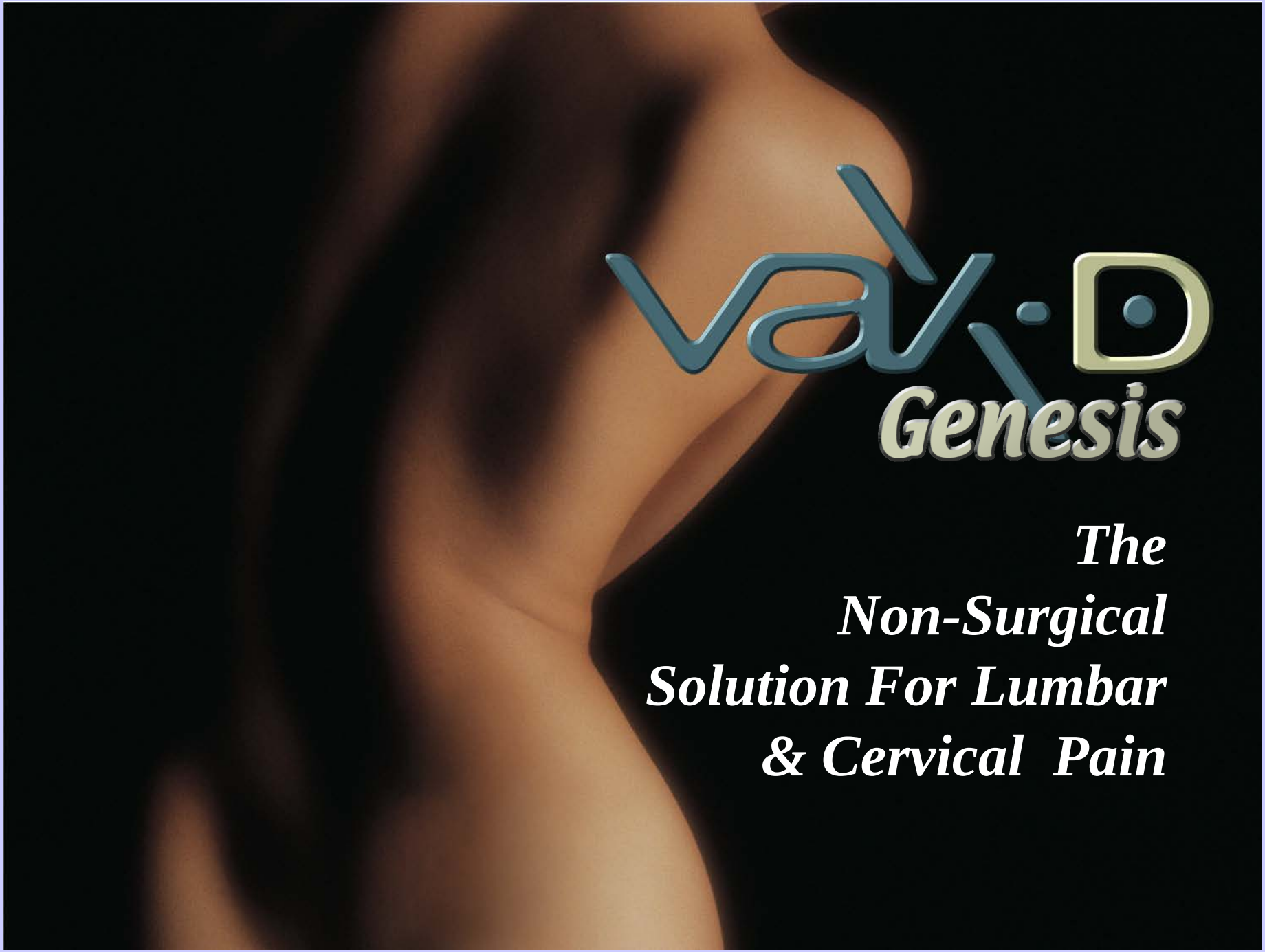

vax·D
Genesis
The
Non-Surgical
Solution For Lumbar
& Cervical Pain

Consider These Facts On

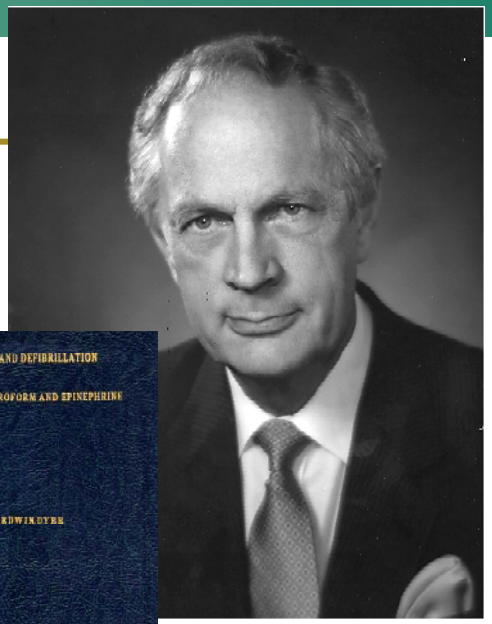
Back Pain & Back Surgery…

FACTS:

- More money is spent on the treatment of chronic pain than is spent on heart disease, AIDS and cancer combined.
- 5.4 million Americans are disabled annually due to back pain.
- 70% of patients who had back surgery still complained of back pain. 23% complained of constant pain, and 35% were still under treatment.
- The average cost for back surgery is about $40,000.00
- Only 37% of patients undergoing their first back surgery returned to work. Only 27% of patients with more than one back surgery return to work.

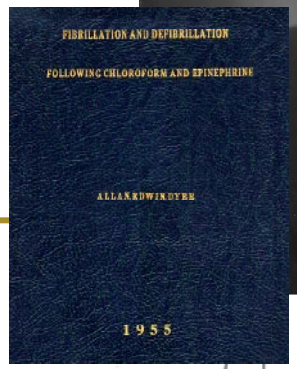
Allan E. Dyer, B.Sc., Phm. B., M.D. Ph.D.

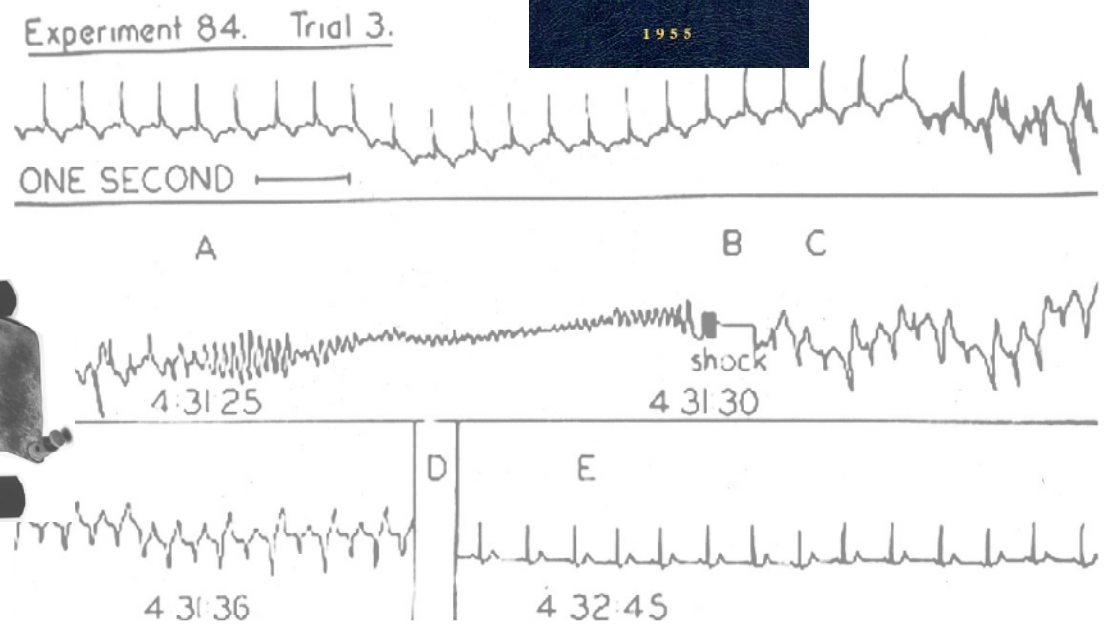
Deputy Minister of Health, Ontario Canada 1978-1988
Inventor of Non-Surgical Spinal Decompression



