The role of ex vivo testing to investigate spine biomechanics and improve spine treatments

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spinner
next generation spine experts

Introduction

- MDR and (common sense) recommend pre-clinical testing of implantable devices and surgical techniques

- Not everything can be tested on living subjects

- Numerical models are a good option but…

  o Require identification of input parameters (e.g. material properties)

  o Must be validated against "ground truth" before being trusted
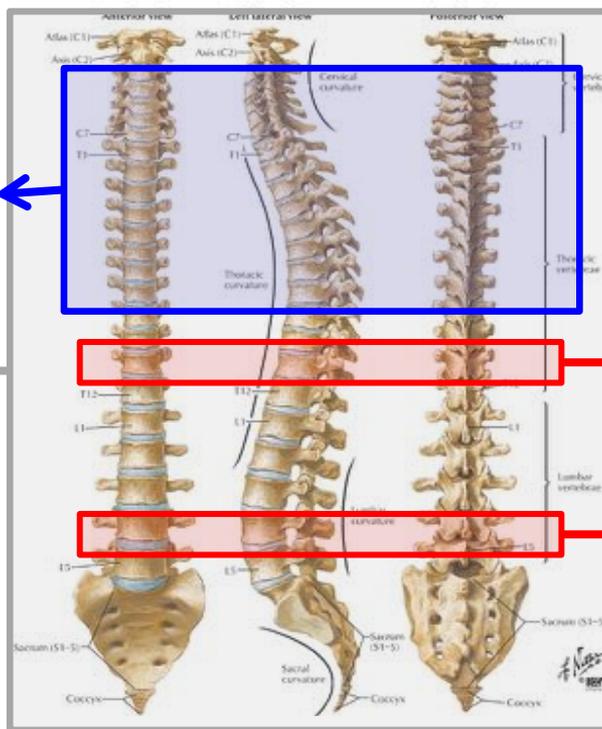
Biomechanical testing

MULTISCALE APPROACH

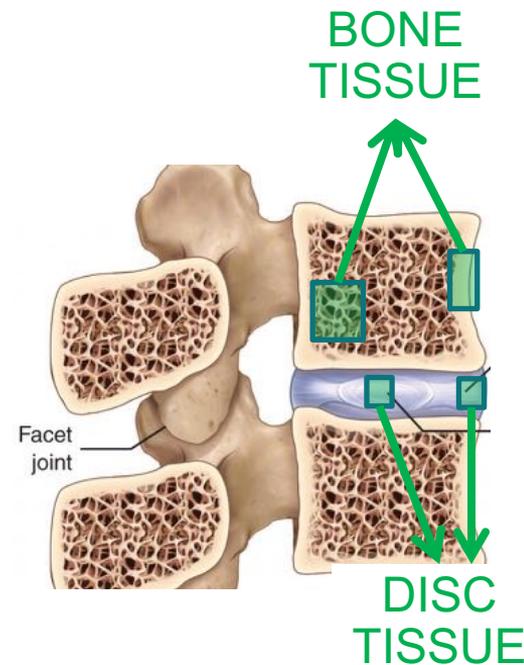**BODY LEVEL**   **ORGAN LEVEL**   **TISSUE LEVEL**

SPINE SEGMENT

WHOLE SPINE
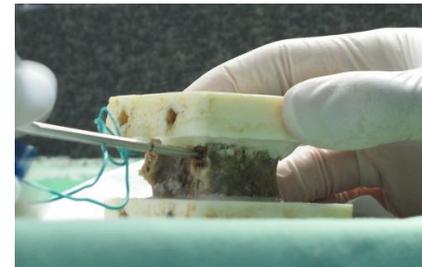
SINGLE VERTEBRA

SINGLE DISC

BONE TISSUE

DISC TISSUE

Facet joint

Effects of percutaneous cement discoplasty (PCD)

Effects of prophylactic vertebral augmentation with cement

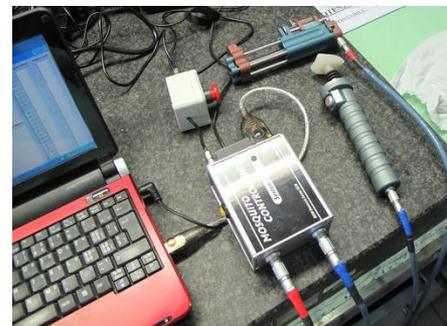# Mechanical effectiveness of vertebral augmentation

Injected material:

- PMMA cement

Injection system[1]:

- Controlled injection speed
- Controlled injected volume
- Real-time measured flow and pressure:
  - Cement viscosity monitored

(1) Loeffel M, Ferguson SJ, Nolte LP, Kowal JH. "Vertebroplasty: characterization of bone cement spreading as a function of viscosity, bone porosity, and flow rate" Spine 2008
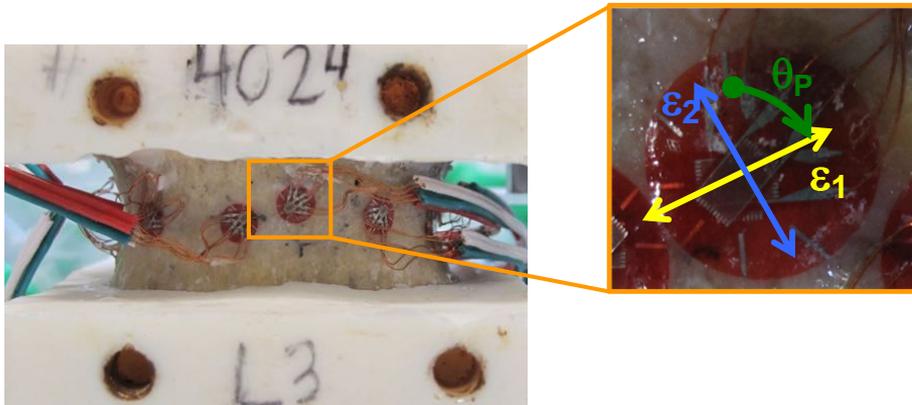
Quality of augmentation

Indicators:

