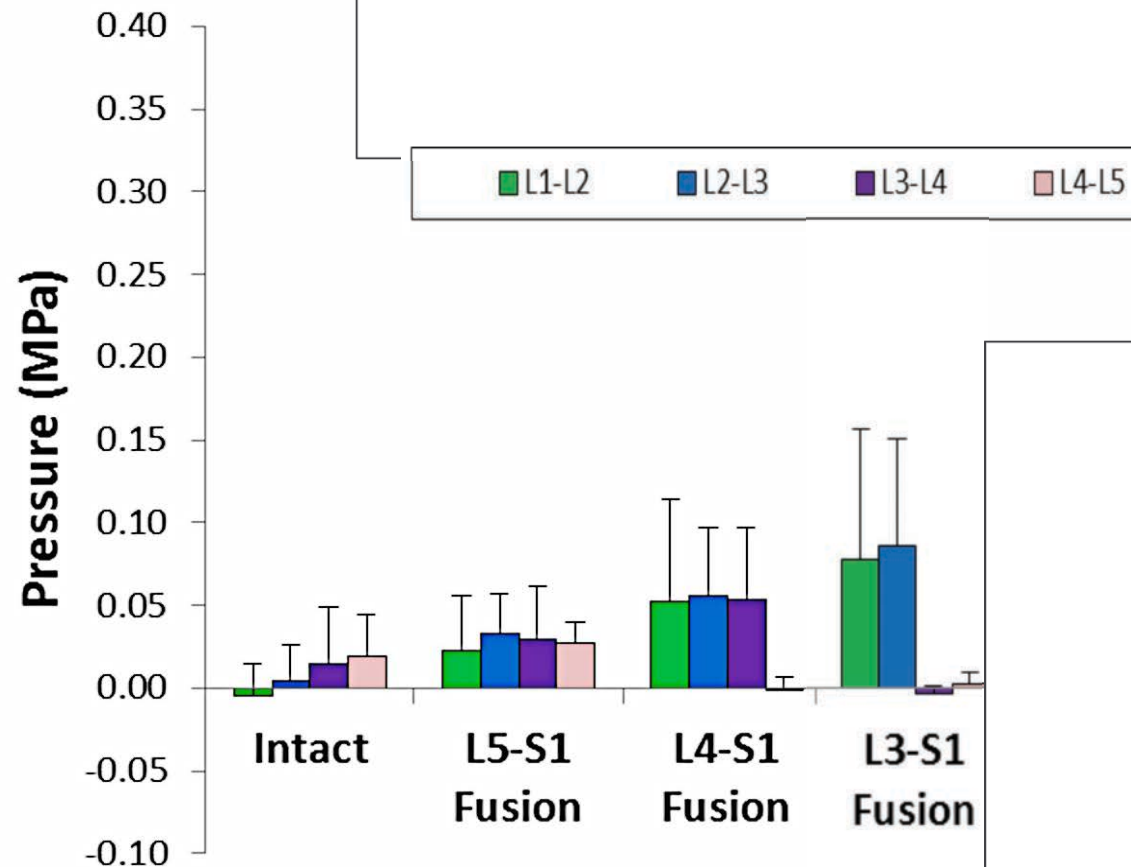
- Foraminal stenosis
- Likely post op instability
- Correct painful deformity
- Non-union
- Large or Recurrent disc herniation
- Discogenic back pain
- Instability



