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

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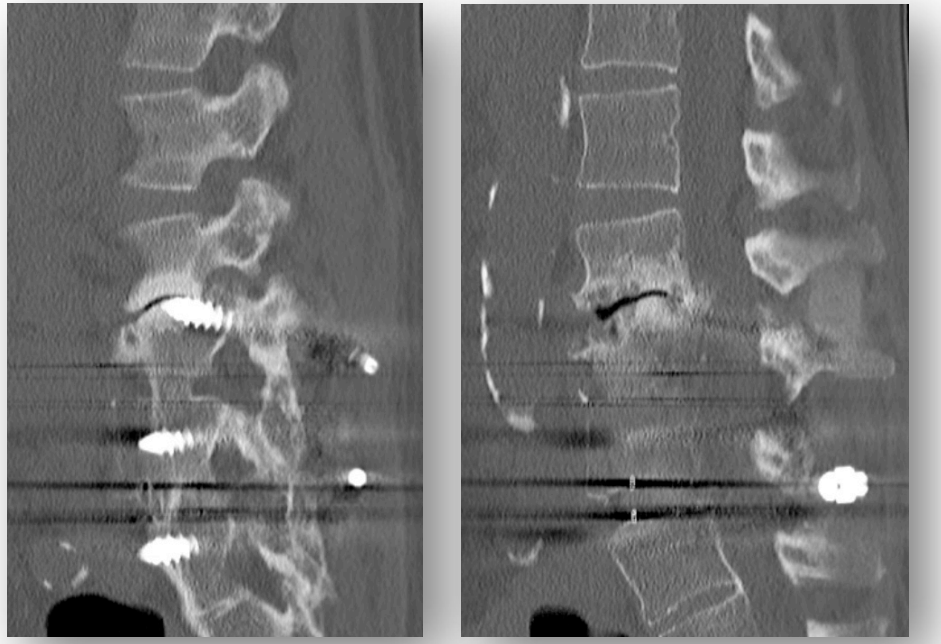
Disclosures

Sears	Paradigm Spine – Consultant Medtronic – Royalties, Consultant NuVasive – Consultant
Maislin	Paradigm Spine – Consultant
Davis	Paradigm Spine – Research support
Errico	Paradigm Spine – Research support
Bae	Paradigm Spine – Research support

Background

- **1,288,496 primary posterior lumbar fusions in the U.S. between 1998 and 2008**
  - Pumberger et al. *J Bone Joint Surg Br*. 2012
- **ASD**:
  - Annual incidence – **2.5%**
  - 10-year prevalence – **22%**
    - Sears et al. EuroSpine & *Spine J*. 2011



Background

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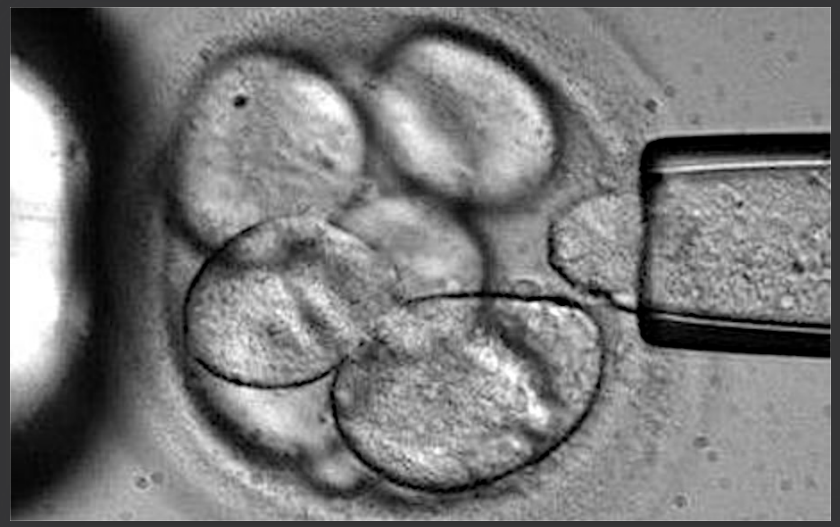
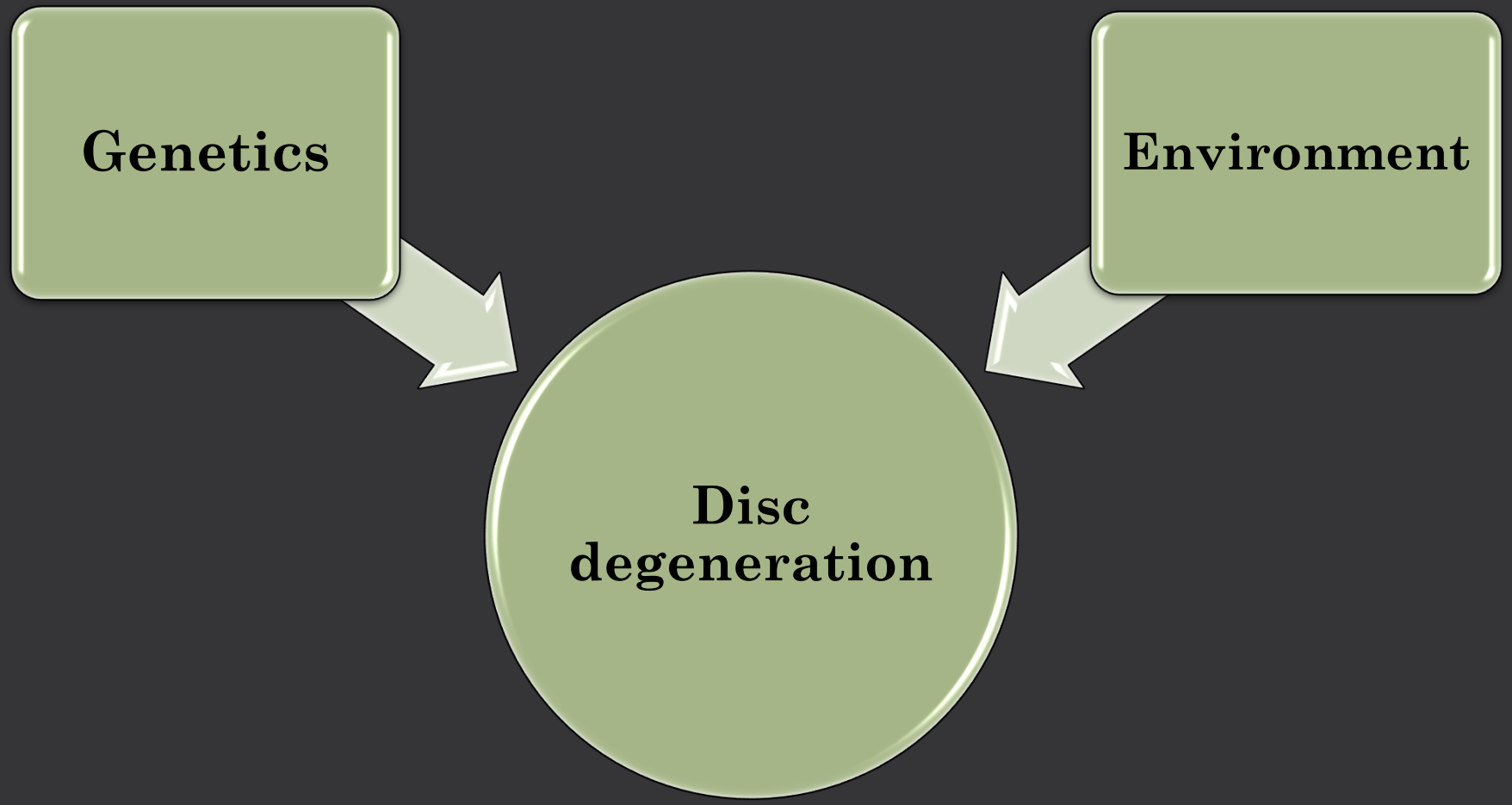
  - Pumberger et al. *J Bone Joint Surg Br*. 2012
- **ASD**:
  - Annual incidence – **2.5%**
  - 10-year prevalence – **22%**
    - Sears et al. EuroSpine & *Spine J*. 2011
- Up to **250,000 further surgeries** for ASD in the U.S. by 2018?



