

# Non fusion technologies



**Jwalant S. Mehta**

MS (Orth); D (Orth); FRCS (Eng); MCh (Orth); FRCS (Tr & Orth)



# Clinical pathway



Invasiveness



Spine arthroplasty

Soft stabilizations

Injections:

- Facet blocks
- Root blocks
- Epidural steroids

Physiotherapy

Medications

Alternative therapies

Minimally Invasive Spinal Surgery (MISS)

Fusion

Time

# Minimally invasive alternatives

⊕ IDET

⊕ Nucleoplasty

⊕ Vertebroplasty (Kyphoplasty)

⊕ Chemo-discolysis (Oxygen-ozone mixture)

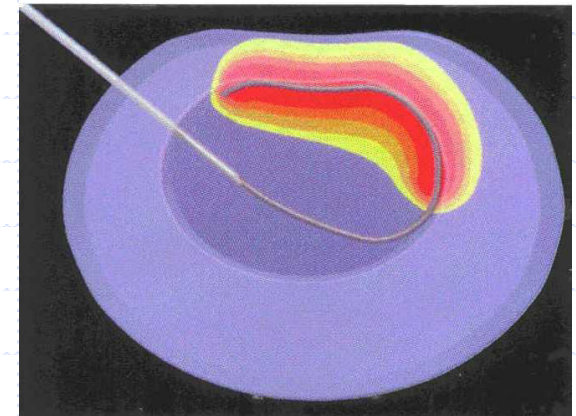
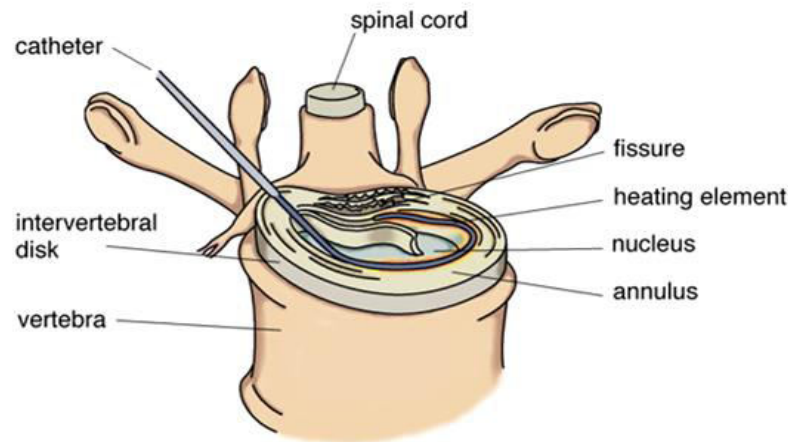
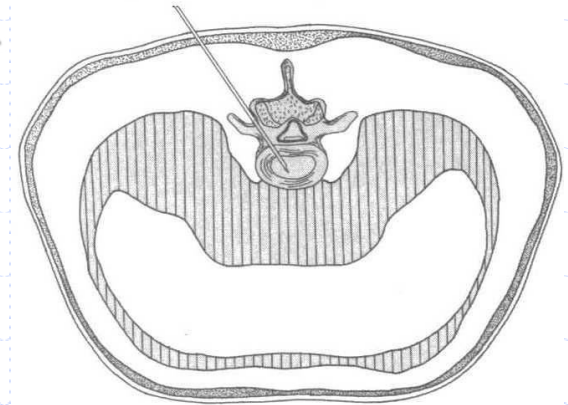
⊕ Laser disectomy



# Intra Discal Electrothermal Therapy

Minimally invasive option for fusion

Saal & Saal Spine 2000



# IDET: Principles

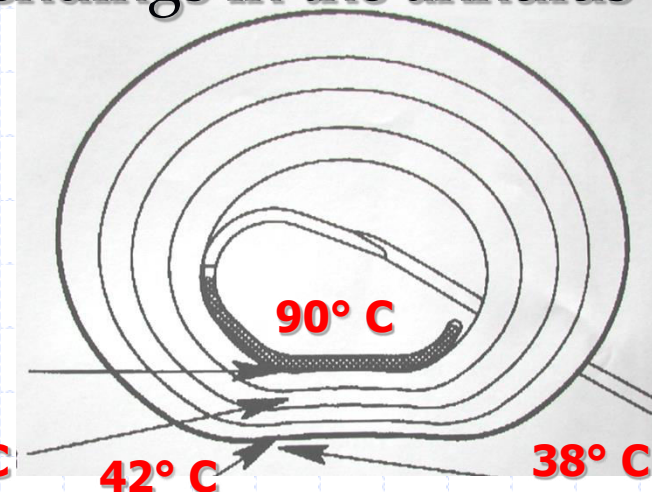


⊕ Annular collagen shrinkage

- ❖ Bonds break at 60° C
- ❖ Stabilise fissures

⊕ Thermocoagulation of nerve endings in the annulus

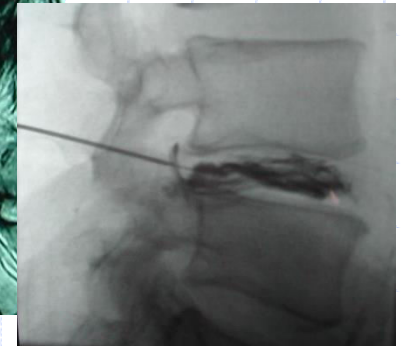
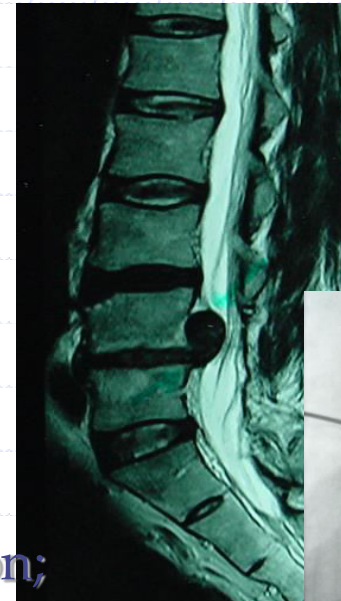
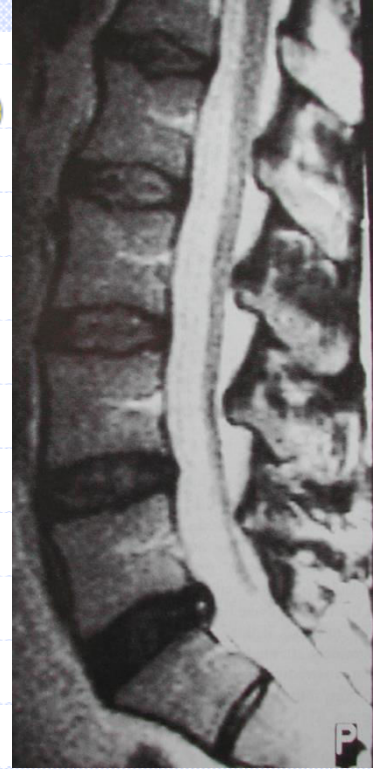
⊕ Thermal mapping





