

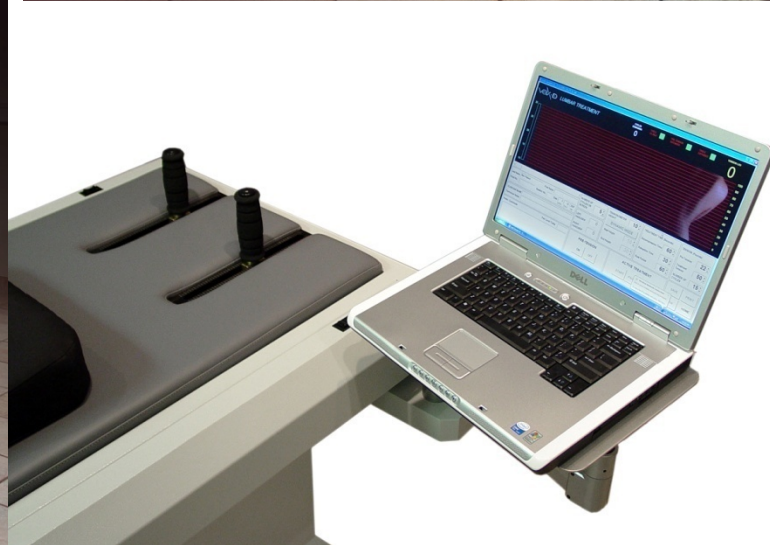


# Genesis Equipment

*Lumbar Treatment*



*Cervical Treatment*



*Laptop Control Center*

# Versatility in Treatment Choices



**Lumbar Prone**

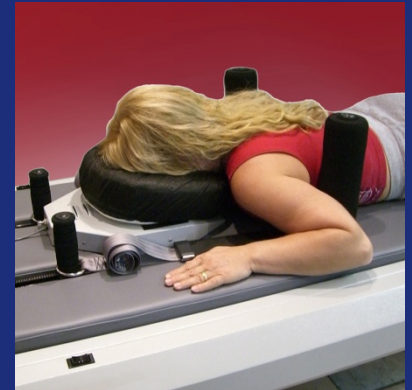


**Lumbar Supine**

## Handgrips



## Arm-Rests



## Cervical



# DECOMPRESSION



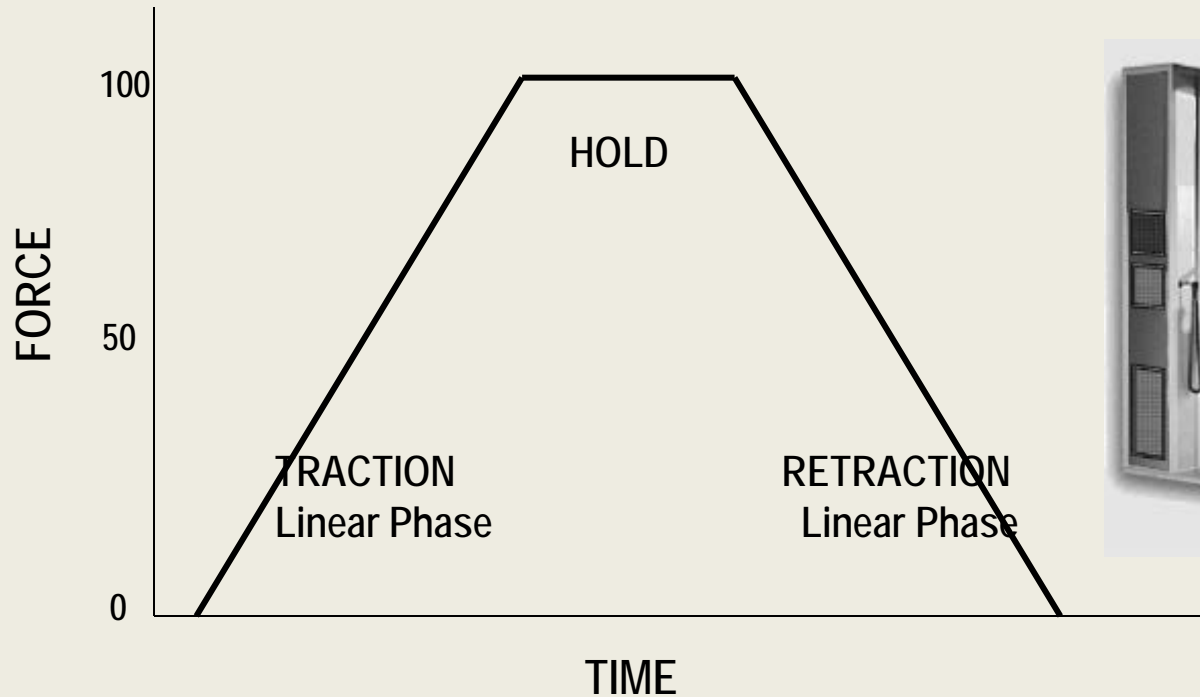
# DISTRACTION



# DISTRACTION<sup>x</sup>



# DISTRACTION DEVICES

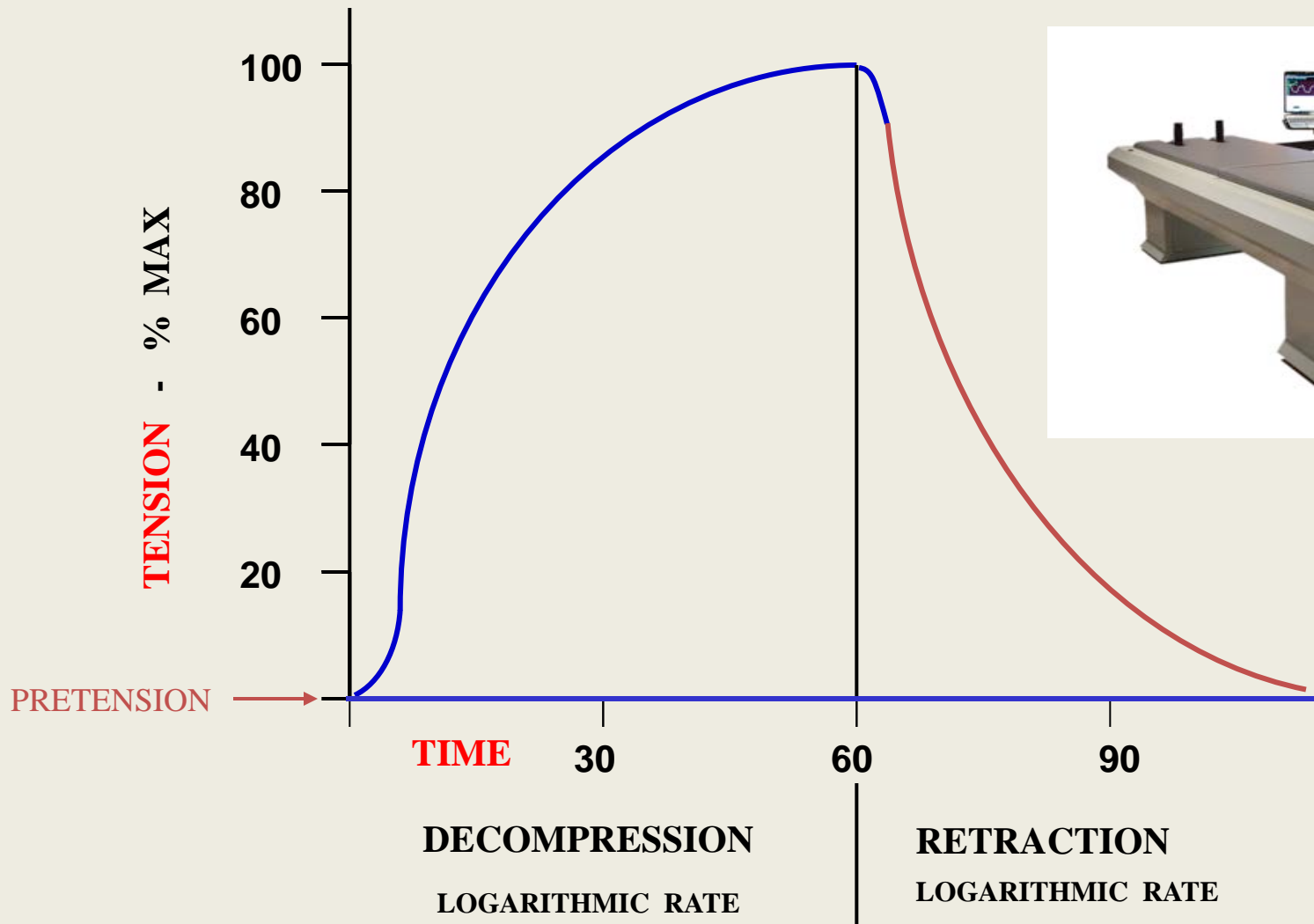


**DISTRACTION IS NOT DECOMPRESSION**

**Proprioceptors recruit back and trunk muscles guarding**

**Chest harness INCREASES intrathoracic & intradiscal pressure**

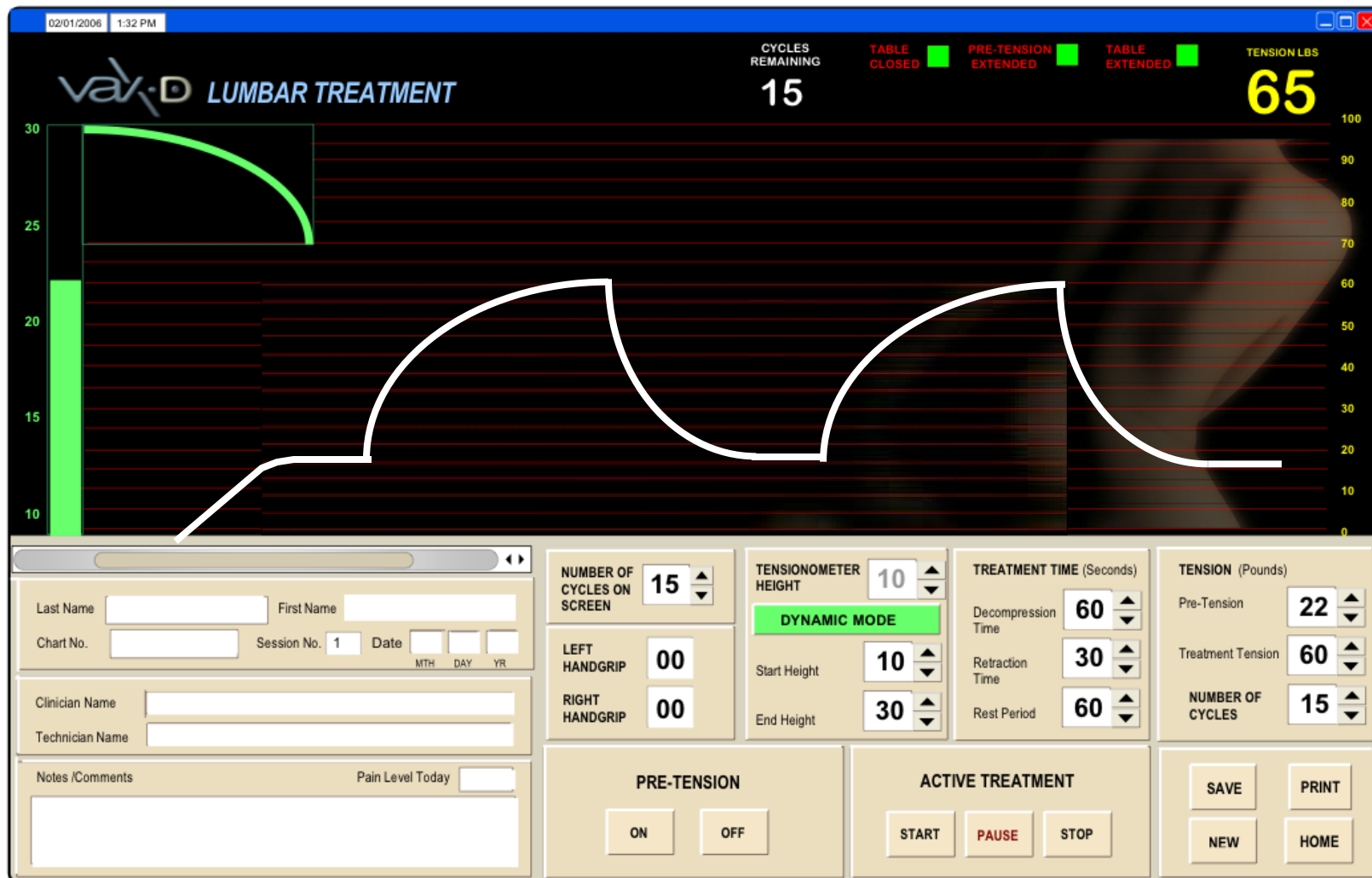
# VAX-D DOUBLE LOG THERAPY CURVE



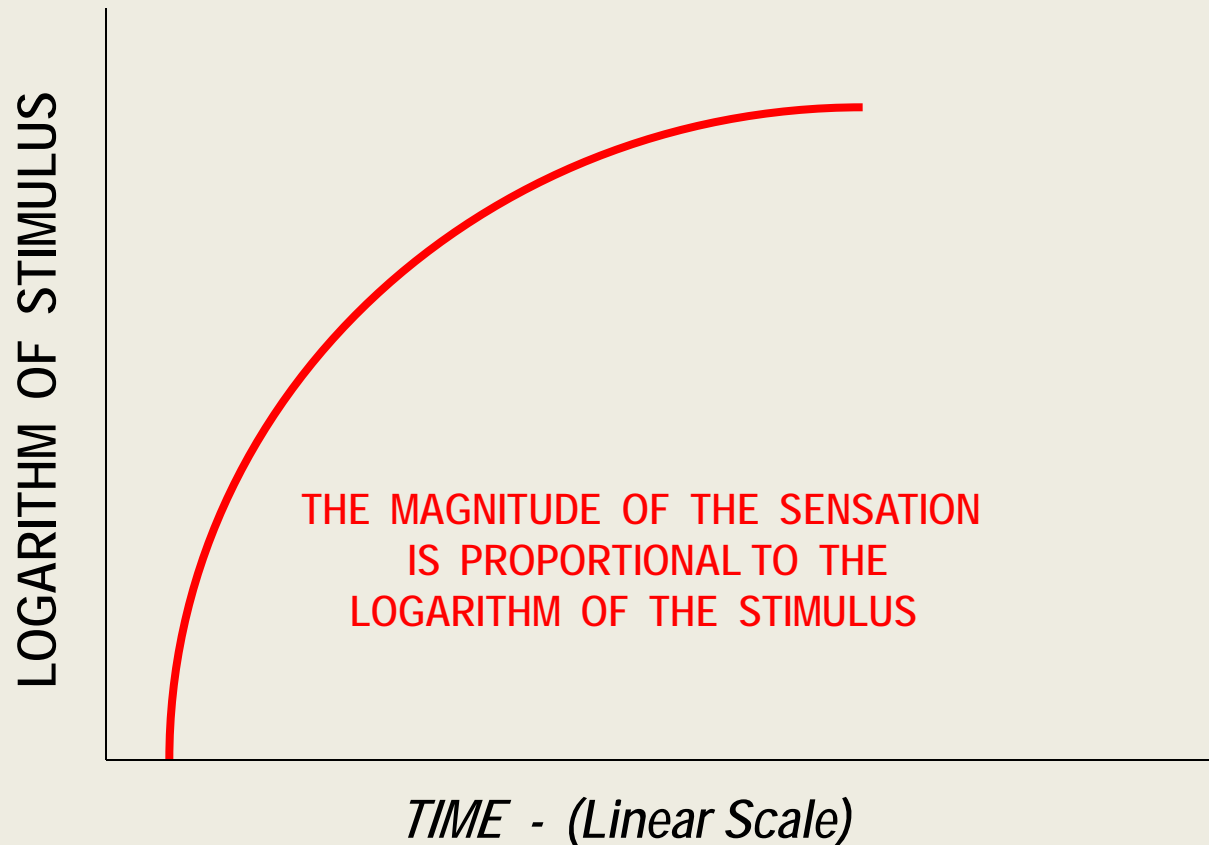
Logarithmic Formula

$$\text{Exp} [ C \times \text{Ln} (Bt) ] = N B T^n + [ N \times \text{Ln} ]$$

# GENESIS TREATMENT SCREEN - REAL TIME CHART



# Fechners Law of Biological Response



VAX-D employs and patented the inverse of this principle :

**Tension** ( *stimulus*) is applied at a **Logarithmic Time** scale  
Avoids proprioceptor / reflex muscle guarding

# United States Patent [19] Dyer

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[11] **Patent Number** **6,039,737**  
[45] **Date of Patent** **Mar. 21, 2000**

---

[54] **OPERATION OF A VERTEBRAL AXIAL  
DECOMPRESSION TABLE**

[76] Inventor: Allan E. Dyer,

[21] Filed: Oct. 29, 1998

[30] **Foreign Application Priority date**

Aug. 12, 1998 [AU] Australia .....79929/98

[51] Int. Cl. 7 .....A61b 17/56

[52] U.S. Cl. ....606/58; 606/54

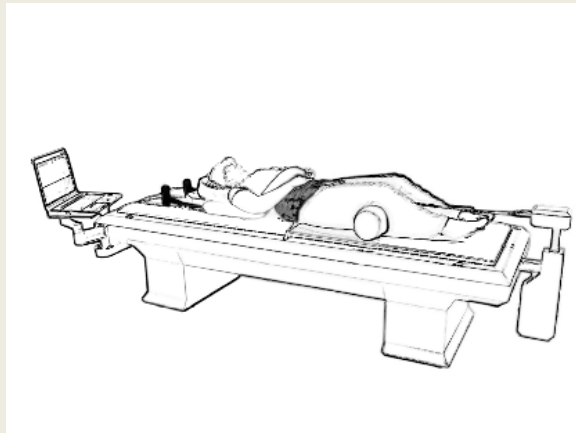
[58] Field of Search .....606/54, 53, 57

[56] **References cited**

**U.S. PATENT DOCUMENTS**

4,995,378 2/1991 Dyer .....128/75

5,115,802 5/1992 Dyer .....602/33

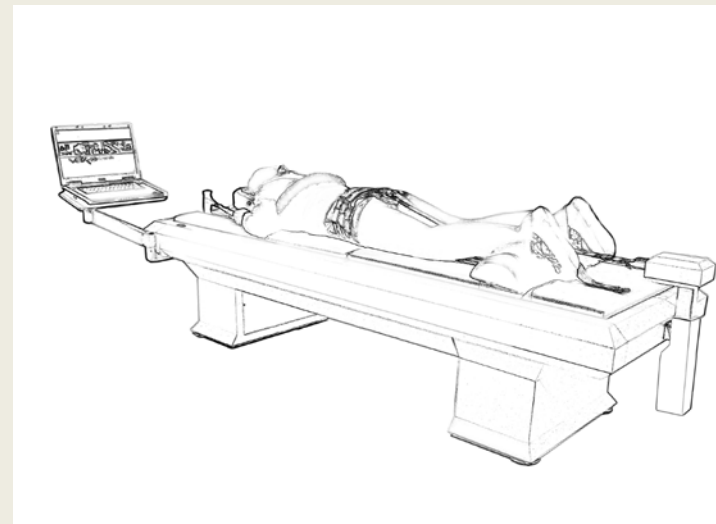


Primary Examiner - Michael Buiz  
Assistant Examiner - Jonathan D. Goldberg  
Attorney, Agent or Firm - Blackwell Sanders Peper Martin

[57] **ABSTRACT**