Ph. D. Thesis

Trans-Thoracic Cardiac Defribillation 1955





Rio Grande Regional Hospital Study

HCA Affiliated Hospital

Gustavo Ramos MD, William Martin MD

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

Effects of Vertebral Axial Decompression On Intradiscal Pressure

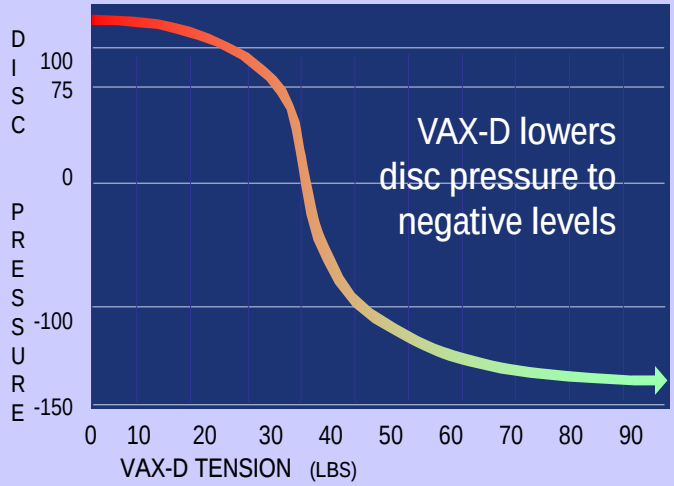
Journal of Neurosurgery 81: 350-353, 1994

The Birth of A Phenomenon:

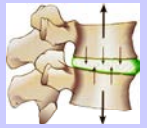
The Discovery of Spinal Decompression

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 SPINAL DECOMPRESSION.**

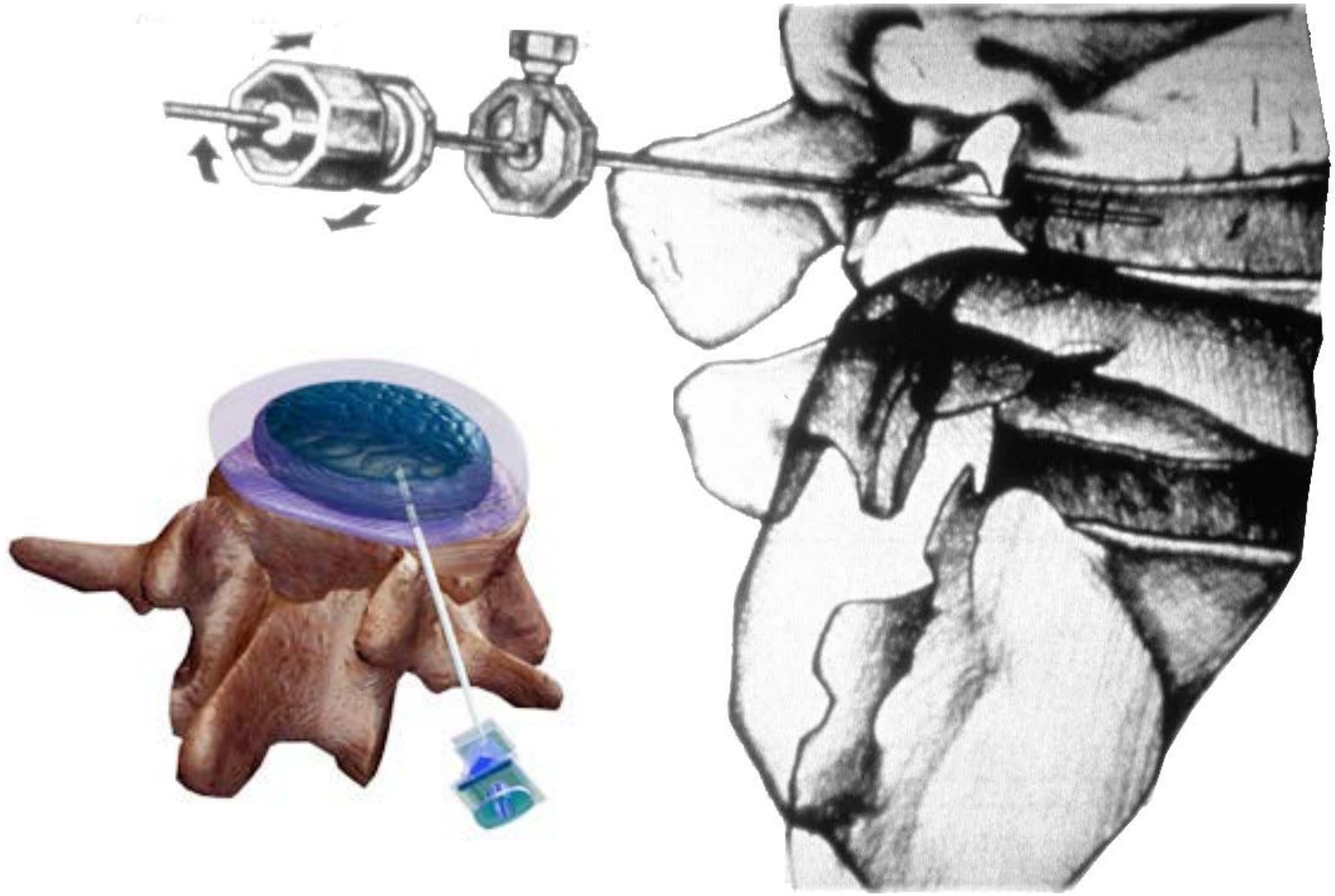


This discovery led to a landmark clinical study that showed for the first time it was possible to lower a intradiscal pressure in-Vivo with a non-surgical treatment.