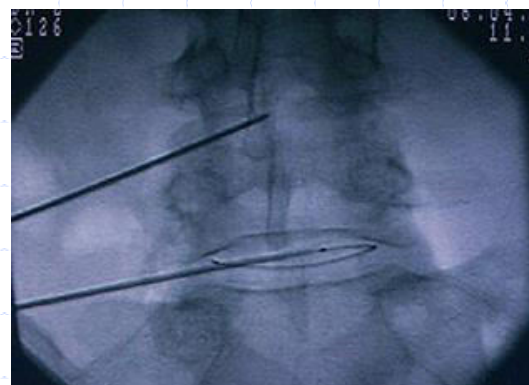
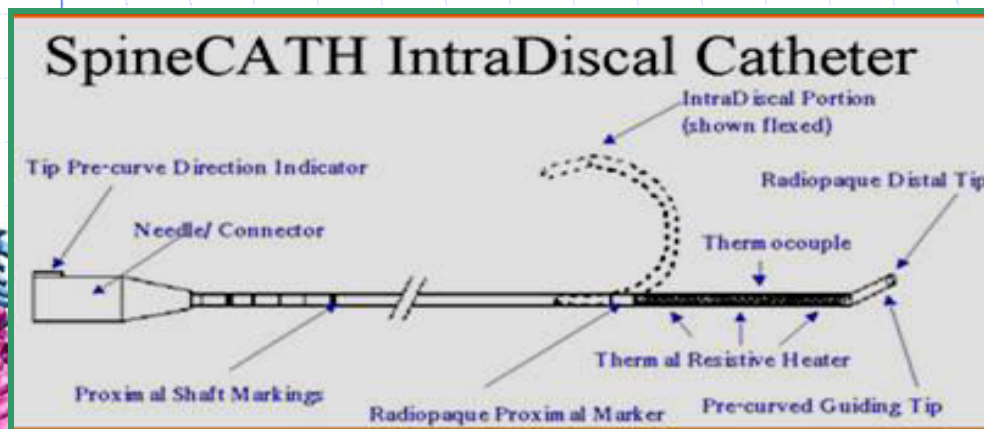
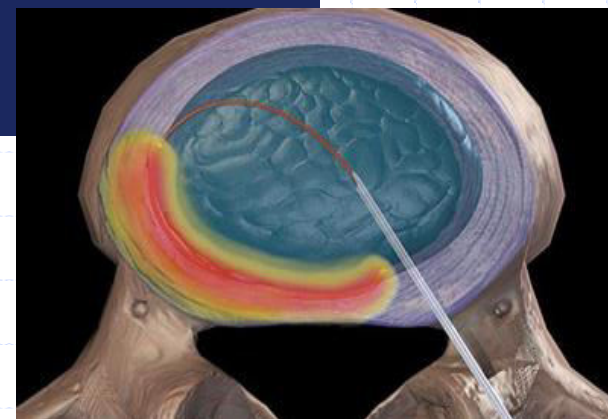
# IDET: **Indications**

- ⊕ Severe; persistent back pain (6mo)
- ⊕ Failed non-op programme
- ⊕ No root compression
- ⊕ MRI: N disc height
- ⊕ Discogram: **Positive**
- ⊕ Contra-indications: Severe degeneration; stenosis; large herniation



# IDET: Technique

90° C for 5 min





# IDET: results

## ⊕ Saal & Saal Spine 2000

- ❖ 81 % decrease in pain
- ❖ 19 % no change

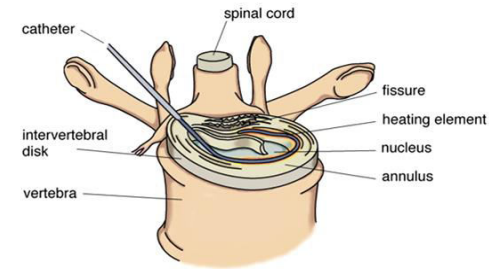
## ⊕ Karasek; Bogduk Spine 2002 :

- ❖ 54% pain ↓ by ½
- ❖ 1 in 5 have complete relief
- ❖ 53 patients, 2y follow up





# IDET: recent reports



⊕ 2 year FU in active soldiers: 47 % (6 mo); 16 % (2 y).

**Not an option for fusion**

**Freeman BA et al Spine J Dec 2003**

⊕ Pain and function after IDET: 20 patients; 6 mo FU.

**Not effective**

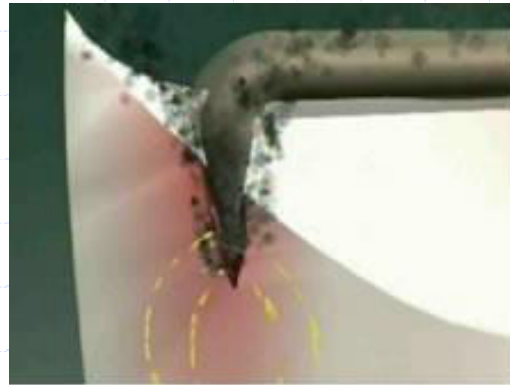
**Spruit et al Eur Spine J Dec 2002**

# Coblation

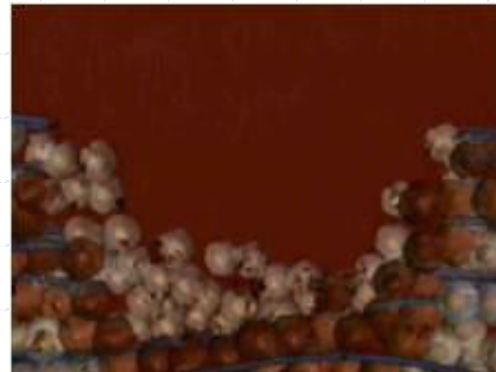
## Thermal coagulation

## Coblation

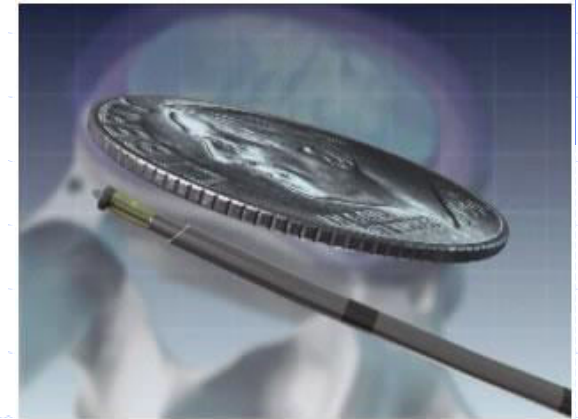
Tissue level



Molecular level



# Coblation – assisted Nucleoplasty



## Spine Wand

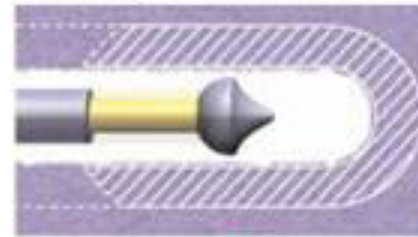
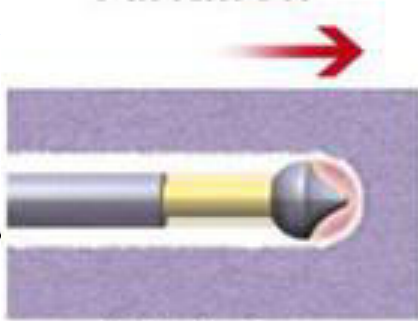
- ❖ Controlled levels of heat ( $< 70^{\circ}$ ) to the herniated disc
- ❖ FDA approved for contained herniated disc (2001)

