VIII Congresso de Cirurgia Espinhal

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Porque usar estabilizacao dinamica na coluna lombar?

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Why Use Dynamic Stabilization in the Lumbar Spine?

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Adjacent Segment Disease

Consequences of Fusion:

- Biomechanical/animal studies have shown that the fusion process results in…
  - Increased intradiscal pressure
  - Increased facet loading
  - Hypermobility
  - Disc degeneration at the adjacent level
- Retrospective studies show that symptomatic ASD ranges from 5.2 – 18.5%

Adjacent Segment Disease

Risk Factors for ASD:

- Individual patients characteristics (age 55+, osteoporosis, female, postmenopausal, etc.)
- Addition of instrumentation
- Damaging inferior facet of adjacent segment
- Number of segments fused
- Sagittal malalignment
- Condition of the adjacent disc
- Presence of lumbar stenosis

Park, P., Garton, H. J., Gala, V. C., Hoff, J. T., McGillicuddy, J. E. "Adjacent Segment Disease after Lumbar or Lumbosacral Fusion: Review of the Literature", Spine, 29(17): 1938-1944, 2004

Addressing ASD Risk Factors

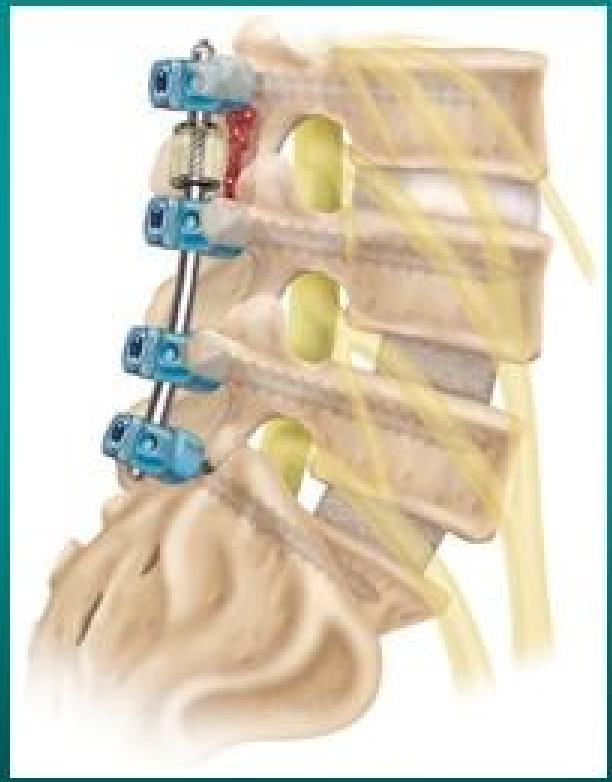
Instrumentation

- Provide stability without rigidity of standard titanium rods

Addressing ASD Risk Factors

Number of segments fused

- Create a transitional zone above or below a rigidly fused segment



Addressing ASD Risk Factors

Condition of the adjacent disc

- Distribute loading forces by creating progressive segmental stiffness over two or more levels

European Experience: Flexible Stabilization with Graf Ligament

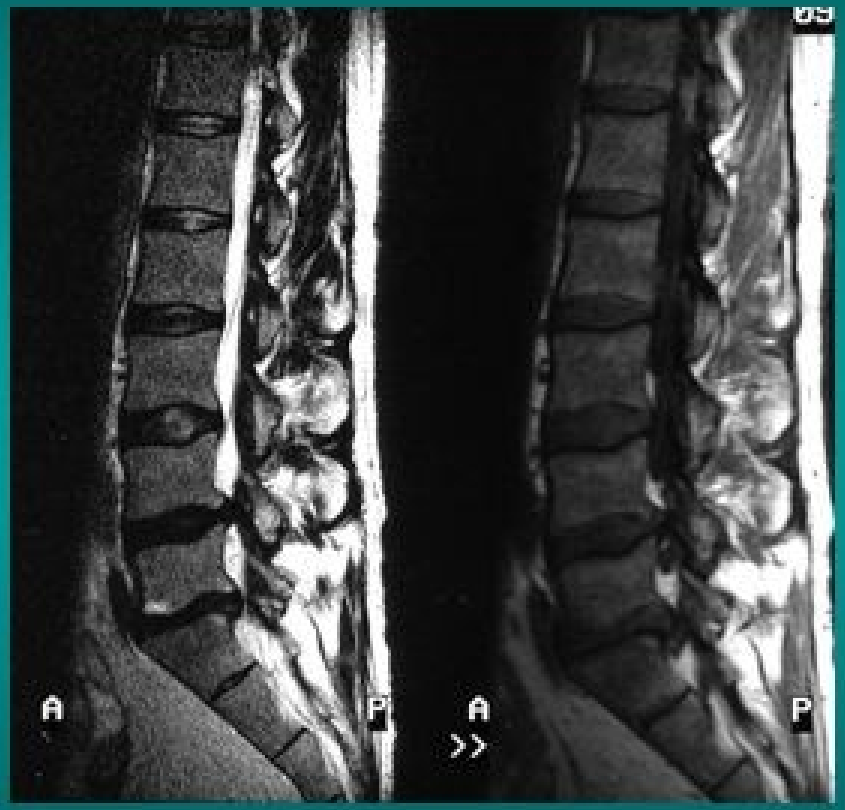
- 2 yr f/u
- 93% excellent Graf ligament
- 78% excellent ALIF
- Oswestry Disability Index ($P<0.05$)

Fig. 1 Radiograph showing Graf ligaments and pedicle screws

Fig. 2 Hartshill horseshoe cage in the disc space with screws in the vertebral bodies stabilizing the lumbar segment

Sanjeev Madan, Nicholas R. Boeree, "Outcome of the Graf ligamentoplasty procedure compared with anterior lumbar interbody fusion with the Hartshill horseshoe cage, Eur Spine J (2003) 12 :361–368

European Experience: Hybrid Graf Ligament Flexible Stabilization



Courtesy Peter Dyson, MD

European Experience: Degenerative Hybrid Dynesys

Back pain with bilateral mild radiculopathy

Courtesy Gerald Veeckmans, MD

AGILE Device

Rods

Commercially pure Titanium, grade 4

* Identical to CD Horizon® Legacy™

Cable

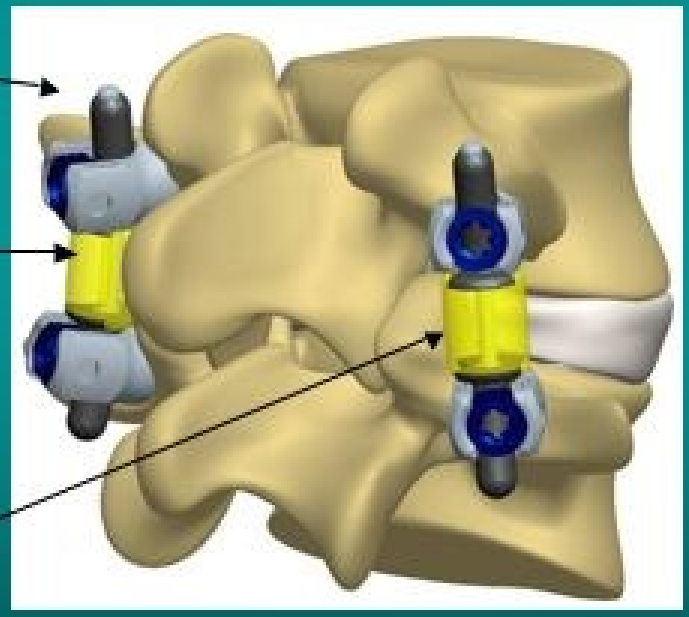
Titanium alloy (6Al-4V)