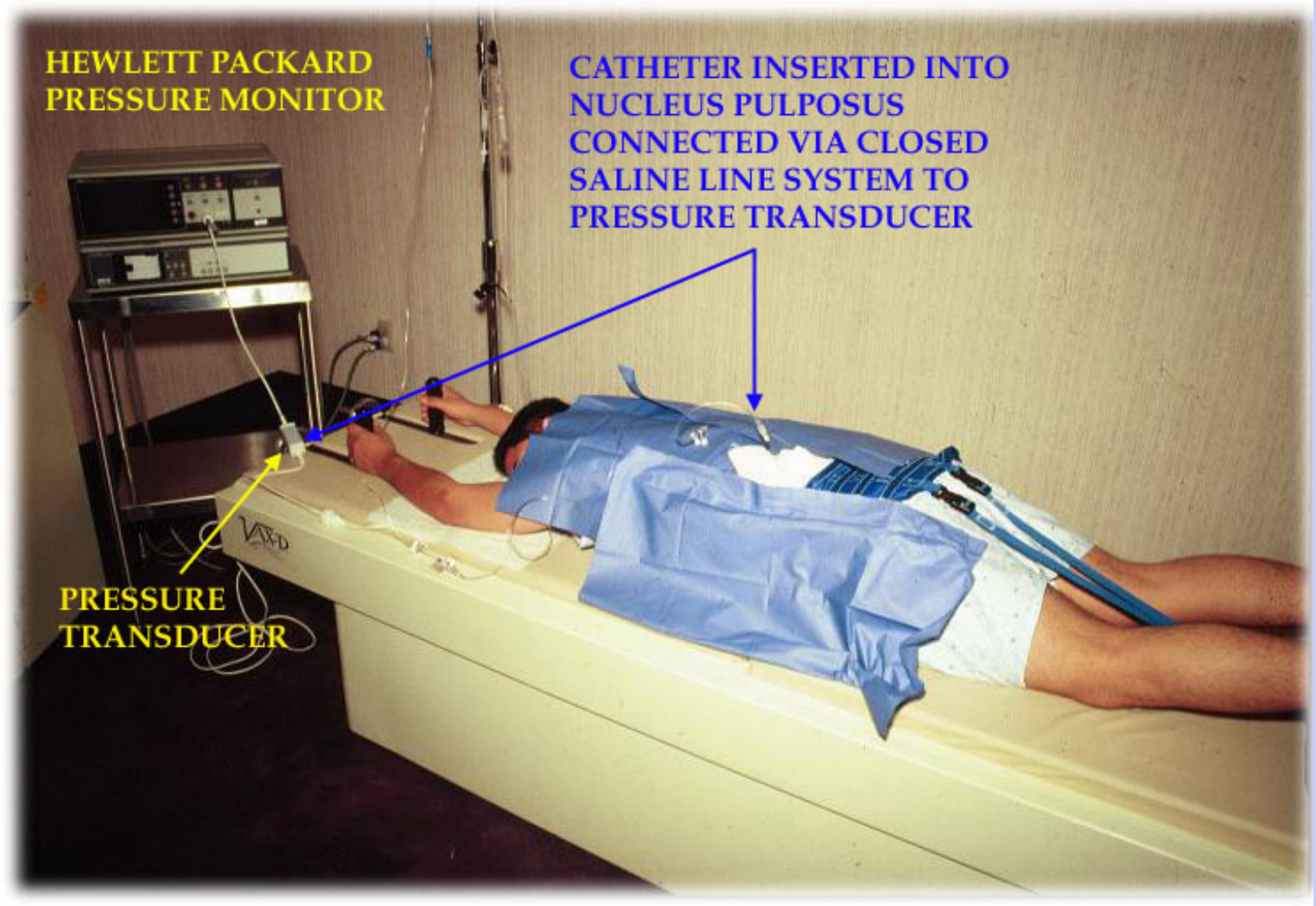


Intradiscal Pressure Measurements

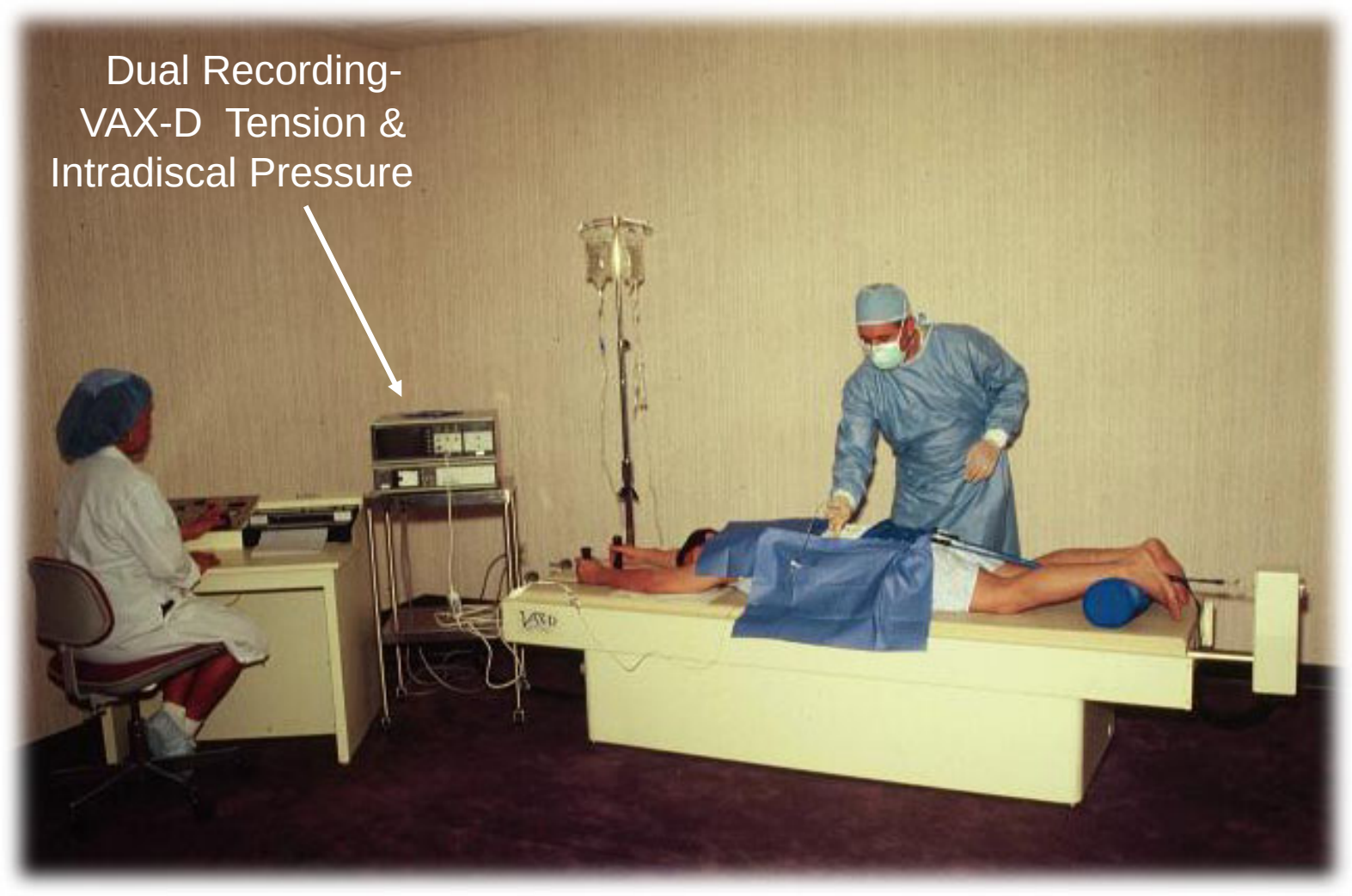
Catheter Inserted Via A Cannula Into The Nucleus Pulposus