# Coblation – assisted Nucleoplasty

## Nucleoplasty Channeling

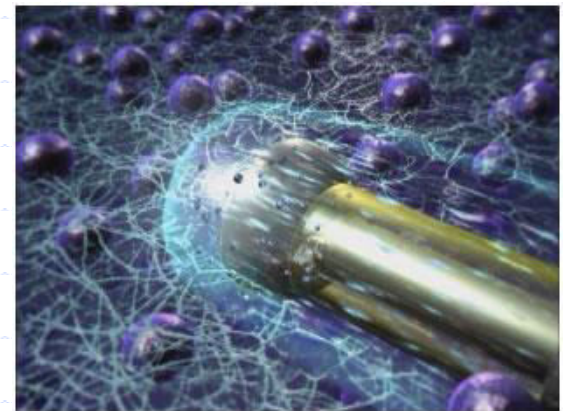
Ablation

Coagulation



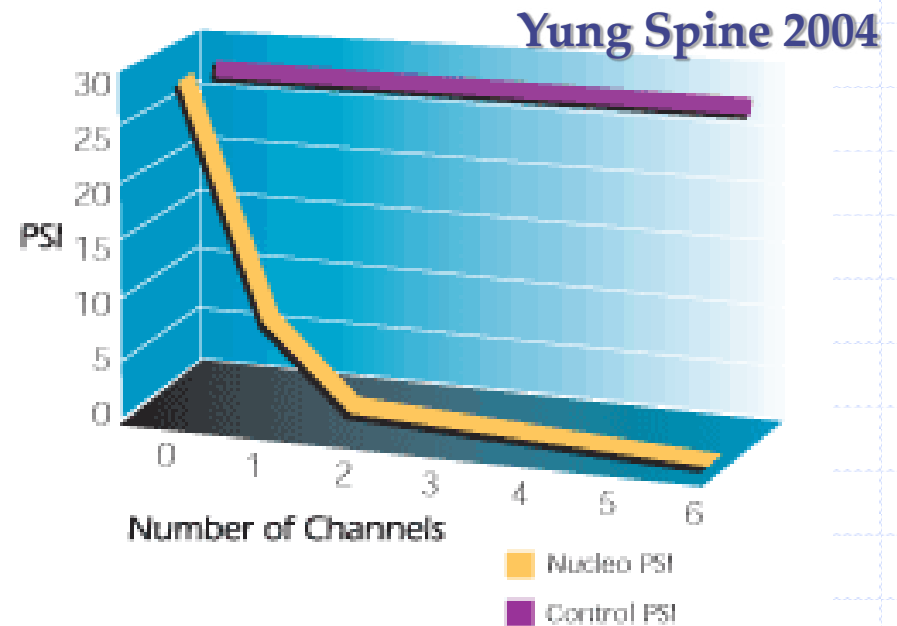
Ablate in

Coagulate on withdrawal





# Coblation – assisted Nucleoplasty



- ❖ Channels created within the disc
- ❖ ↓ intra-discal pressure → ↓ Pain

# The beginnings of soft stabilization

⊕ **Henri Graff , of Lyon, France:**  
**"a fused" spine is not physiological**

⊕ **Gilles Dubois in France and Hans Müller in Germany devised a new system that was:**  
**"a more gentle alternative to fusion"**





# Should we be fusing?



Invasiveness

- ⊕ Fusion rates 100 % but  $\neq$  clinical outcomes

Boos ESJ 1997

- ⊕ Efficacy of fusion questioned

Gibson: Cochrane review Spine 1999

- ⊕ Problem areas:

- ❖ Adjacent level degeneration
- ❖ Young patients
- ❖ Multisegmental disease

Fusion



Time



# Soft stabilizations

**A system that favorably alters the movement and load transmission of the motion segment**



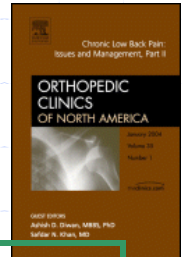


# Soft stabilizations

## Objectives:

1. Motion segment remains mobile!
2. Alters load bearing pattern
3. Control abnormal motion
4. Physiologic load transmission





# Dynamic stabilization devices

## Inter-spinous distraction:

- ❖ Wallis
- ❖ X Stop

## Inter-spinous ligament:

- ⊕ Elastic ligament
- ⊕ Loop system

## Ligaments across pedicle screws:

- ⊕ Graf ligamentoplasty
- ⊕ Dynesys
- ⊕ FASS

## Semi-rigid metallic devices:

- ❖ DSS I
- ❖ DSS II
- ❖ EQUATION

Sengupta OCNA 35 (2004) 43 - 56

AO Spine Monsoon Seminar

Oct 10, 2004



# Inter-spinous distraction devices

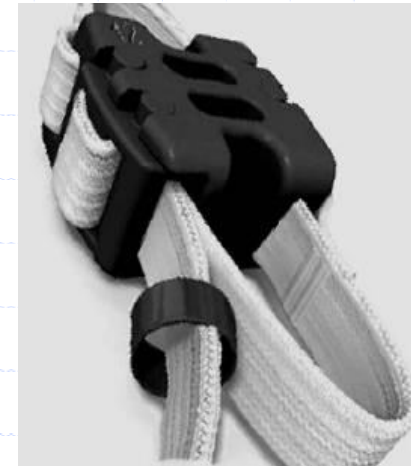
⊕ Floating devices

⊕ Silicone spacers **Mims et al Spine 1991**

⊕ Ti + dacron tape / PEEK  
**Senegas Clin Orth 1988**

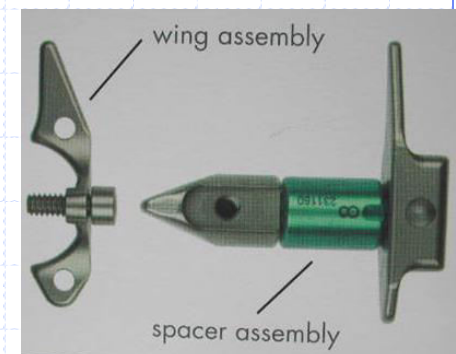
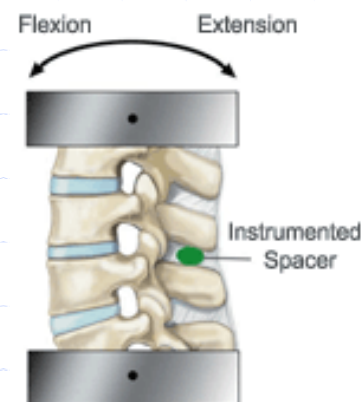
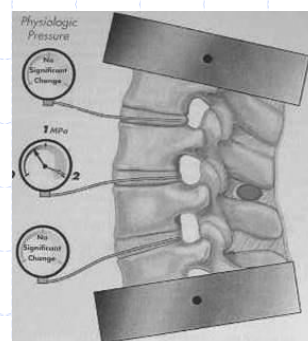
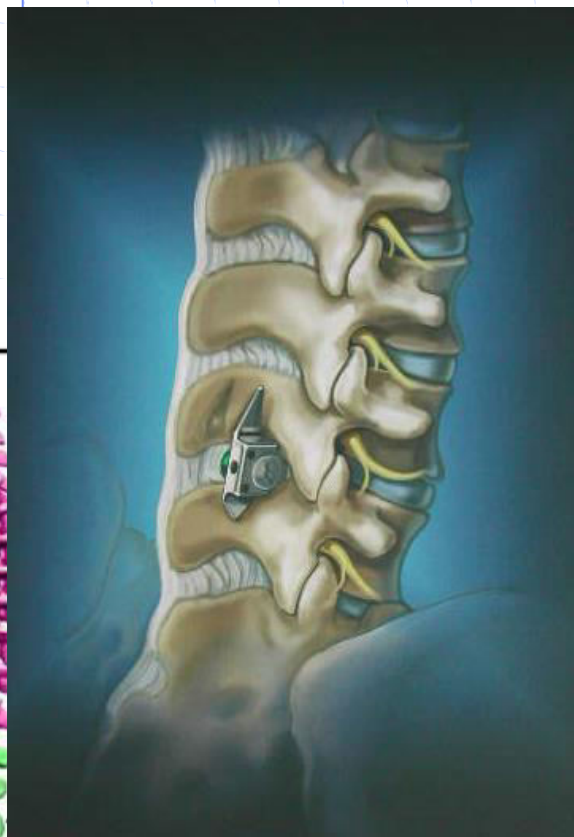
⊕ Suggested indications:

- ❖ Large disc; revision discectomy
- ❖ Disc adjacent to fusion
- ❖ Isolated Modic I with back pain



**Wallis**

# Inter-spinous distraction devices: X stop



## ↓ Pressure:

**Post ann** 63 %

**Nucleus** 41 %

**Facets** 58 %

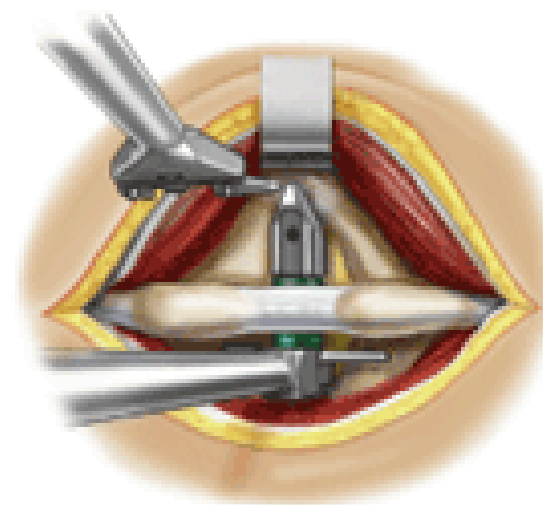
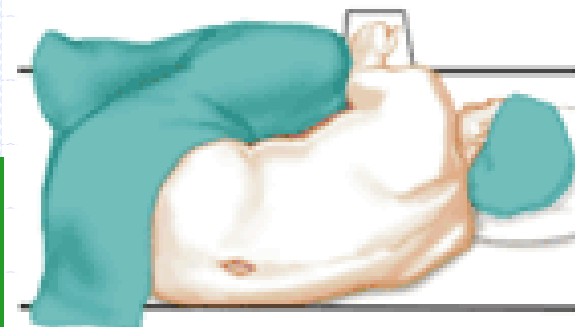
St. Francis Medical Technologies Inc.



# Inter-spinous distraction devices: X Stop

## Proposed indications:

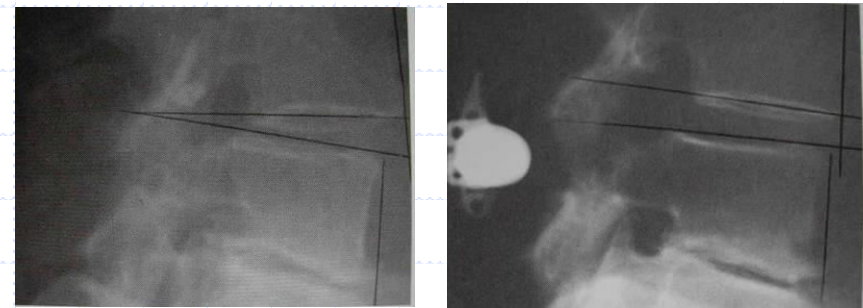
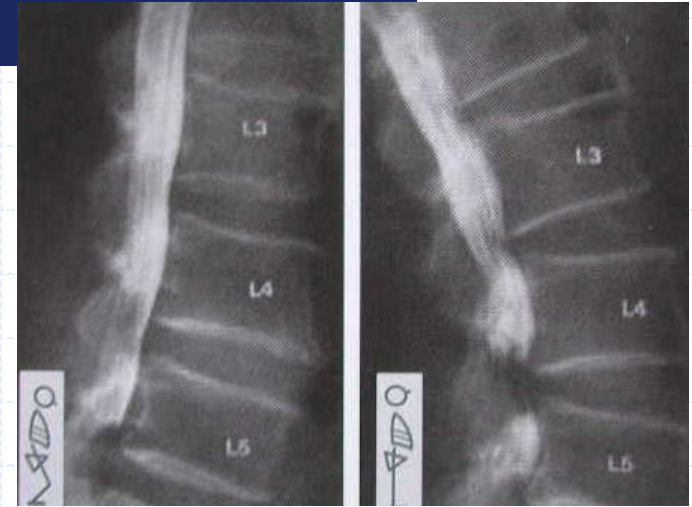
- ⊕ 50 +
- ⊕ Intermittent neurogenic claudication
- ⊕ Narrow at 1 – 2 levels



# Prospective randomized multicentre trial

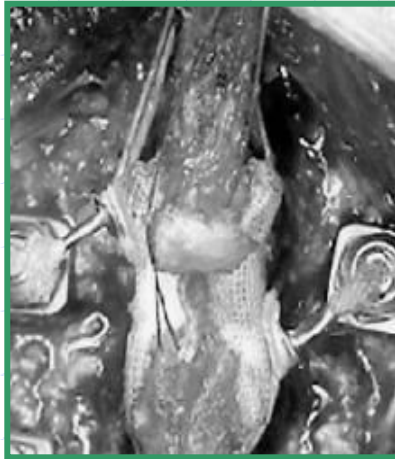
## Zuckerman ESJ 2004

- ⊕ 200 pts; 1 yr
- ⊕ Safe & effective
- ⊕ Pts with co-morbidities
- ⊕ Better than non-op
- ⊕ Comparable to decompression?



# Inter-spinous ligament devices:

## Elastic ligament



### Proposed indications:

- 1) Early disc degeneration
- 2) Large primary disc
- 3) Recurrent disc
- 4) Level adjacent to fusion

### Purpose:

- ⊕ Stabilize post ligament complex
- ⊕ ↓ stress on post annulus; facet

# Elastic stabilization with posterior shock absorber

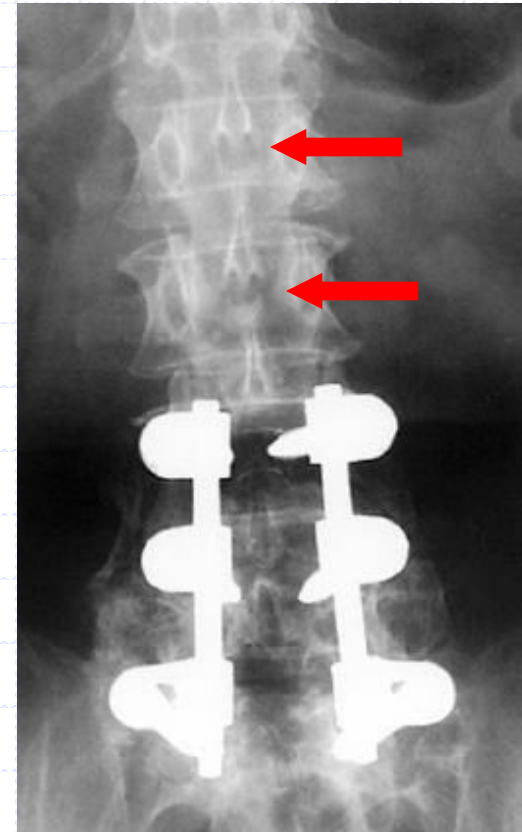
## Caserta et al ESJ 2002

⊕ Study period: 1991 – 2001

⊕ Procedures:

- ❖ 57 stand alone
- ❖ 25 combined

⊕ Best results in recurrent disc



'Topping off' fusion



# Typical clinical scenario

## Caserta et al ESJ 2002



35 / F

Degenerate L4/5 + early instability

Persistent back pain

Painfree & mobile at 1 yr



Pre-op: Fl; Ext



1 yr FU: Fl; Ext

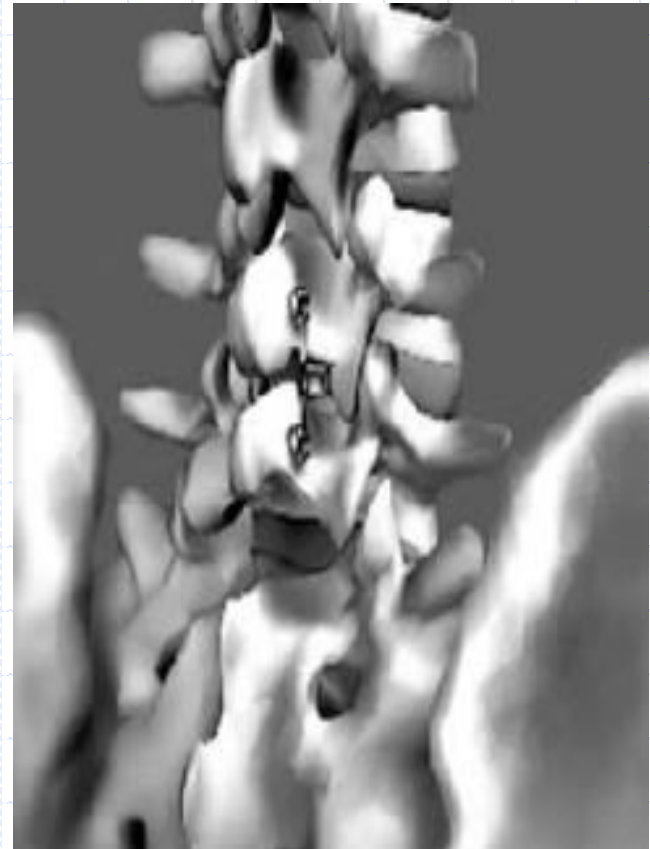


# Inter-spinous ligament devices:

## Loop System

Garner ESJ 2002

- ⊕ Tension band device
- ⊕ Braided polyethylene cable  
locking clip  
optional ferrule
- ⊕ Tensioned with device  
Clip locks construct



Spineology Inc.

# Device for Intervertebral Assisted Motion

## ⊕ Mechanism:

- ❖ ↓ loading on disc
- ❖ Posterior tension band
- ❖ Unload facets

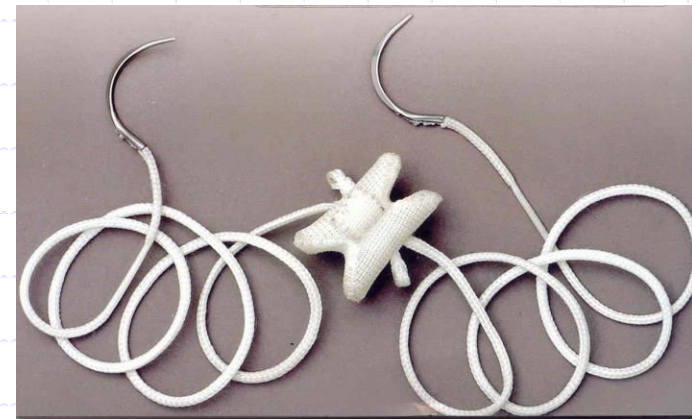
## ⊕ Structure:

- ❖ 2 laces
- ❖ Silicone spacer
- ❖ Tensioner
- ❖ ± laces

## ⊕ Limited use



Medtronic Sofamor Danek



# Ligaments across pedicle screws

⊕ Graf ligamentoplasty

⊕ Dynesys

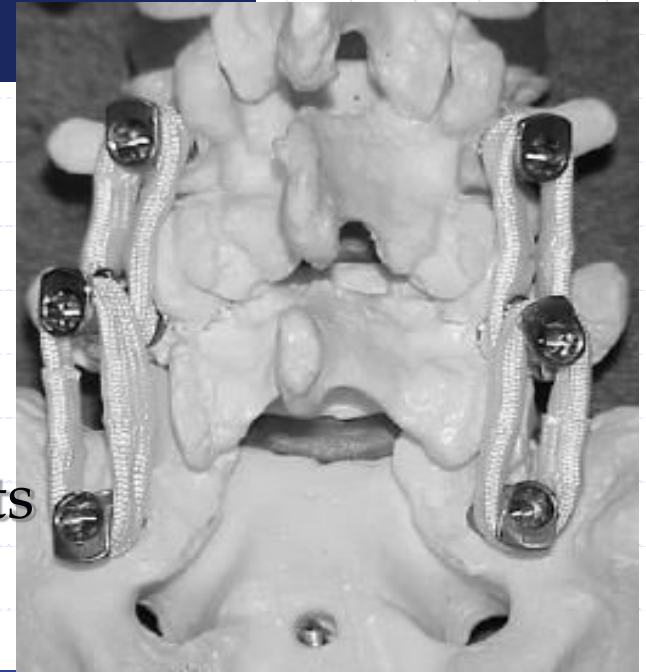
⊕ Fulcrum Assisted Spinal System (FASS)





# Graf ligament

- ⊕ Henry Graf **Rachis 1992**
- ⊕ Non elastic, braided polyester
- ⊕ Rotational control by locking facets



- 💣 Tense in flexion; lax in extension
- 💣 Load transferred to posterior annulus
- 💣 Accelerated disc degeneration

# Graf ligament: **results**

- ⊕ Suitable for mild and early degeneration

Hashimoto 59 pt; 3.5y **Spine July 2001**

- ⊕ Graf v/s PL fusion

Higher revisions in Graf group at 2 yrs

Hadlow et al **83 pts; 2 y Spine May 1998**



Beneficial results despite progressive degeneration

Gardner, Pande 31 pt; 7.4 yr **ESJ Oct 2002**

Excellent / good in 72 %

Grevitt 50 pts; 2 y **ESJ 1995**



# Dynamic Neutralisation System

## DYNESYS

- ⊕ Investigational device
- ⊕ CentrePulse AG, Switzerland
- ⊕ Gilles Dubois in France and by Hans Müller in Germany
- ⊕ First implanted in 1994
- ⊕ Several multi-centre trials underway in Europe & North America