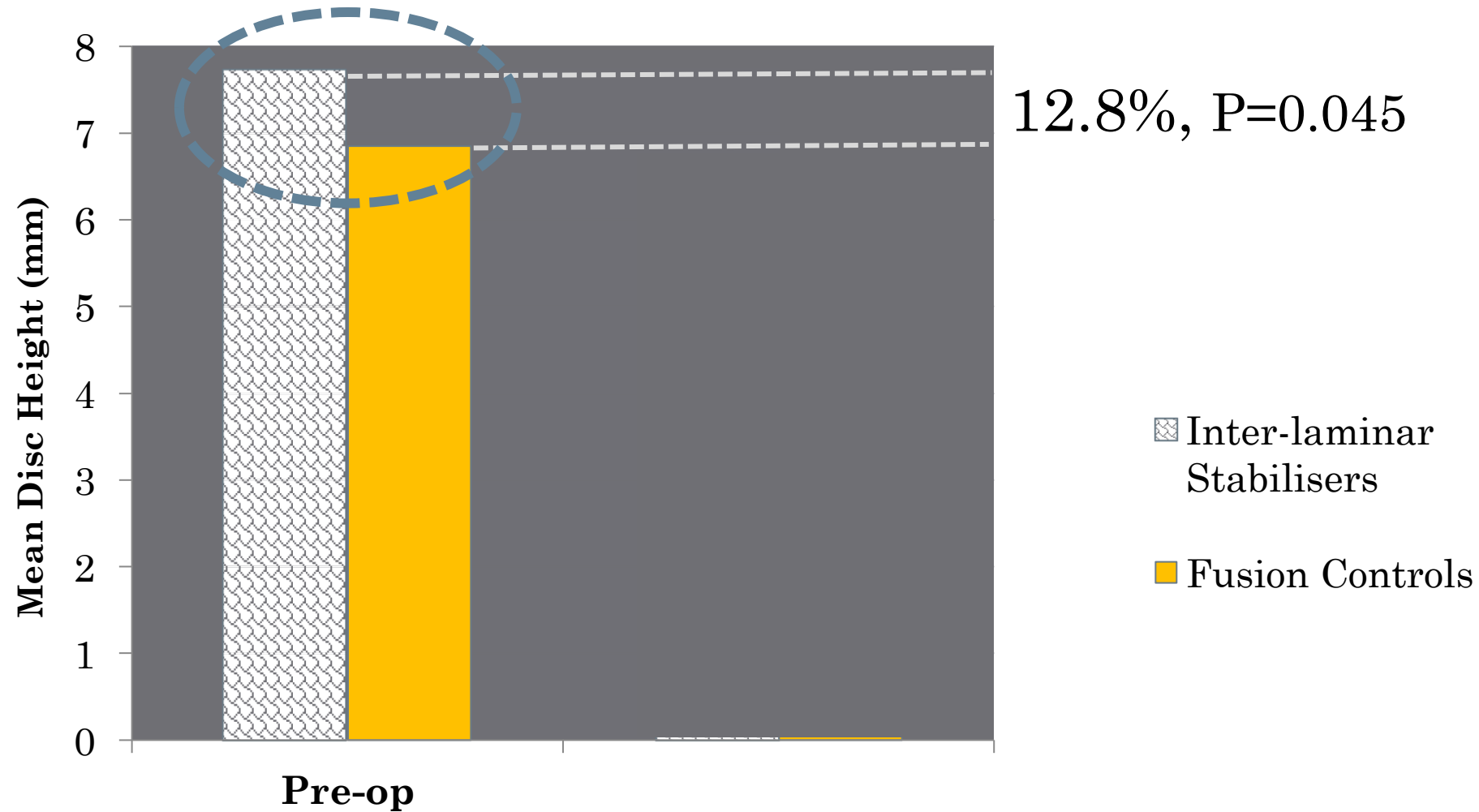
Genetics of ASD

- Omaid et al. *Eur Spine J.* 2016
 - Studied candidate gene effects on ASDegen.
 - 285 patients from 4 RCTs
 - @ 13 (± 4)yrs post fusion or non-op management.
 - Consider ASDegen. to be multifactorial with aging discs influenced by:
 - genetics
 - fusion
 - much of the variance still to be accounted for

Change in Intradiscal Pressures (Peak Flexion)

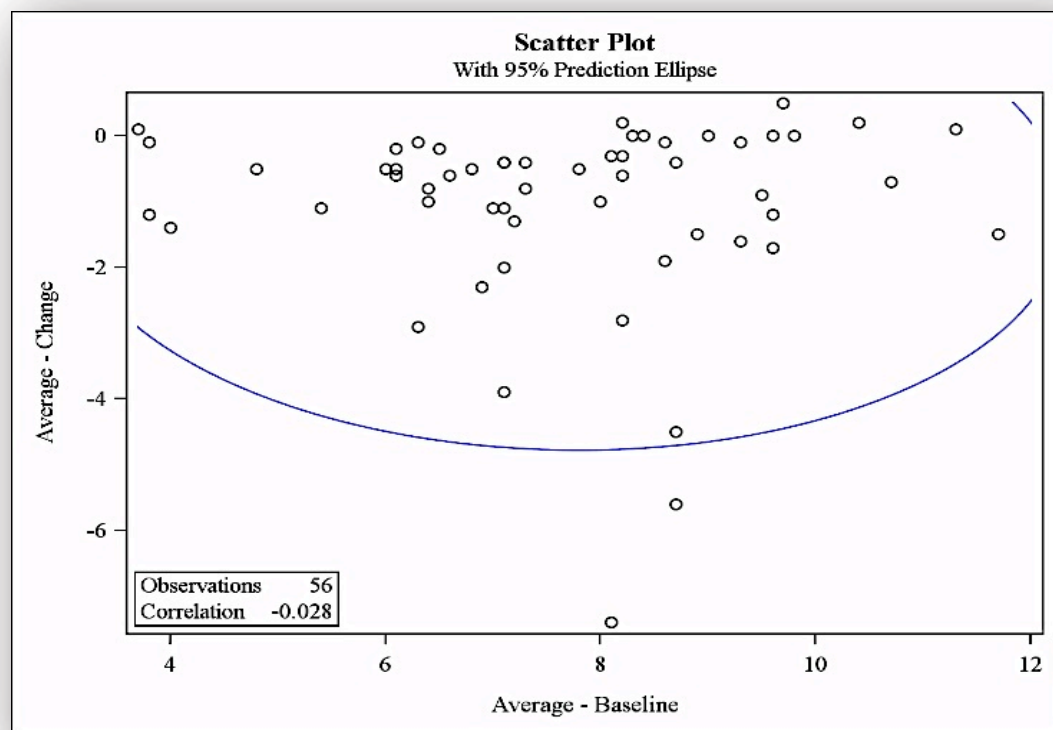


Results – disc space height (1st adjacent level)