A vertebral axial decompression table is operated by applying a baseline tension to the two table parts, increasing tension to about 50% of the maximum above baseline , then **logarithmically increasing tension to maximum tension.** Thereafter, tension is linearly relaxed back to baseline. This cycle is repeated a programmed number of times to effect a therapy. Data concerning the table operation is transmitted to allow remote monitoring and re-programming of the table.

**23 Claims, 8 Drawing Sheets**





**Anderson G, Schultz A, Nachemson A.**  
**Intervertebral Disc Pressures During Traction.**  
*Scan J Rehabil Suppl 19983; 9:88-91*

“If the purpose of spine traction is to reduce pressures within the disc and/or open up the disc space, it has to be administered in a way which allows the trunk muscles to relax.”

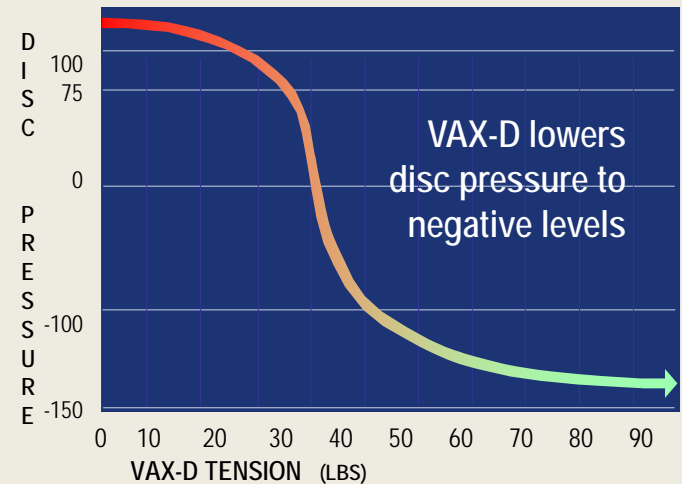
VAX-D advanced technology is  
designed to avoid muscle guarding  
and thereby achieves  
disc decompression

# The Birth of A Phenomenon: The Discovery of Disc Decompression

In 1994 Dr. Allan Dyer and neurosurgeon Dr. Gustavo Ramos and radiologist Dr. William Martin at the Departments of Neurosurgery and Radiology, Rio Grande Regional Hospital, McAllen, and Division of Neurosurgery, Health Sciences Center, University of Texas, undertook to measure the pressures inside the intervertebral disc as patients received VAX-D treatment.

With a fluoroscopically guided cannula/catheter and pressure monitoring equipment, **they measured the patients' disc pressures drop to negative levels. This was the birth of DISC DECOMPRESSION.**

This discovery led to a landmark clinical study that showed for the first time it was possible to lower a intradiscal pressure in-Vivo with a non-surgical treatment.



# Rio Grande Regional Hospital Study

*HCA Affiliated Hospital*



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**Gustavo Ramos MD, William Martin MD**

Departments of Neurosurgery and Radiology, Rio Grande Regional Hospital,  
& Division of Neurosurgery, Health Sciences Center, University of Texas

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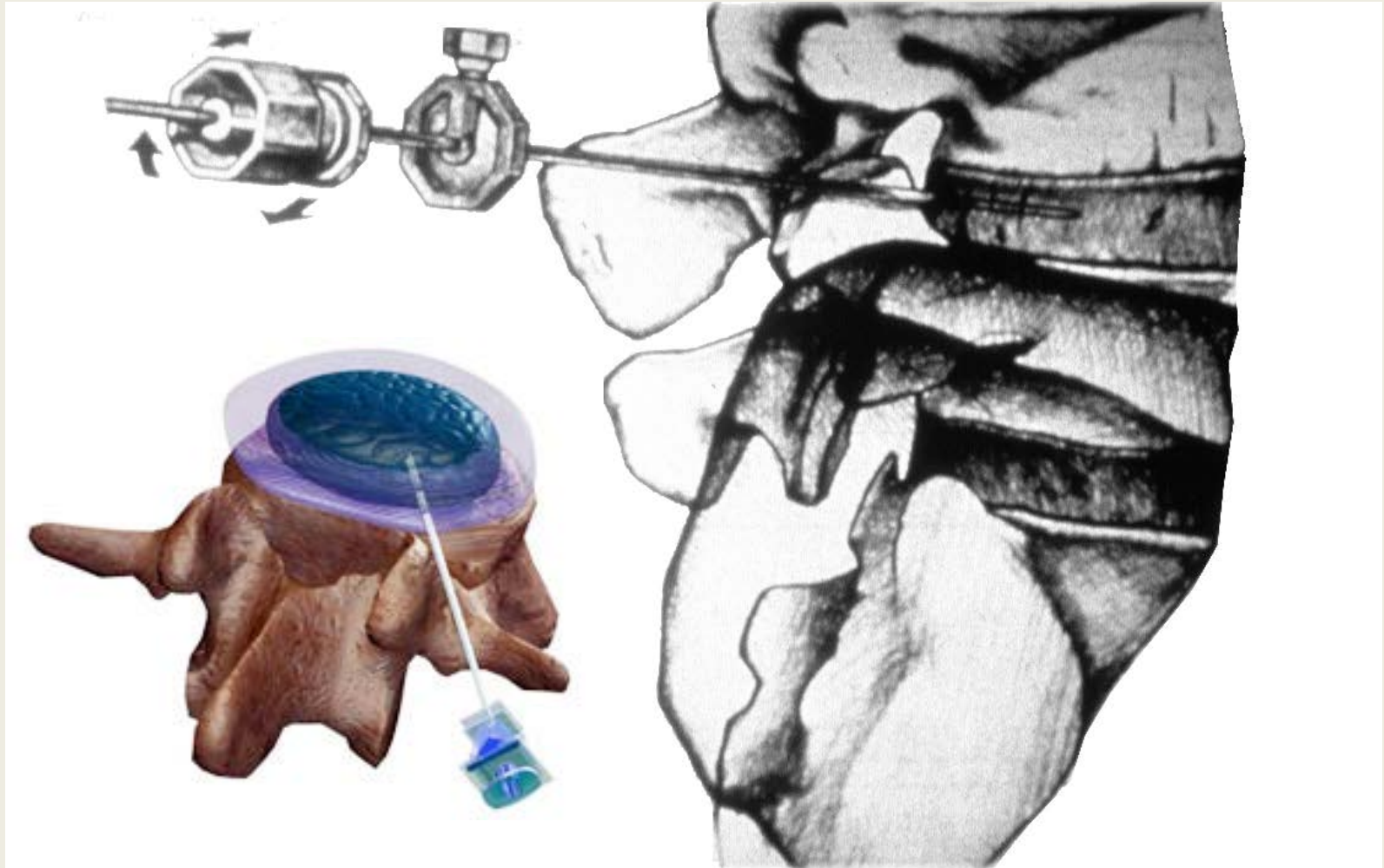
## **Effects of Vertebral Axial Decompression On Intradiscal Pressure**