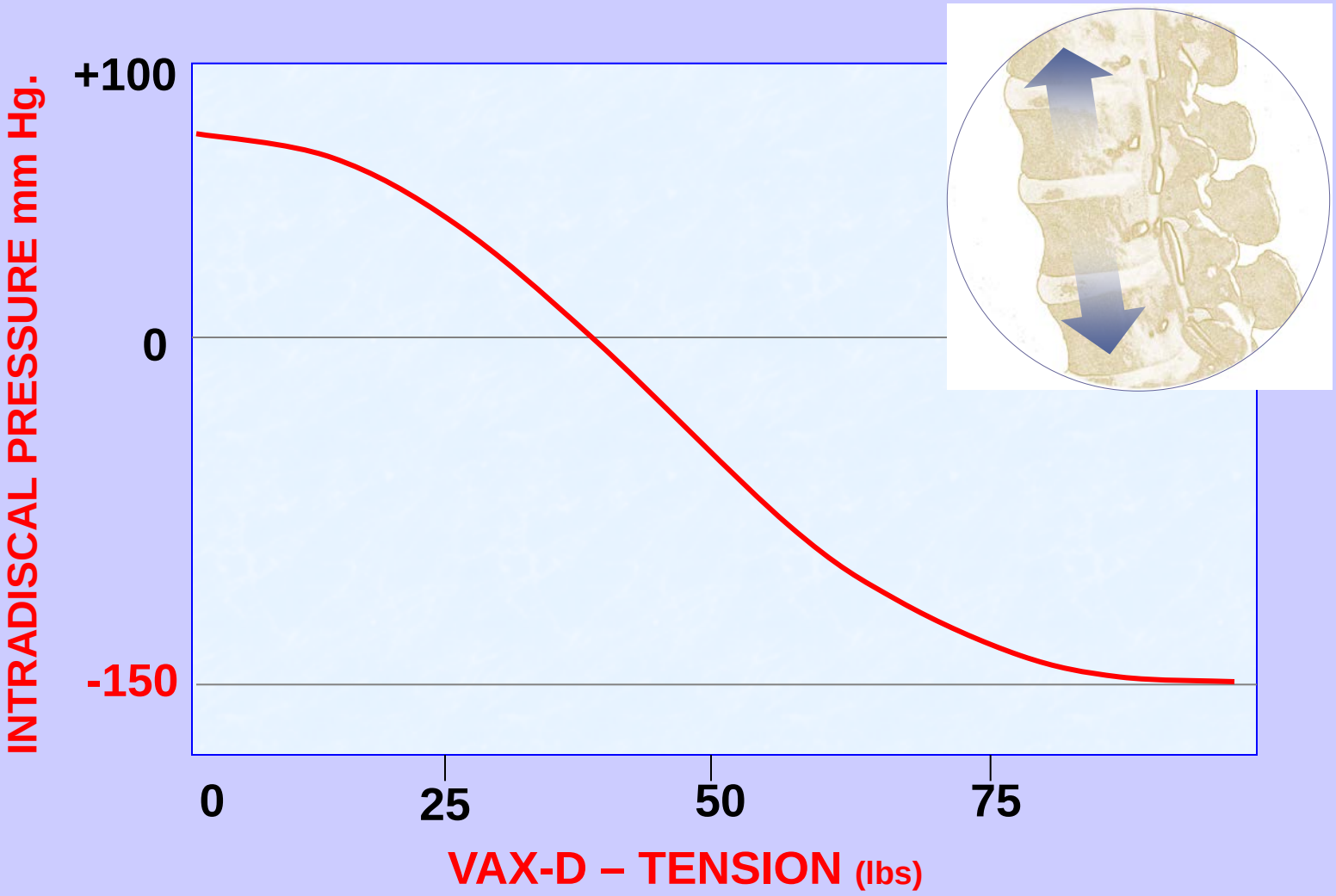
Recording Intradiscal Pressure Changes During *VAX-D*



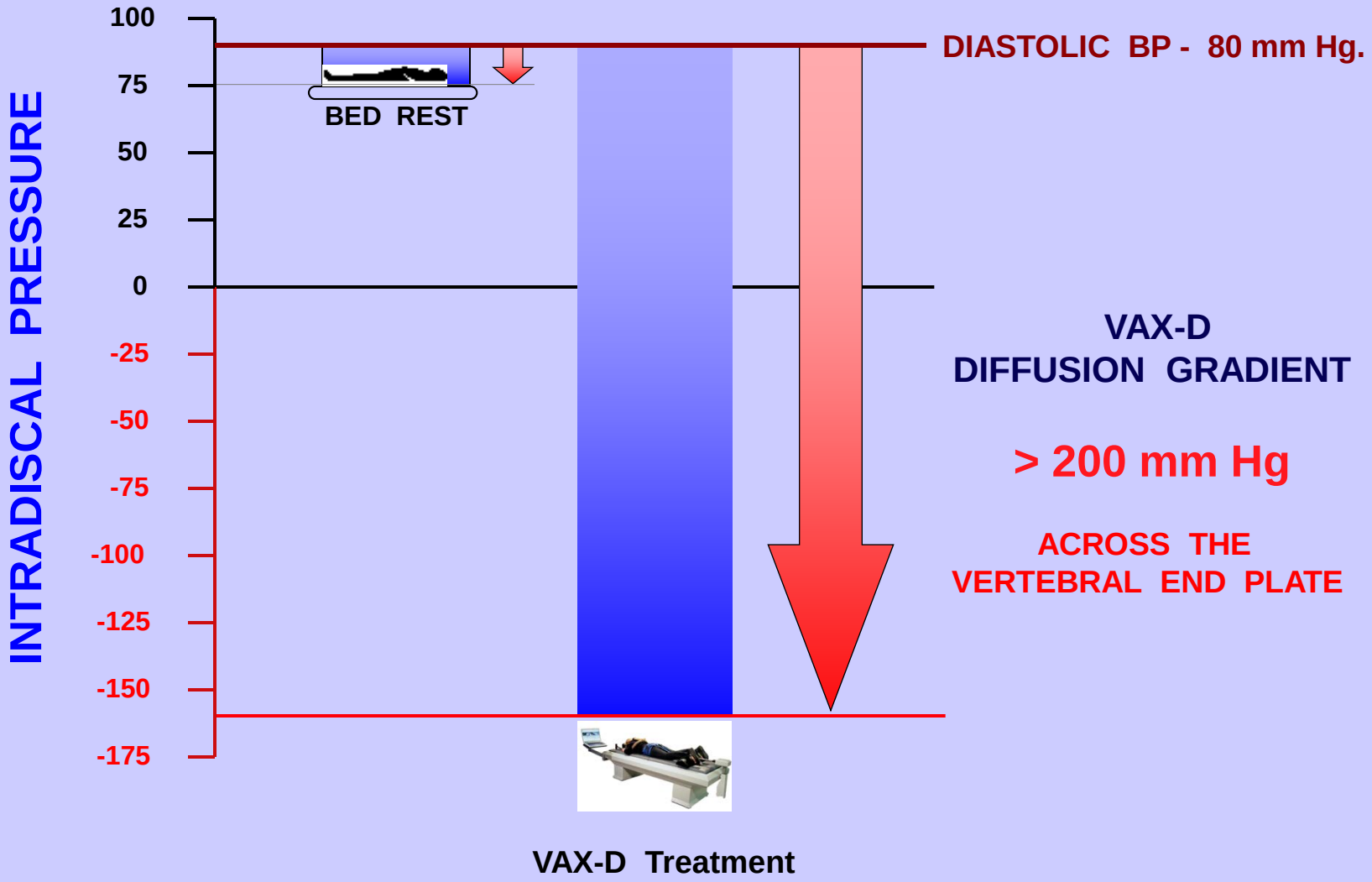
Dr. Ramos Monitoring Disc Pressure and VAX-D Tension



Intradiscal Pressure Reduced to Negative Levels During VAX-D Treatment



Diffusion Gradient Into Disc



Diffusion Gradient Into Disc

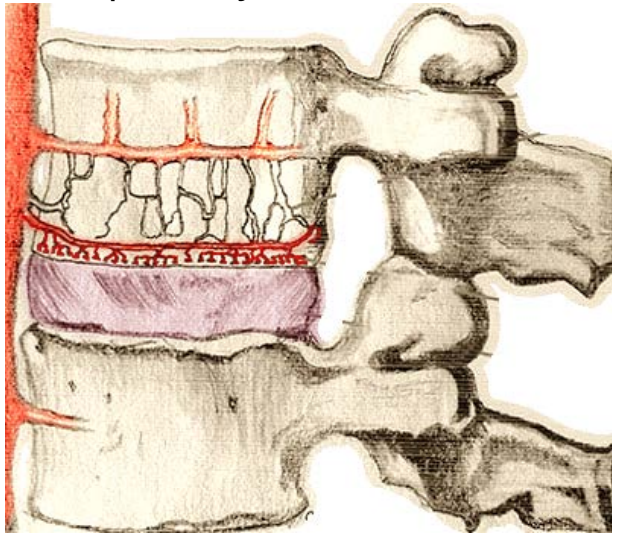
Cellular metabolism in the disc occurs through **glycolysis;** the disc cells *require **glucose and oxygen*** for cellular survival and the produce ***lactic acid*** at high rates.