Pre-programmed biological response?


Genetics
Environment
Disc degeneration

Aim

- Does lumbar spinal fusion contribute to adjacent segment degeneration?

Methodology

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

Spine

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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, MD§

Methodology

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

Methodology

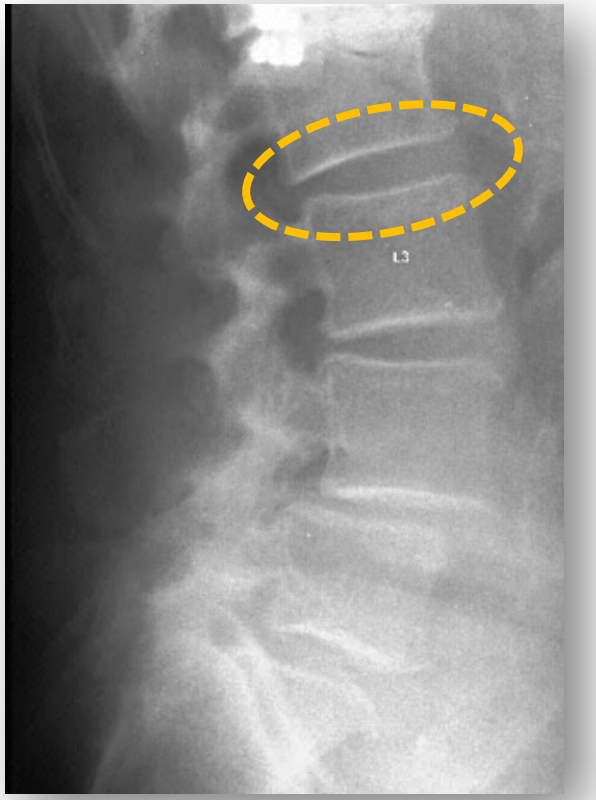
- Inter-laminar dynamic spacer IDE RCT
  - **two-level arm**
  - 55 investigational & 27 fusion controls