- Access:
  - Uni- or bi-pedicular

- Injected volume

- Cement leakage

- Cement symmetry:
  - A/P and R/L

- Cement sphericity:
  - Sphere, ellipsoid, diffuse

- Endplate contact:
  - None, one, both

Mechanical testing
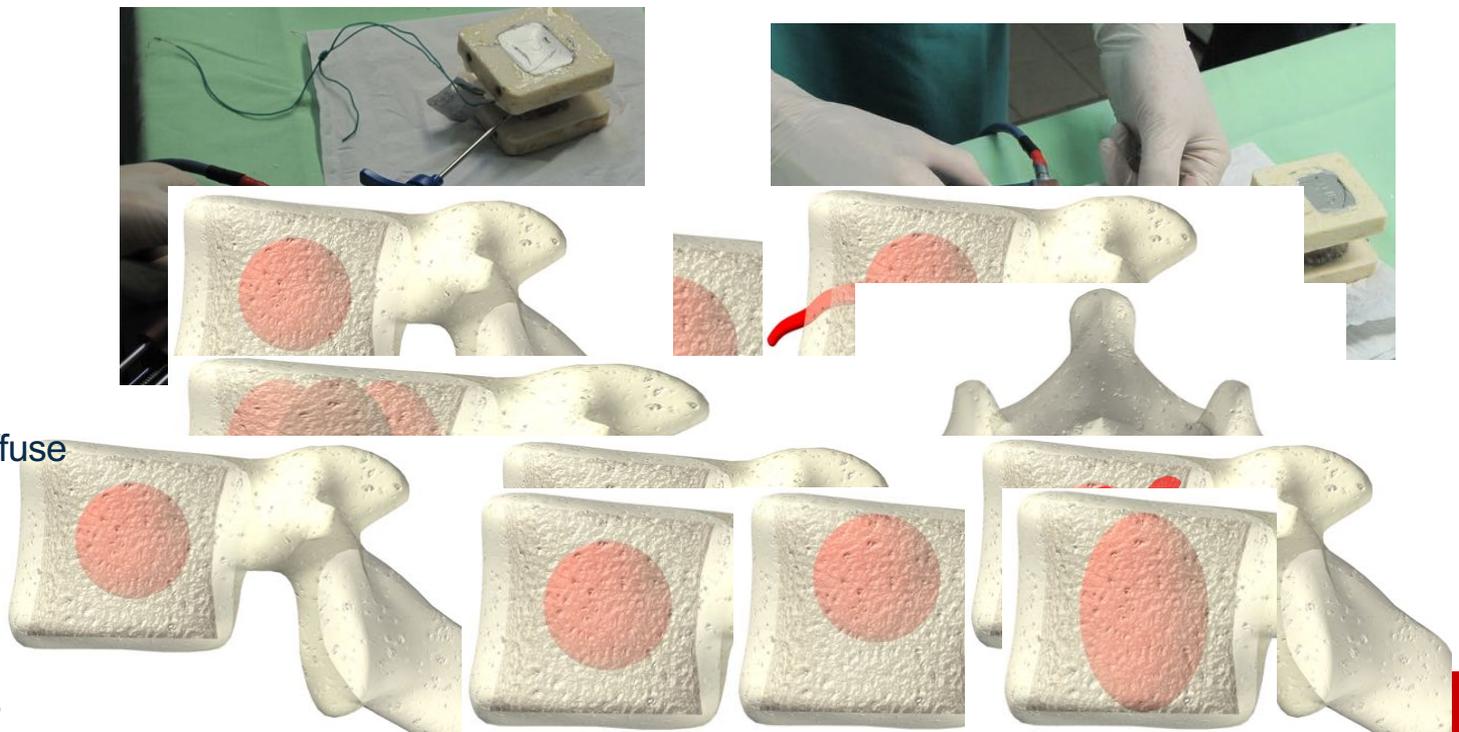
Strain measurement

- 8 strain gauges / vertebra

- Triaxial stacked rosettes
  - Principal strains (ε_1, ε_2)
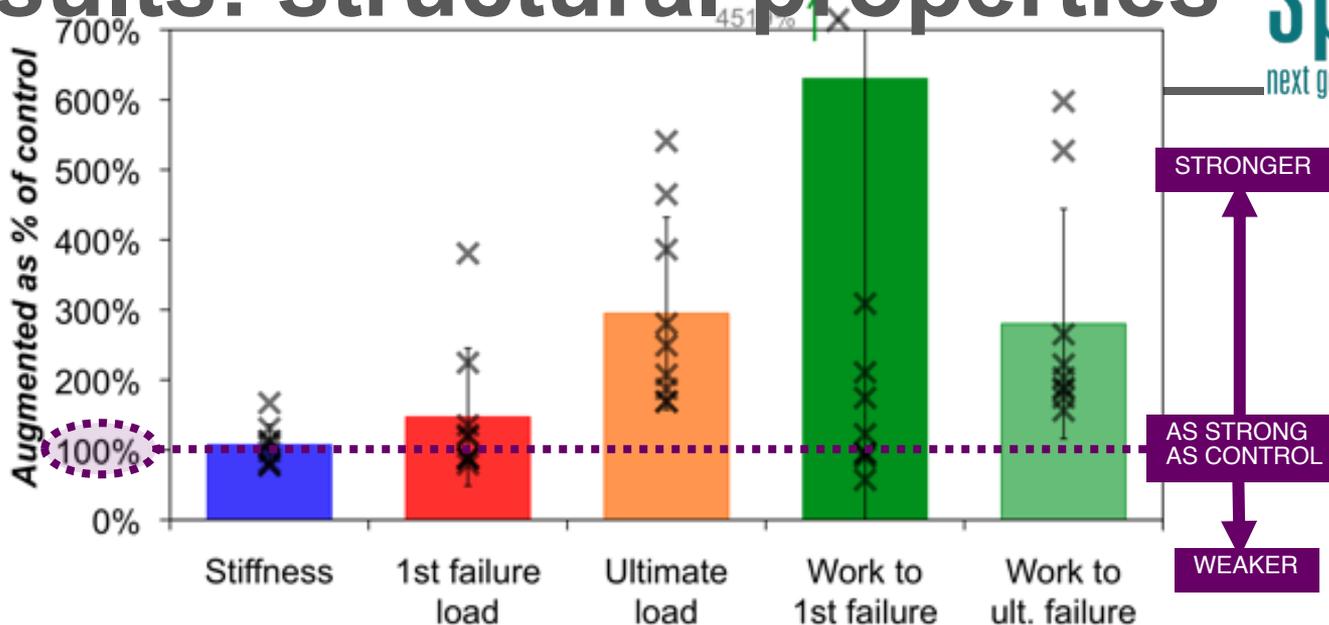 - Direction of principal strain (θ_P)

Loading

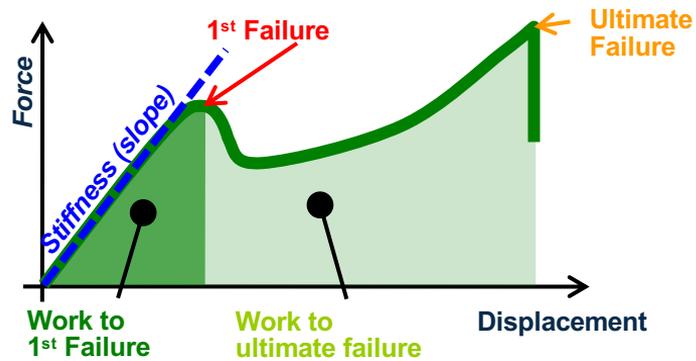- Non-destructive testing in different directions
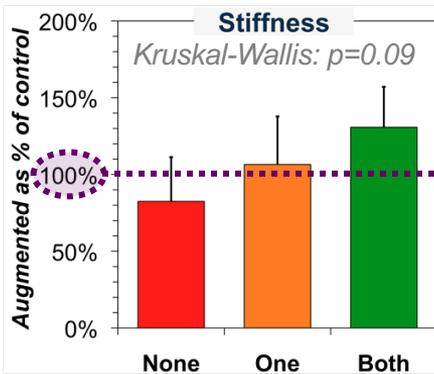- Destructive testing

Results: structural properties

- Force and work to ultimate load significantly greater than control (t-test) but…

- …some augmented specimens are *weaker* than the control
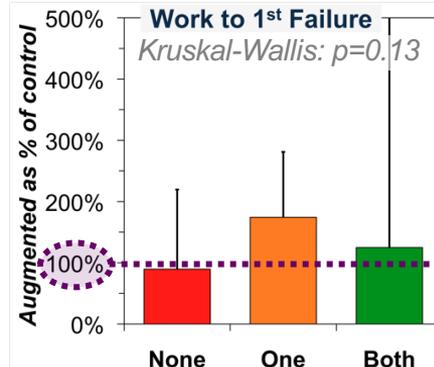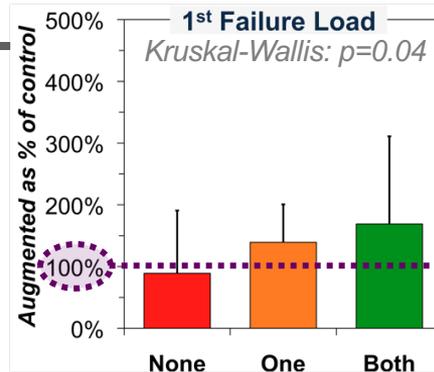
Results: effect of endplate contact