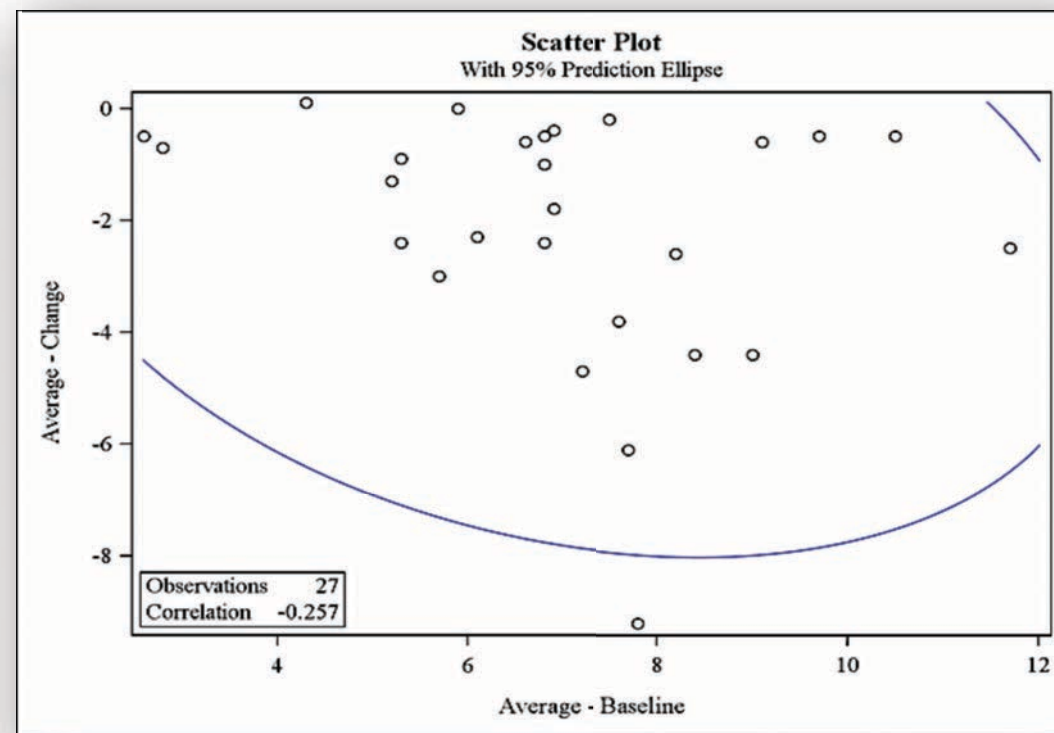


Correlations

Disc height: pre-op *vs.* change in height



Interlaminar stabiliser group



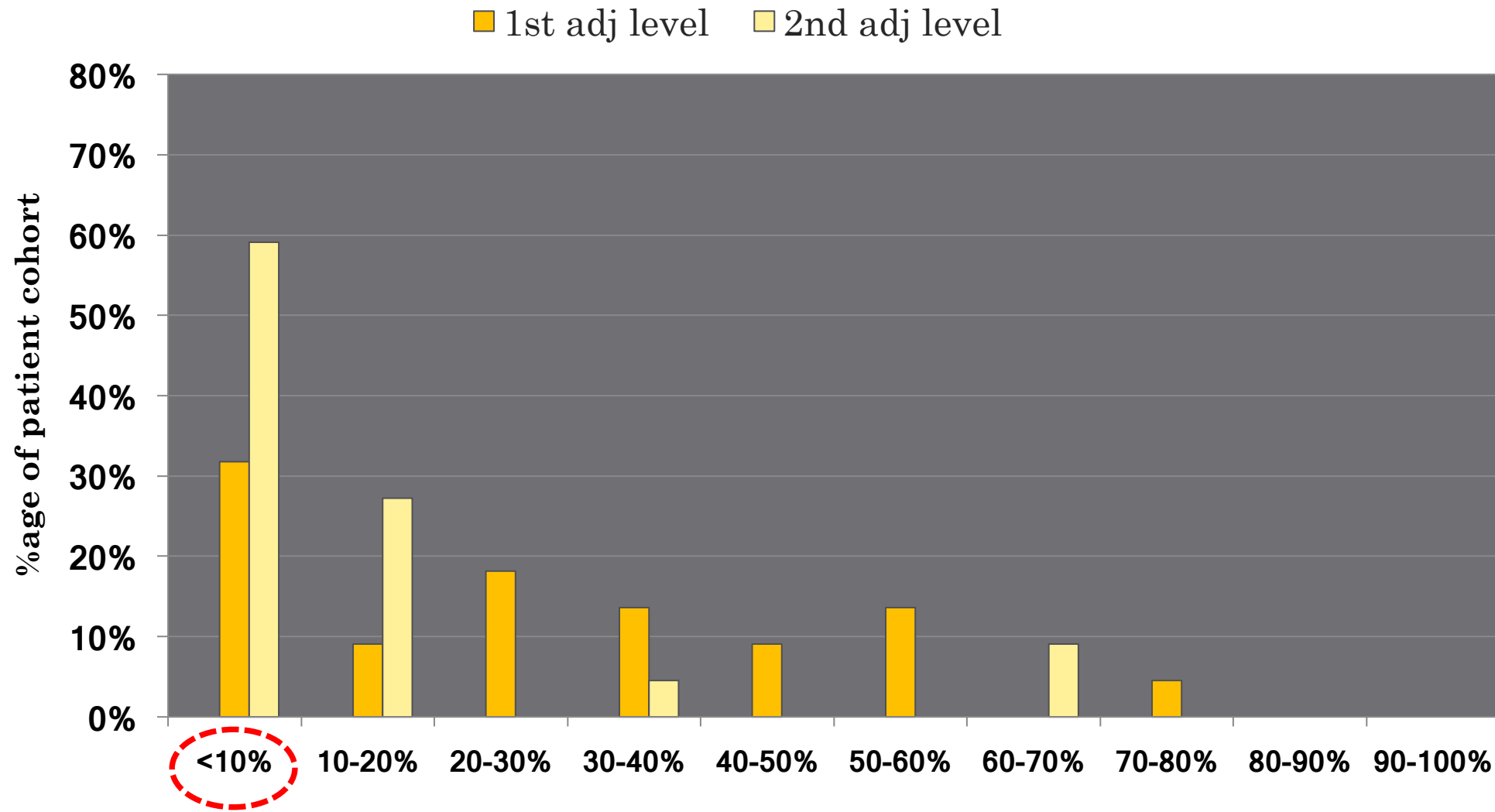
Fusion group

Multivariate Risk Factor Analysis

(Cox proportional-hazards regression)

Covariate	Relative Risk ^(95%CI)	P value
Age = <45yrs	x 0.25 (0.10 to 0.63)	0.003
Age = 45-60yrs	x 0.55 (0.34 to 0.87)	0.01
2 levels fused	x 2.1 (1.42 to 3.25)	0.0003
3 or 4 levels fused	x 3.0 (1.89 to 4.86)	<0.0001
Lowest level fused = L5	x 1.7 (1.15 to 2.41)	0.007
Adjacent level laminectomy	x 2.4 (1.09 to 5.17)	0.03

Results – Frequency distribution of relative disc-space height reductions @ 60-months – **Fusion patients only**



Discussion

Study Strengths:

- Randomised patient cohorts
- Accurately measured post-operative changes in disc-space height