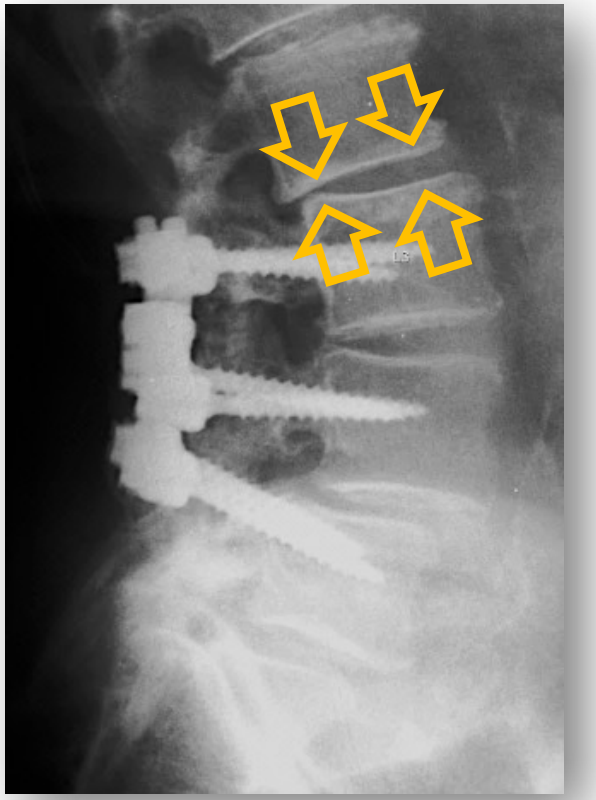
Methodology

- 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

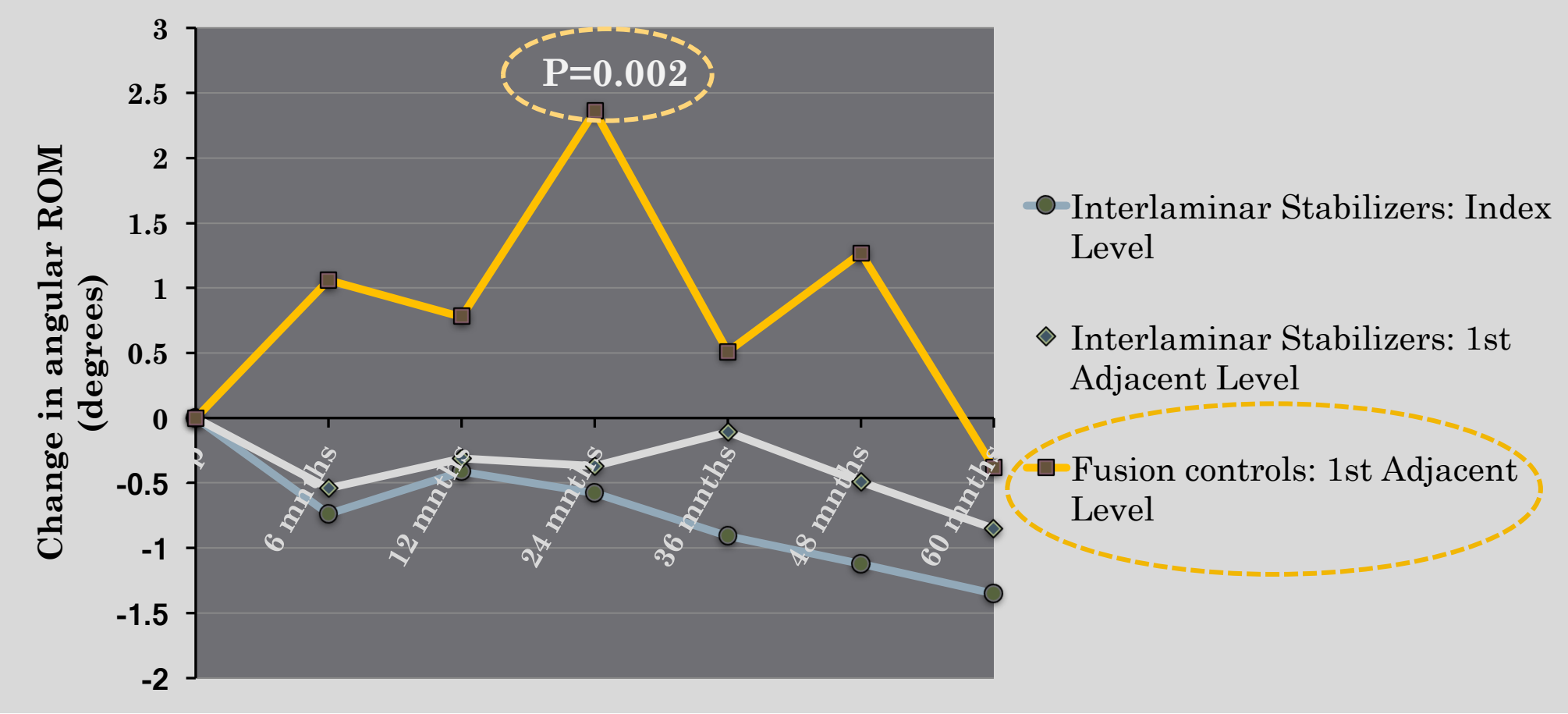
Methodology

- Disc-space heights