None **One** **Both**

Stiffness — *Kruskal-Wallis: p=0.09*

1st Failure Load — *Kruskal-Wallis: p=0.04*

Ultimate Load — *Kruskal-Wallis: p=0.03*

Work to 1st Failure — *Kruskal-Wallis: p=0.13*

Ultimate Work — *Kruskal-Wallis: p=0.02*

- Augmentation has a mild effect on stiffness:
  – Increasing with endplate contact

- First failure:
  – No endplate: F,W slight decrease
  – One endplate: slight increase
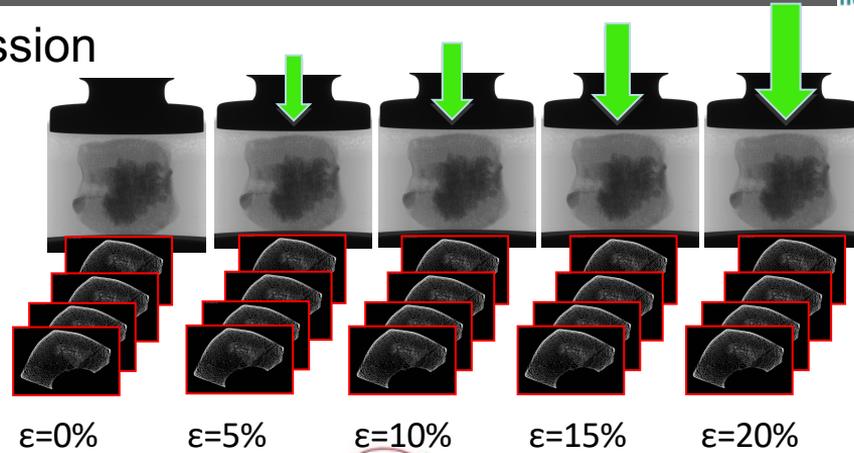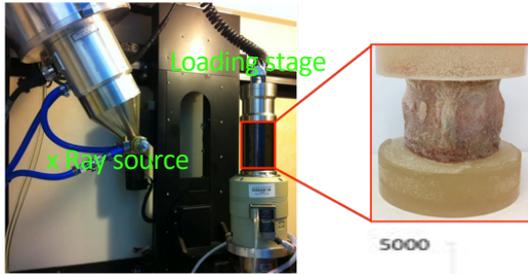 – Both endplates: strong increase
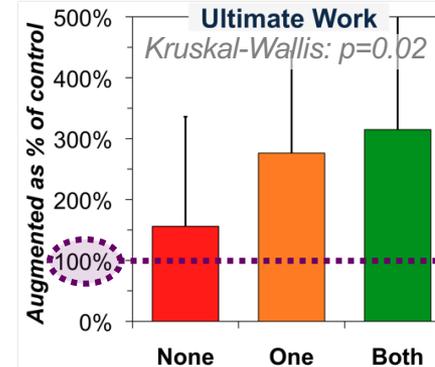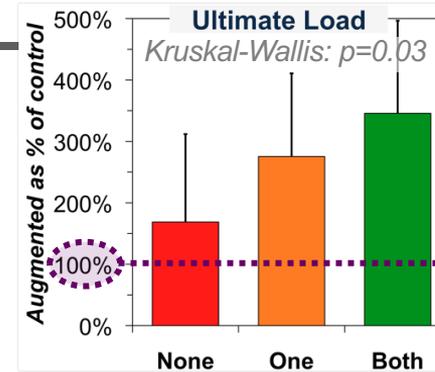
- Ultimate failure:
  – F and W always increase
  – Much better with both endplate contact

Operating principle of DVC

- Hi-res 3D imaging:
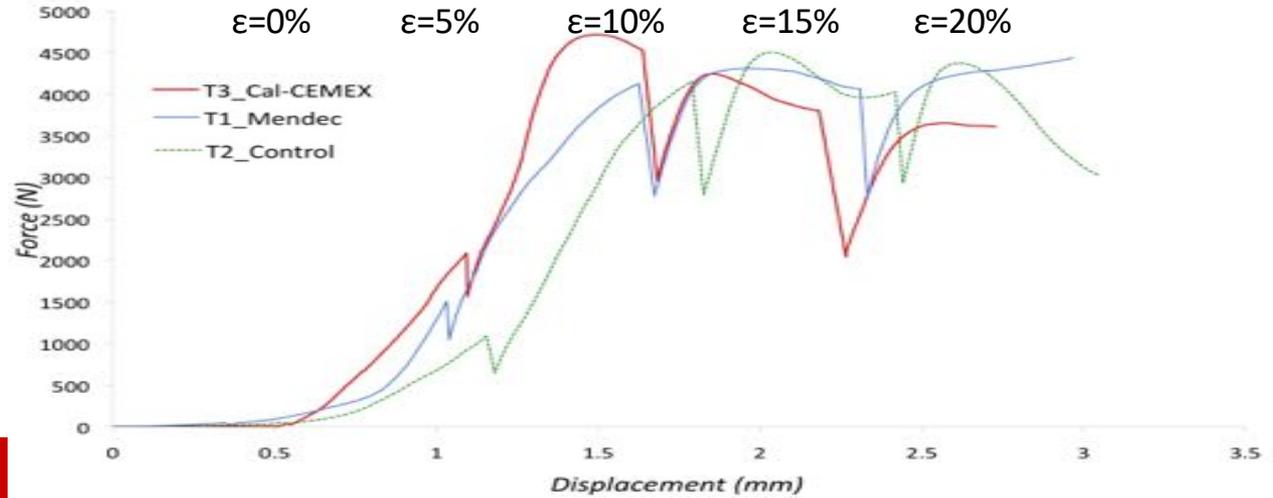 – e.g. micro-CT

- Incorporating dedicated *in situ* loading system
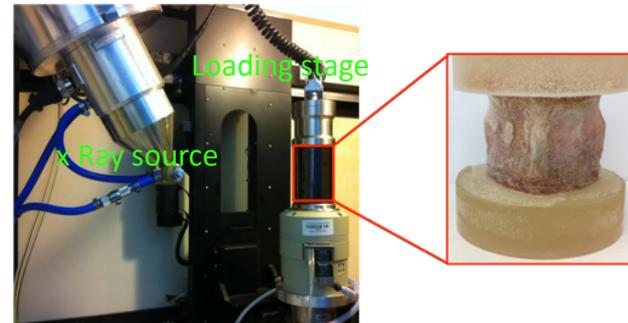
Prophylactic augmentation: inside the vertebra

- Step-wise destructive compression

- µCT imaging at each step

Loading stage

x Ray source

ε=0%   ε=5%   ε=10%   ε=15%   ε=20%

- Settings
  - 89 kV voltage
  - 116 µA current
  - 40-35 µm voxel size
  - Time ~90 min

- T3_Cal-CEMEX
- T1_Mendec
- T2_Control

Force (N)

Displacement (mm)