# Components of Dynesys



**Pedicle screw**



**Polyurethane spacer:**  
**Resists compression**

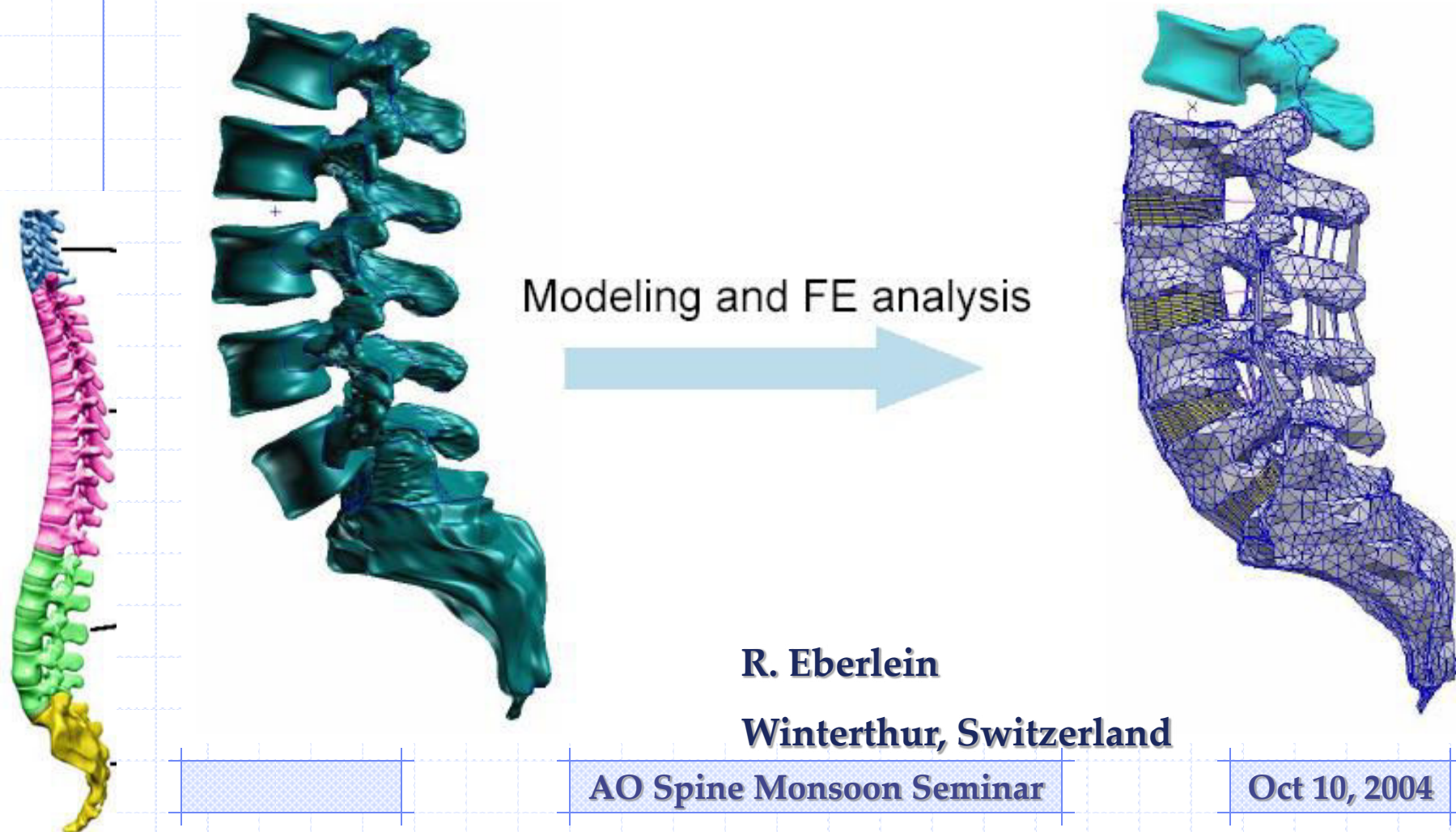


**Polyethylene cord:**  
**Tensile forces**

**Pre-loaded system: uniform rigidity**



# Finite element analysis



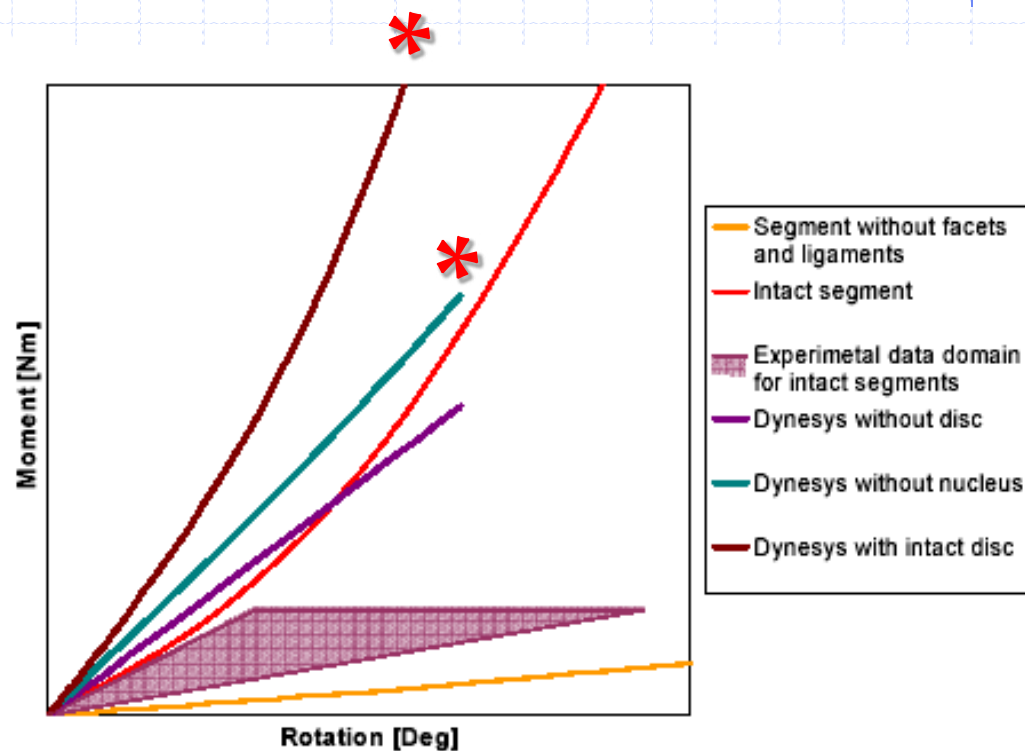
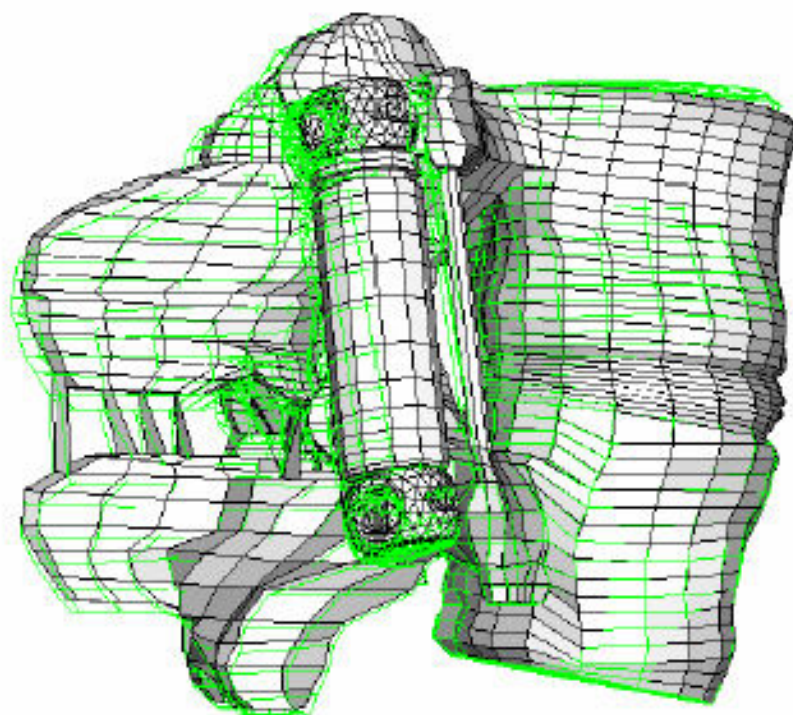
**R. Eberlein**