Study Limitations:

- Secondary data analysis
 - Variation in several baseline variables
 - p values: $0.007 < p < 0.02$
- Findings may not be applicable to all forms of spinal fusion
 - What was it exactly about the fusion that contributed to the observed increase in ASDegen?

Conclusions

Based on accurately measured post-operative changes in disc-space height:

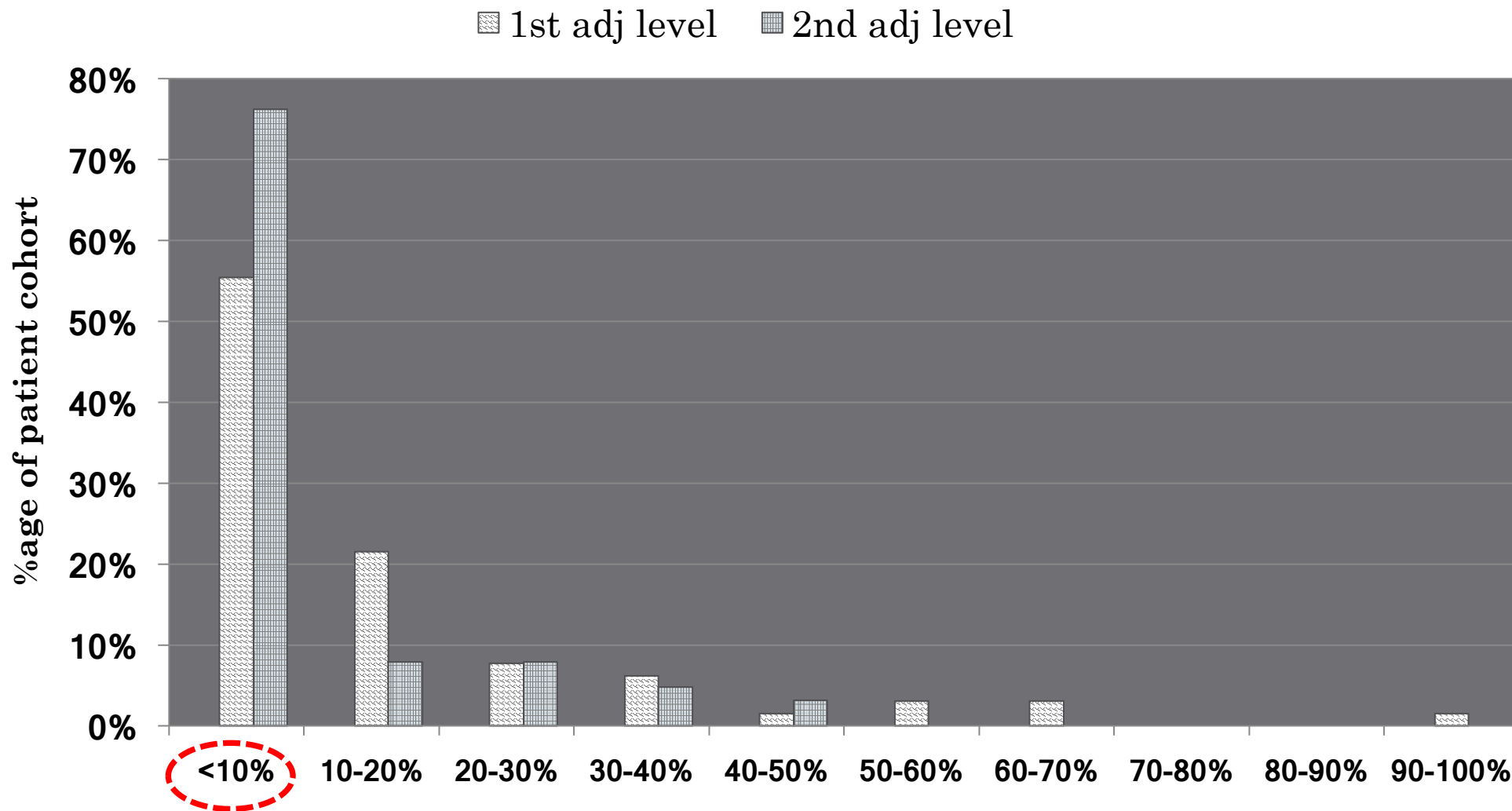
- High-level *in vivo* evidence: **lumbar spinal fusion is a risk factor for ASDegen.**
- Increased ASDegen may be associated with temporary increase in adjacent level angular ROM in fusion patients.
- The finding of less severe ASDegen at
 - 2nd adjacent levels &
 - patients randomized to motion preservation surgerysuggests **factors other than fusion also play a role in ASDegen.**