• Failure mechanism:
– Starts from cement-bone boundary
– Damage by cement injection?
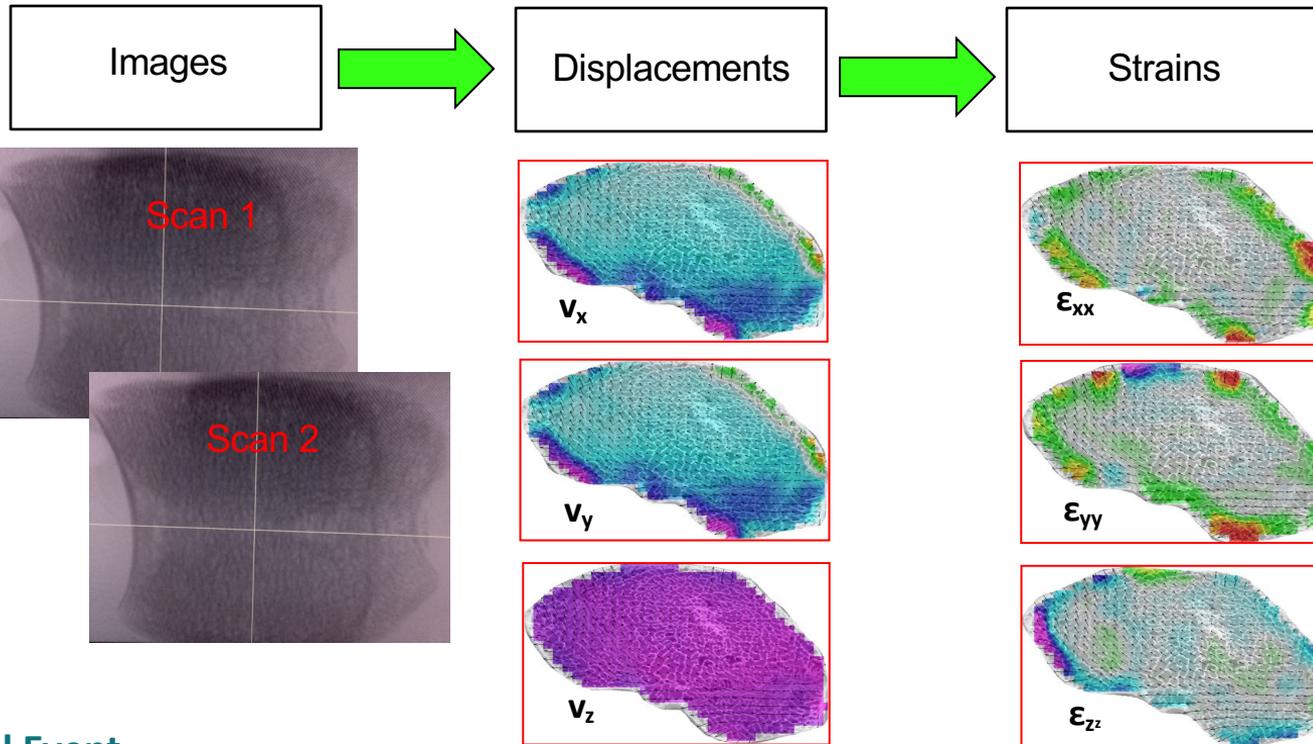
– Propagates through vertebra

(1) Danesi, Tozzi, Cristofolini "Application of
digital volume correlation to study the efficacy
of prophylactic vertebral augmentation"
Clinical Biomechanics 2016.

ε=0%

ε=20%
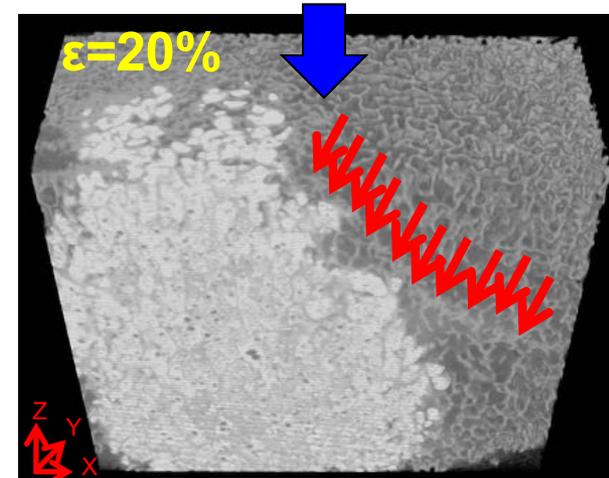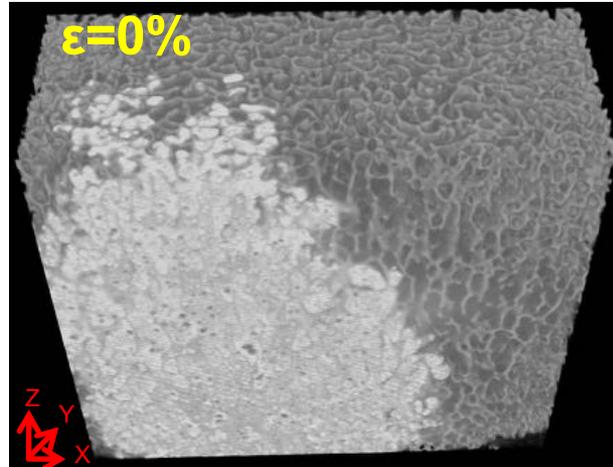
Operating principle of DVC
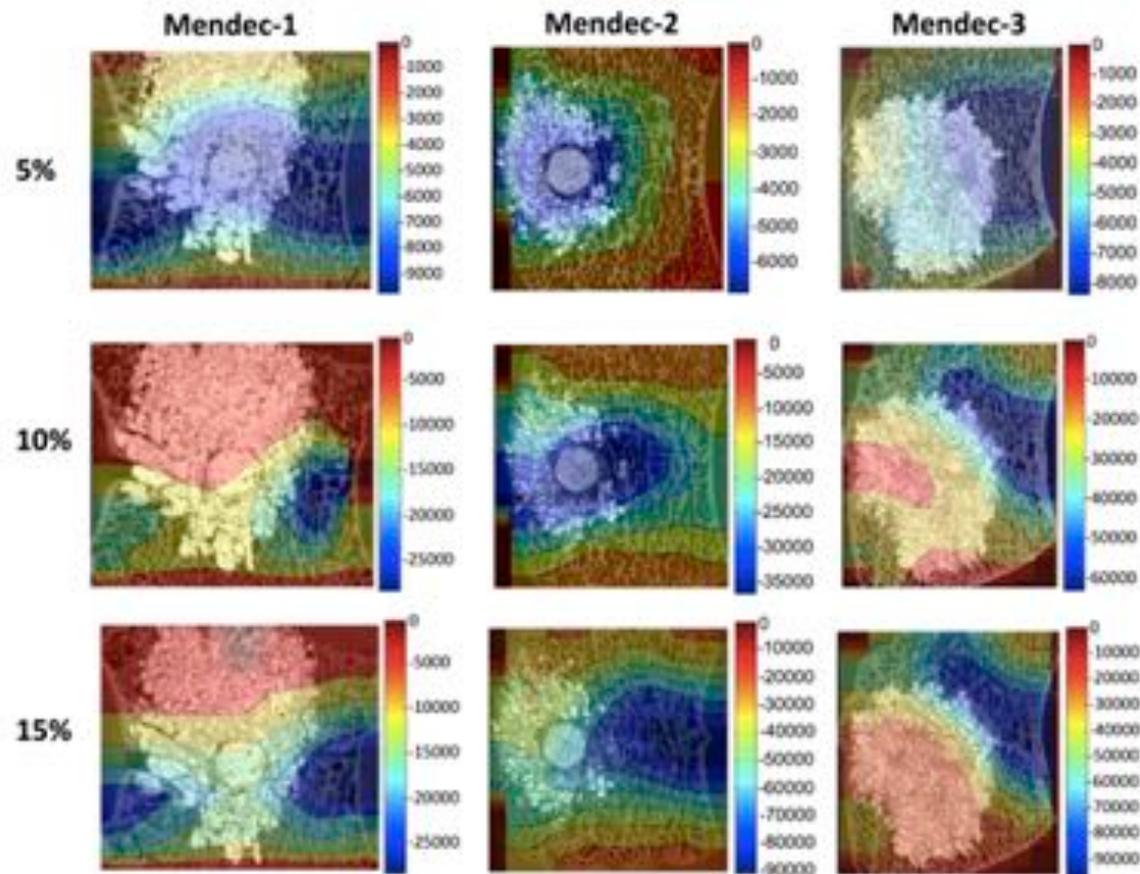
detect shift for t ⟶ t+dt
by cross correlation

Derivation

| Images | | Displacements | | Strains |

Scan 1

Scan 2

v_x

v_y

v_z

ε_{xx}

ε_{yy}

ε_{zz}

- # Strain distribution [1]

(1) Danesi, Tozzi, Cristofolini "Digital volume correlation to study the efficacy of vertebral augmentation" Clinical Biomechanics 2016.