**Winterthur, Switzerland**

**AO Spine Monsoon Seminar**

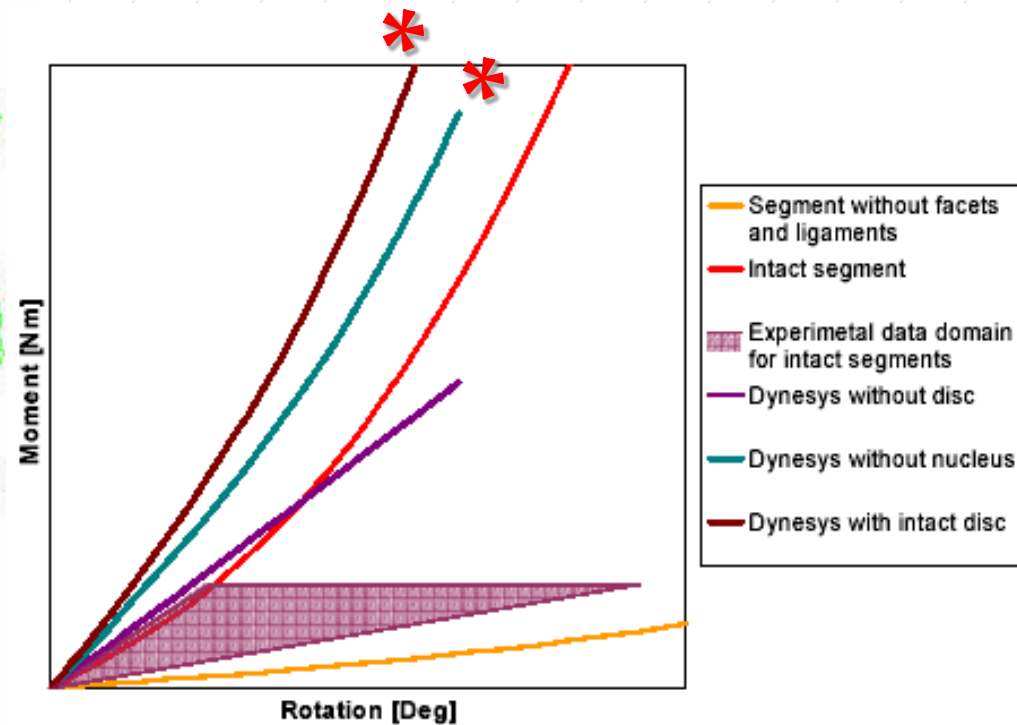
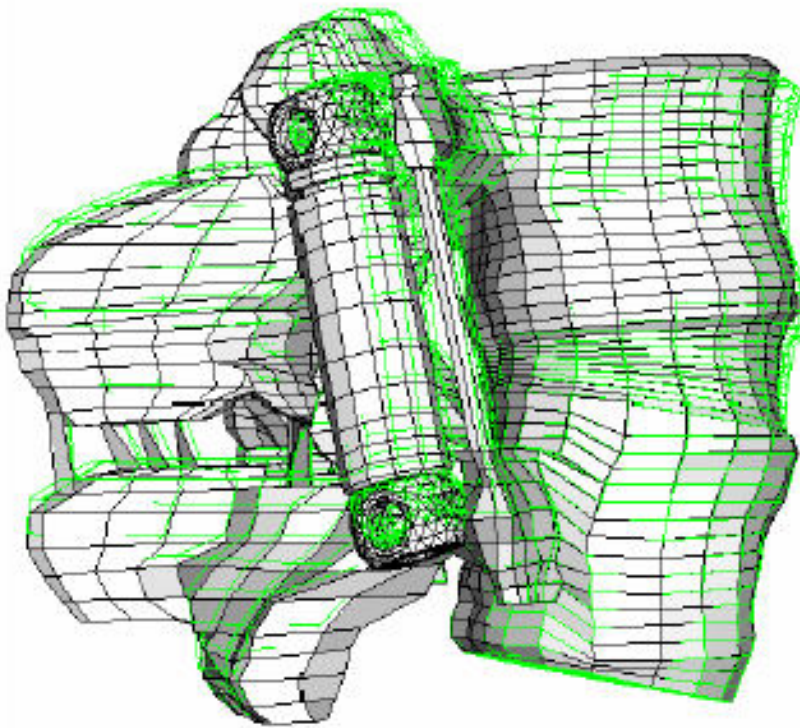
**Oct 10, 2004**

# FEA validation testing: Flexion



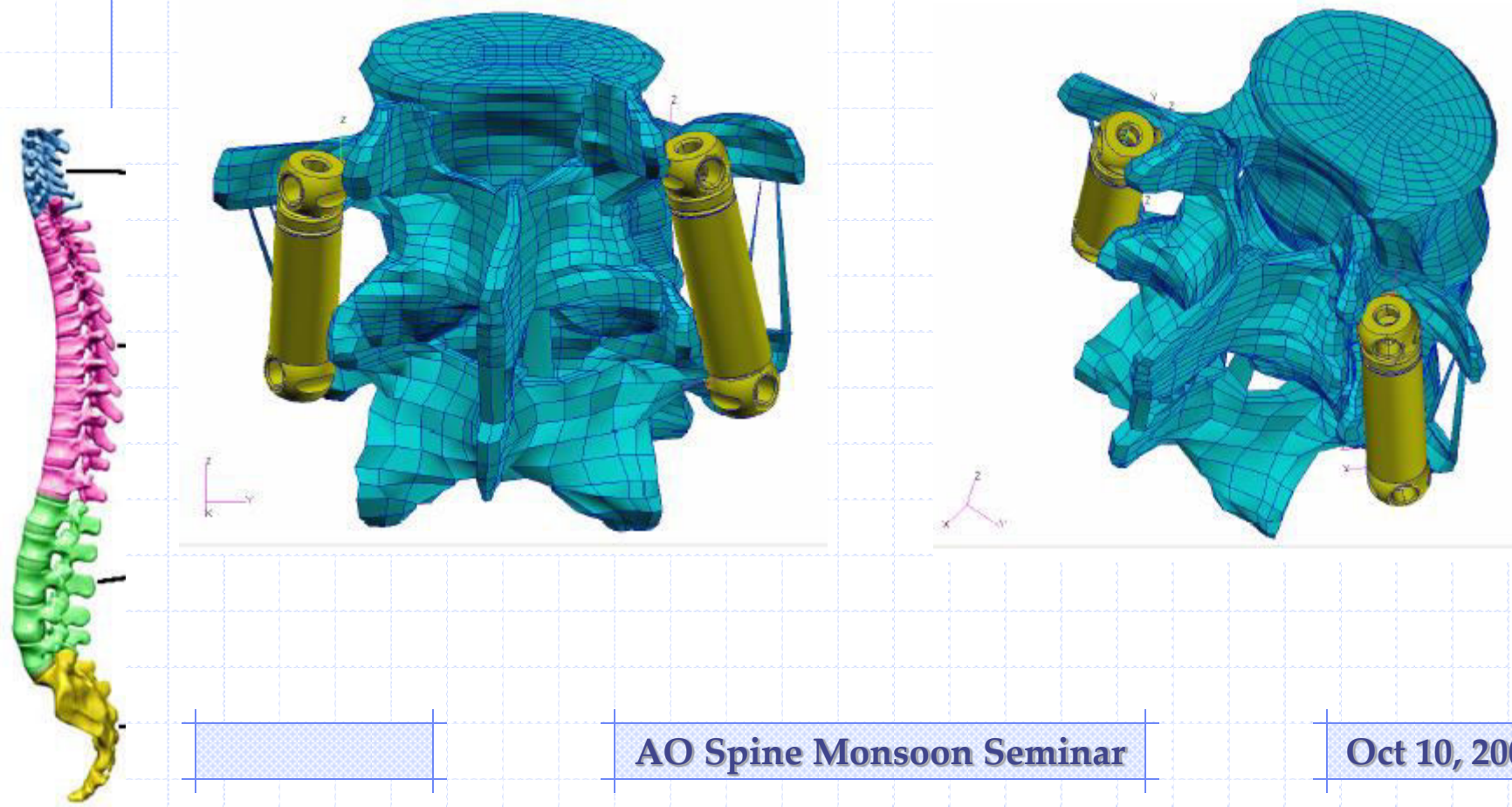
# FEA validation testing: Extension

Unloads all of the disc





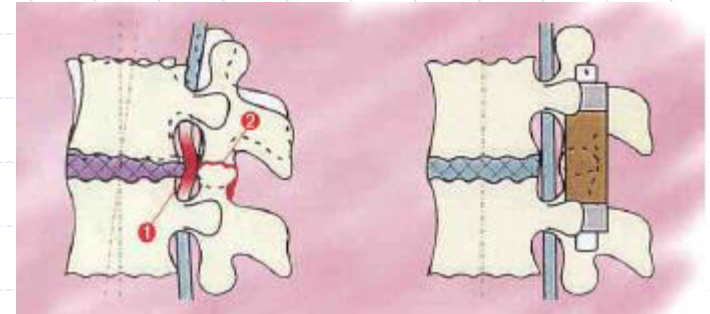
# Rotational 'cushion'