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.

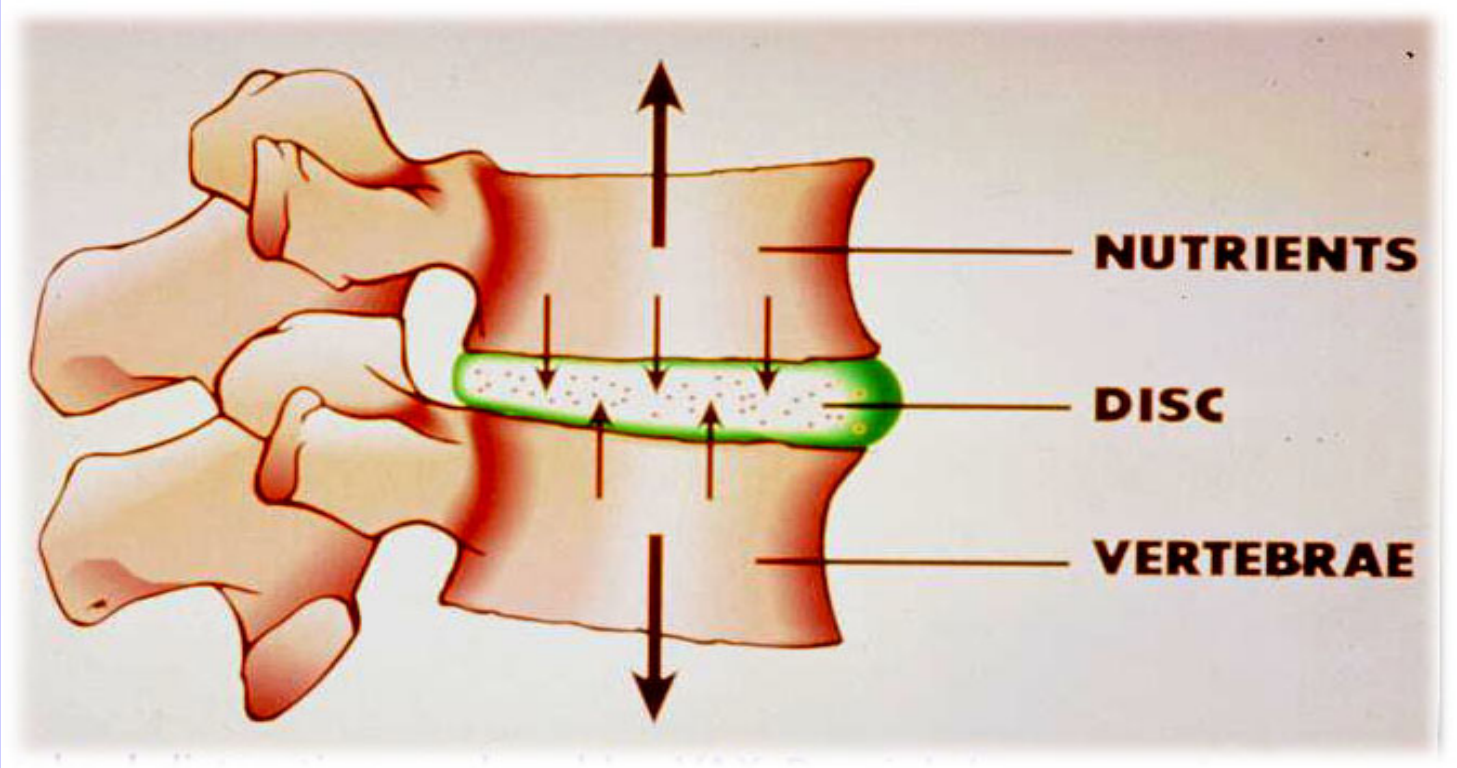
Small molecules such as **glucose** and **oxygen** reach the disc by diffusion under gradients established by the balance between the rate of transport through the tissue to the cells and the rate of cellular demand. Lactic acid is removed by the reverse pathway.

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.

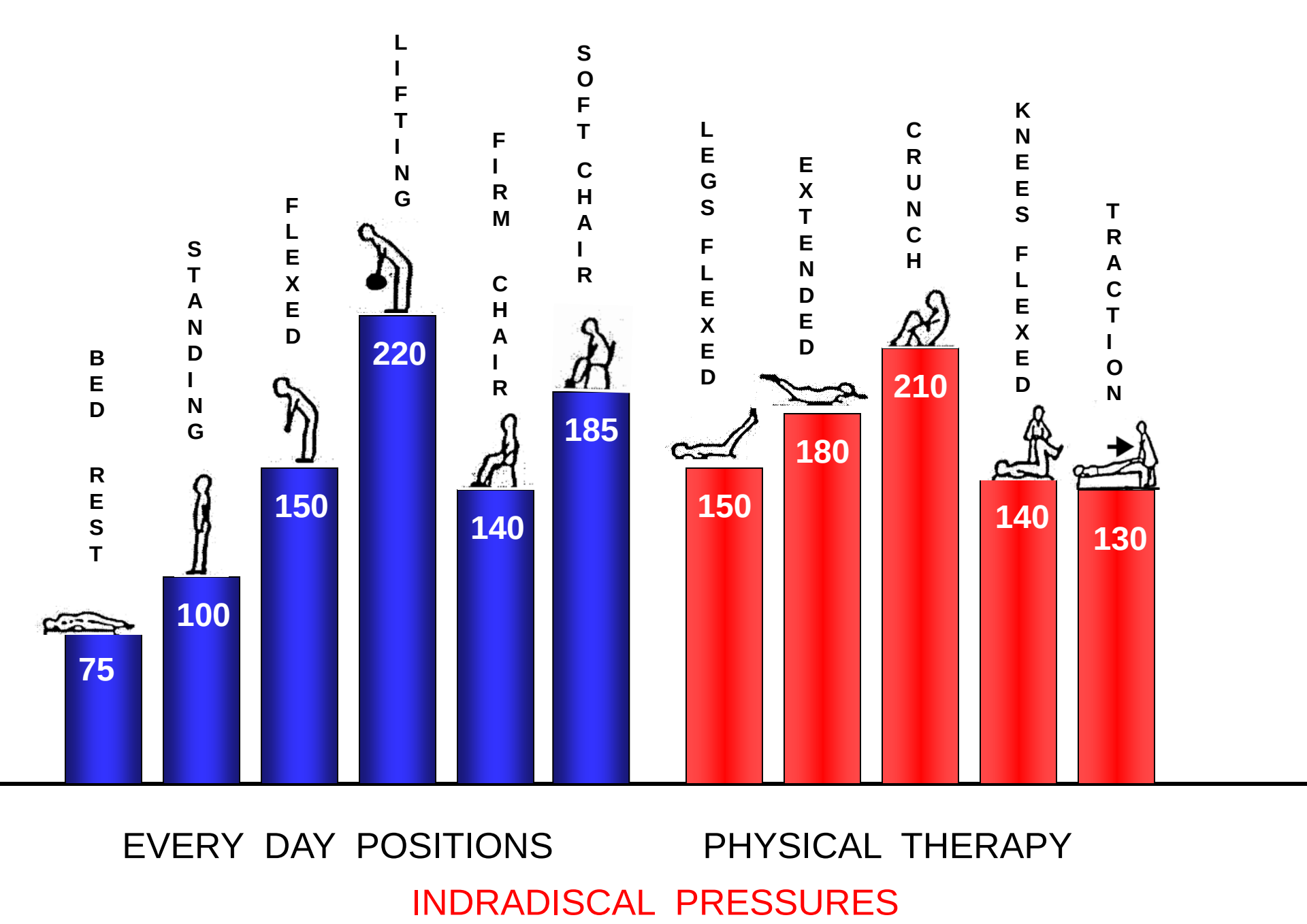


VAX-D DECOMPRESSION



"Vertebral distraction producing decompression creates a favorable diffusion gradient across the endplate enhancing disc nutrient transfer promoting the natural healing process"

Kirkaldy-Willis - Managing Low Back pain


BED REST
75
STANDING
100
FLEXED
150
LIFTING
220
FIRM CHAIR
140
SOFT CHAIR
185
LEGS FLEXED
150
EXTENDED
180
CRUNCH
210
KNEES FLEXED
140
TRACTION
130
EVERY DAY POSITIONS
PHYSICAL THERAPY
INDRADISCAL PRESSURES

Science & Medicine:

VAX-D Decompression Treatment

HOW DOES VAX-D WORK?