* Identical to Atlas™ Cable

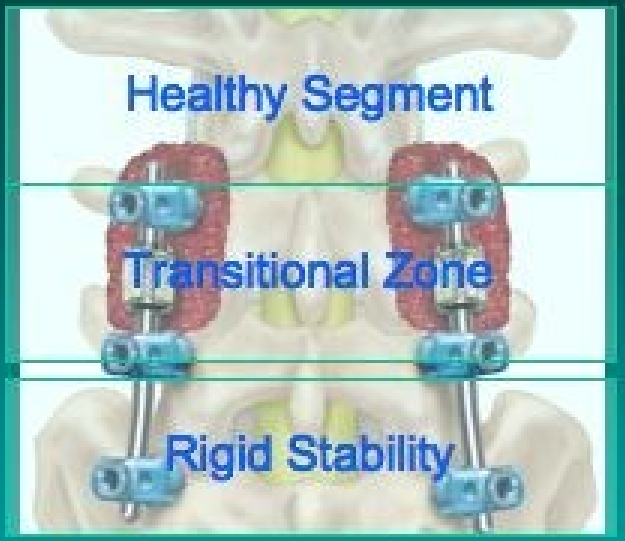
Spacer

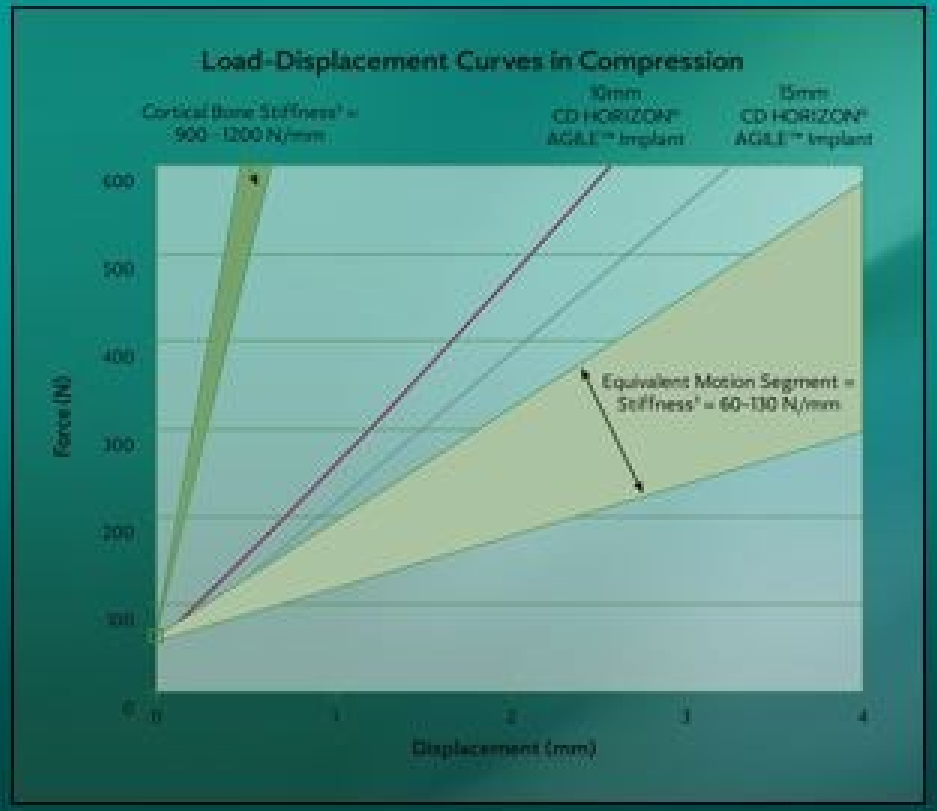
Polycarbonate Urethane

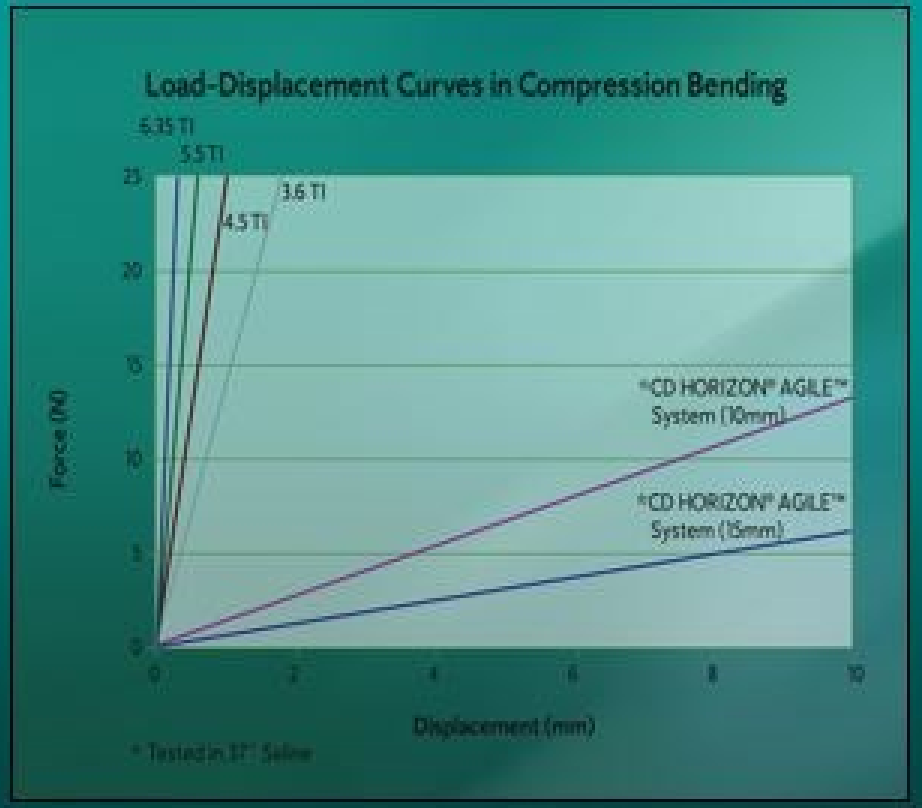
* Identical to Dynesys Dynamic Stabilization System (Zimmer Spine)



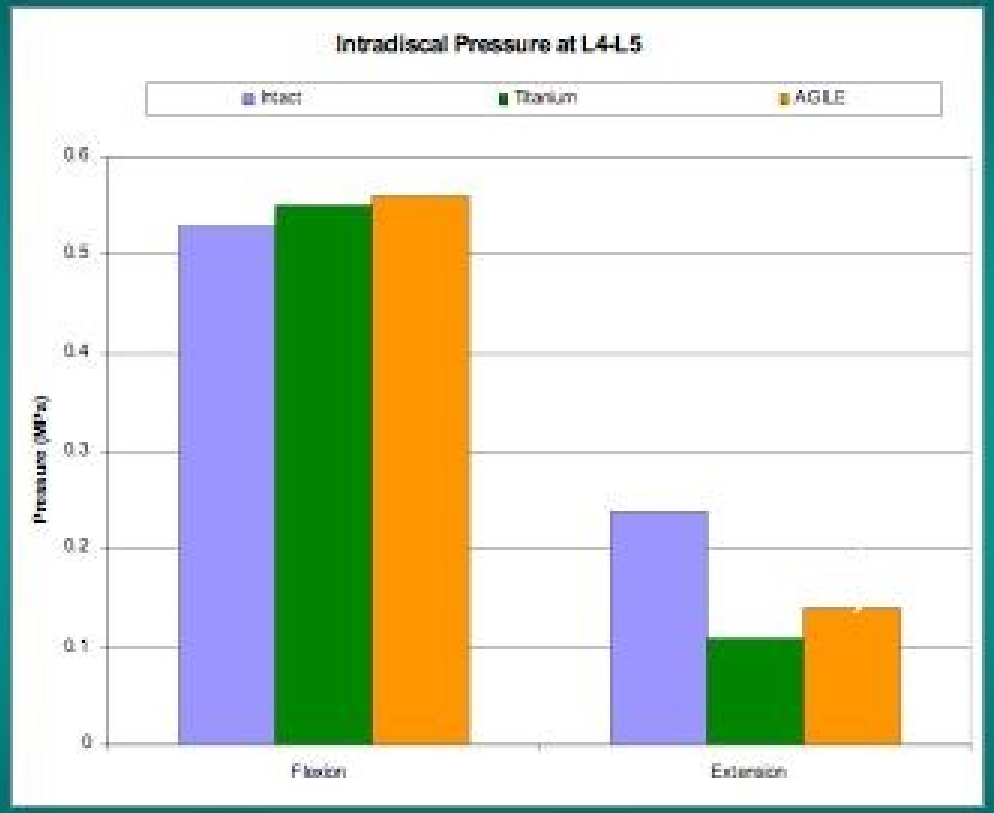
- The AGILE Device stiffness is between cortical bone and an un-instrumented motion segment