Acknowledgements

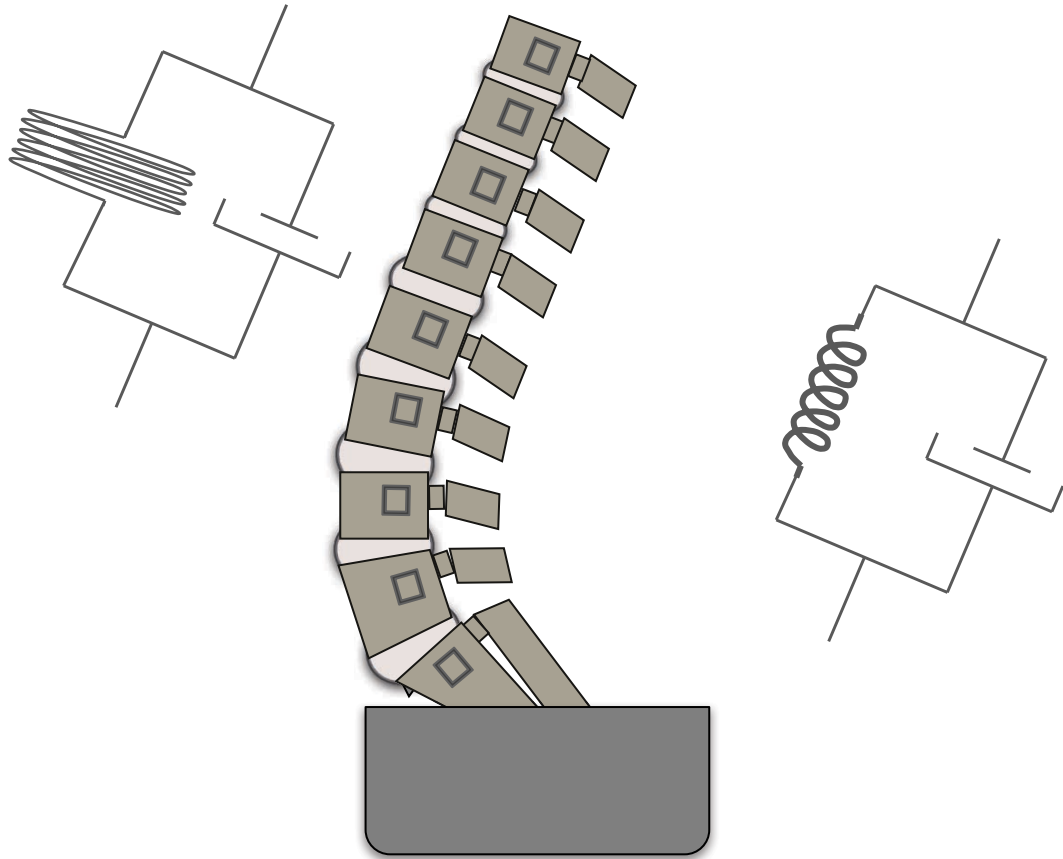
- Paradigm Spine LLC, NY for financial support
- Greg Maislin and Biomedical Statistical Consulting, PA
- Medical Metrics, TX
- My co-authors