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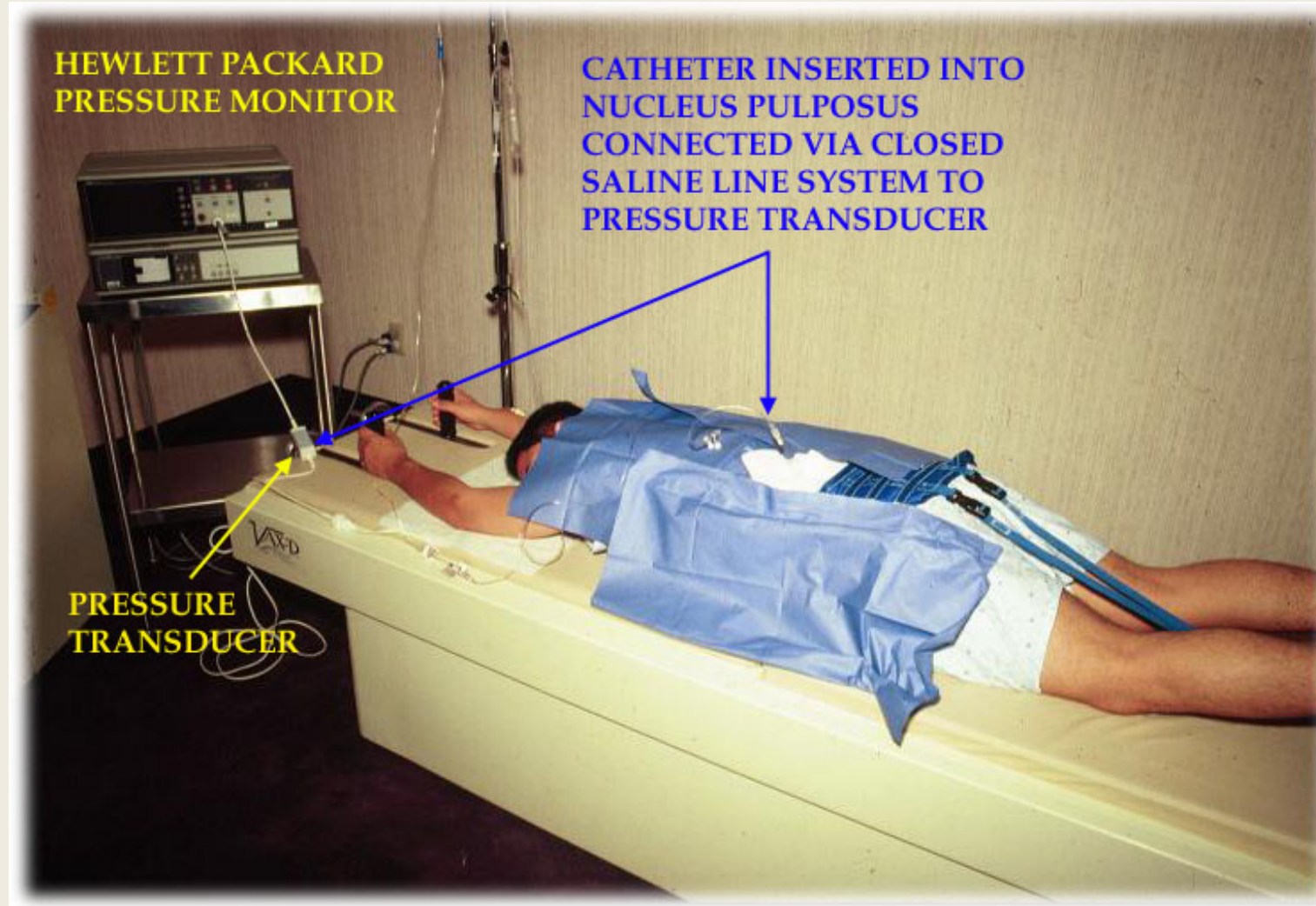
*Journal of Neurosurgery 81: 350-353, 1994*

# ***Intradiscal Pressure Measurements***

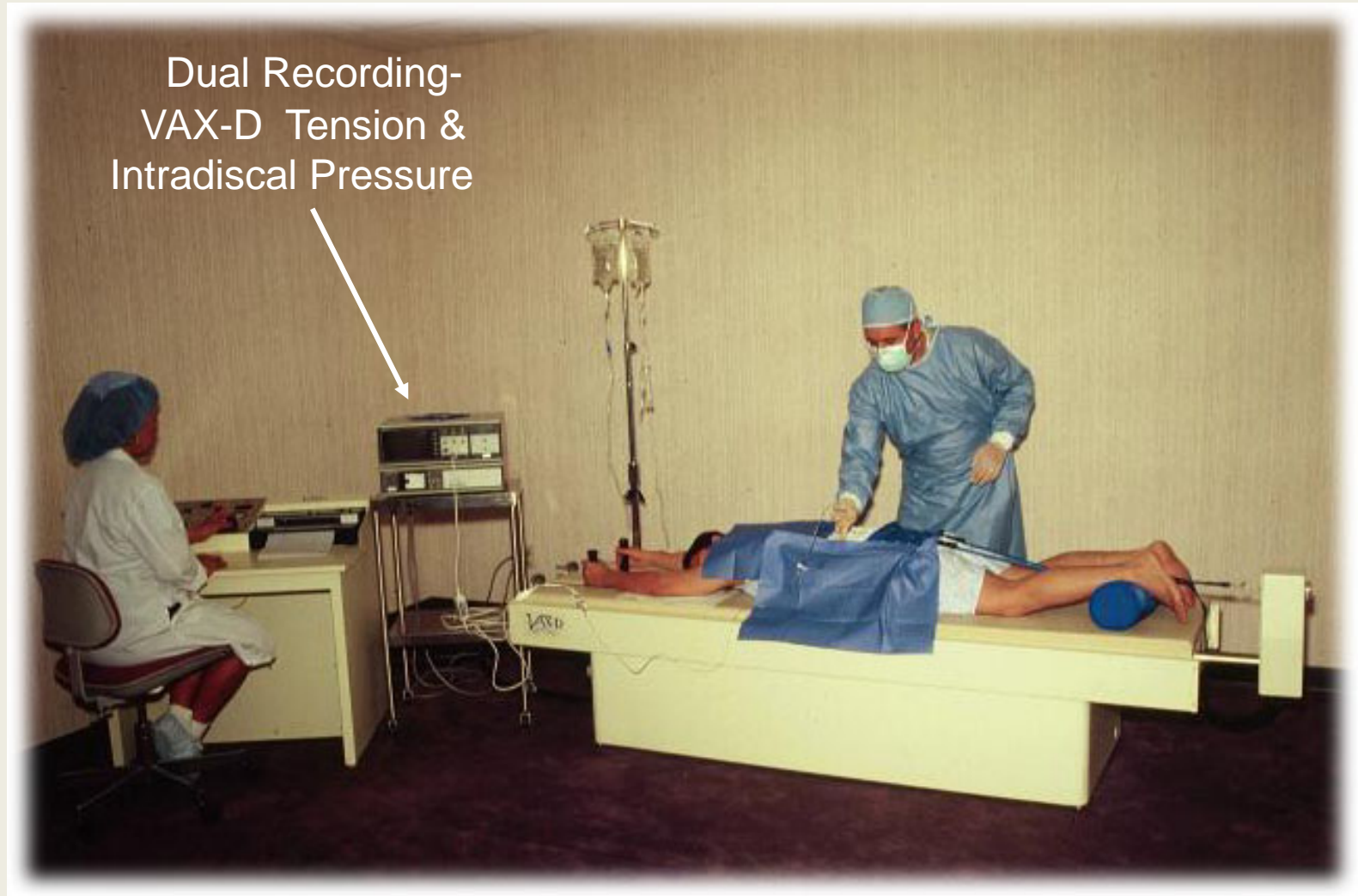
*Catheter Inserted Via A Cannula Into The Nucleus Pulposus*