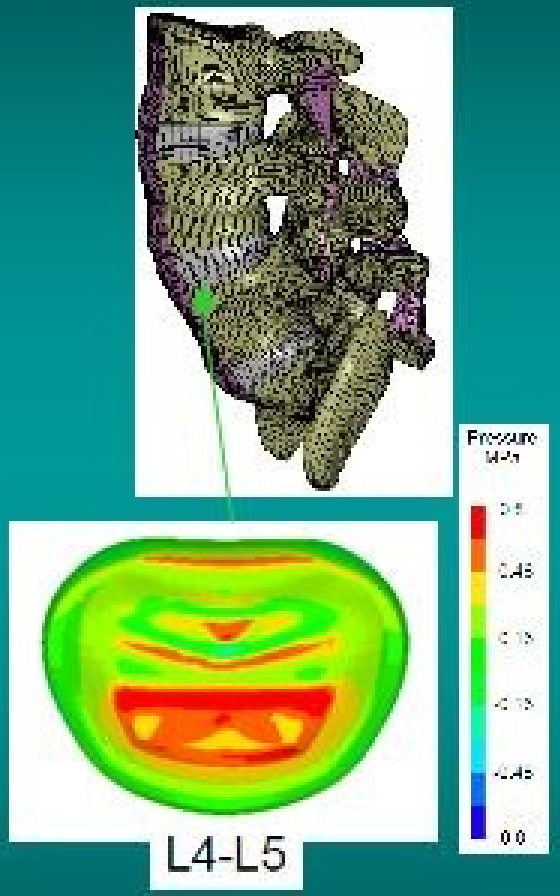






Disc Pressure





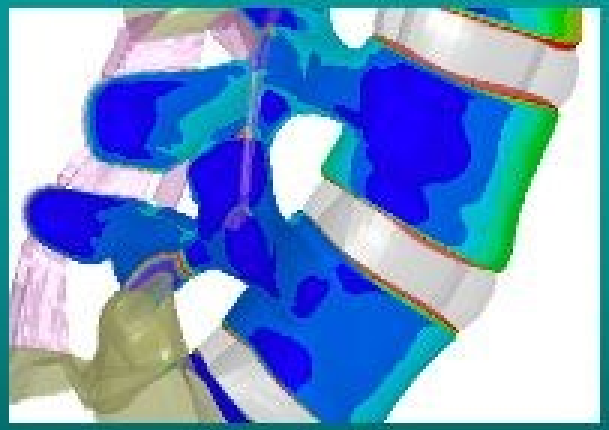
Intradiscal pressure is reduced during extension by approximately 40% for the AGILE device relative to intact during extension.

Load Transfer During Extension

INTACT

Facets 56 N

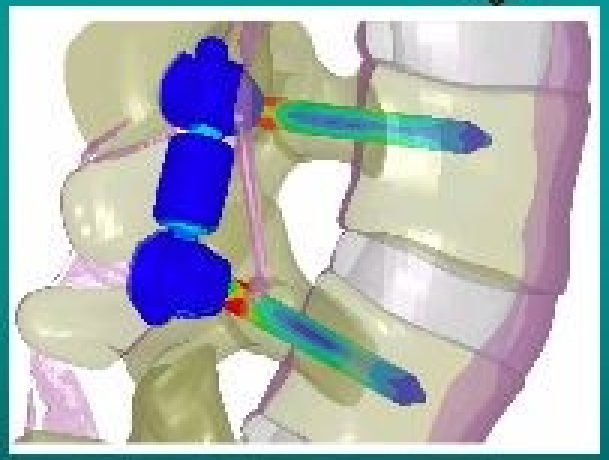
Disc 449 N



AGILE

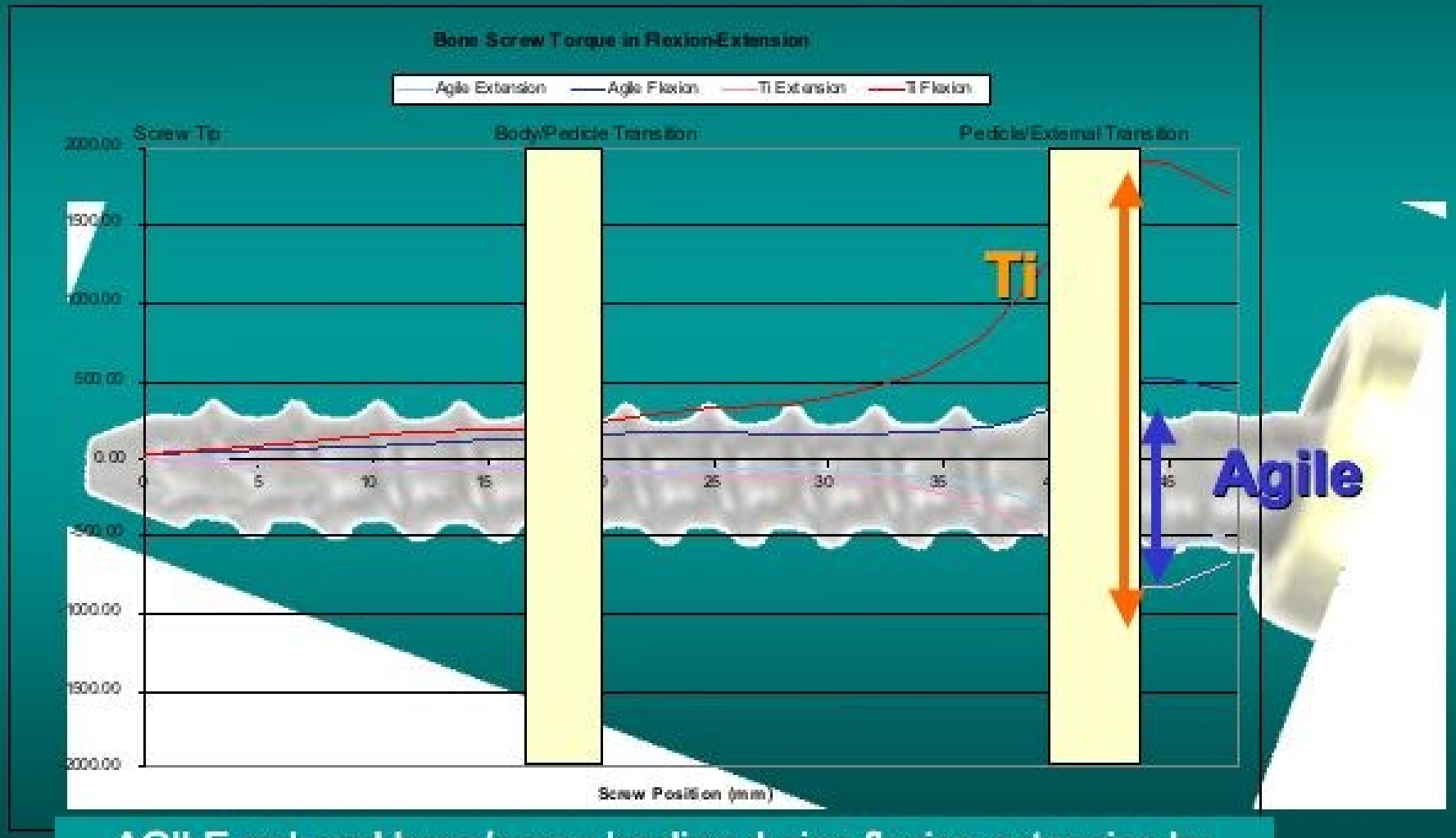
Facets 2.3 N

Disc 200 N



Load is transferred from the disc and facets to the device.
AGILE off loads the disc, facets and surrounding ligaments.