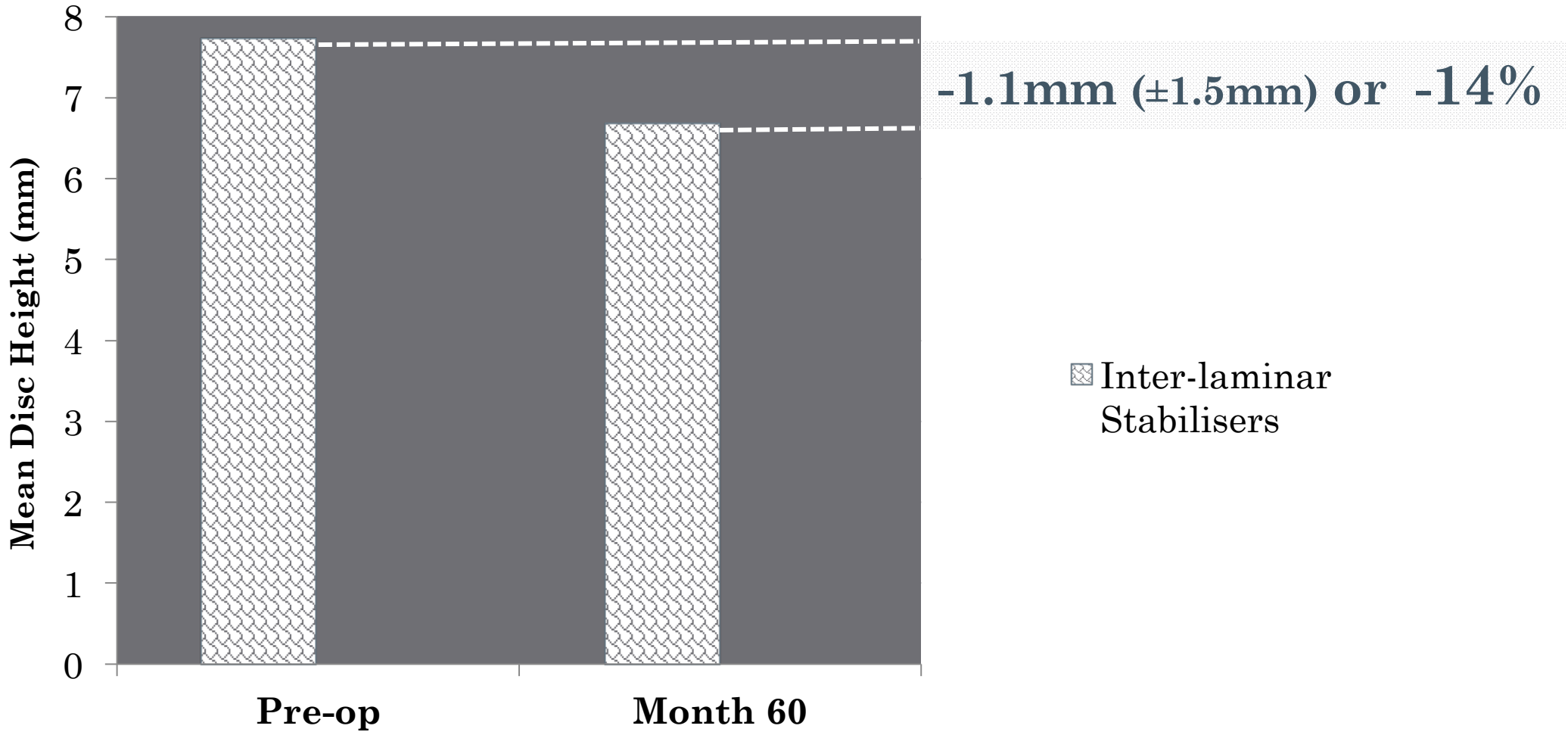




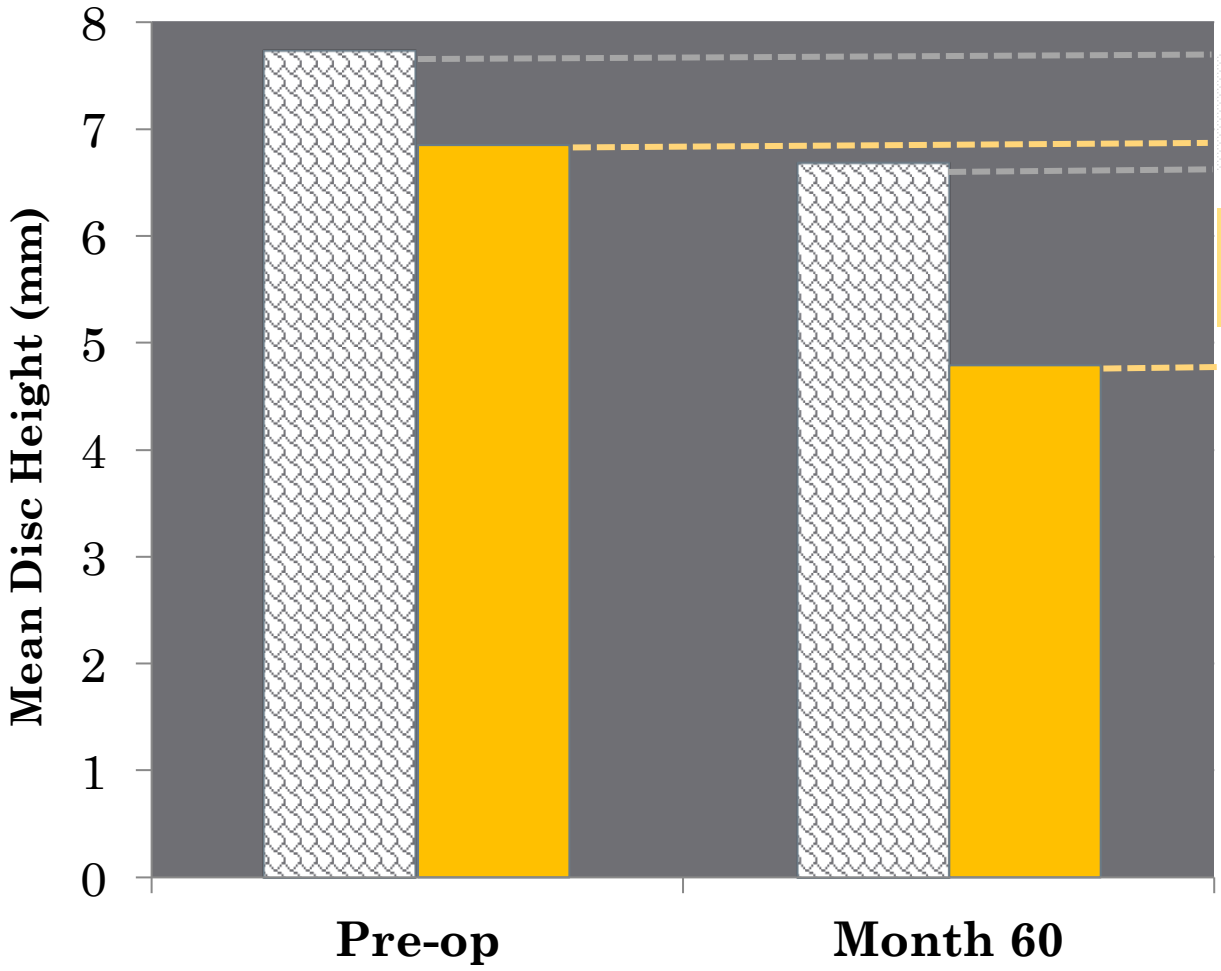
Results – Segmental angular ROM



Results – disc space height (1st adjacent level)



Results – disc space height (1st adjacent level)