## RECORDING INTRADISCAL PRESSURE CHANGES DURING VAX-D

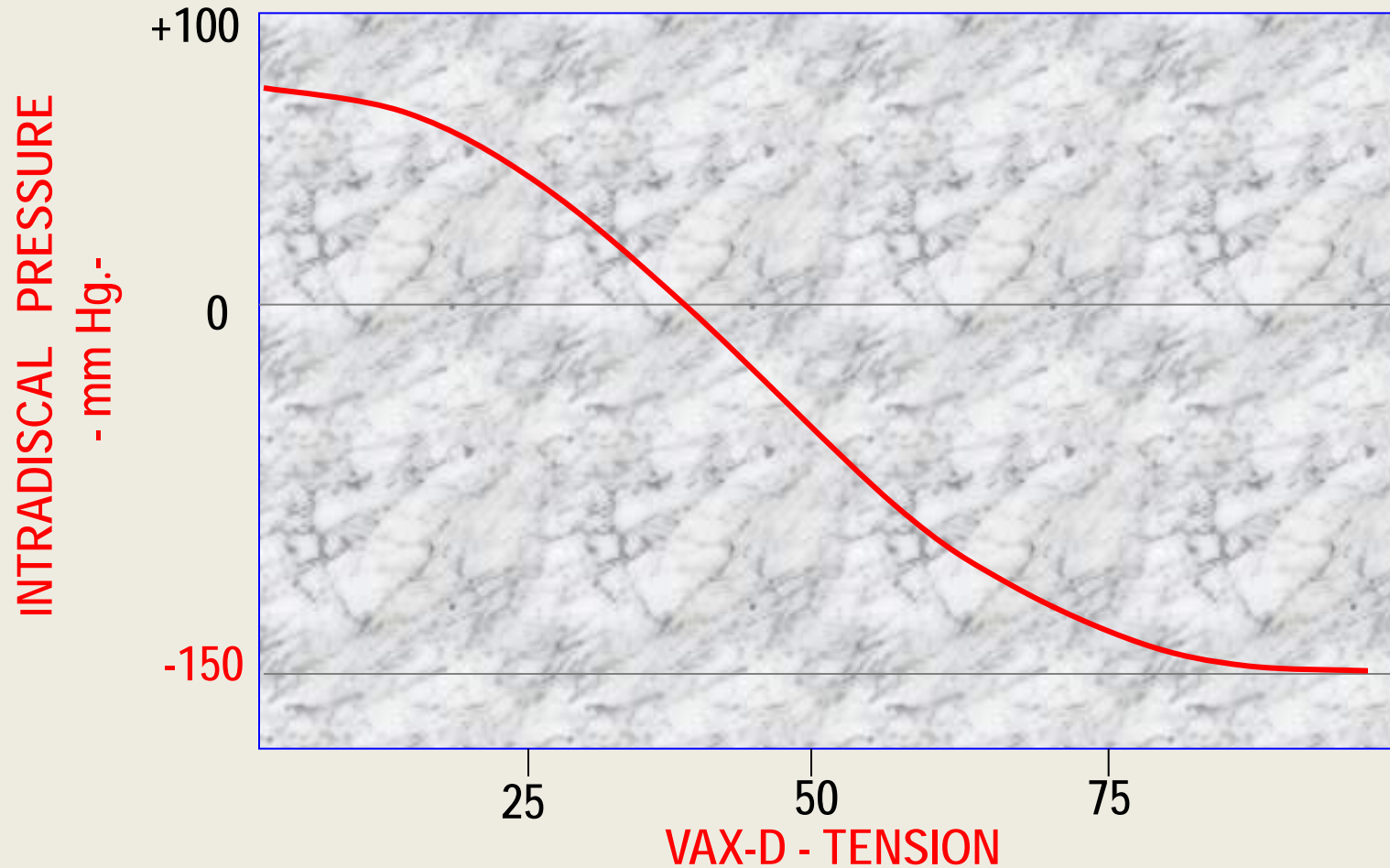


# ***Dr. Ramos Monitoring Disc Pressure and VAX-D Tension***

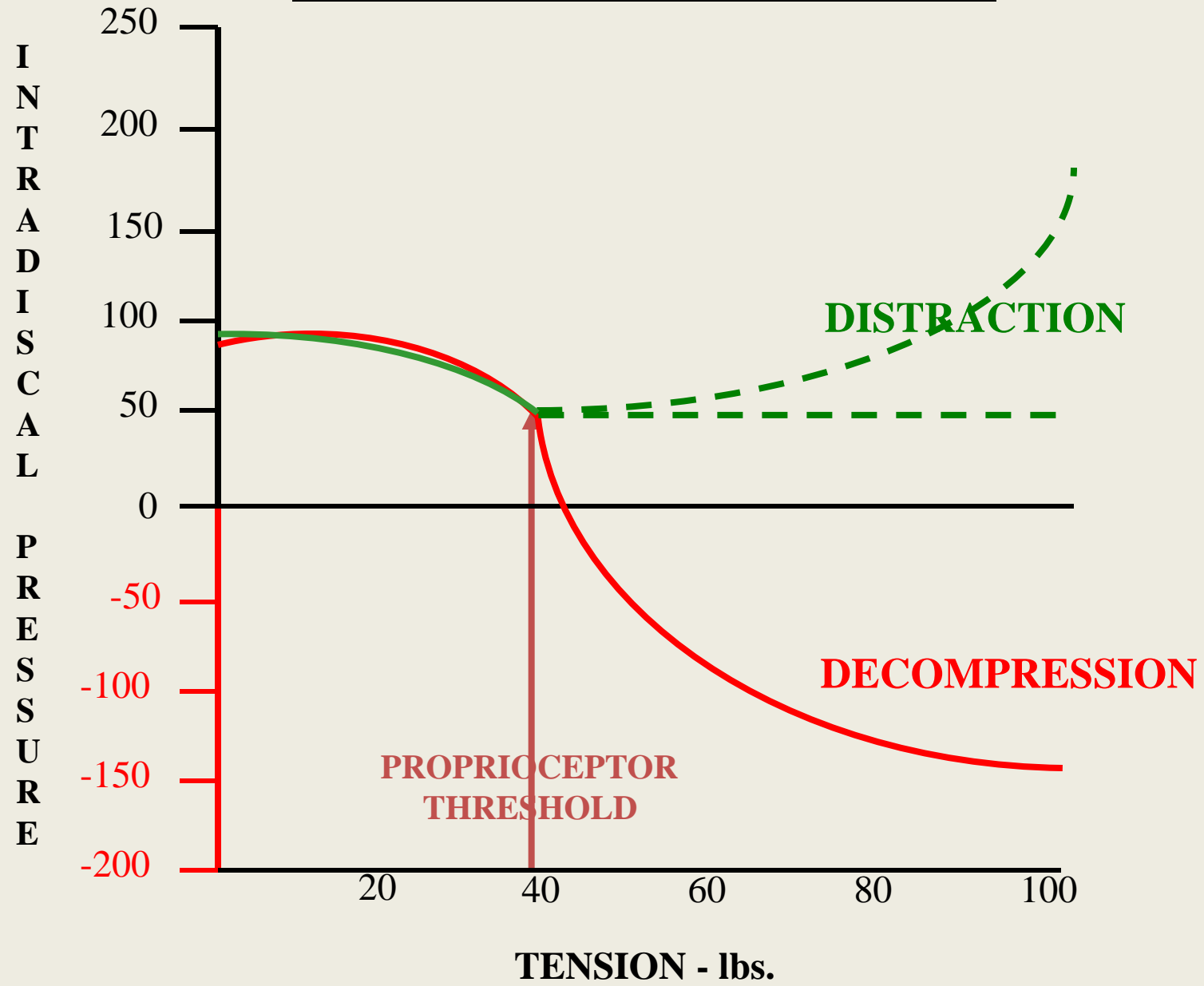


# Intradiscal Pressure Reduced to Negative Levels During VAX-D Treatment

Journal Neurosurgery 81: 350-353, 1994



# DECOMPRESSION vs DISTRACTION





# VAX-D vs. Traction

## VAX-D

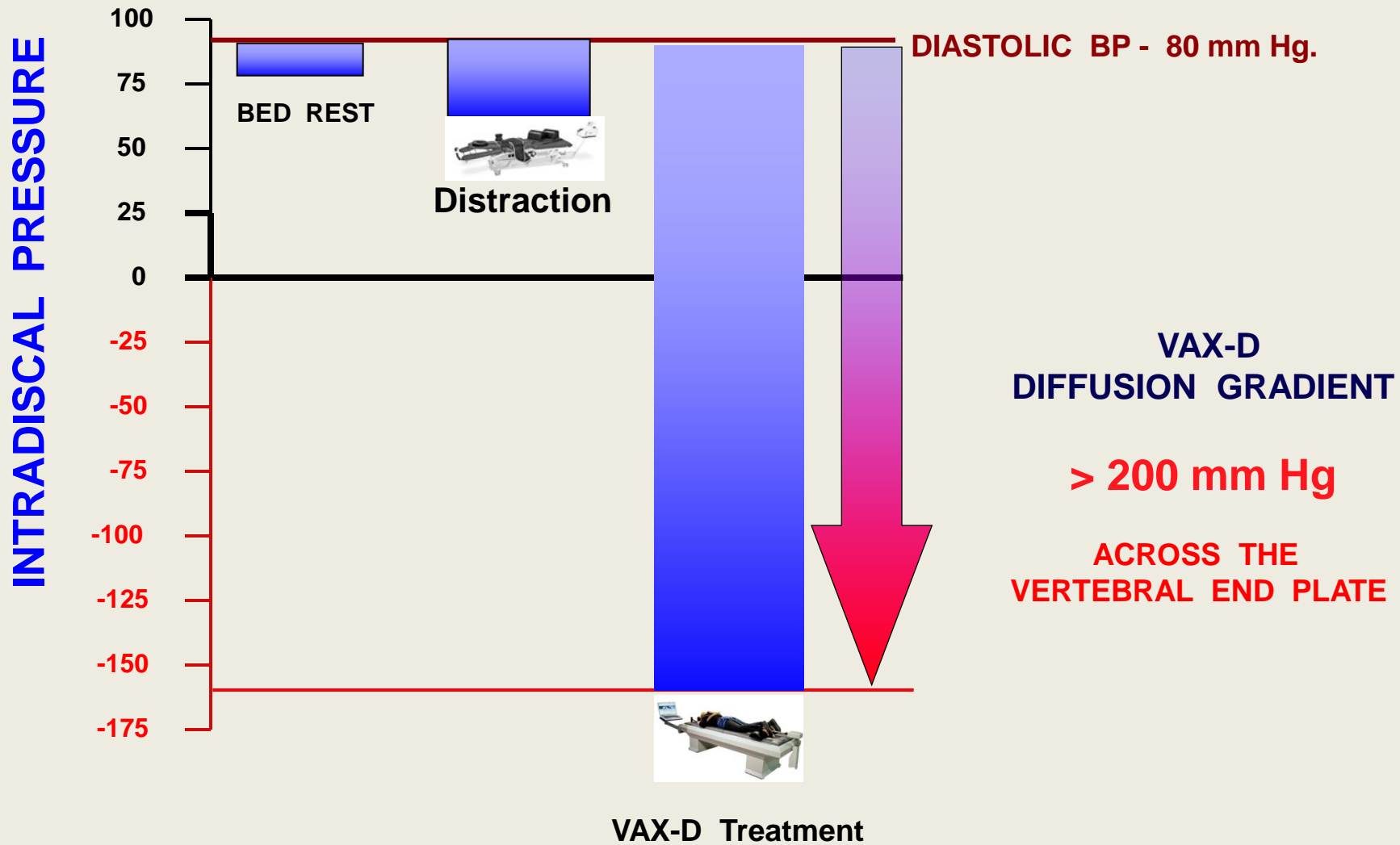
- **Intradiscal Pressure reduced to negative levels (1)**
- **Negative IDP enhances Oxygen and Nutrient diffusion into the disc (3)**
- **Aerobic metabolism fosters bio-physiological functions and cellular repair activity (3,5)**

## Traction

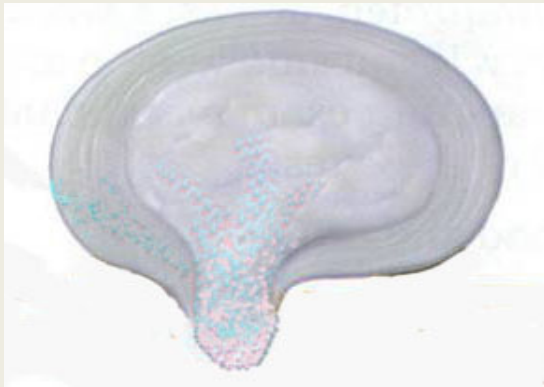
- **Intradiscal Pressure unchanged or increased (2)**
- **Positive IDP inhibits diffusion with lactic acid accumulation (4)**
- **Anaerobic metabolism inhibits cellular activity and repair functions (5)**

1. Effect of Vertebral Axial Decompression On Intradiscal Pressure. *J Neurosurg* 81: 1984.
2. Intervertebral Disc Pressures During Traction. *Scand. J. Rehabil. Med.* 9: 1983
3. An Overview of Vertebral Axial Decompression., *Can. J. Clin. Med.* , 5; 1998.
4. The Effect of Lactate and ph on Proteoglycan and Protein Synthesis rates in the Intervertebral Disc. *Spine*, 17: 1992.
5. Nutrition of the Intervertebral Disc: Solute Transport and Metab., *Connective Tissue Research*,8: 1981

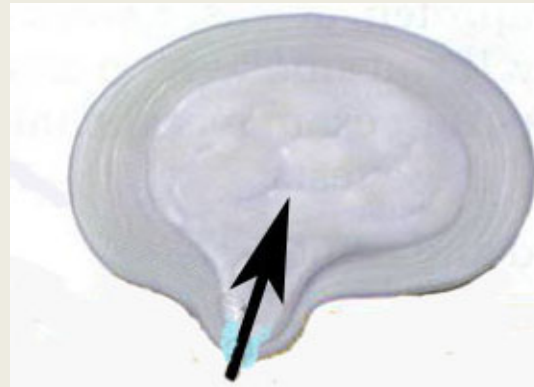
# Diffusion Gradient Into Disc



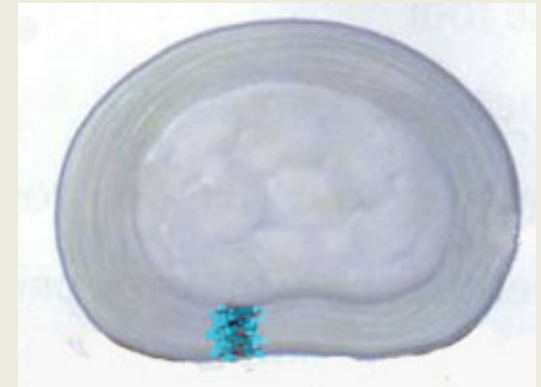
# Vertebral Axial Decompression



**Herniated  
Nucleus  
Pulposus**



**Protrusion  
Retracted by  
Decompression**



**Annular  
Fissure  
Closed**

BEFORE VAX-D

Left posterior  
large extruded disc  
compressing  
thecal sac

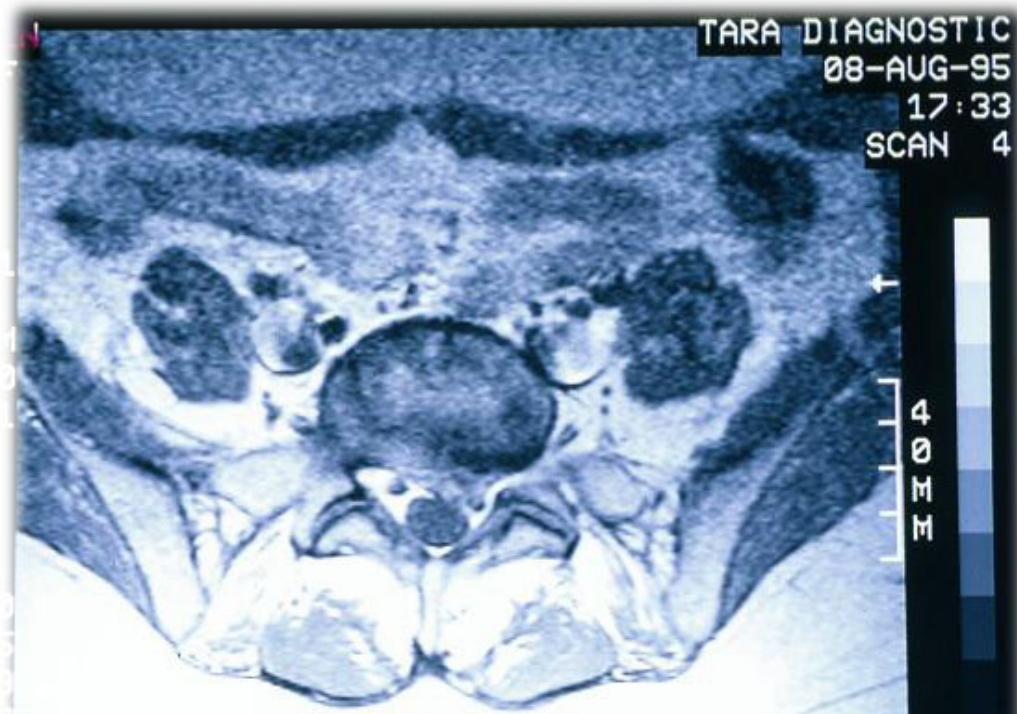


AFTER VAX-D

“ This the most dramatic  
reduction of an extruded  
segment I have seen “

Curvel A. Ferrari MD





## BEFORE VAX-D

Left posterior  
Extruded disc  
compressing &  
retro-displacing  
left nerve root