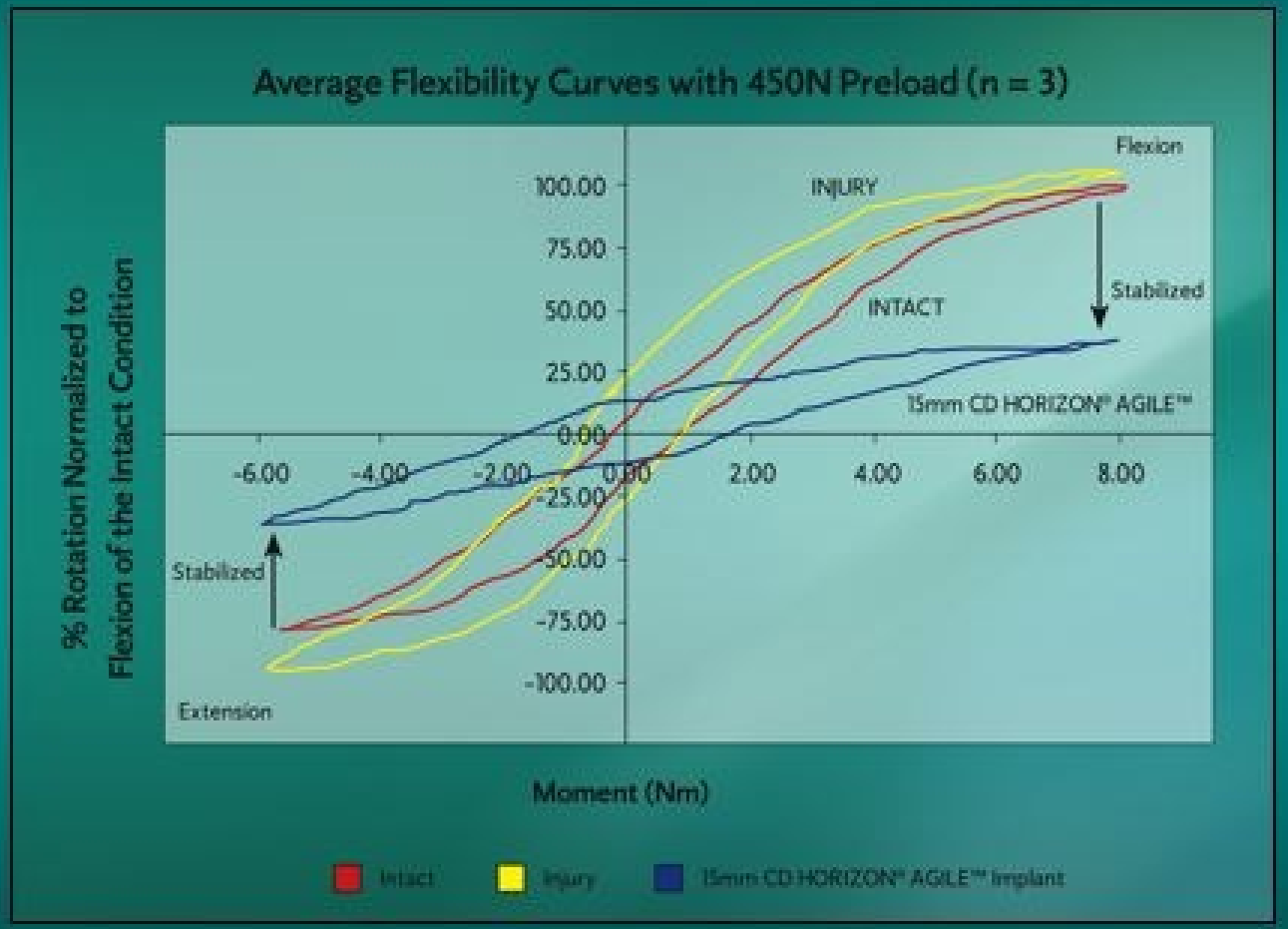
Reduced Bone/Screw Loading



AGILE reduced bone/screw loading during flexion-extension by approximately 61% relative to 5.5 titanium

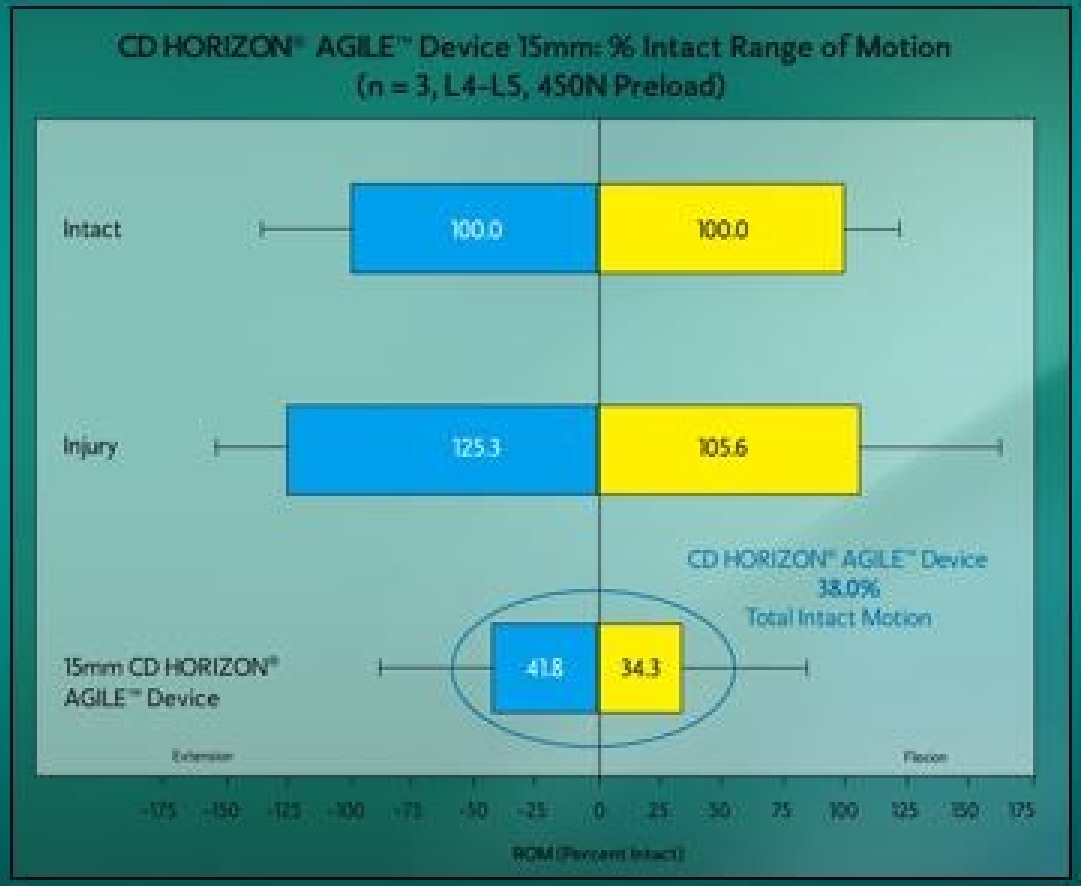
Flexibility Curves

The AGILE Device stabilizes the spinal segment after a destabilizing procedure while allowing for controlled micro-motion