Thank you

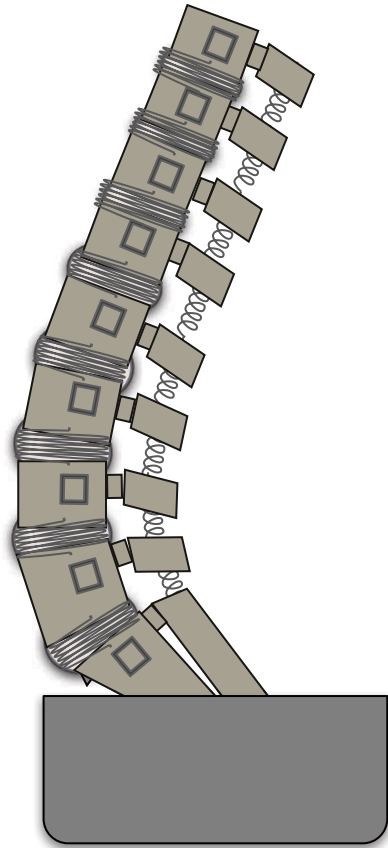
Results – Frequency distribution of relative disc-space height reductions @ 60-months – **Interlaminar stabilisers**



The spine: a tower of damped, segmental 'spring' elements

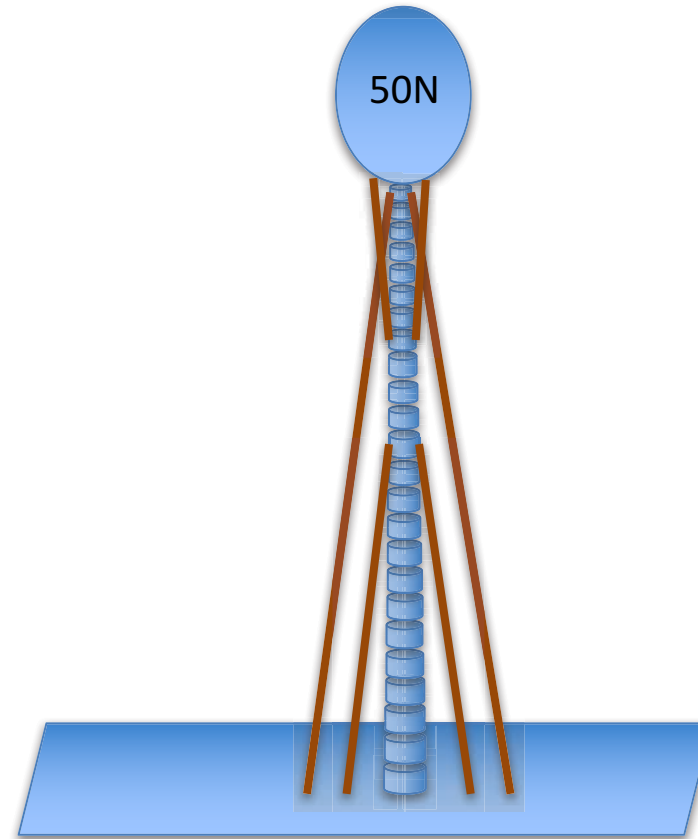
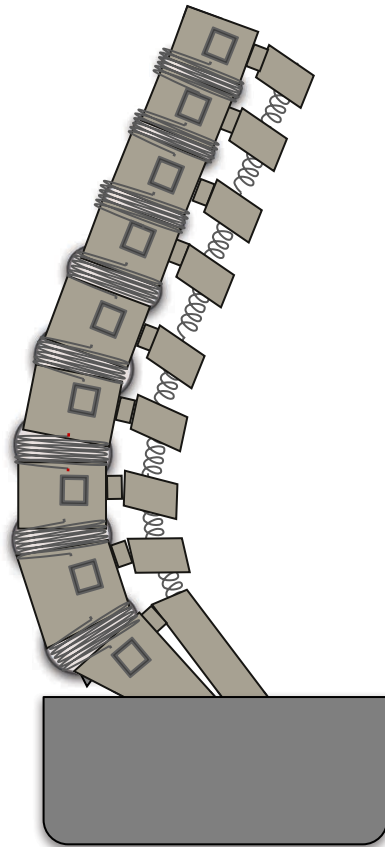