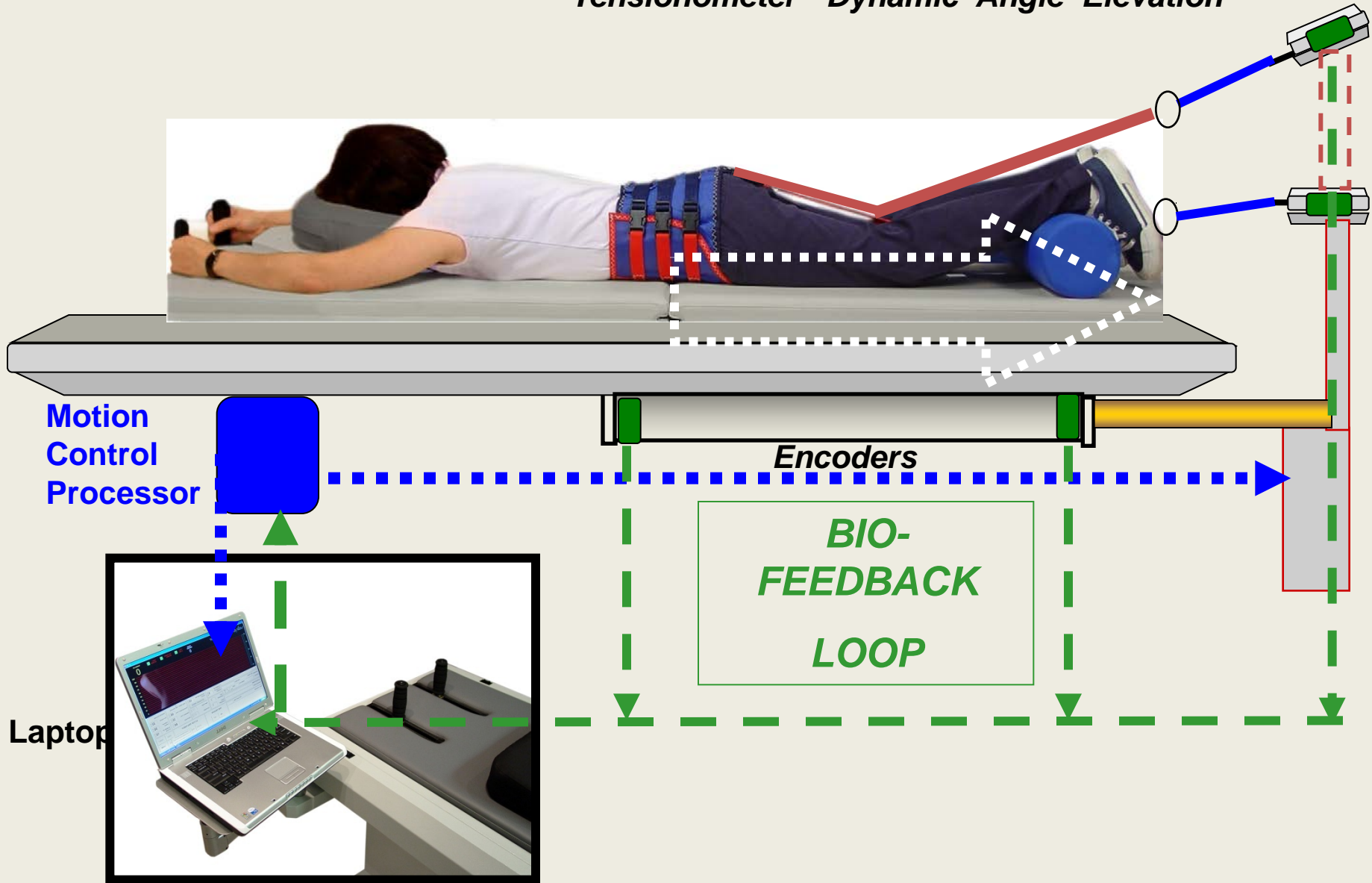


## AFTER VAX-D

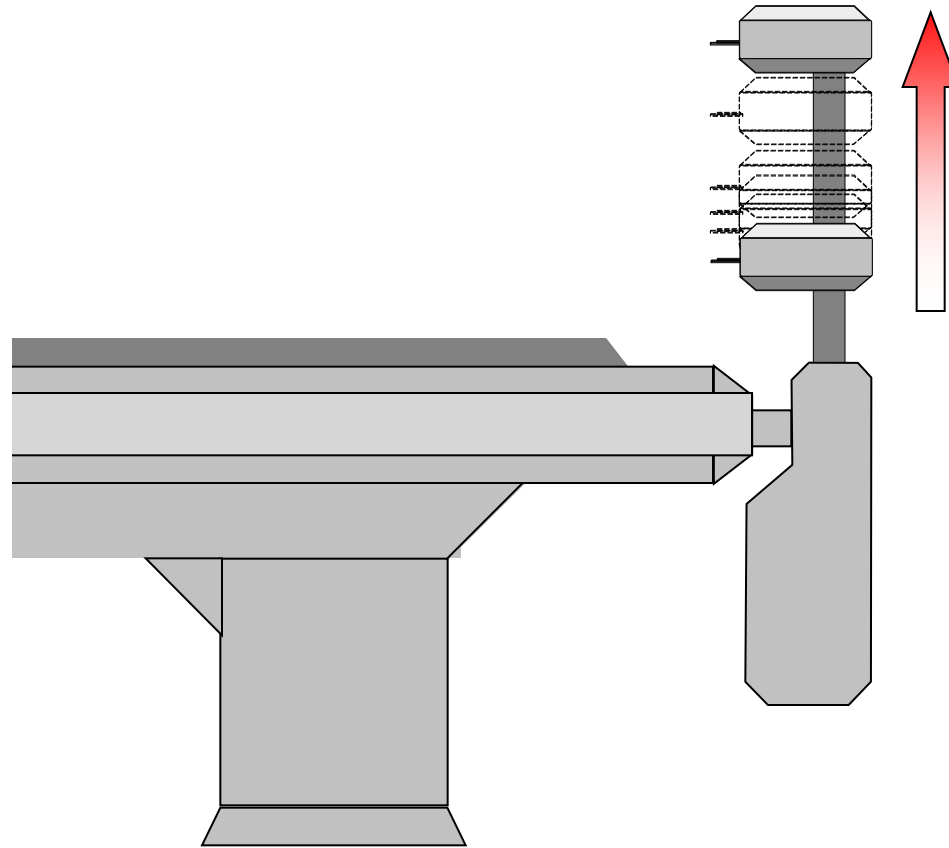
Extruded disc  
retracted  
Left nerve root  
decompressed

Radiologist: Curvel A. Ferrari MD

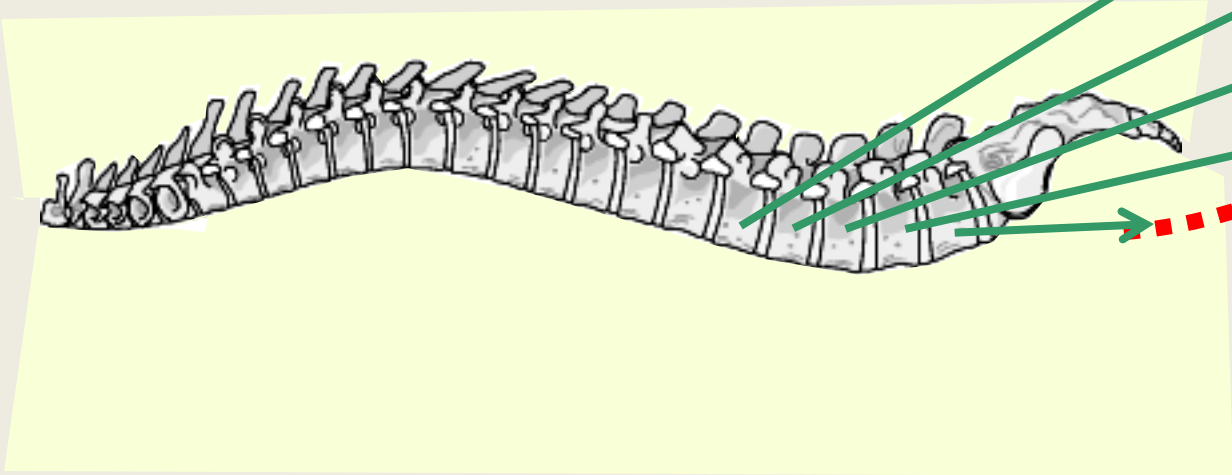
# Tensionometer - Dynamic Angle Elevation