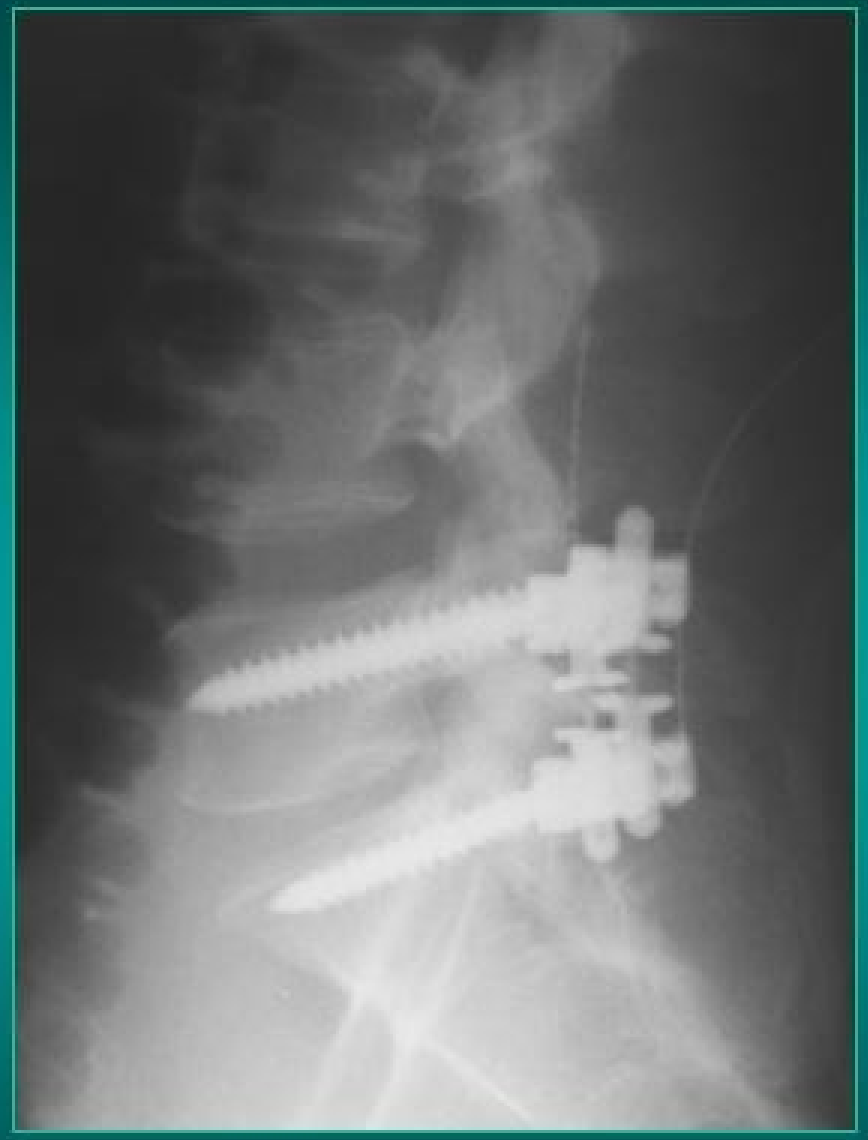


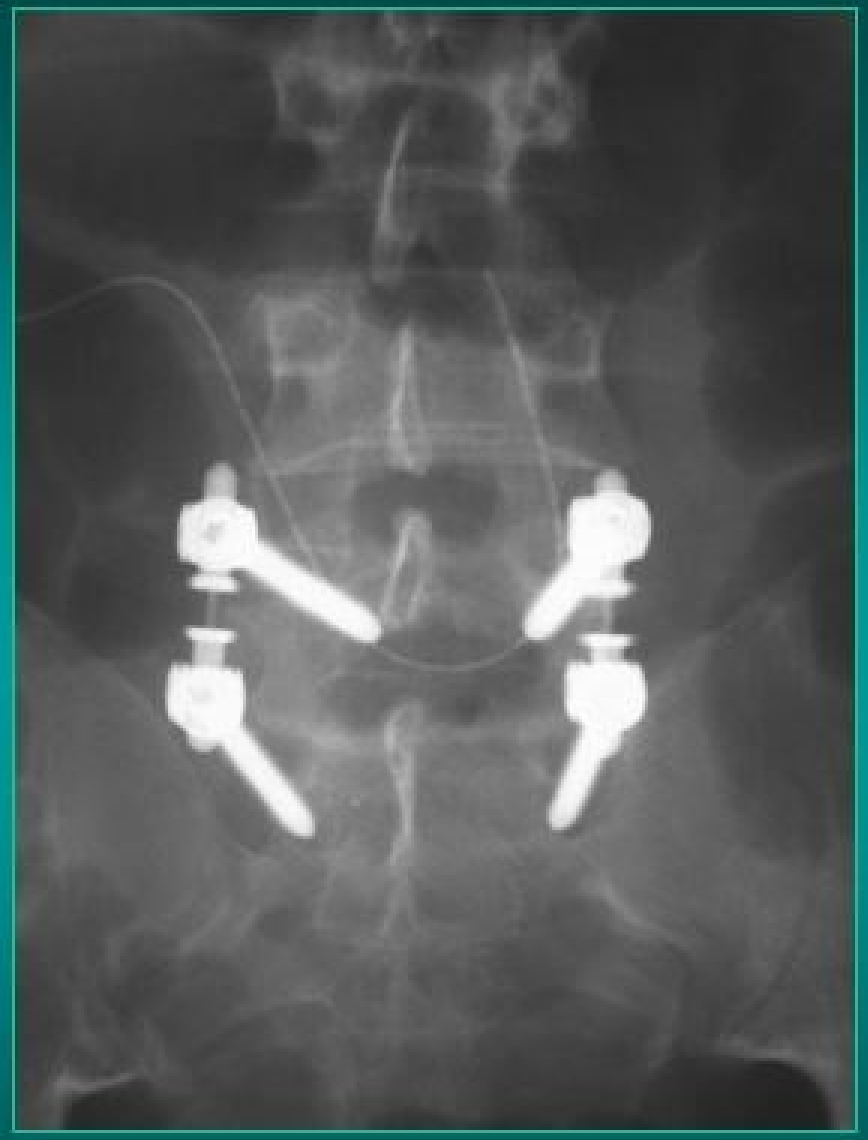
Range of Motion

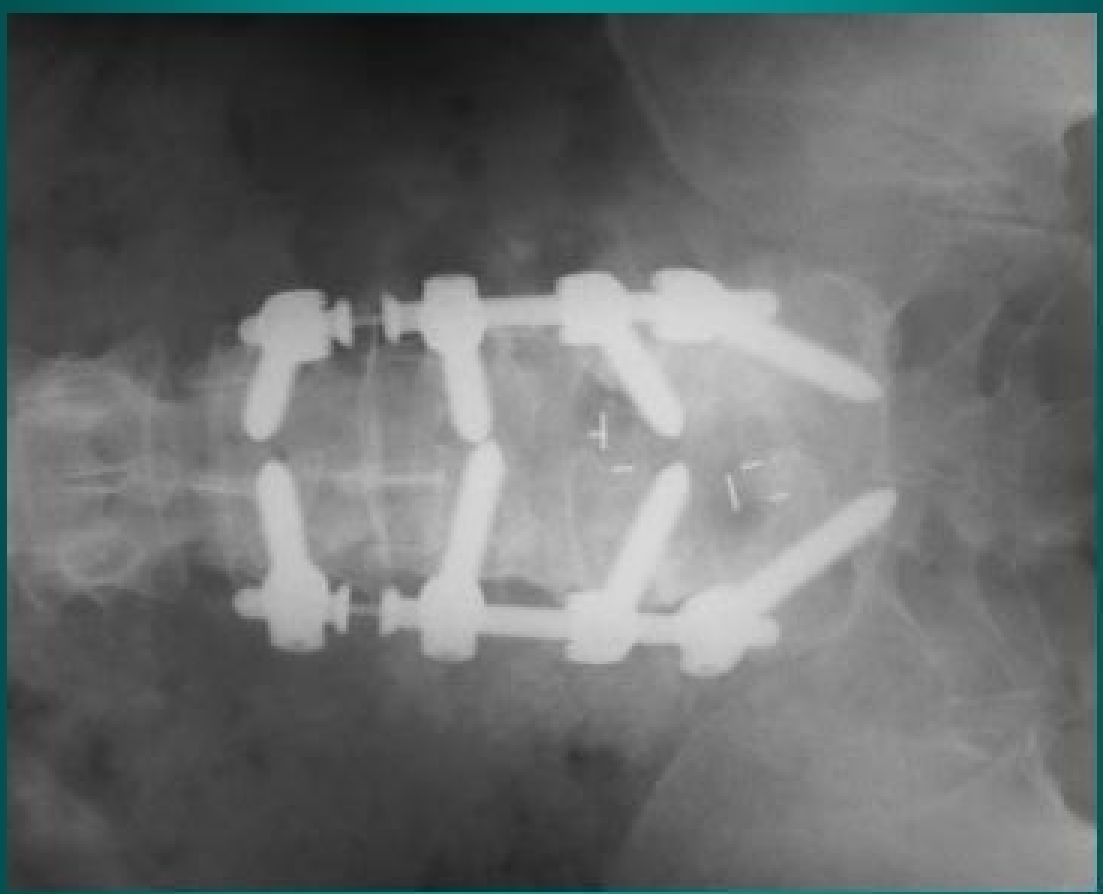
The AGILE Device allows for 38% of intact motion in biomechanical testing