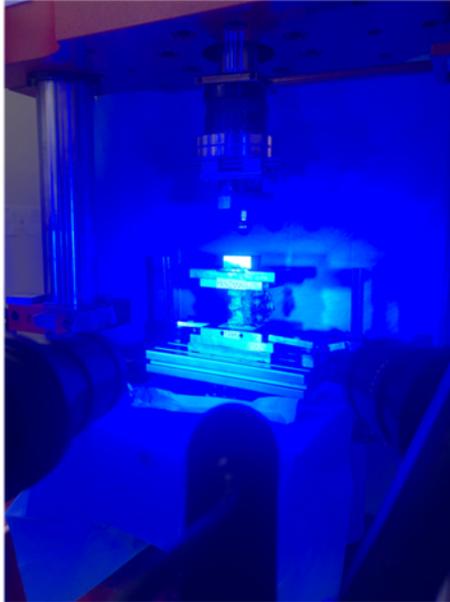# *Mechanical consequences of vertebral metastases*

Our new 4-cameras DIC

- More than 210° around the specimen
- Tracking of fiducial markers => robust identification of boundary conditions
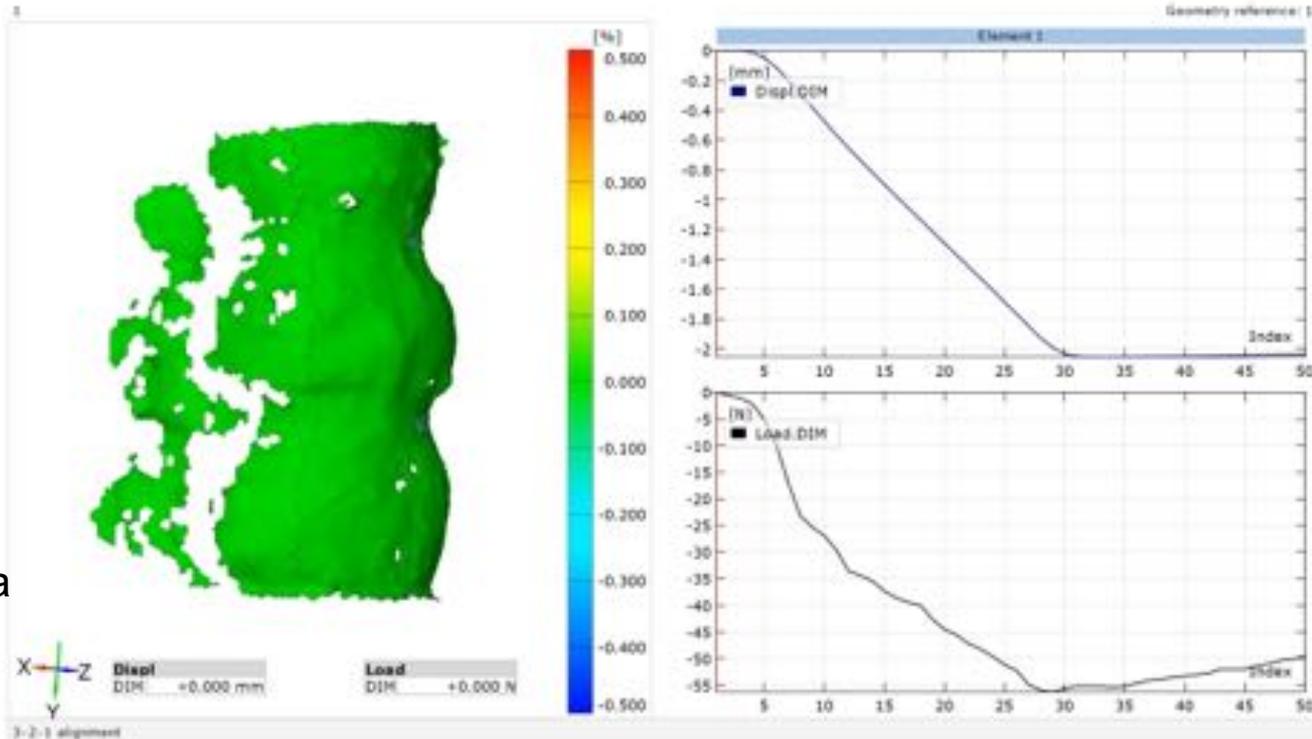- Easy communication with FE
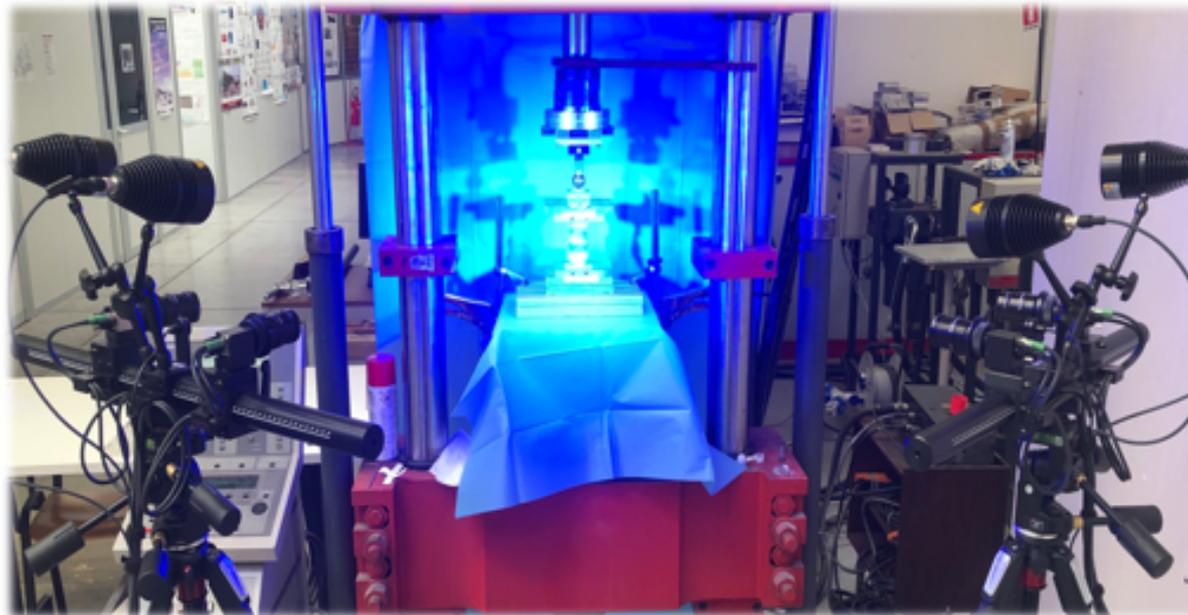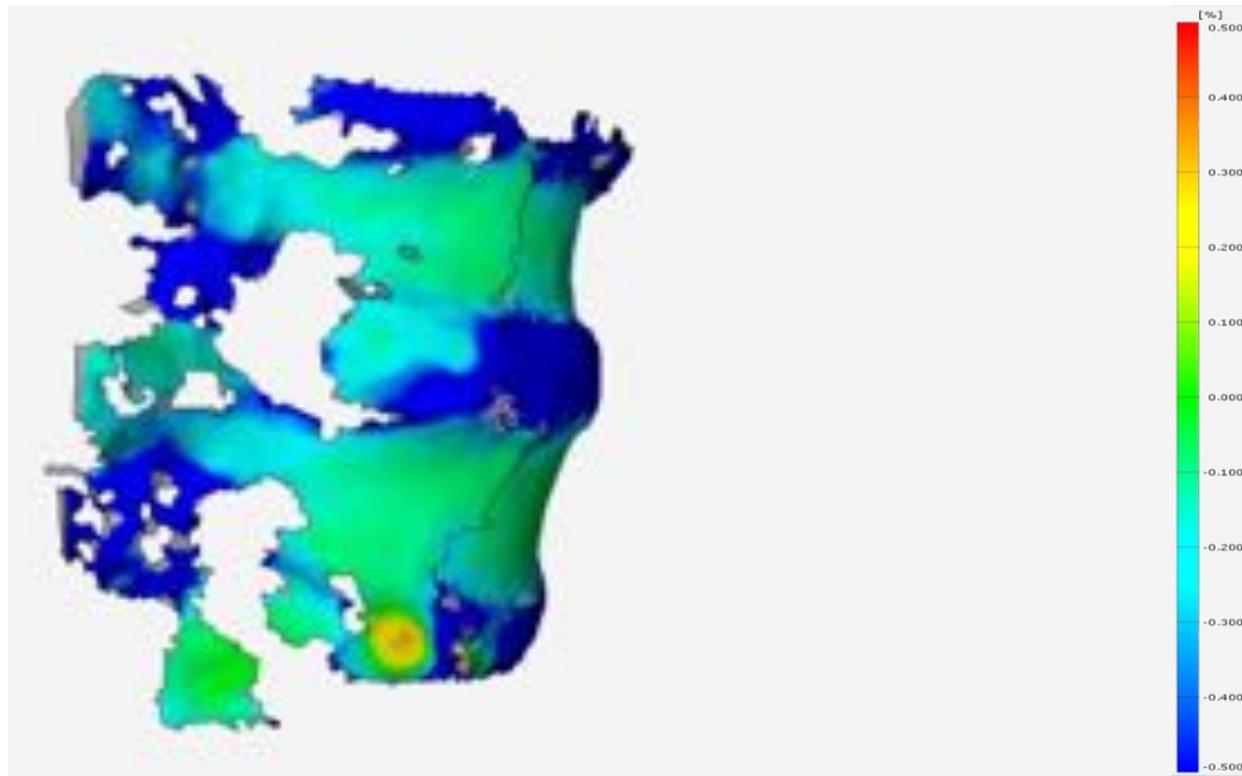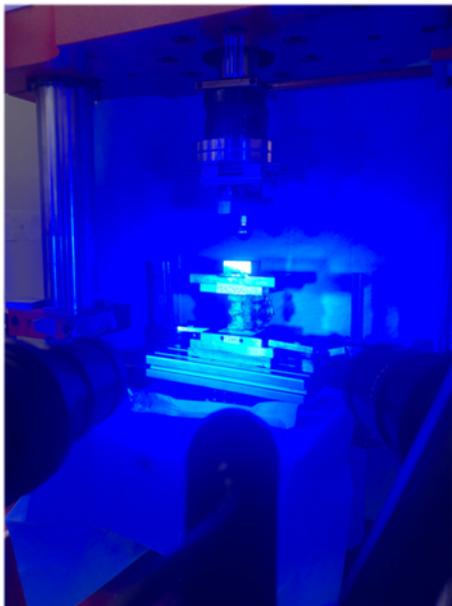
DIC on spine: effect of metastases