-1.1mm (±1.5mm) or -14%

-2.2mm (±2.2mm) or -30%

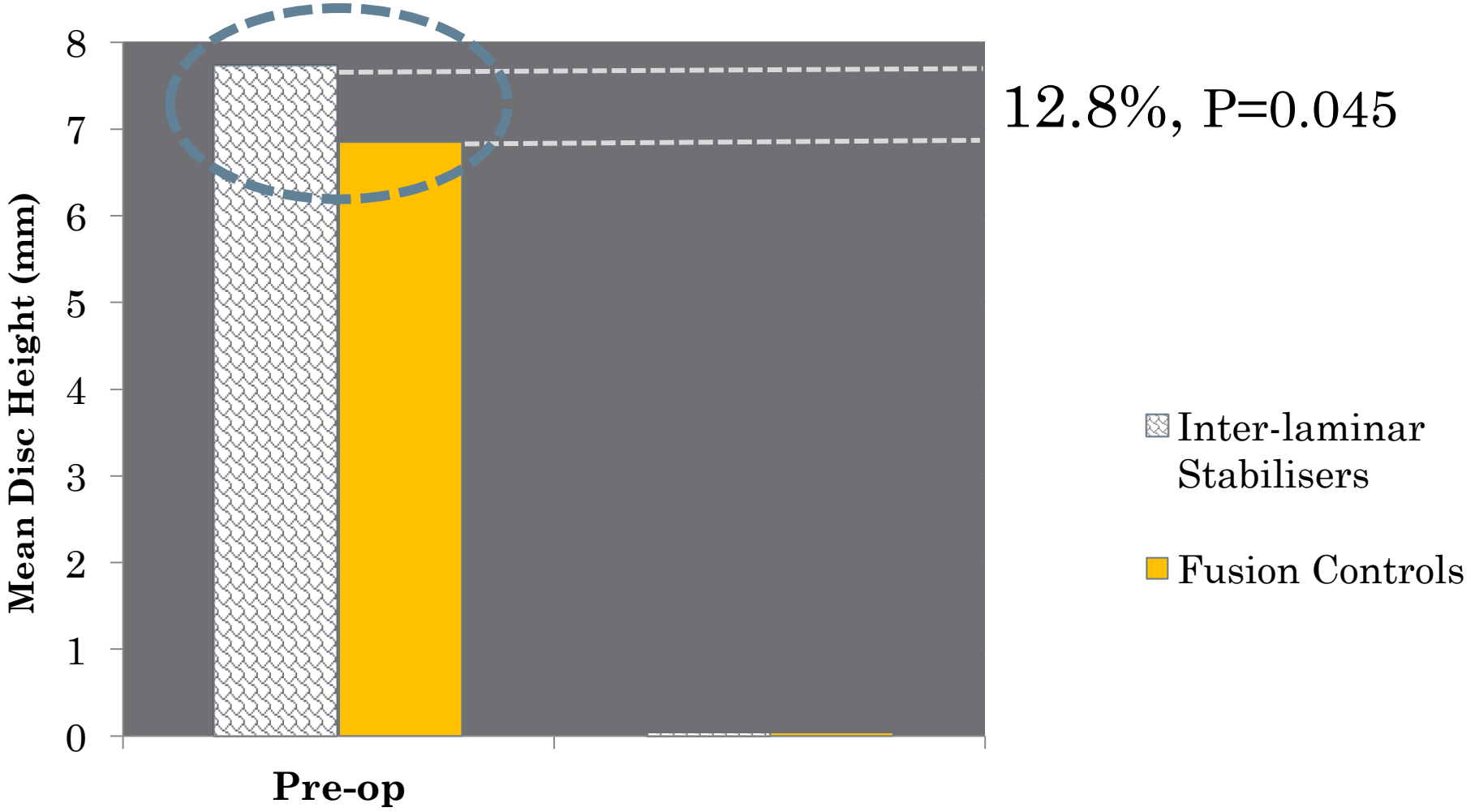
P=0.007*

Inter-laminar Stabilisers

Fusion Controls

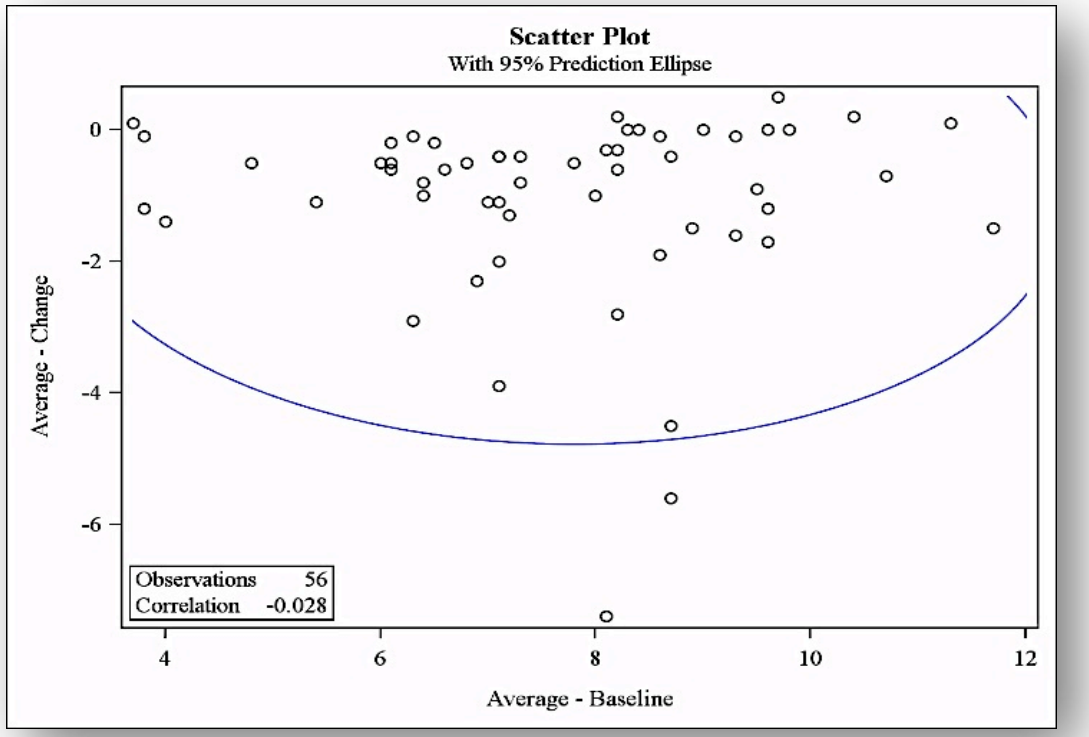
* Wilcoxon rank sum

Results – disc space height (1st adjacent level)