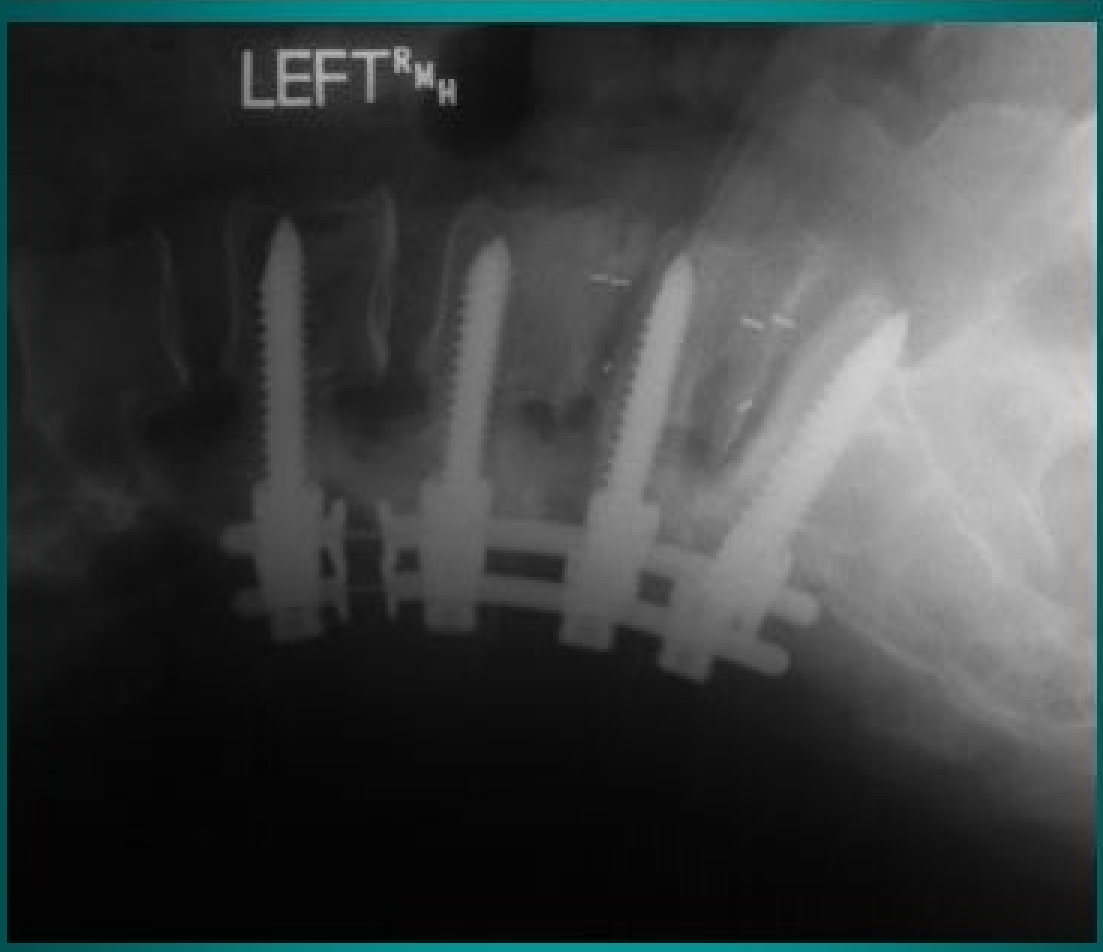


30 YO Male L5-S1 with Retro-Spondylolisthesis



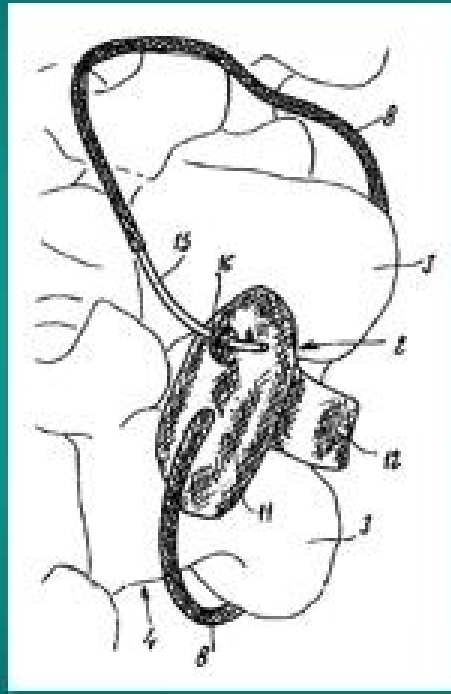





LEFT R W H

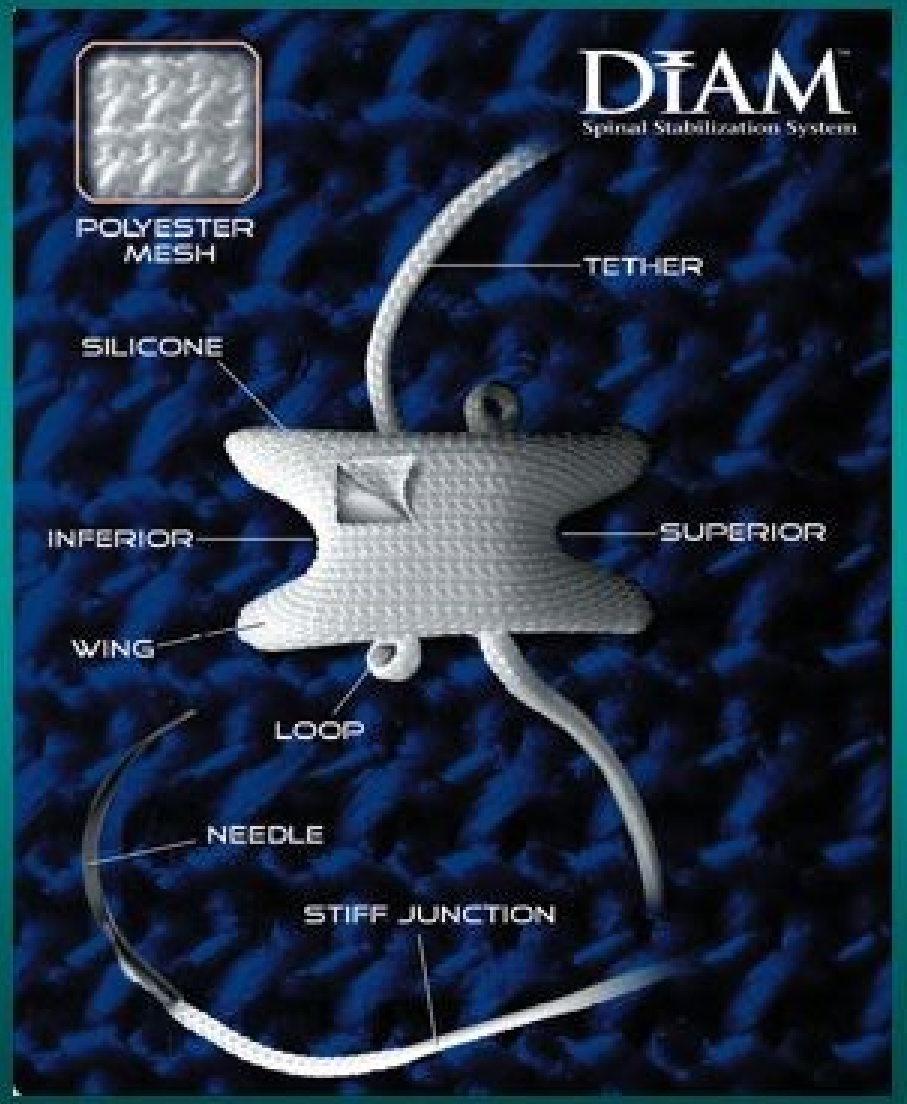
DIAM

- DIAM stands for **D**evice for **I**ntervertebral **A**ssisted **M**otion.
- First conceived by Dr. Jean Taylor in Cannes, France in 1994.
- First implanted in 1996 in Monaco.



Anatomy of a DIAM Device

- Interspinous Process Spacer
  - Stiff Silicone Core
    - NuSil MED 4765
    - MAF 579
  - Polyester Jacket
- Fixation Cables
  - Braided Polyester
  - Stainless Steel Needle/Leader
- Titanium Crimps



DIAM Implantation

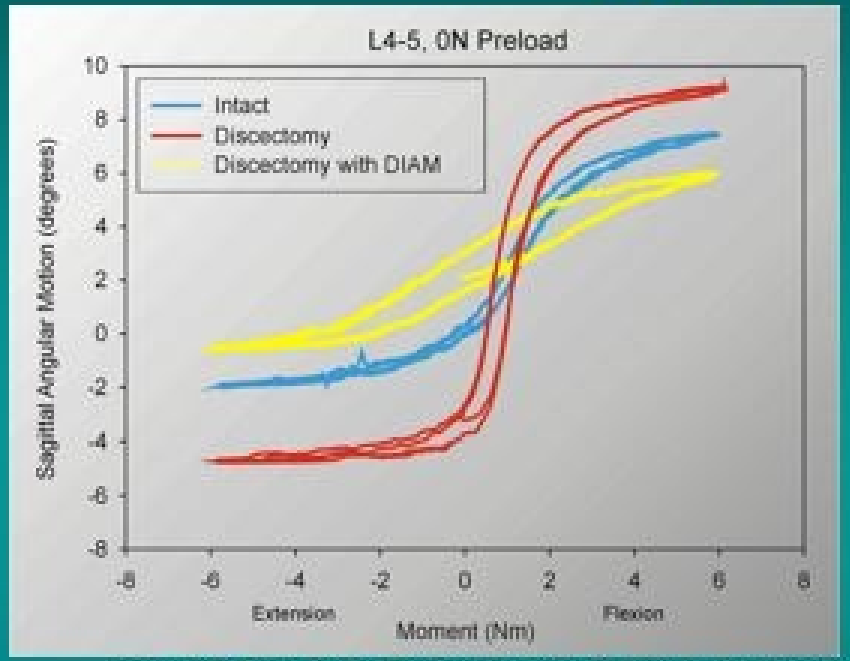
- Minimally invasive posterior midline exposure
- Complete sparing of the supraspinous ligament

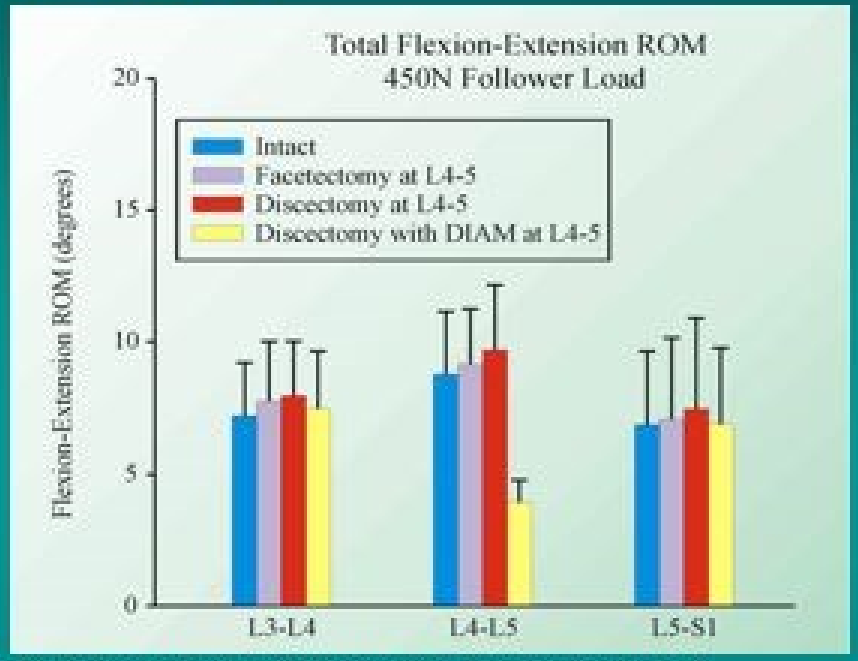
Mechanical Testing Results

- Stiff/strong enough to maintain distraction
- Pliant enough to prevent bone erosion
- Will not lose strength over time