- Strain in metastatic vertebra
- Strain in adjacent healthy control

ASME J Biomech Eng 2018; BONE 2021

- Strain in metastatic vertebra
- Strain in adjacent healthy control

ASME J Biomech Eng 2018; BONE 2021

Biomechanical role of the anterior longitudinal ligament (ALL)

- 6 cadaveric human spines
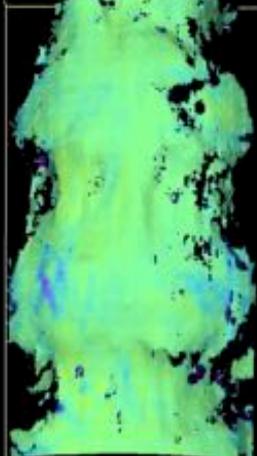- Ulm Spine tester (6 DoF)
- Two 5Mpix cameras
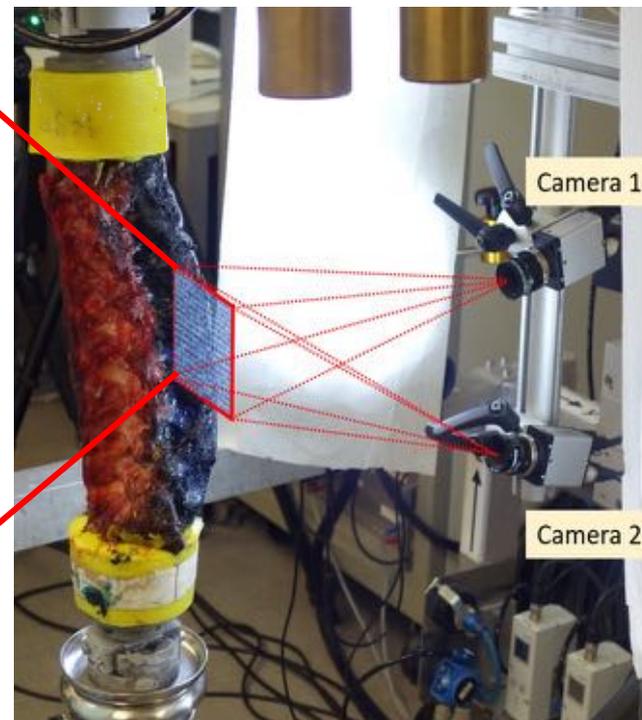
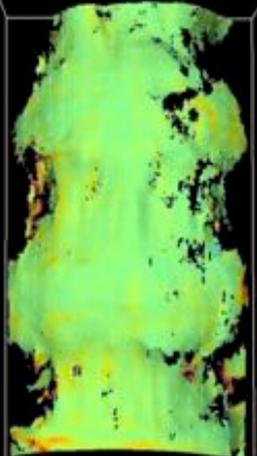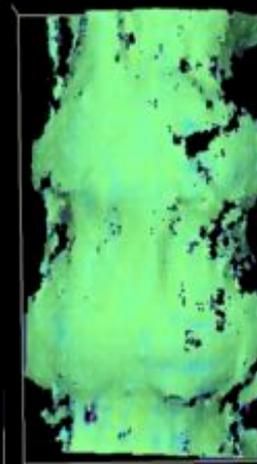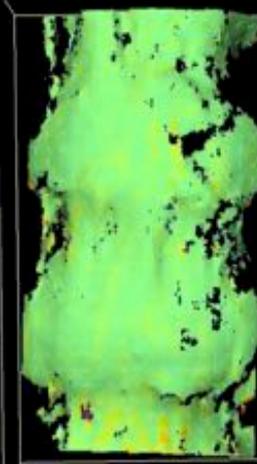# DIC: strain in spine ligaments