# *Tensionometer Height Adjustable*



*Upward Dynamic Curve  
Shifts Decompression Higher*





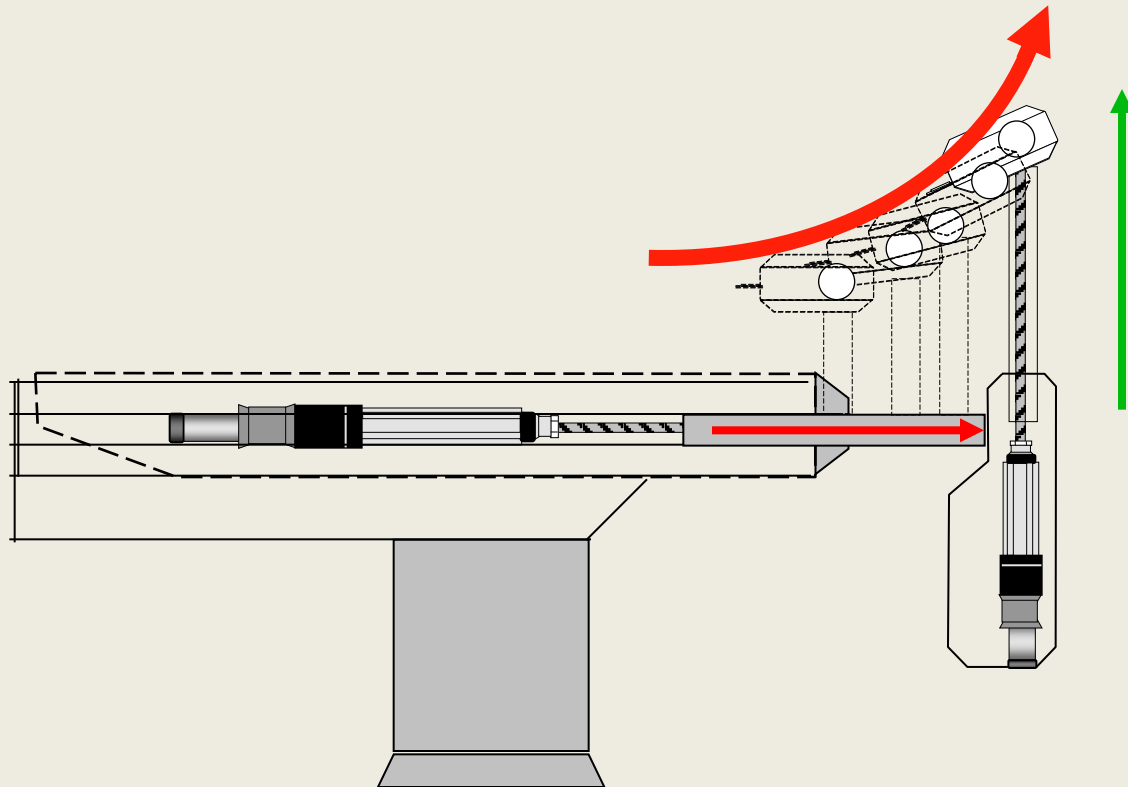


## ***VAX-D Cervical Head Harness***

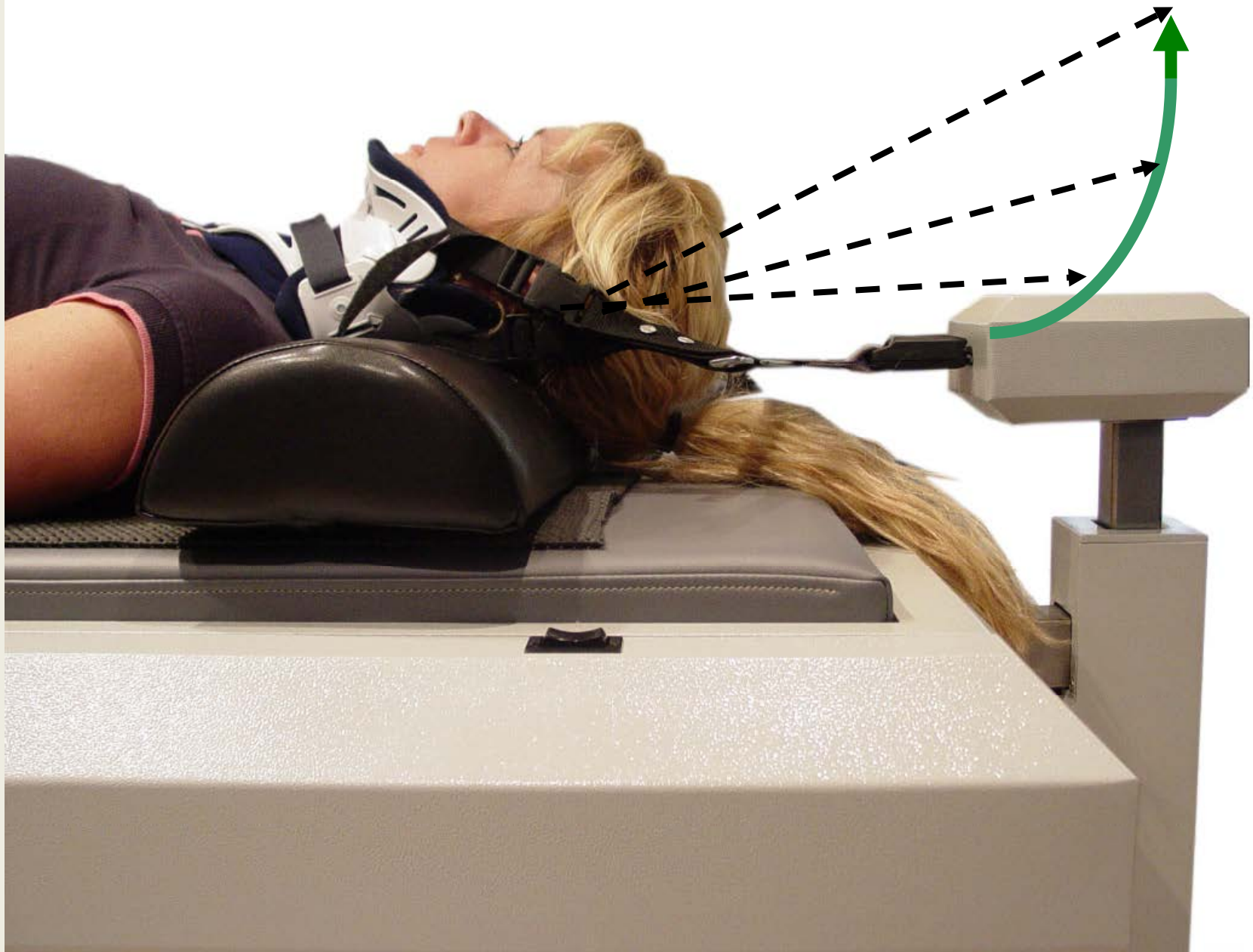
- 1. Distributes the force circumferentially**
- 2. Adjustable ventral and dorsal straps allow adjustment of tension TMJ or Occiput and laterally**
- 3. Provides immobilization when rising from Table and for a brief period post treatment until proprioceptors recover**



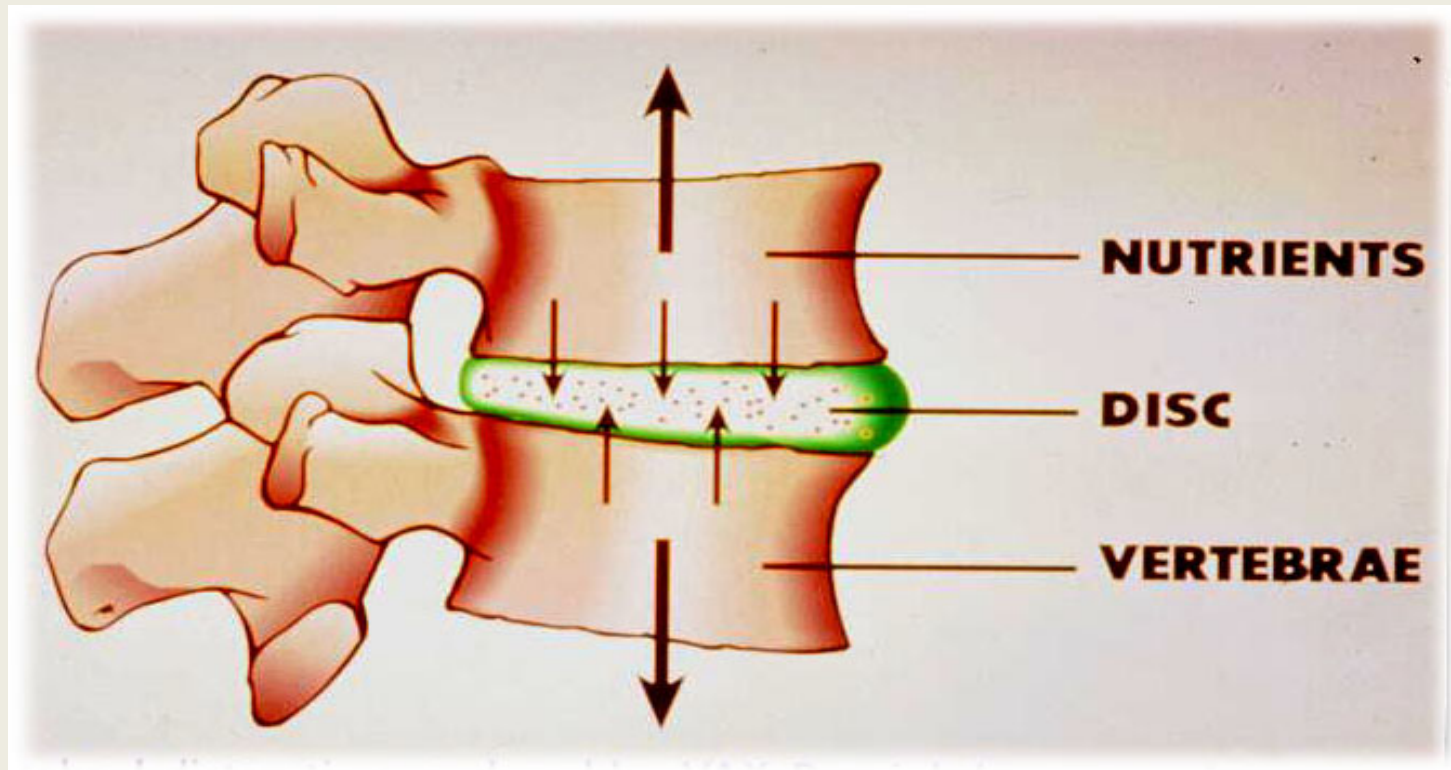
# Dynamic Flexion / Decompression Curve



*DYNAMIC SYNCHRONIZED - FLEXION / DECOMPRESSION*



## **VAX-D DECOMPRESSION**



**“Vertebral disc decompression creates a favorable diffusion gradient across the endplate enhancing disc nutrient transfer promoting the natural healing process”**

***Kirkaldy-Willis - Managing Low Back pain***

## Diffusion Gradient Into Disc

Cellular metabolism in the disc occurs through **glycolysis**; the disc cells *require* **glucose and oxygen** for cellular survival and produces **lactic acid** at high rates.

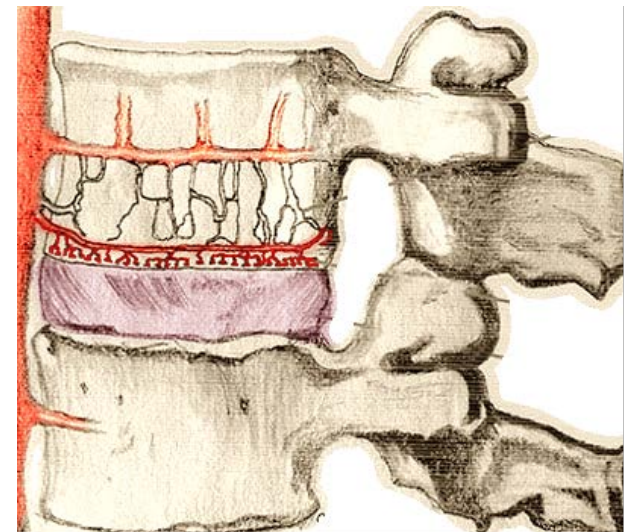
The disc is avascular so the the cells depend on the blood supply from the capillary network at the vertebral endplate, and by the vascular plexus in the annulus.

Small molecules such as **glucose** and **oxygen** reach the disc by diffusion under gradients established by the balance between the rate of transport through the tissue to the cells and the rate of cellular demand.

Lactic acid is removed by the reverse pathway.

Diffusive transport can fall to critical levels with degenerative changes to the endplate.

Loss of nutrient supply can lead to cell death, matrix degradation and hence to disc degeneration.



# INTERNAL DISC DISRUPTION VAX-D PROTOCOL

## METHYLPREDNISOLONE - 4 TO 8 MG.

Taken orally 2 to 3 hours before each VAX-D session

First week - One dose each day

Second week - One dose Monday, Wednesday & Friday

## DOXYCYCLINE - 200 MG. (Matrix Metalloproteinase Inhibitor)

Taken orally 2 to 3 hours before each VAX-D session

One dose each day

NB: Doxycycline should not be used for patients allergic to Tetracyclines

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*For optimum absorption: Medications should be ingested on an empty stomach  
No Antacids with Doxycycline*