- Static
  - 2199 ± 83N max compression load
  - Failure strength of spinous process = 339N*
- Creep
  - 1.2mm @ 450N
- Fatigue
  - 480N run out
  - 10 M cycles

Biomechanical Stability
(Cadaveric Spine)





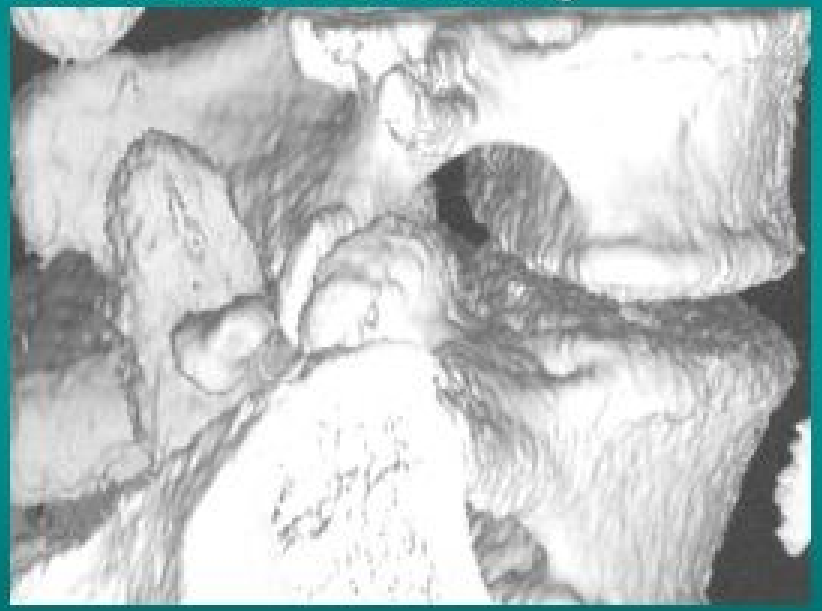
From Phillips et al. Biomechanics of Posterior Dynamic Stabilizing Device (DIAM) after Facetectomy and Discectomy. Spinal Arthroplasty Society Annual Meeting, New York, NY, 2005.

Conclusions:

- Successful stabilization of the unstable segment
- Prevention of extremes of motion, which are thought to cause back pain
- Physiologically compatible stability, as opposed to rigid devices
- Adjacent level motion not affected