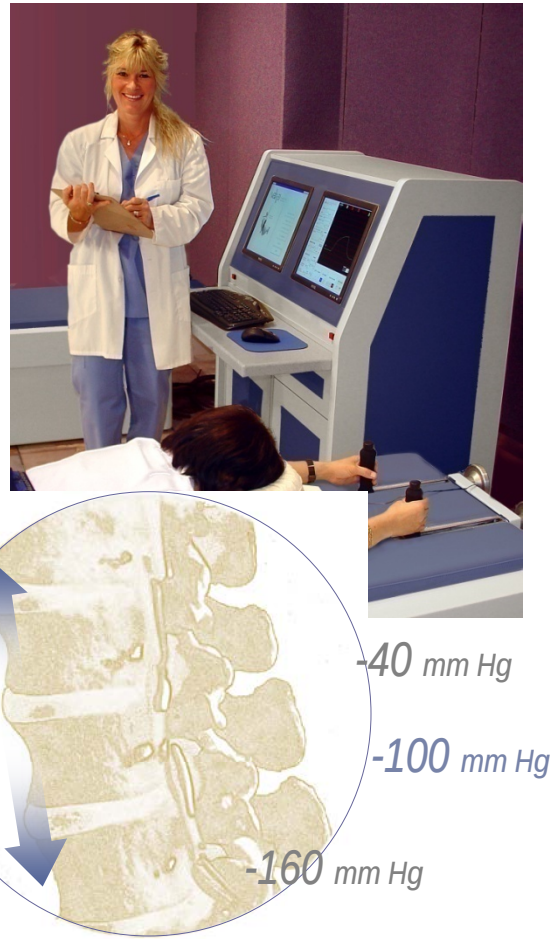
1. **VAX-D Decompresses the discs and neurological elements. This reduces the hydrostatic effects of the nucleus (protrusion, herniation, etc) .**

2. **Reducing the disc pressure to negative levels increases the diffusion gradient from the endplate into the disc, which brings oxygen, fluids and nutrients into the disc. The exchange of fluids reduces lactic acid build up.**

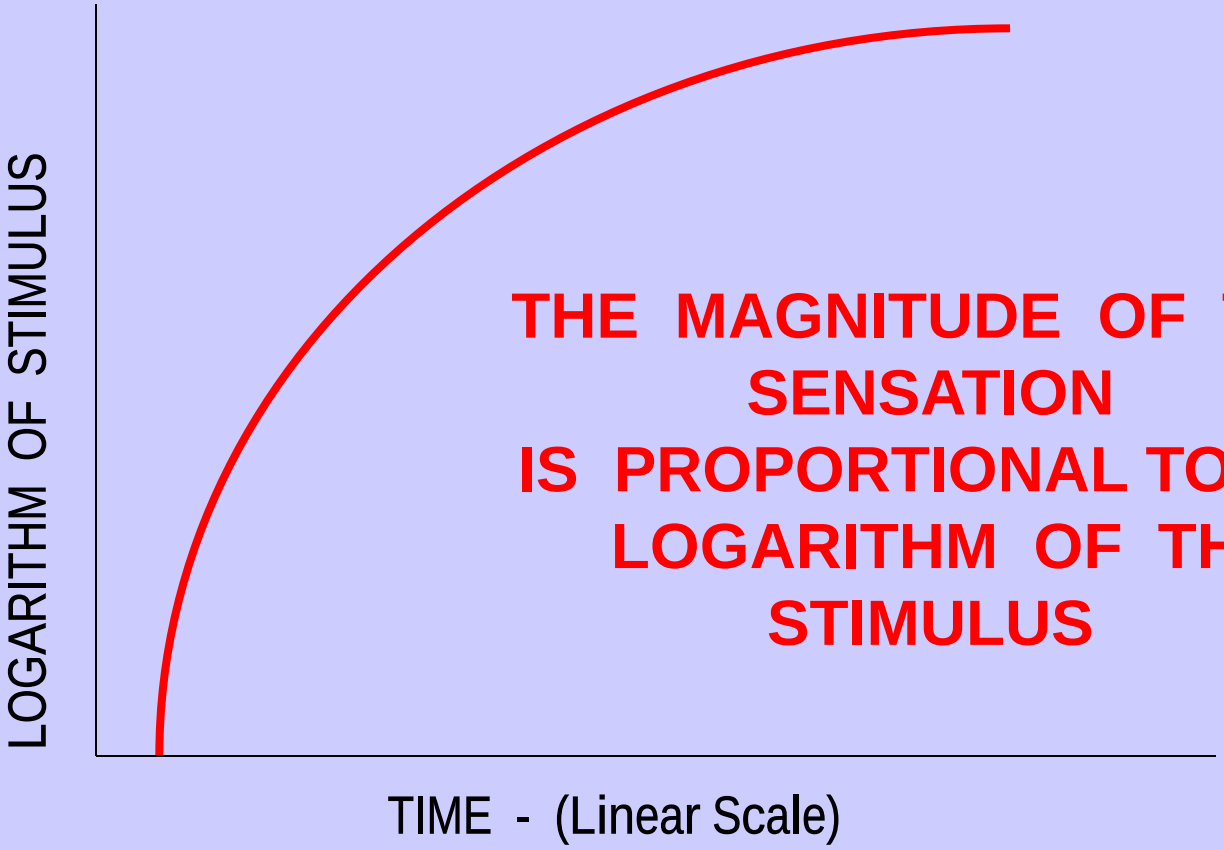
3. **Along with the increased diffusion of fluids, the flow of pharmaceutical agents will also be increased.**