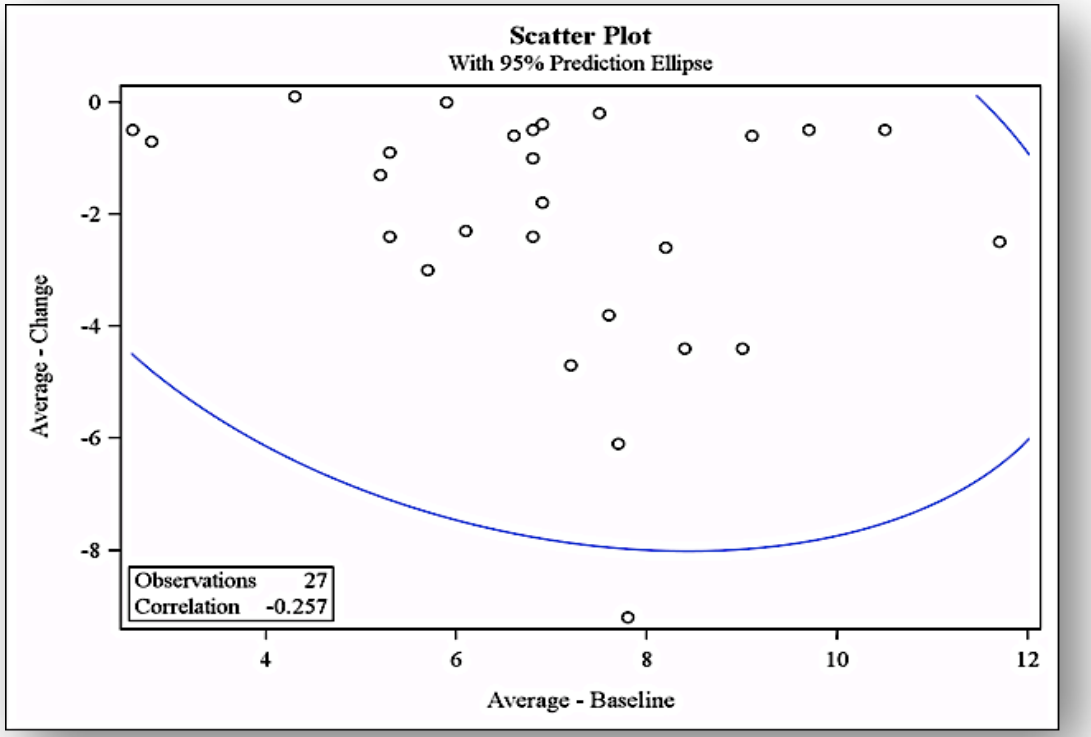


Correlations

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



Interlaminar stabiliser group

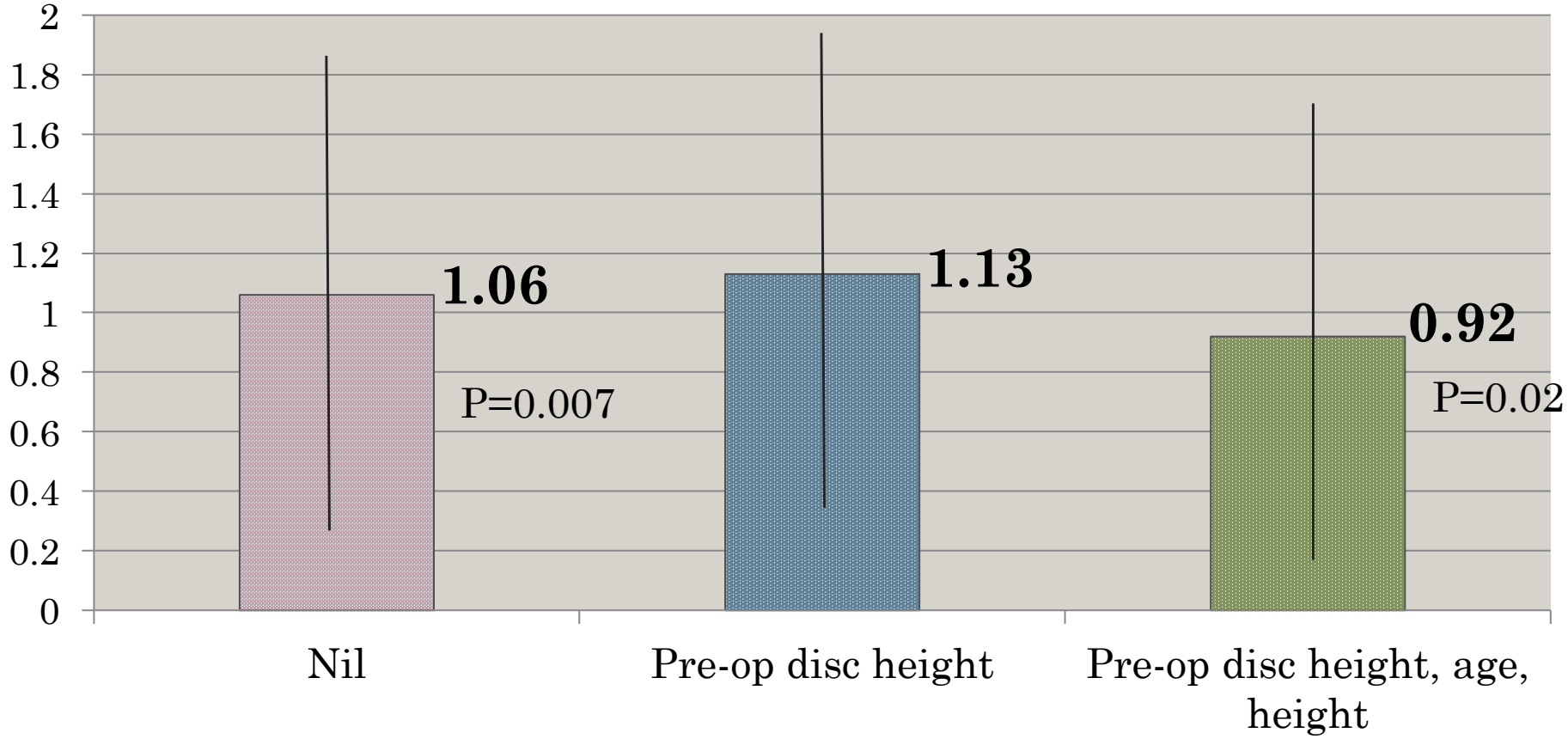


Fusion group

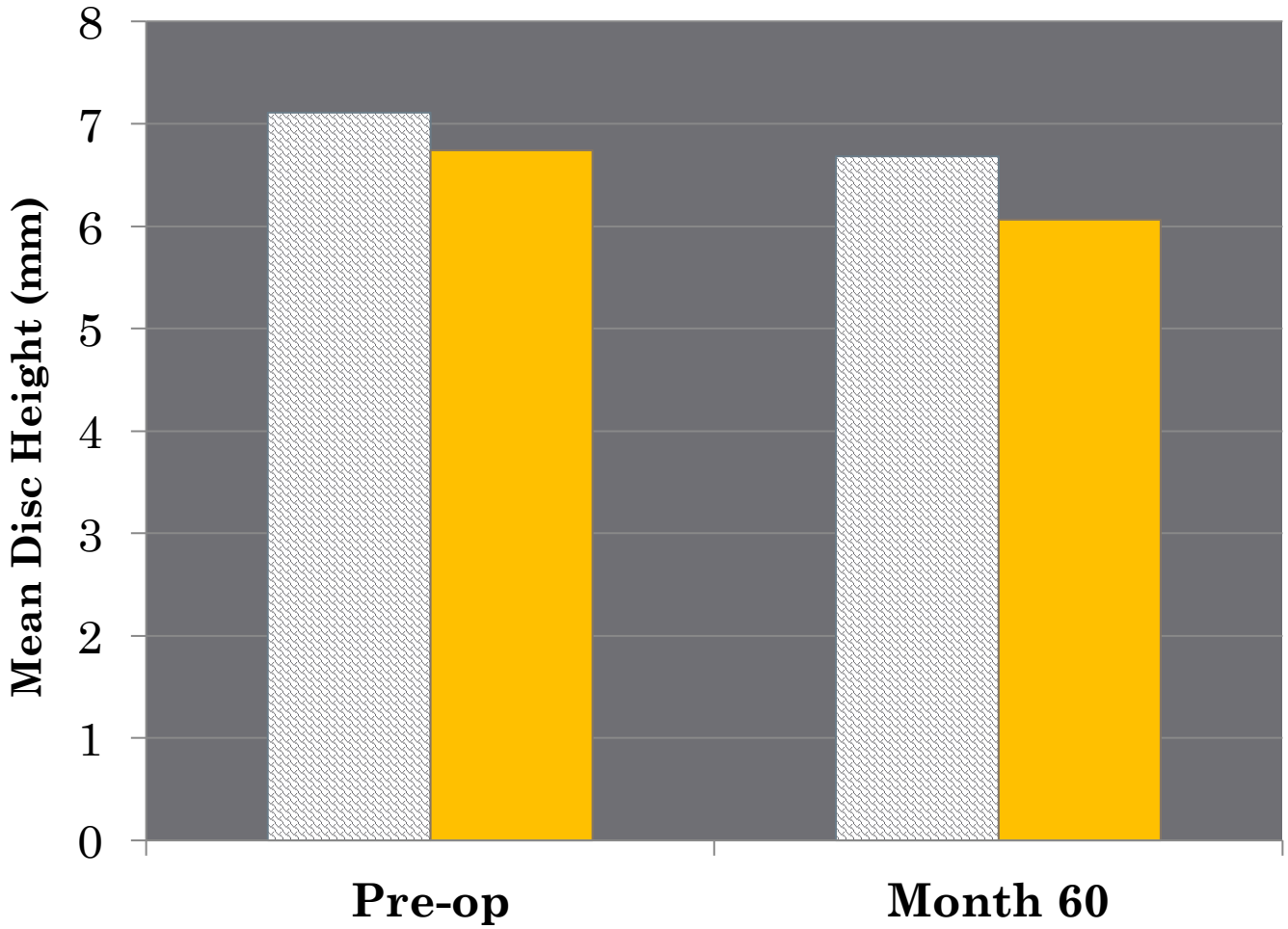
Between group differences: loss of disc-space height (mm. @ 5-years).