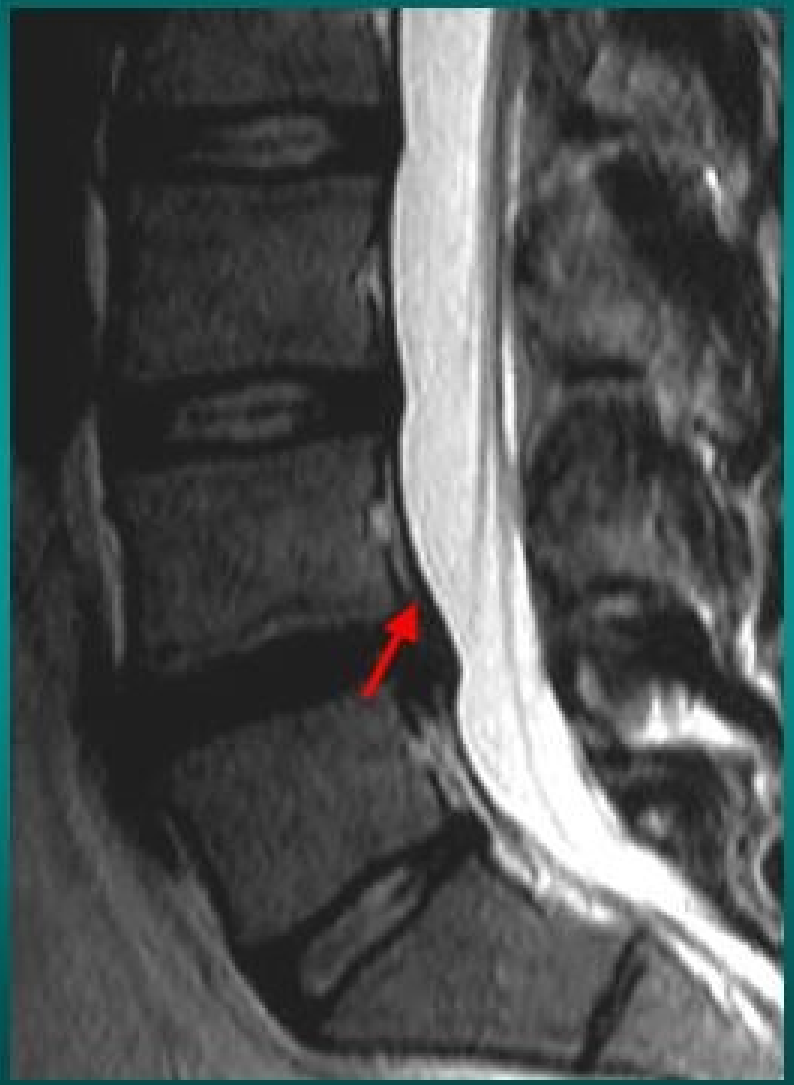
DIAM GOALS

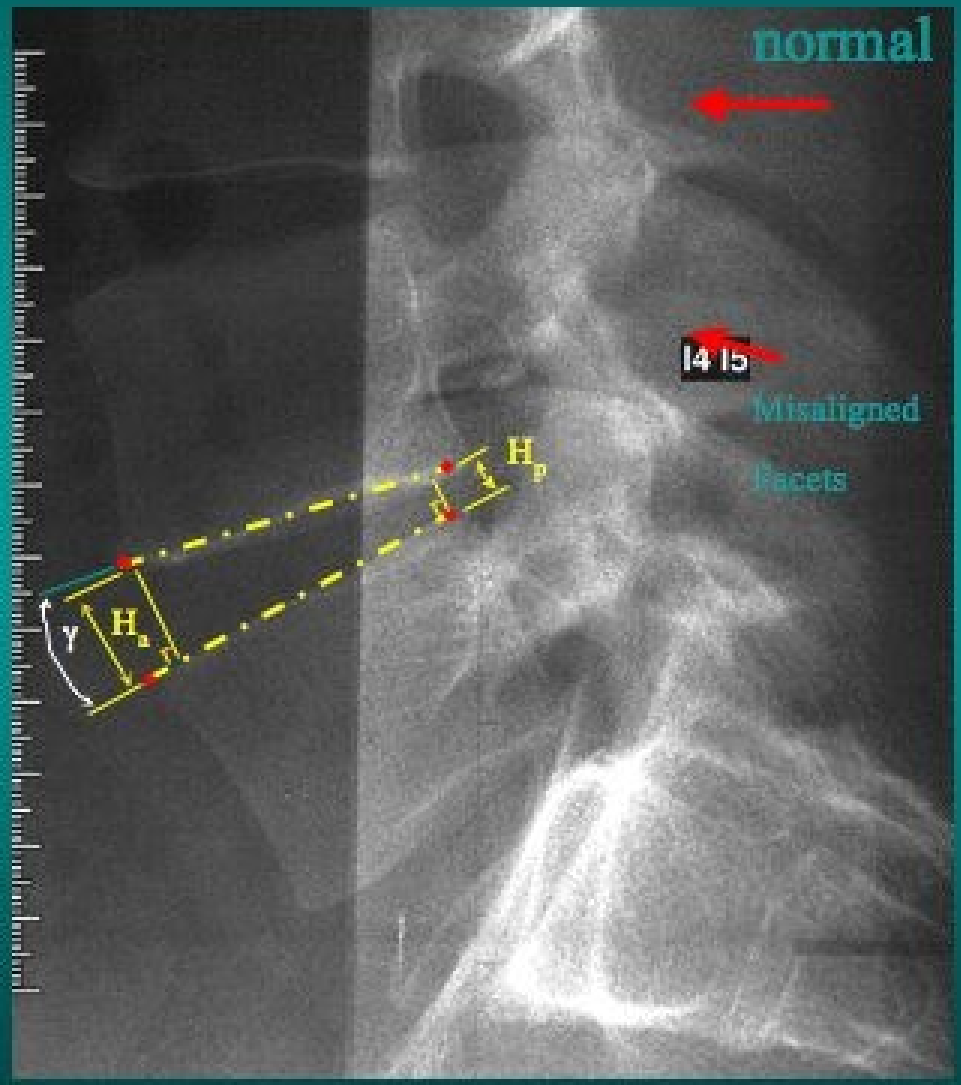
1. Neuroforaminal widening



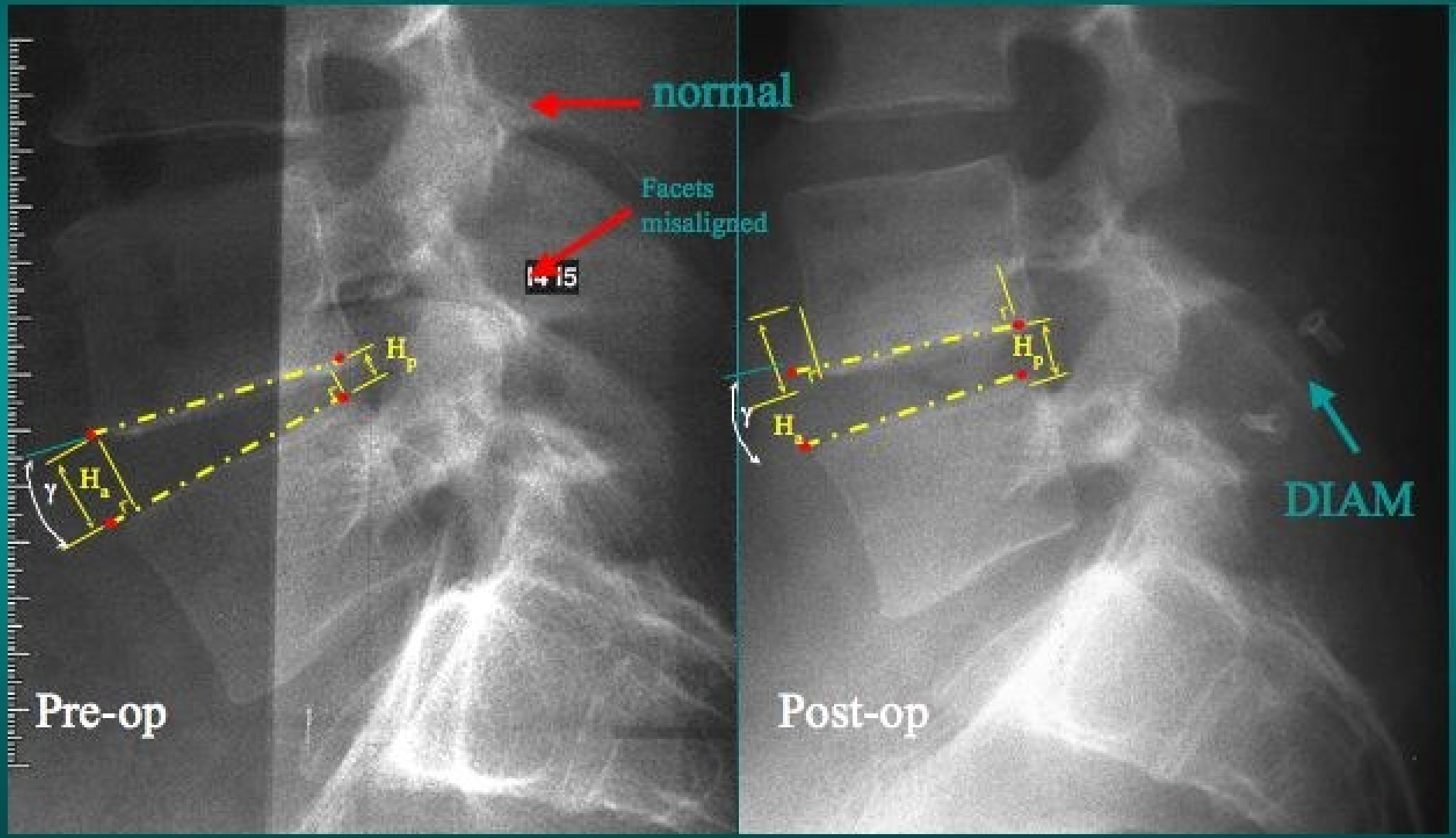
2. Normalize motion of facet joints and segment

Abnormal Alignment of the Spine



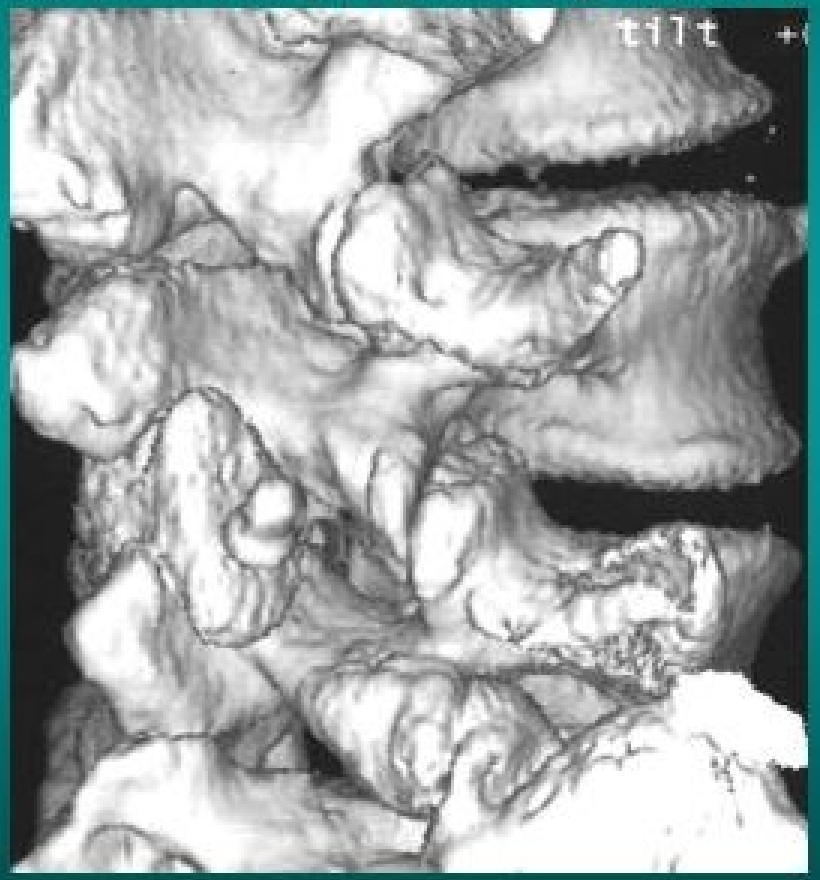


Abnormal Alignment of the Spine



DIAM Goals

3. Restore proper alignment



DIAM Goals

4. Neuroforaminal widening

5. Normalize motion of facet joints

Summary of Clinical Experience

- 14 different published European studies with 527 patients
- Based on individual study success criteria, 455 (86%) patients have been published as successful cases at follow-up.
- 15,000+ current DIAM patients

THE USE OF DIAM IN THE DEGENERATIVE SPINE:
Italian Multicentric Clinical Experience

Milan: Sforzesco Castle

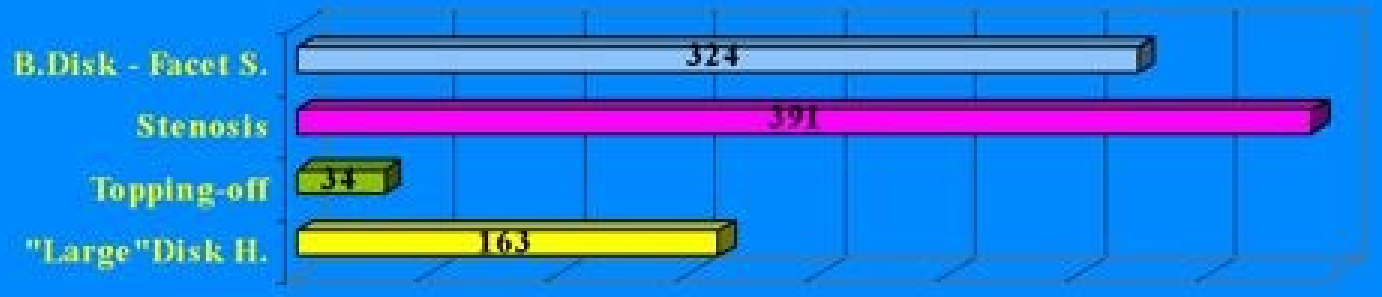
DIAM INDICATIONS

- BLACK DISK-FACET SYNDROME
- SOFT AND/OR FORAMINAL STENOSIS
- LARGE DIMENSION LUMBAR DISK HERNIATIONS IN YOUNG PATIENTS
- TOPPING-OFF

G. Guizzardi (Florence), P. Petrini (Perugia), A.P. Fabrizi (Bologna), G. Fornasar (Trieste), S. Caserta (Milan) Presented at SAS NY 2005

THE USE OF DIAM IN THE DEGENERATIVE SPINE:
Italian Multicentric Clinical Experience

- 12-48 months follow-up



Treated Pathologies

Milan: The Duomo

Low Stiffness Instrumentation
good idea or gimmick?

- Good concept
- Good biomechanical testing
- Expanding clinical science