4. **THE GOAL OF VAX-D TREATMENT IS TO REDUCE THE INFLAMMATORY CASCADE IN THE DISC AND SURROUNDING TISSUES.**

5. **THIS ALLOWS THE DISC TO HEAL NATURALLY.**

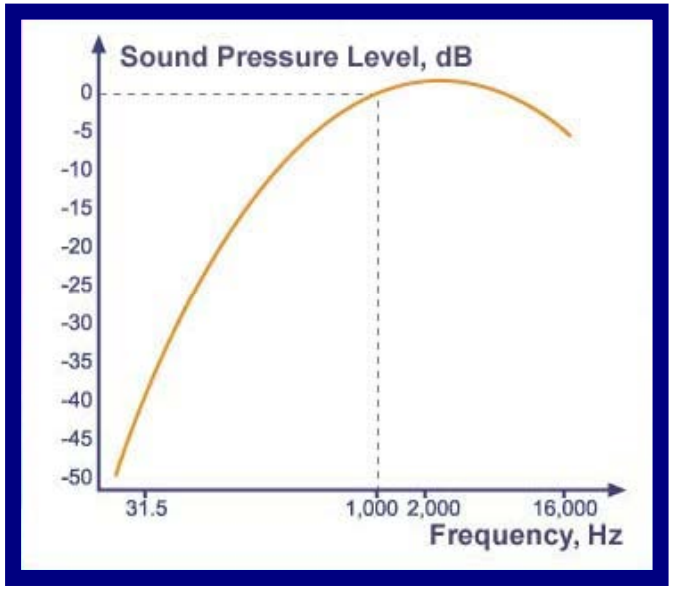


Fechner's Law of Biological Response

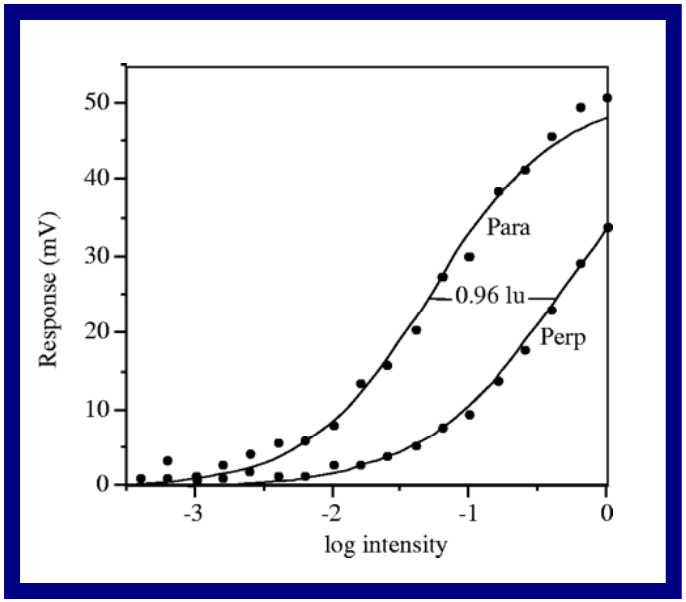


VAX-D employs the inverse of this principle and applies the tension in a reverse Logarithmic curve. This avoids stimulating the proprioceptors in the back and spine.

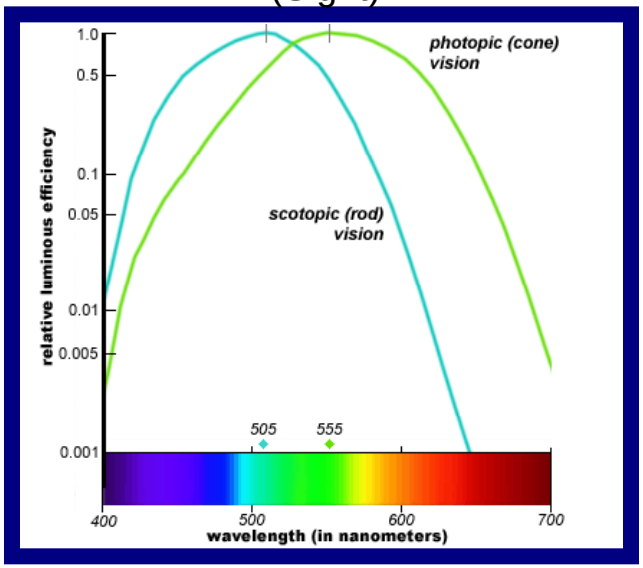
Sound Sensitivity
(Hearing)



Mechanoreceptor Sensitivity
(Touch)



Light Sensitivity
(Sight)



The MAGNITUDE of the Sensation is proportional to the Logarithm of the Stimulus

What is VAX-D Treatment?

1. Patient wears a pelvic or cervical harness for treatment.

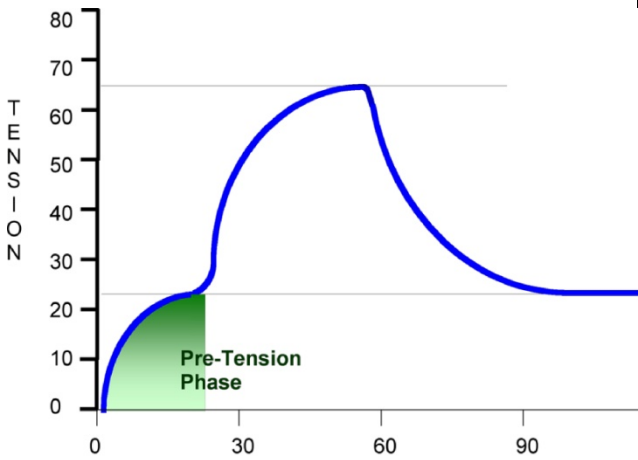
2. A baseline tension is applied.

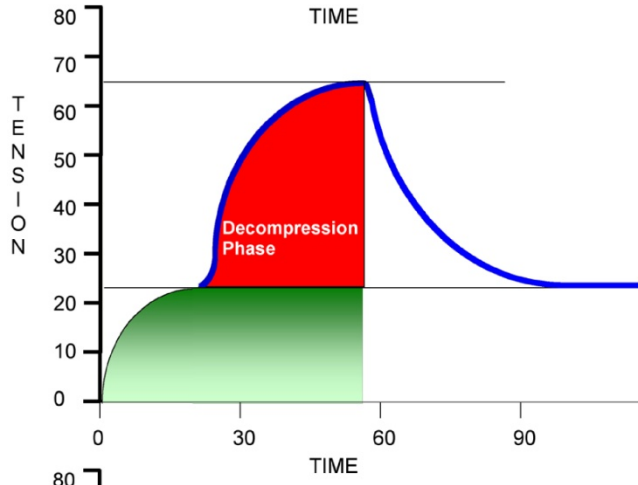
3. Decompression Phase: VAX-D applies tension to a patient's spine in a logarithmic time/force curve (for 60-90 seconds / variable)

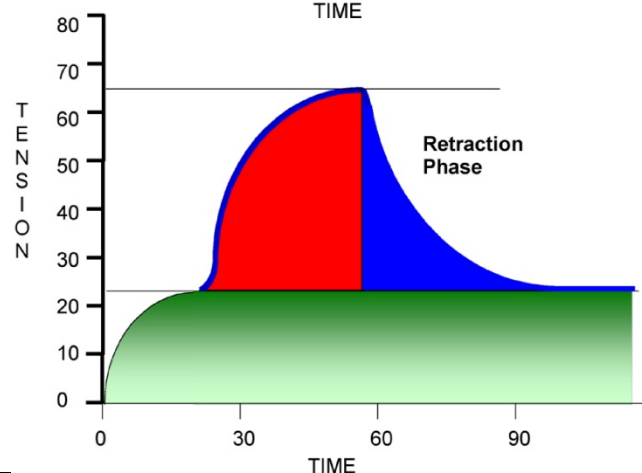
4. Retraction Phase: The tension is released in a reverse log curve. (for 40-90 seconds / variable).