CASE

RI J 48/M  
MI041980 1824.102  
3/11  
4:30 (8, 2:15)  
NEUTRAL/SIT

M 481  
W 902  
08:47 AM  
Oct-02-2004

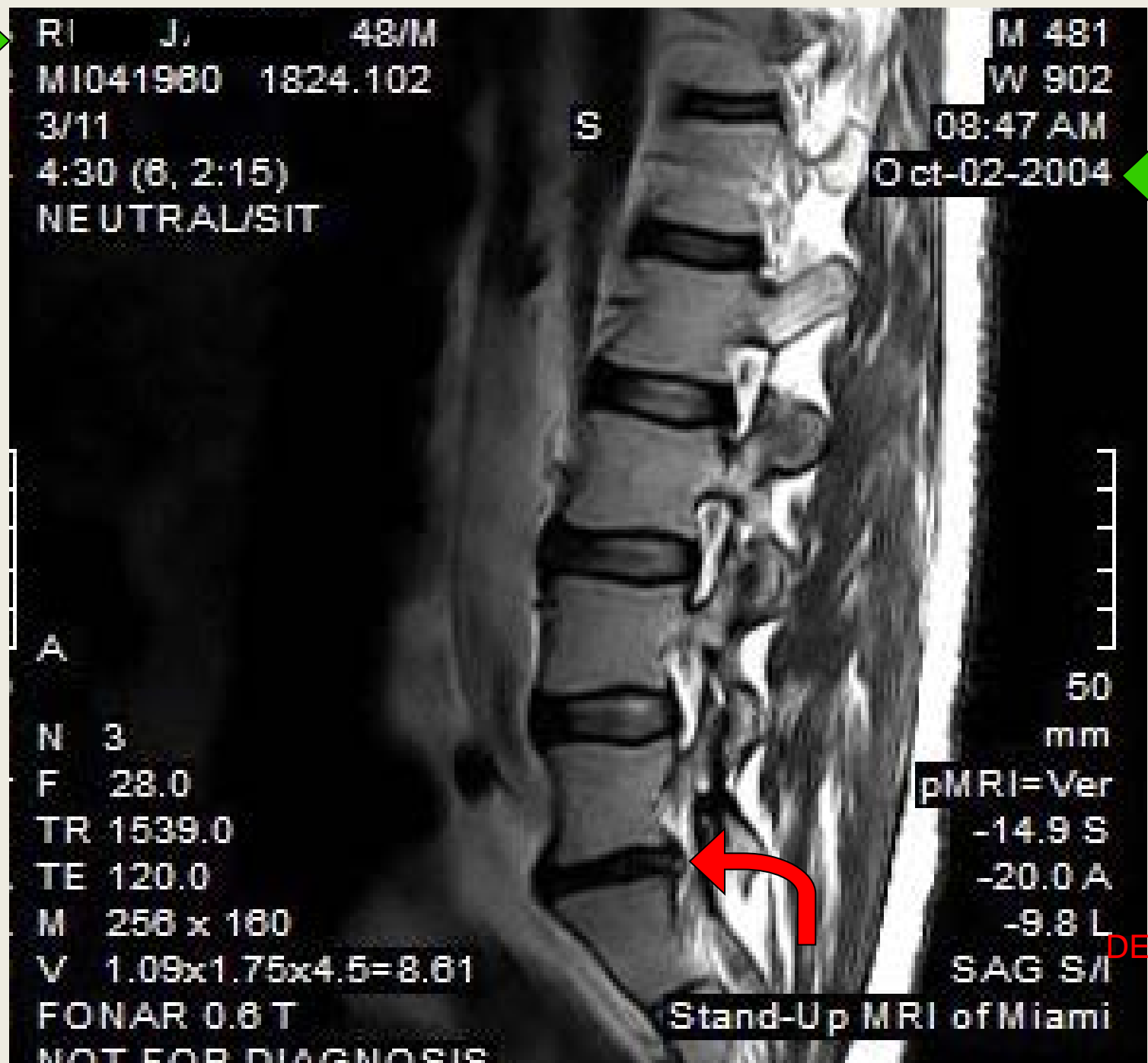
DATE  
BEFORE  
VAX-D

A  
N 3  
F 28.0  
TR 1539.0  
TE 120.0  
M 256 x 180  
V 1.09x1.75x4.5=8.61  
FONAR 0.8 T  
NOT FOR DIAGNOSIS

pMRI=Ver  
-14.9 S  
-20.0 A  
-9.8 L  
SAG S/I

IDD  
DESICCATION

Stand-Up MRI of Miami



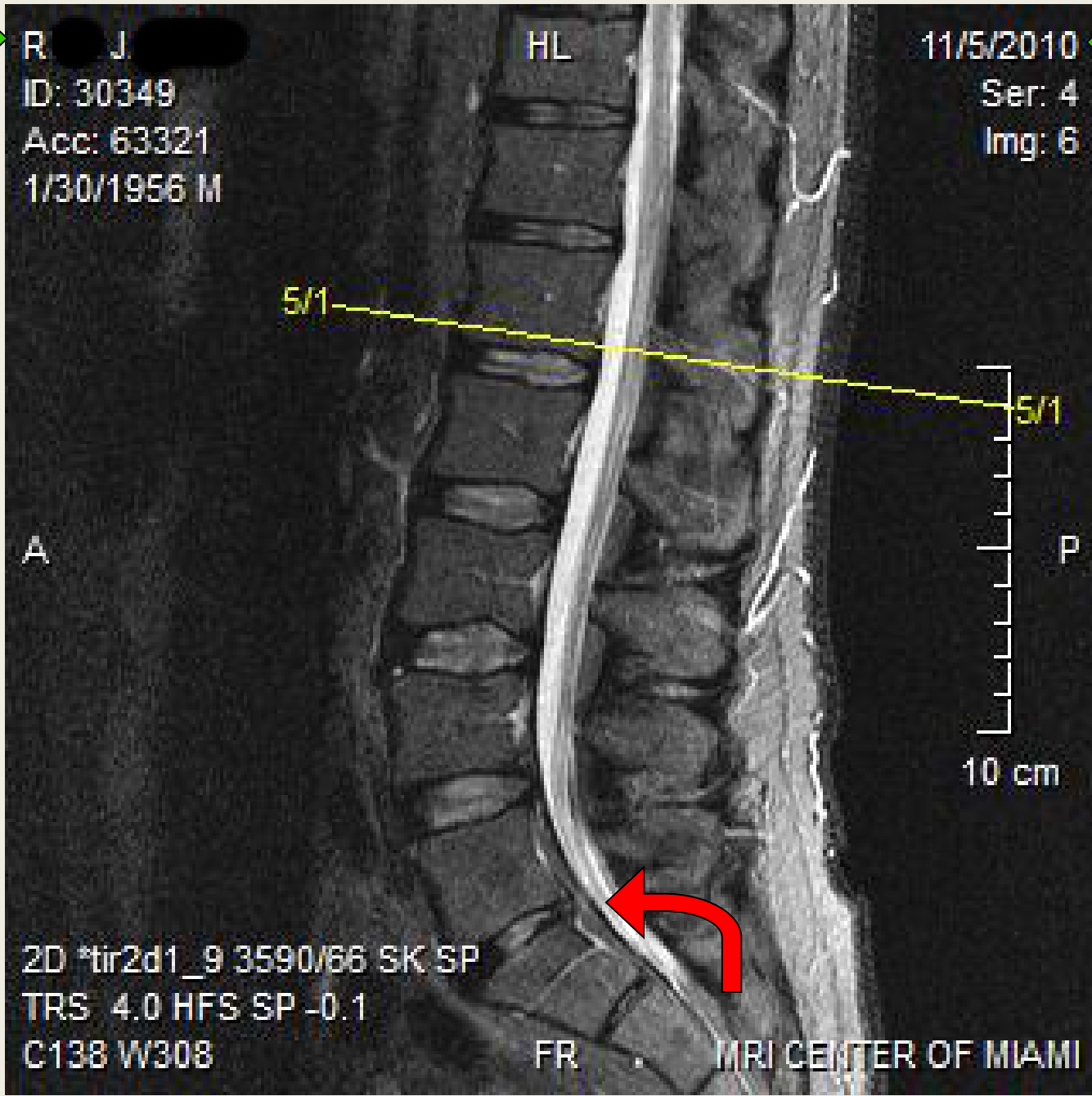


CASE

R J  
ID: 30349  
Acc: 63321  
1/30/1956 M

11/5/2010  
Ser: 4  
Img: 6

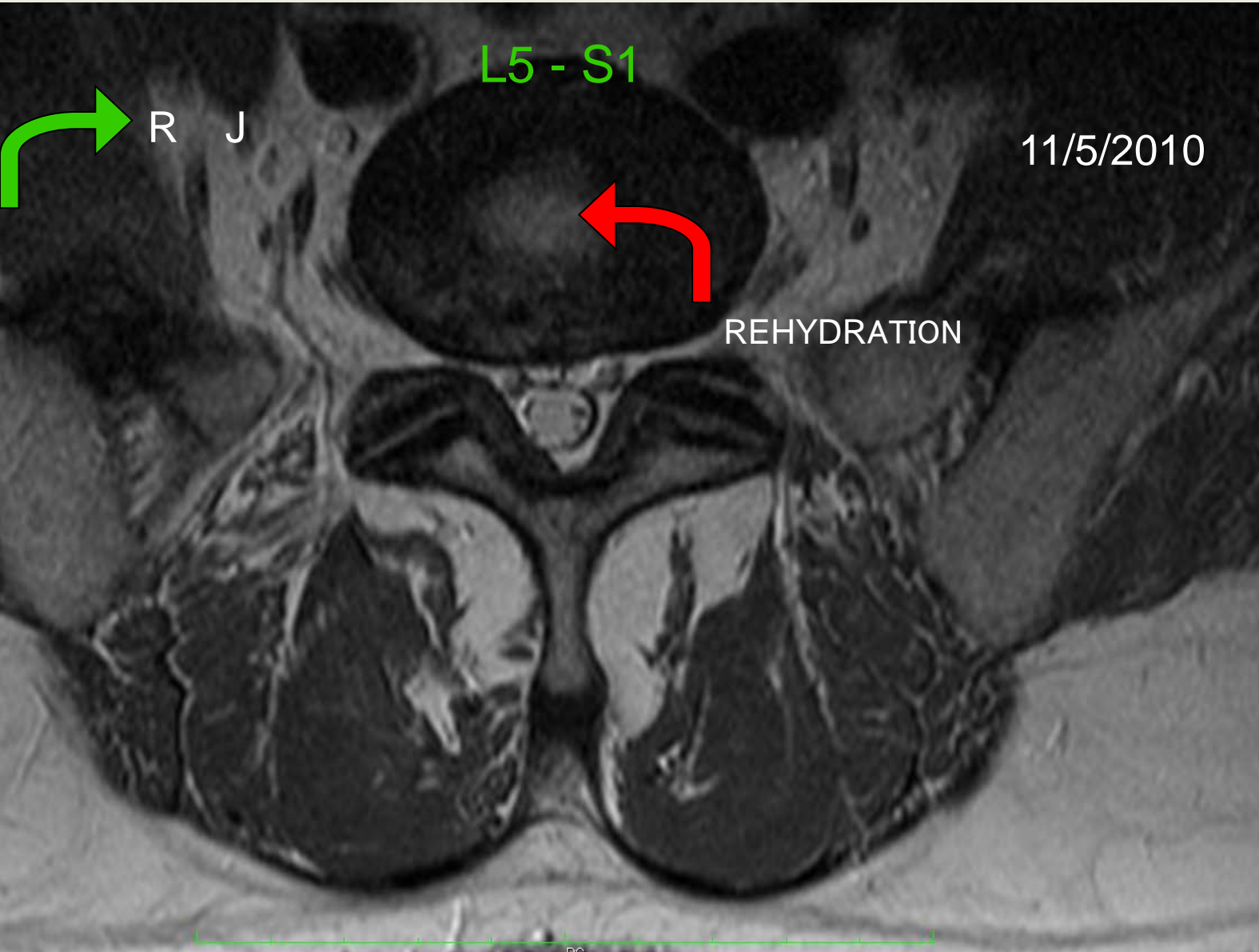
DATE  
AFTER  
VAX-D



2D \*tir2d1\_9 3590/66 SK SP  
TRS 4.0 HFS SP -0.1  
C138 W308

FR MRI CENTER OF MIAMI

REHYDRATION  
L5 - S1 DISC



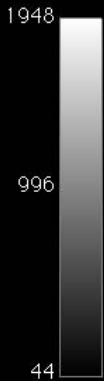
L5 - S1

R J

11/5/2010

REHYDRATION

2010  
JR L5-S1



TE: 36 TR: 5  
FS:  
11/8/10 1:47:50  
Mod: k 0

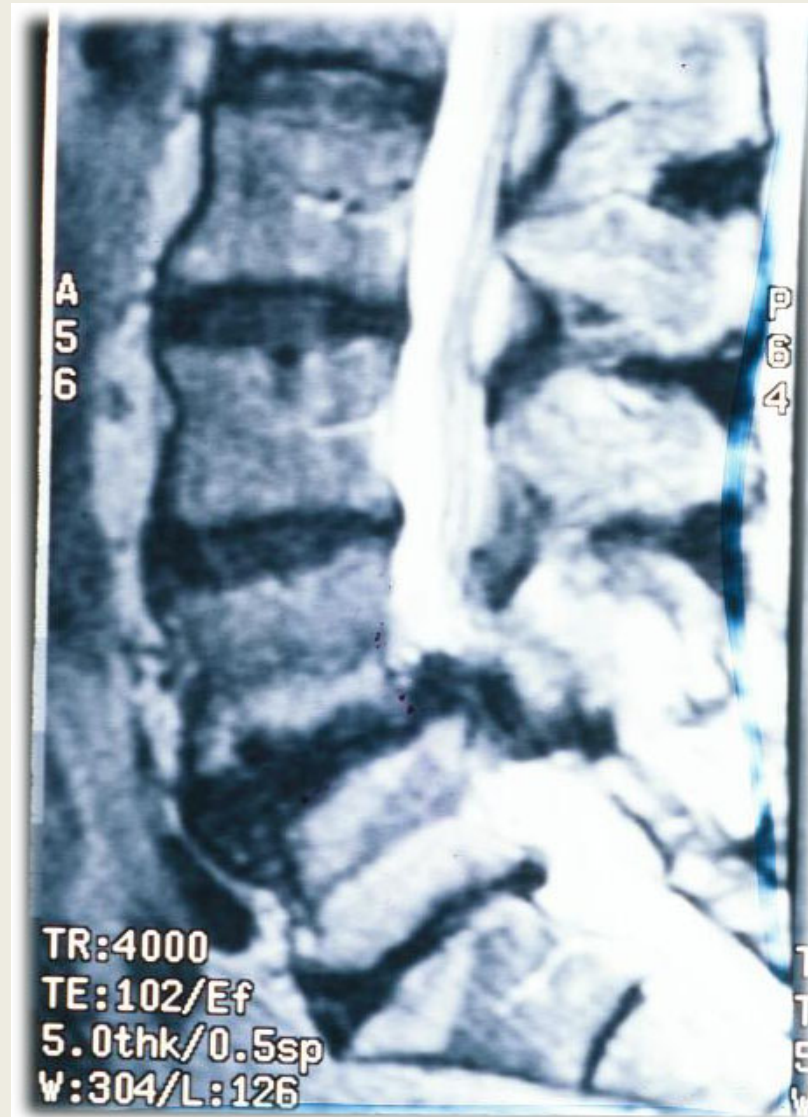
## **CONTRAINDICATIONS**

- 1. Fracture**
- 2. Neoplasm**
- 3. Ankylosing Spondylitis**
- 4. Cauda Equina Syndrome**
- 5. Osteoporosis**
- 4. IDET - Intradiscal Electrothermal Annuloplasty**

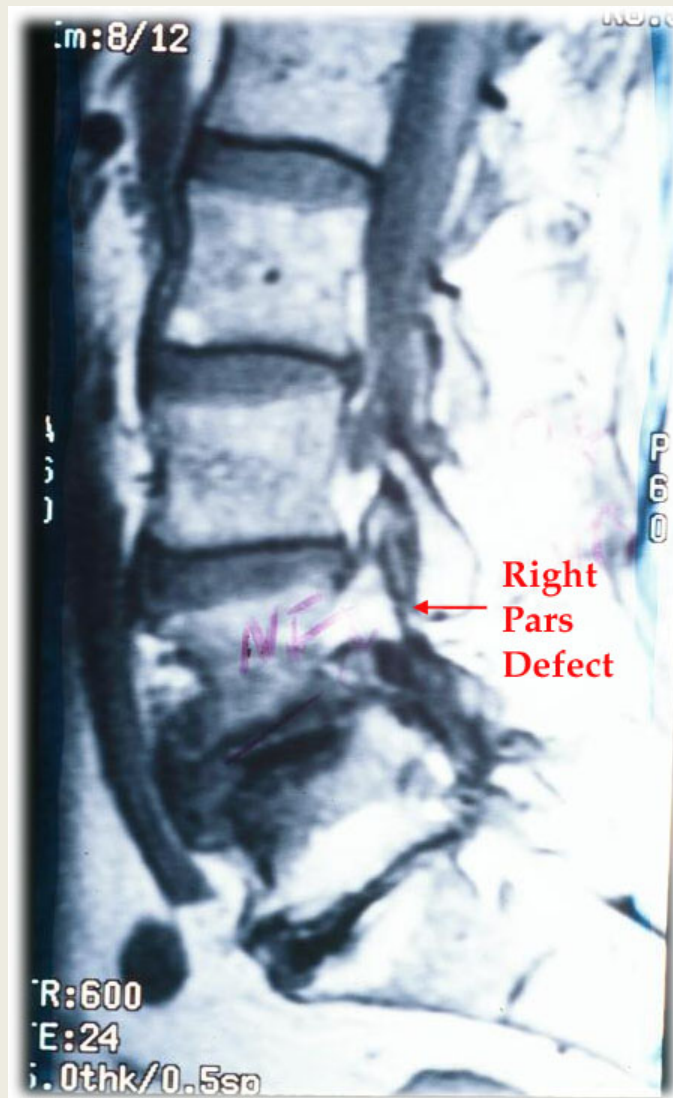
## **PRECAUTIONS**

- 1. Unstable Spondylolisthesis**
- 2. Arthrodesis with Instrumentation**
- 3. Rotator Cuff Tear**