ANCOVA correction for pre-op variations in:

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



Disc space heights (2nd adjacent level)



-0.47mm (±0.8mm)

-1.04mm (±1.5mm)

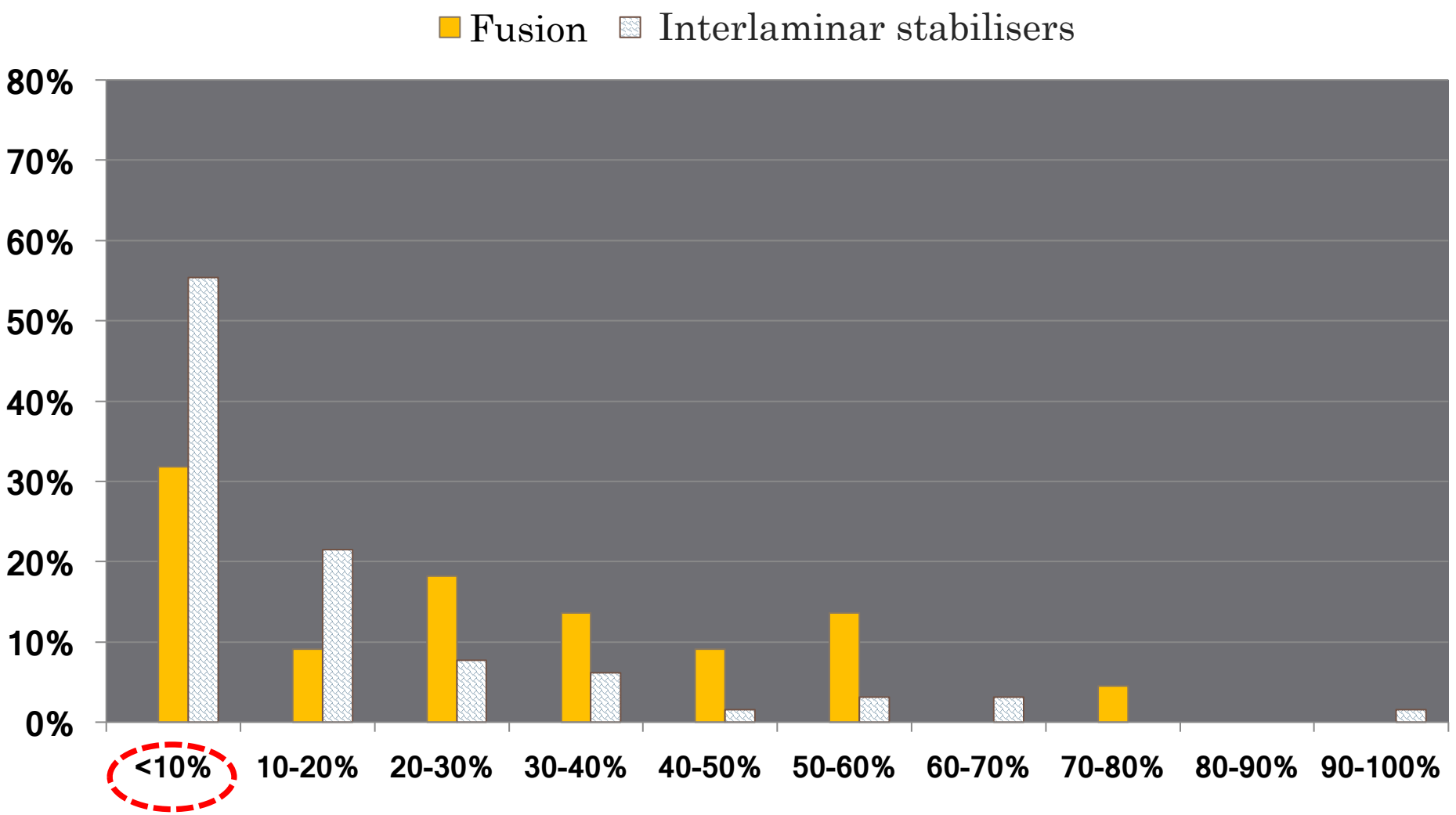
P=0.031*

Inter-laminar Stabilisers

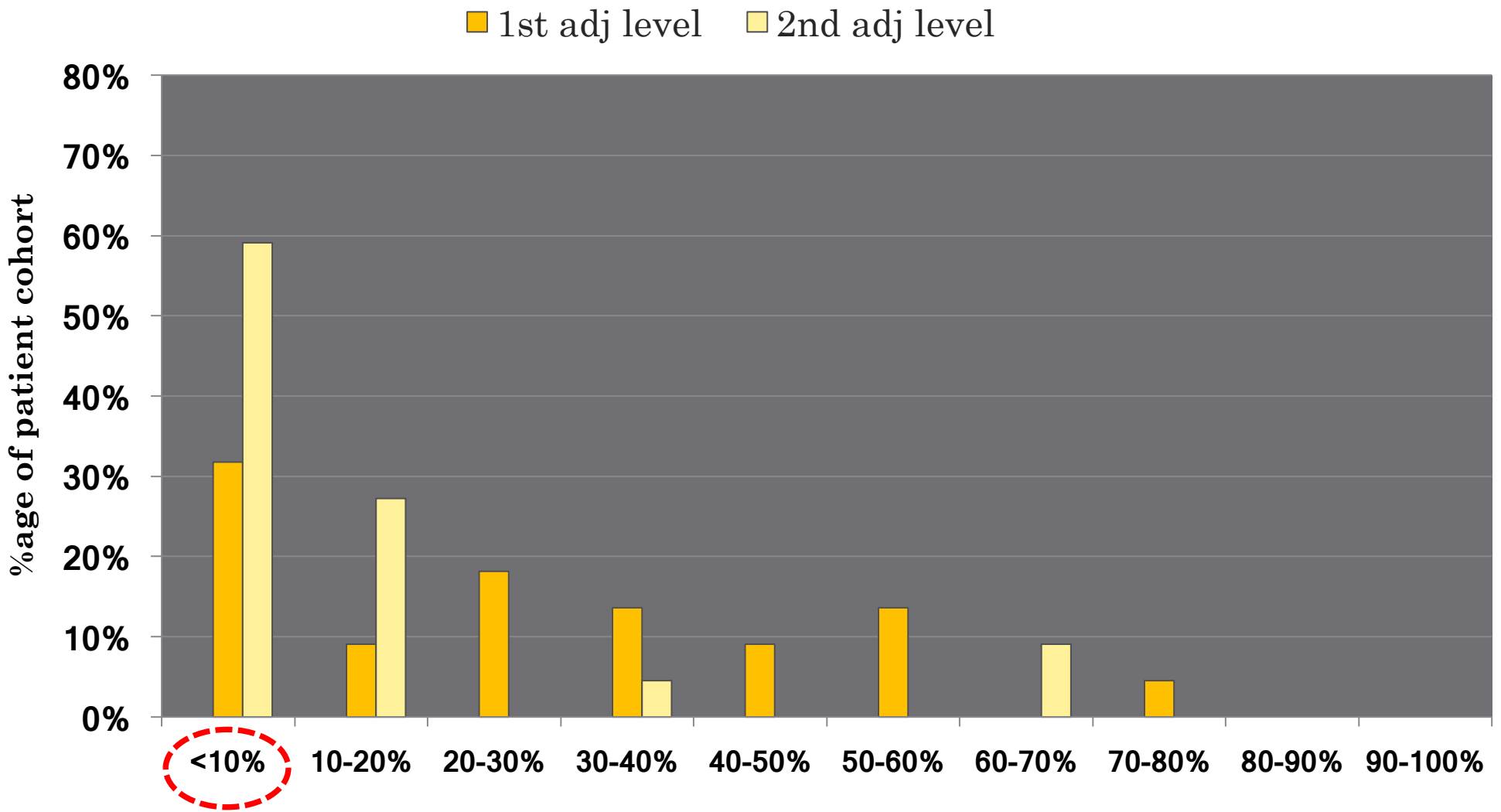
Fusion Controls

* Wilcoxon rank sum

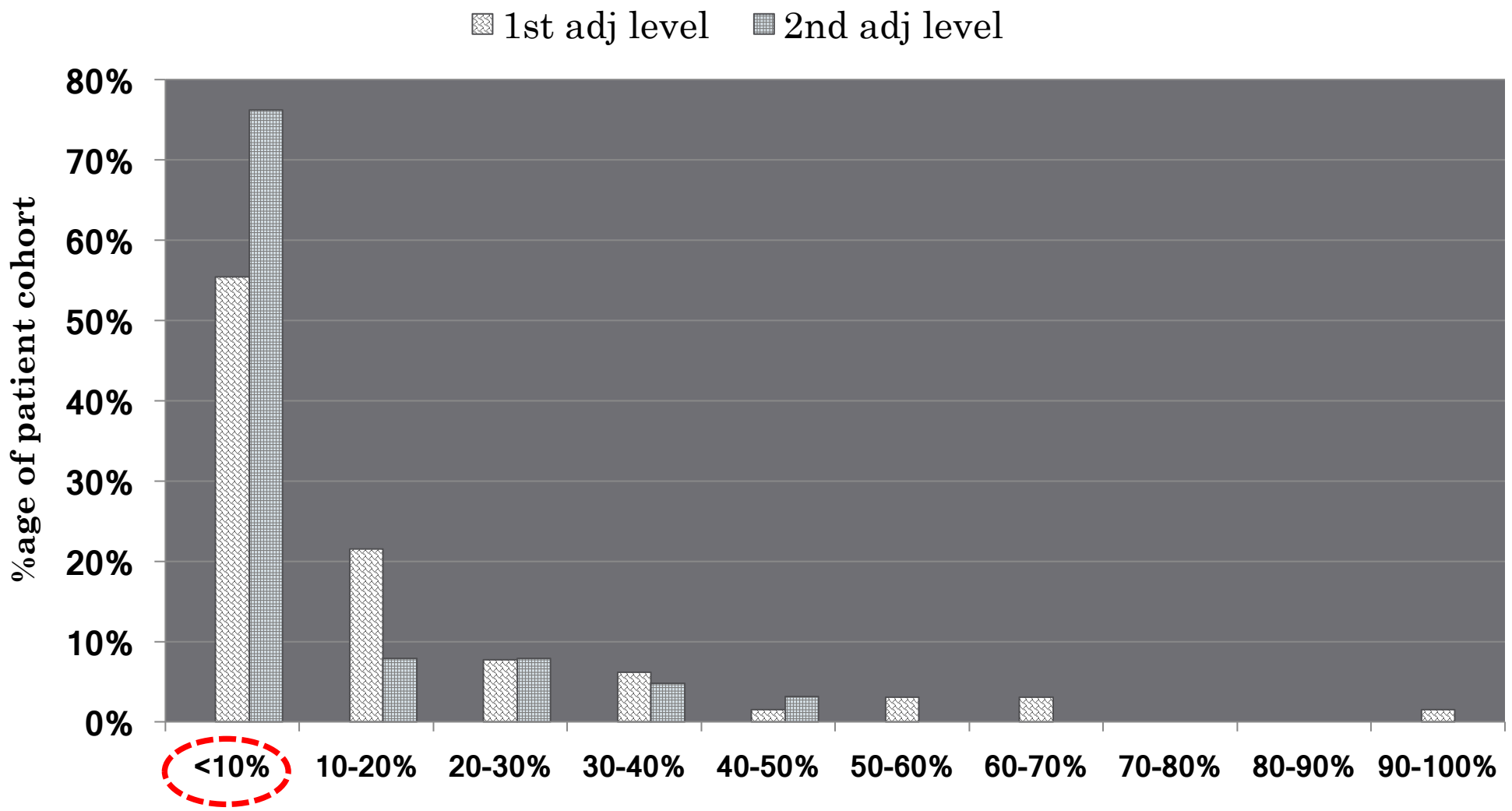
Frequency distribution of Percentage Reductions
in relative disc-space height @ 60-months – 1st adjacent level
Fusion *vs.* ILS



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



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



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 surgery

suggests **factors other than fusion also play a role in ASDegen**.

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- Medical Metrics, TX
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