# Dynamic Neutralisation System

- ⊕ Flexible stabilisation
- ⊕ Restore & maintains anatomy
- ⊕ Stenosis **FDA approved**
- ⊕ Chronic back + leg pain



# Clinical results: **DYNESYS**

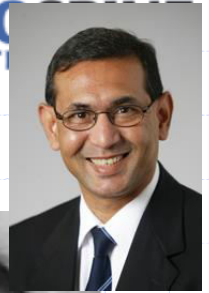
- ⊕ Loss of lordosis is a potential cause of failure  
**Rajaratnam** Int Orthopaedics



- ⊕ Not indicated if marked deformity  
**Putzier** Z Orthop 70 pt; 33 mo

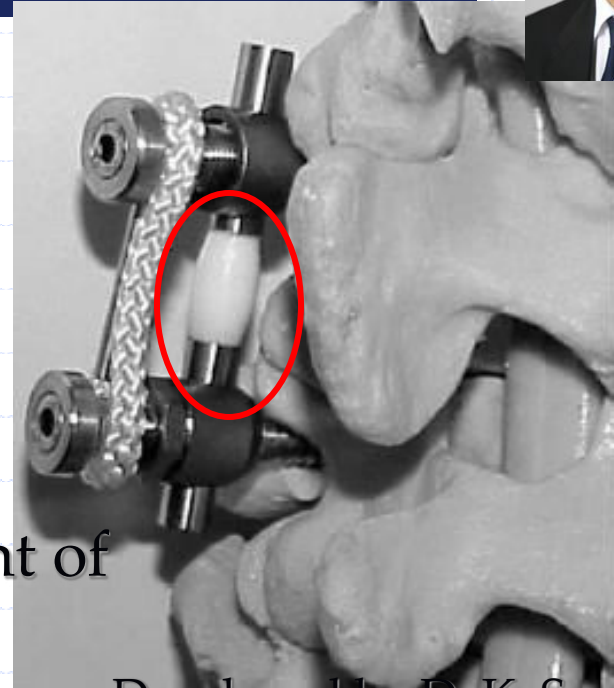


- ⊕ Safe alternative to fusion  
**Stoll** ESJ Oct 2002 83 pt; 38 mo



# Fulcrum Assisted Soft Stabilisation

- ⊕ Load sharing device
- ⊕ Offsets problems with Graf:
  - ❖ Narrow lateral recess
  - ❖ Load on posterior AF
- ⊕ Re-creates lordosis independent of posture / muscle action
- ⊕ No clinical data



Developed by D. K. Sengupta  
(AO, Davos)

**Fulcrum: posterior compression  $\Rightarrow$  anterior distraction**  
**unloading discs**



# Semi-rigid metallic: **Dynamic Spinal Systems**

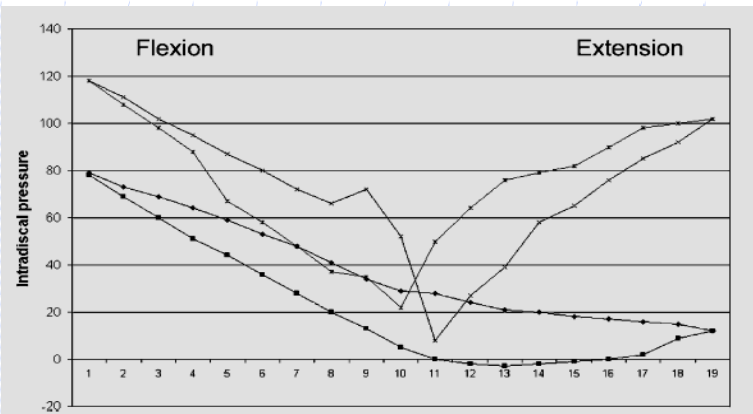
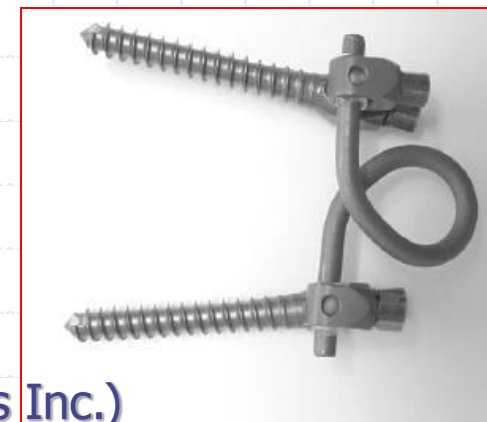
## Pre-tensioned device ensures

- ⊕ unloading disc
- ⊕ optimum IAR of the springs

### DSS I: Ti spring (3mm)



### DSS II: Ti coil (4mm)



**Early clinical results encouraging !**

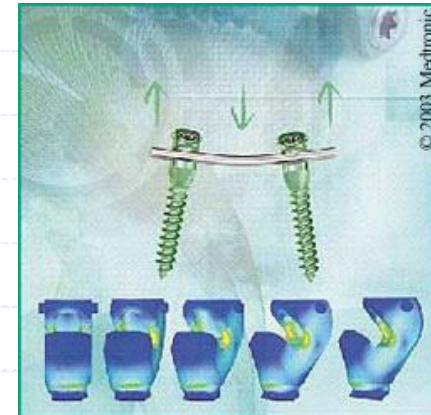
Developed by: D. K. Sengupta (Spinal Concepts Inc.)



# EQUATION™

## Flexible Osteosynthesis Solution

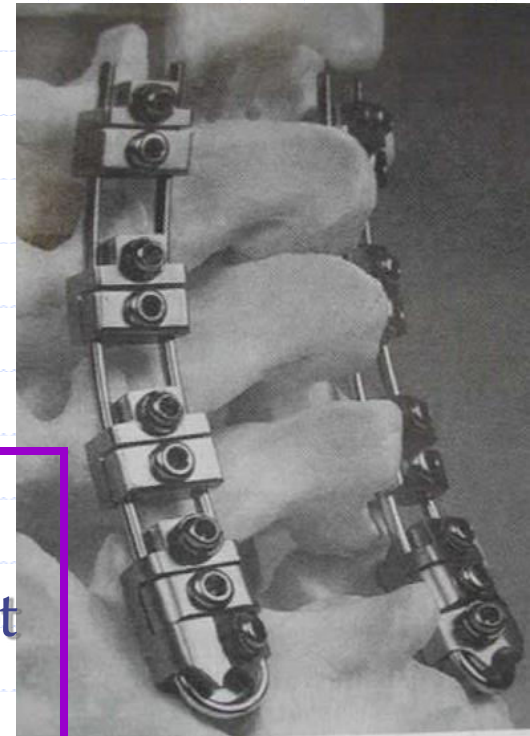
- ⊕ Temporary implant system
- ⊕ Non cervical, posterior spine in the mature spine
- ⊕ Tumours; Deformities; Trauma
- ⊕ Semi rigid stabilization



# Twinflex Dynamic System

- ⊕ Steel rods 2.5 mm
- ⊕ Flat connector
- ⊕ Cannulated pedicle screws
- ⊕ Top loading system

Designed for iso-elasticity  
Flexibility allows the system to adapt  
Dynamic loading of the grafts



**Eurosurgical**

# M<sub>2</sub>H factor