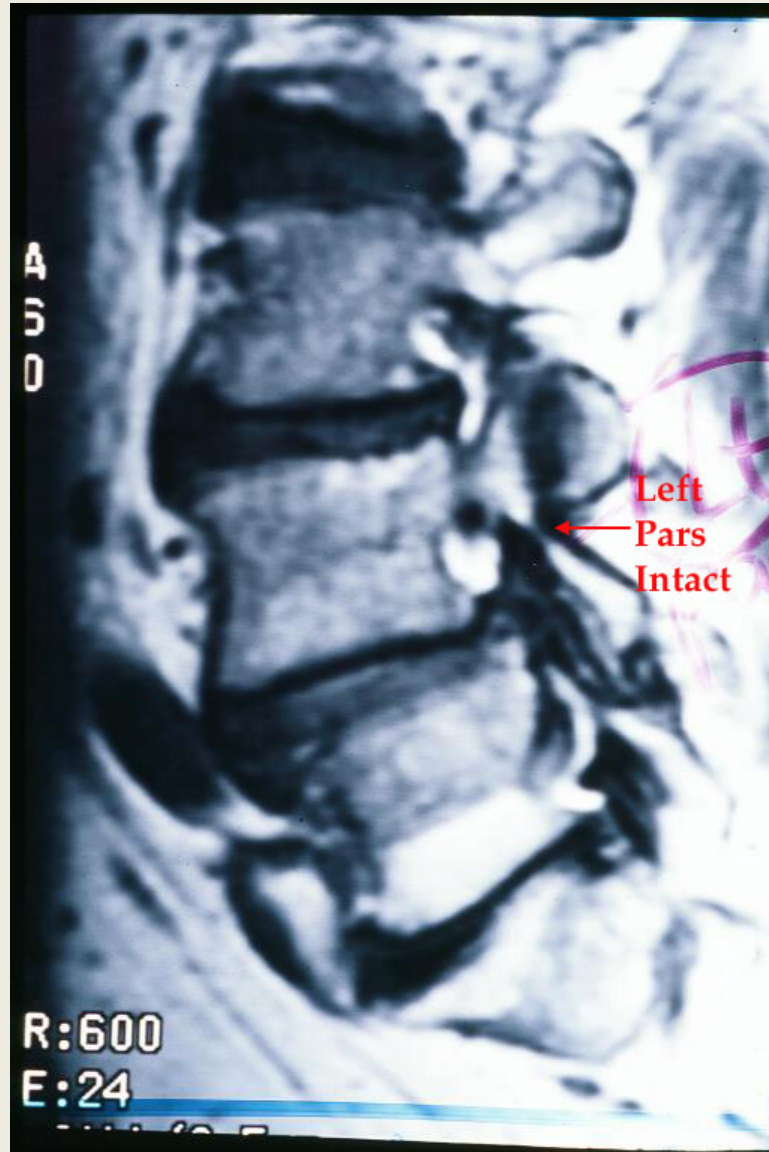
# SPONDYLOLISTHESIS



# SPONDYLOLYSIS



# SPONDYLOLYSIS



# ***VAX-D Genesis G2 • FDA 510(k) 071347***

## **INTENDED USE**

The ***VAX-D Genesis G2 Dynamic Logarithmic Spinal Decompression System*** is designed to relieve pressure on structures that may be causing low back pain, sciatica and neck pain. It relieves the pain associated with herniated discs, degenerative disc disease, posterior facet syndrome and radicular pain. This is achieved non-surgically through the application of logarithmic distraction tensions applied to the patient according to the VAX-D protocol.

## **SUMMARY**

The system is designed to apply tensions to the spine in a smooth logarithmic time/force curve that allows trunk and paraspinal muscles to relax. The operating principles of the VAX-D Genesis G2 permit the application of accurately controlled distraction tensions to the lumbar and cervical spine in order to decompress the intervertebral discs and spinal structures.

The  
United  
States  
of  
America



## The Commissioner of Patents and Trademarks

*Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.*

*Therefore, this*

### United States Patent

No. 6,039,737

#### OPERATION OF A VERTEBRAL AXIAL DECOMPRESSION TABLE

*Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States Of America for the term set forth below, subject to the payment of maintenance fees as provided by law.*

*If this application was filed prior to June 8, 1995 the term of this patent is the longer of seventeen Years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.*

*If this application was filed on or after June 8, 1995 the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S. C 120, 121 or 365(f), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extension.*





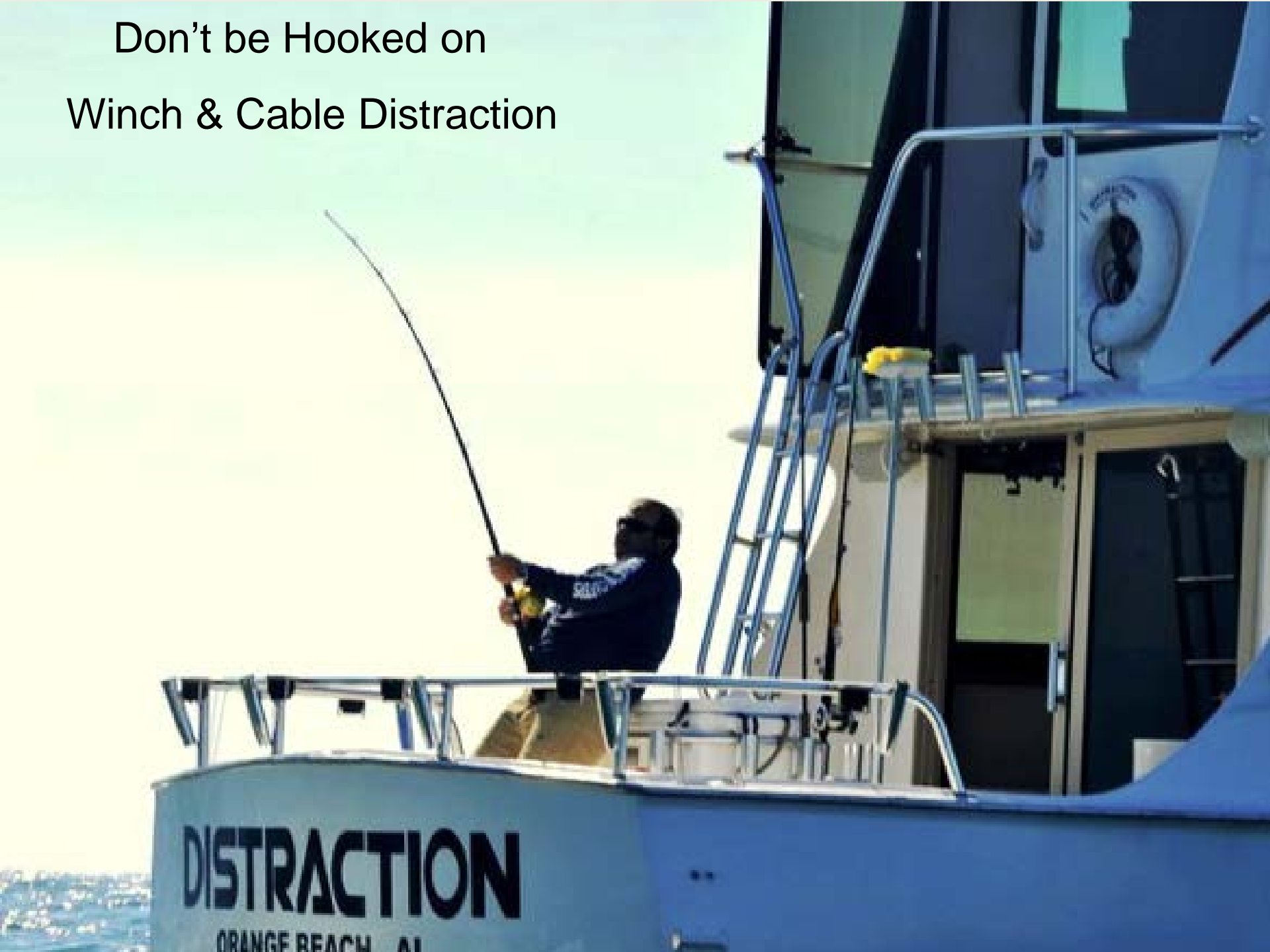
**DISTRACTION WINCH & CABLE**



# Distraction Winch & Cable



Don't be Hooked on  
Winch & Cable Distraction



# Clinical Studies & Publications on VAX-D

## Outcomes After A Prone Lumbar Traction Protocol for Patients With Activity-Limiting Low Back Pain: A Prospective Case Series Study

Beattie PF., Nelson R., Michener L., Cammaratta J., Donely J.  
*Arch Phys Med Rehabil Vol 89, February 2008*

## Short And Long-Term Outcomes Following Treatment with the VAX-D Protocol for Patients with Chronic, Activity Limiting Low Back Pain

Beattie PF., Nelson R., Michener L., Cammarata J., Donely J.  
*Journal of Orthopaedic & Sports Physical Therapy, Volume 35, Number 1, January 2005*

## Efficacy of Vertebral Axial Decompression (VAX-D) on Chronic Low Back Pain: A Study of Dosage Regimen

Ramos G., MD,  
*Journal of Neurological Research, Volume 26, April 2004*

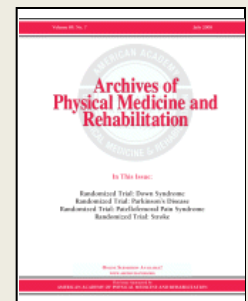
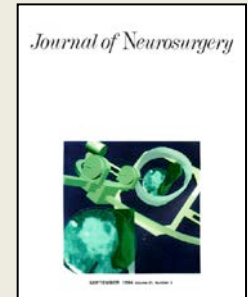
**Effects of Vertebral Axial Decompression On Intradiscal Pressure.** Ramos G., MD, Martin W., MD,  
*Journal of Neurosurgery 81: 350-353, 1994*

## A Prospective Randomized Controlled Study of VAX-D and TENS for the Treatment of Chronic Low Back Pain

Sherry E., MD FRACS, Kitchener P., MB, BS FRANZCR, Smart R., MB, Ch.B  
*Journal of Neurological Research Volume 23, No 7, October 2001*

## Vertebral Axial Decompression Therapy for Pain Associated with Herniated or Degenerated Discs or Facet Syndrome: An Outcome Study

Gose E., Ph.D, Naguszewski W., MD, Naguszewski R., MD,  
*Journal of Neurological Research, Volume 20, No 3, April 1998.*  
*an Journal of Clinical Medicine Vol. 6, No 1, January 1999*



# Clinical Studies & Publications on VAX-D

## Dermatosomal Somatosensory Evoked Potential Demonstration of Nerve Root Decompression After VAX-D Therapy

Naguszewski W., MD, Naguszewski R., MD, Gose E., Ph.D

*Journal of Neurological Research Vol 23 , No 7, October 2001*

## The Effects of Vertebral Axial Decompression On Sensory Nerve Dysfunction In Patients with Low Back Pain and Radiculopathy

Tilaro F., MD, Miskovich D. MD

*Canadian Journal of Clinical Medicine Vol. 6, No 1, January 1999*

## VAX-D Reduces Chronic Discogenic Low Back Pain- 4 year Study

Odell R., MD. Ph.D, Boudreau D. DO

*Anesthesiology News, Volume 29, Number 3 , March 2003*

## Vertebral Axial Decompression

Tilaro F MD,.

*European Musculoskeletal Review 2007; Issue 2, 2007*

## Prospective Randomized Study of VAX-D Therapy for Acute Low Back Distress

Peerless S., MD. FRCP, Meissner L., MD, FRCP

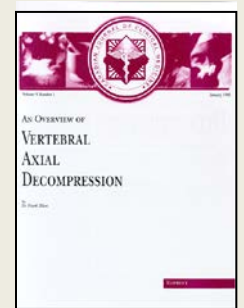
Barnett H. J.M., MD. FRCP, Stiller C. R., MD, FRCP

*The John P. Robarts Institute, University Hospital at London University of Western Ontario, Canada*

## An Industry Based, Retrospective, Cost Analysis of Vertebral Axial Decompression (VAX-D) VS. Surgery For Lumbar Disc Disease: 10 Case Studies

David C. Duncan, MD, Don Keenan, SPHR, Ph.D.

*Sinclair Oil Corporation Study, Tulsa Oklahoma*





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patients...

evidence based  
Medicine.

vaxi-D<sup>®</sup>