The spine: a tower of damped, segmental 'spring' elements



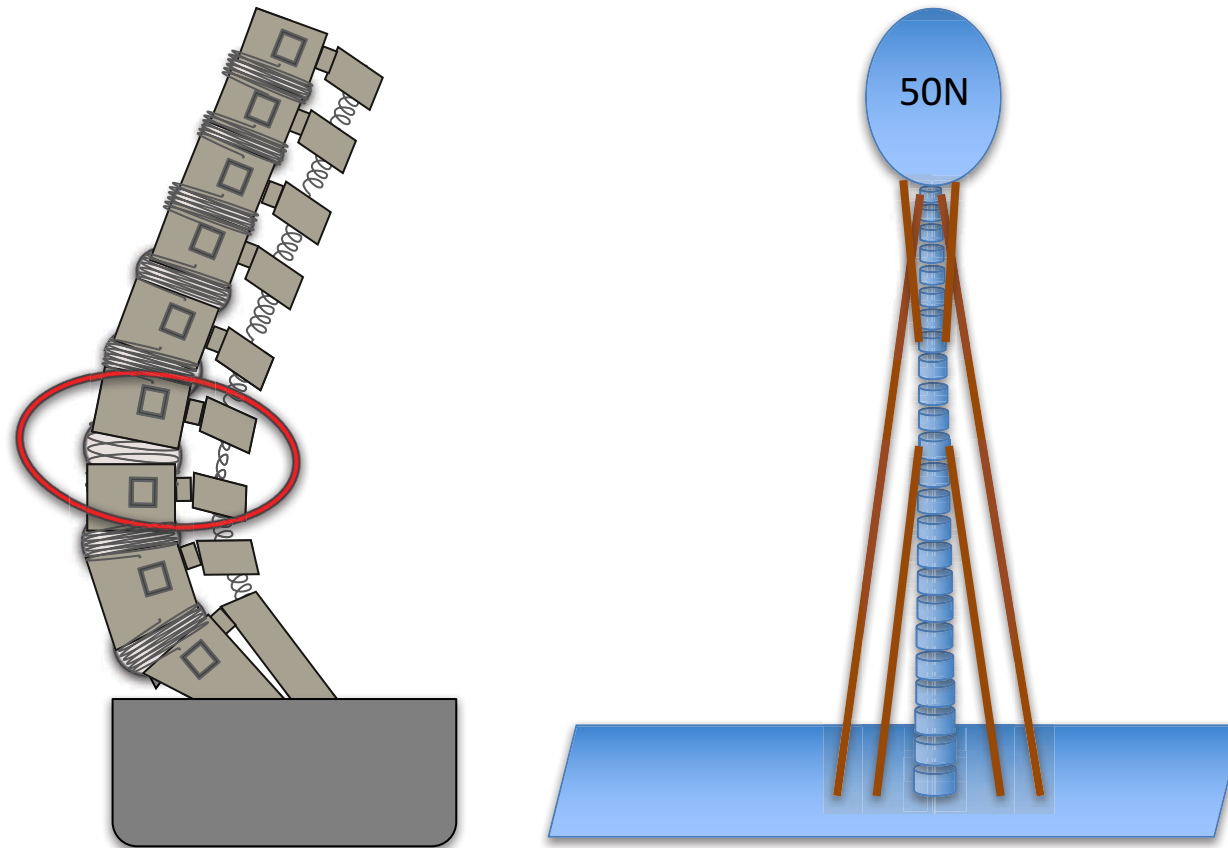
The spine: a tower of damped, segmental 'spring' elements

... stabilized by muscle activity



The spine: a tower of damped, segmental 'spring' elements

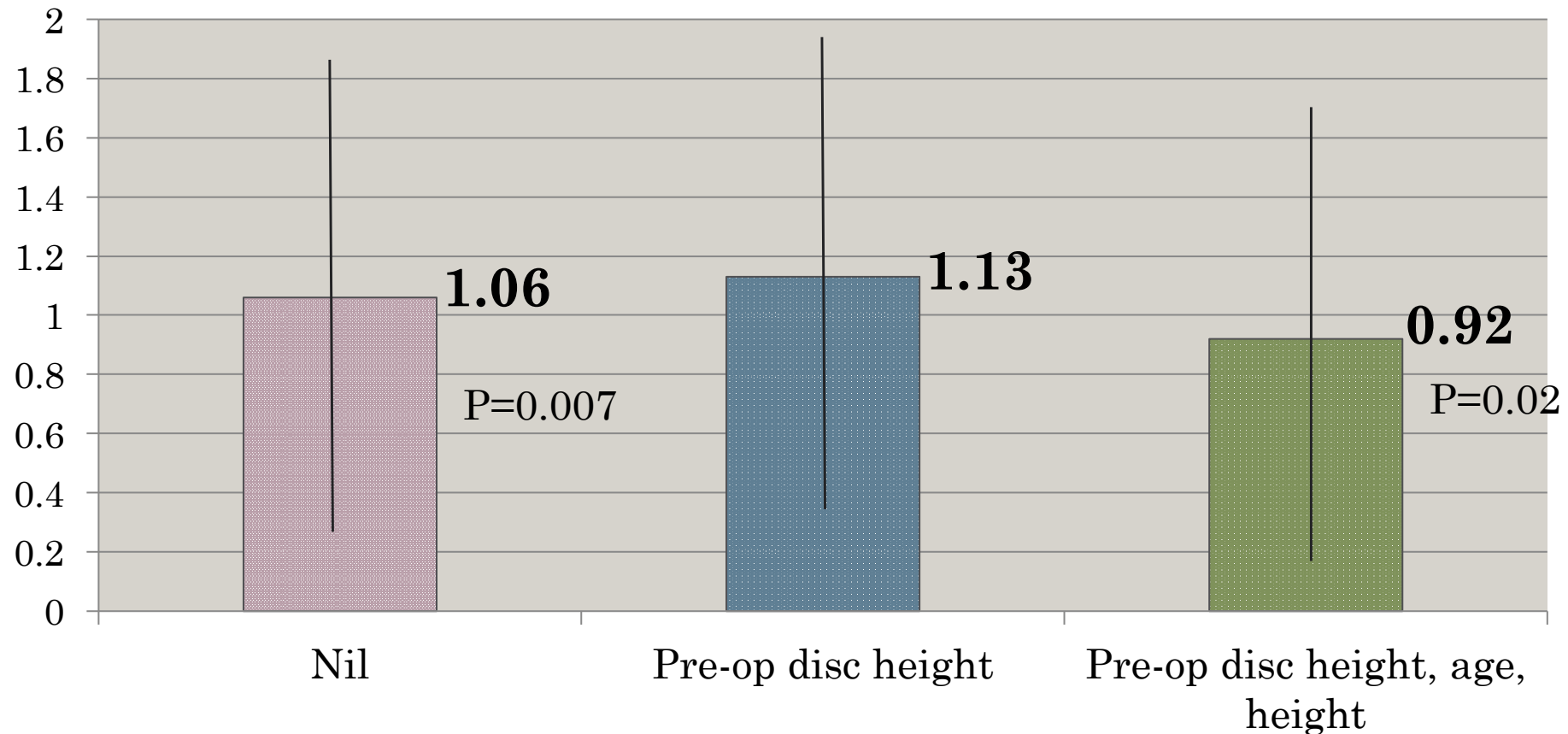
& if a segment starts to wear...