Lateral Bending — Flexion/Extension

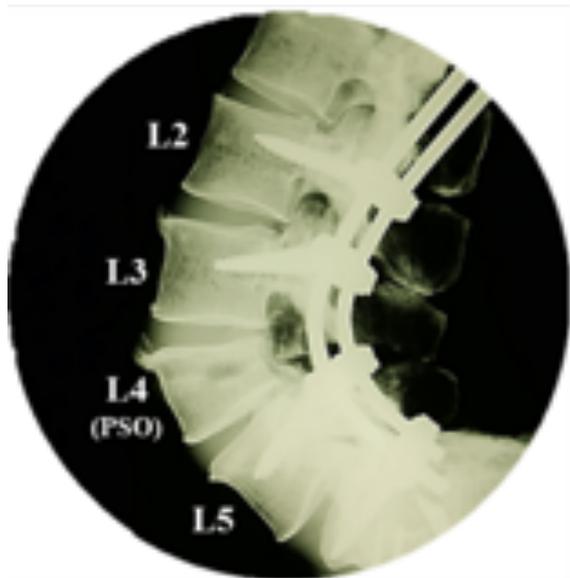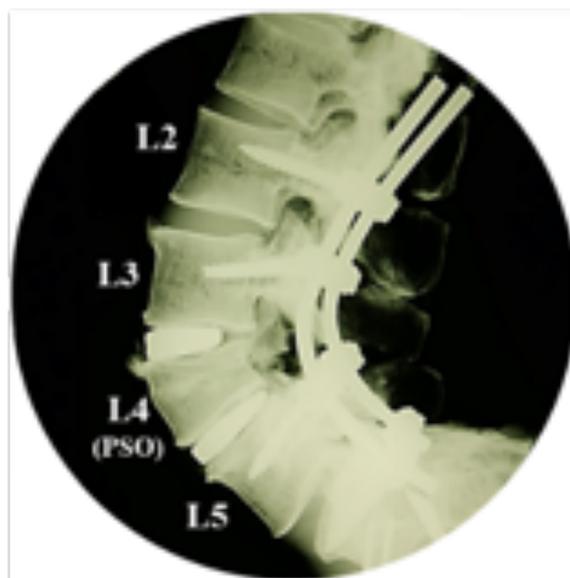Images acquired by the cameras · Max principal strain · Min principal strain · (με) · Images acquired by the cameras · Max principal strain · Min principal strain

PLOS ONE 2020

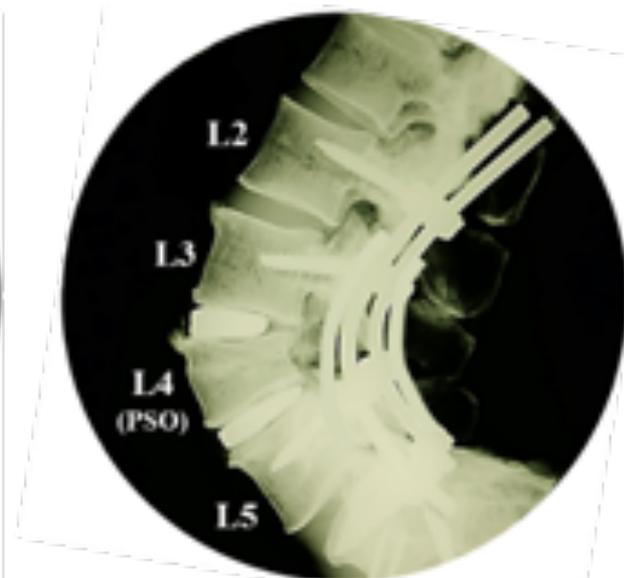# *Biomechanical effects of pedicle subtraction osteotomy (PSO)*
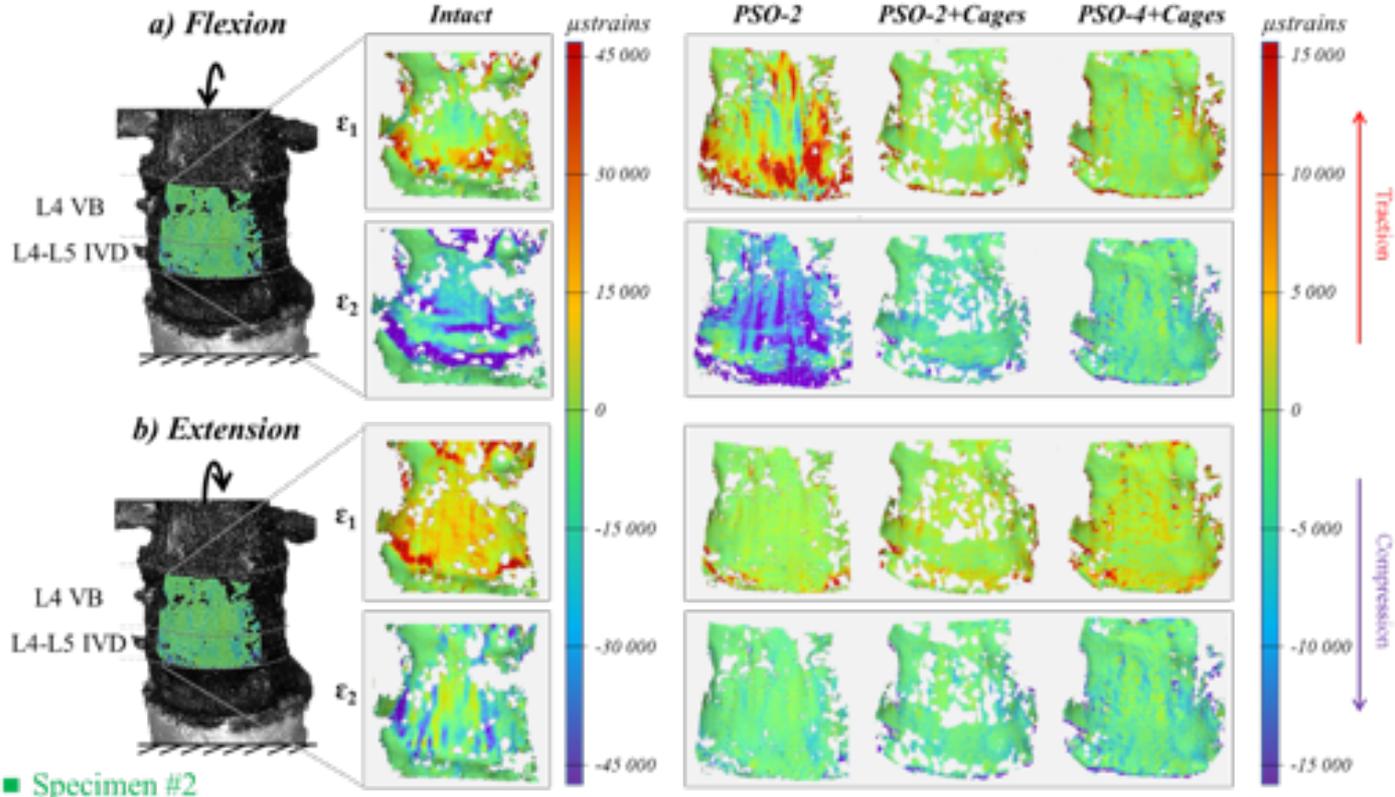
3 fixations tested
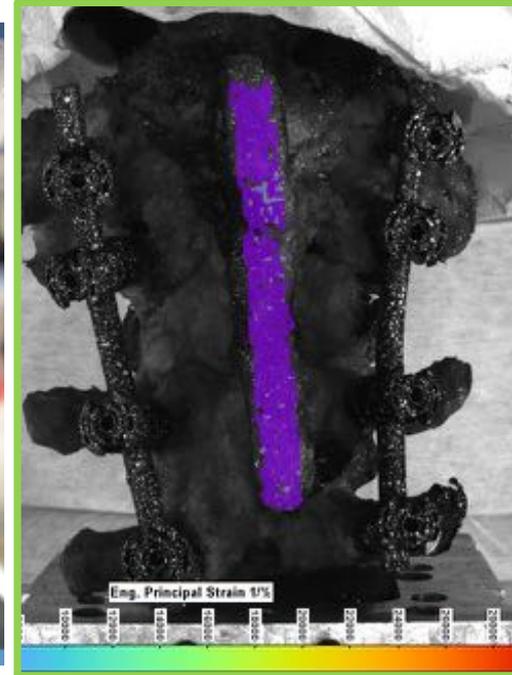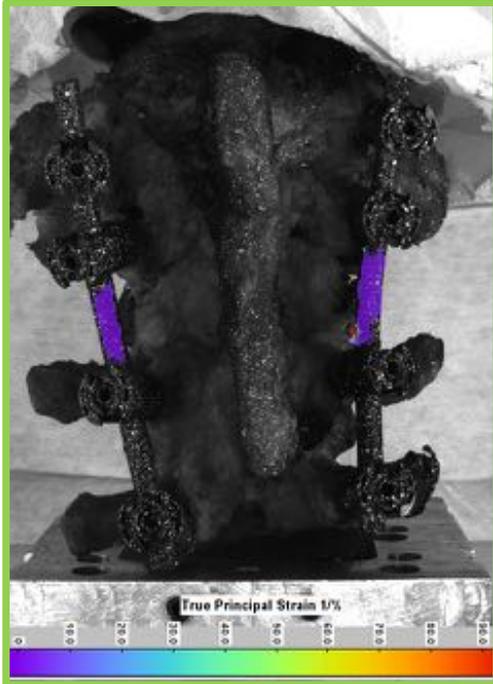

PSO-2   PSO-2+Cages   PSO-4+Cages

Strain in flexion & extension

Scientific Reports 2021

Strain in torsion

Specimen #1

Scientific Reports 2021
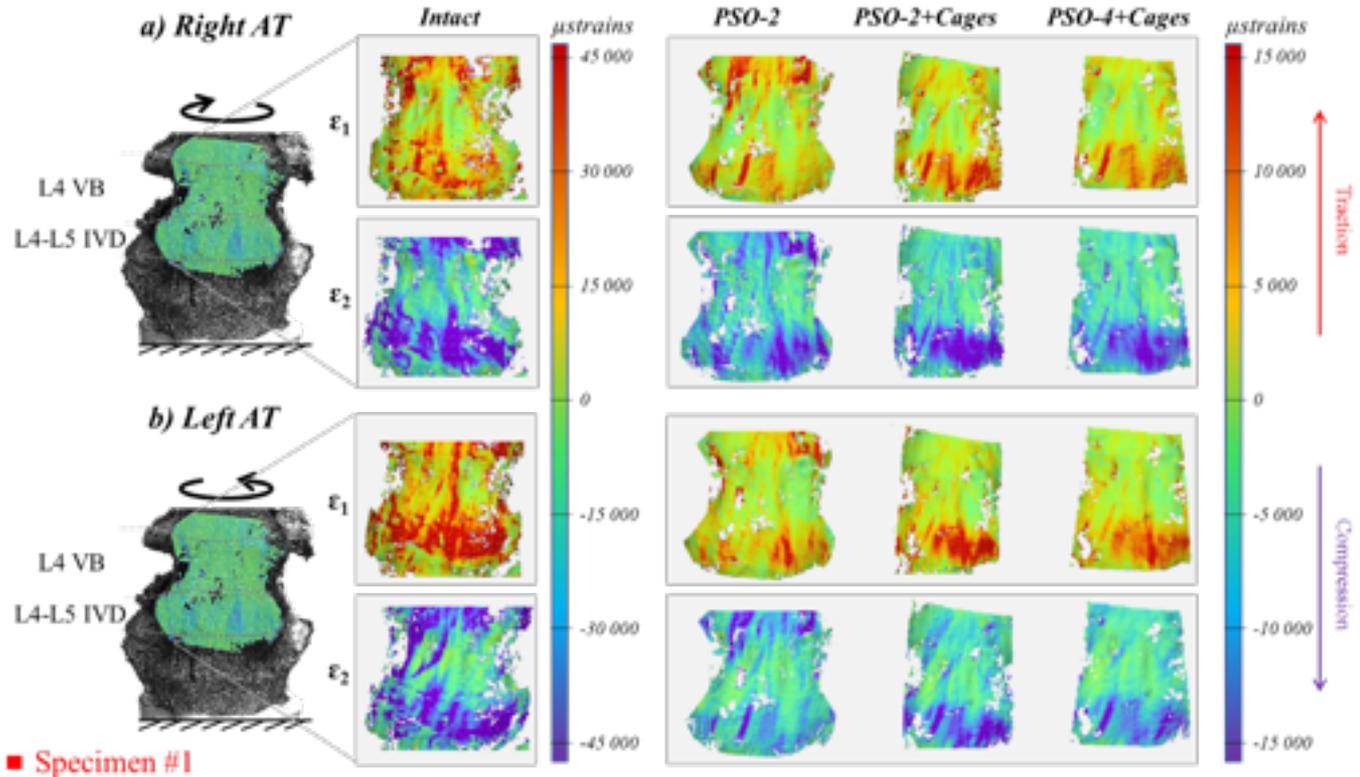
Posterior spinal ligaments and instrumentation

- Pattern and DIC measurement on instrumented spine
- Posterior stabilization rods and screws
- Reduced strain in *supraspinatus* ligament
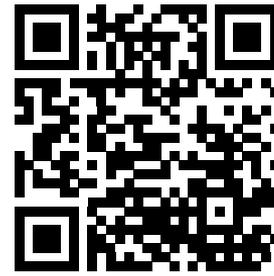
Conclusions

Future directions

Methods:

- Integrate Digital Image Correlation and Digital Volume Correlation
- Build systematic framework to combine DIC/DVC & FEM:
  - Identification
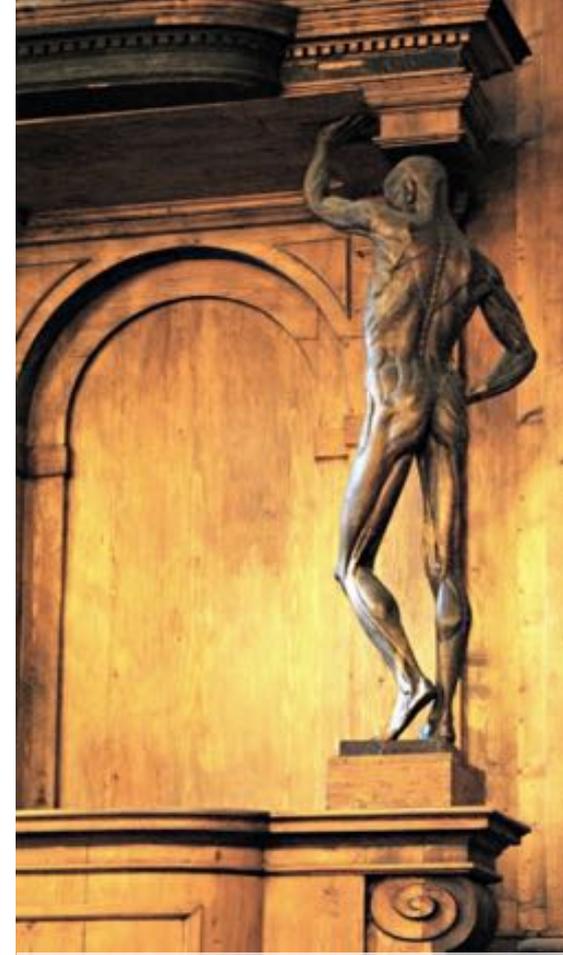 - Validation
  - Exploit synergies

Application to clinical problems:

- Better understanding of vertebral metastases
- Understanding of post-op failures

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Thank you!

"Gli spellati"
Ancient Anatomical Theater
University of Bologna