Between group differences: loss of disc-space height (mm. @ 5-years).

ANCOVA correction for pre-op variations in:

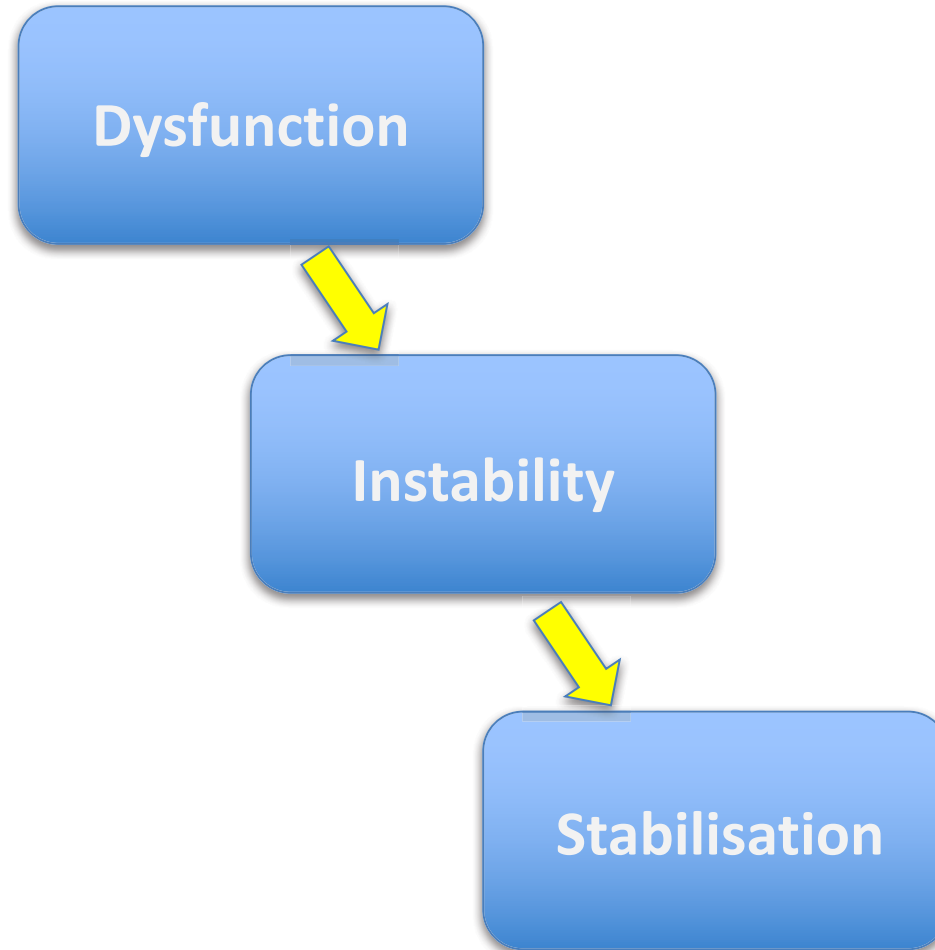
- disc space height
- disc space height, patient age & patient height.



Methodology

- *In vitro*
- Human specimens
- T10-S1: **8 levels**
- Pure moments
- 400N Follower load
- Displacement/Hybrid control
 - based on *in vivo* observations - 21°

Kirkaldy-Willis: Stages of Spinal Degeneration



Kirkaldy-Willis & Farfan.
Clin Orthop Relat Res 1982.