5. Rest Phase: A variable baseline tension is applied during the rest phase (for 20-60 seconds /variable)

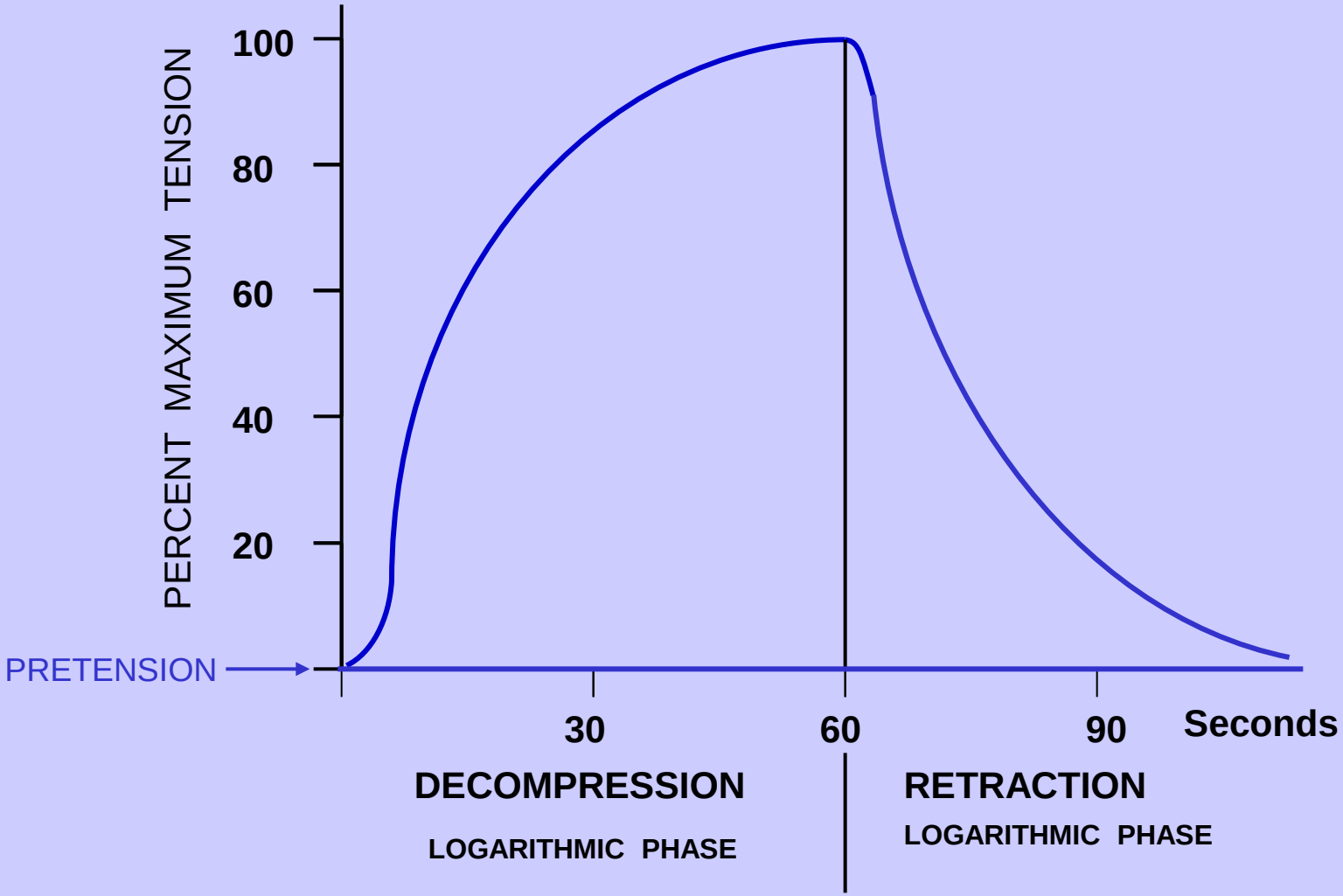
5. Cycles: There are 15 cycles of each phase (variable).







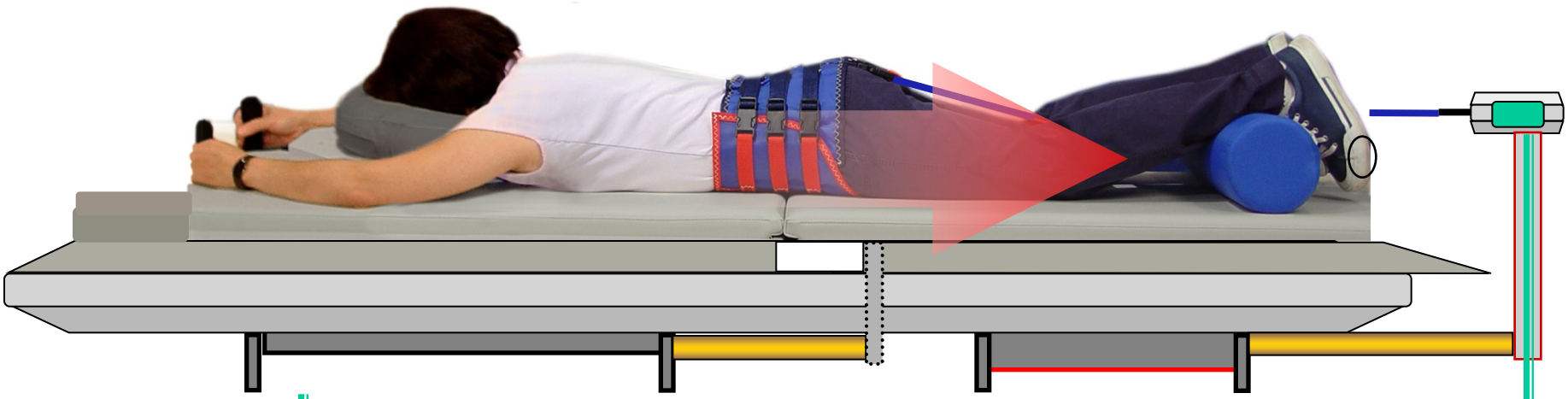
VAX-D Double Logarithmic Treatment Curve



Logarithmic Formula

$$\text{Exp}\,[\,C^{N} \times \text{Ln}\,(Bti)\,] = BTn + [\,N \times In\,]$$

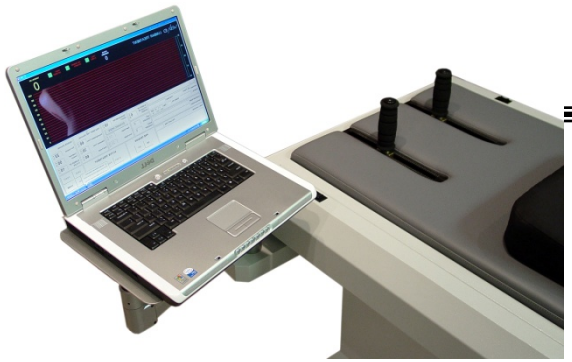
Lumbar Treatment • Decompression Phase



LOGARITHMIC TENSION APPLIED

BIO- FEEDBACK LOOP

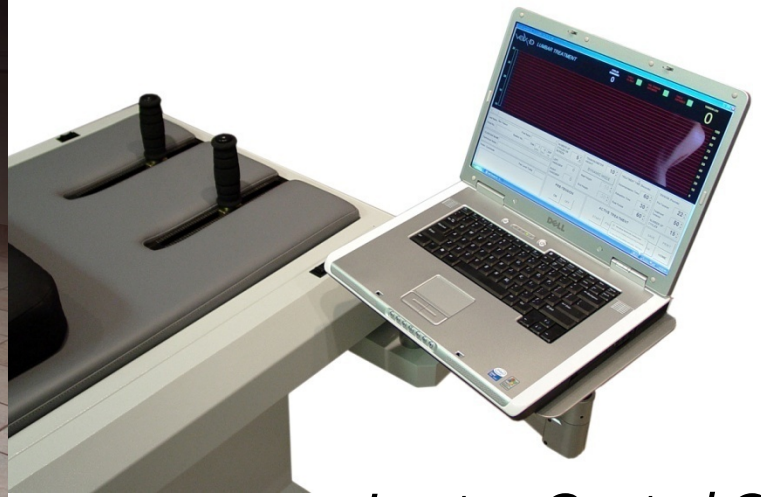
Motion Control Computer



Computer Interface

The lower body (legs/pelvis), movable table pallet, and the tensionometer all move as a 'Unified Motion Segment'

Genesis Equipment



Laptop Control Center

Versatility in Treatment Choices

Lumbar Prone

Lumbar Supine

Handgrips

Arm-Rests

Cervical

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.

VAX-D Lumbar Therapeutic Indications

1. **Herniated Lumbar Discs** **(One or more levels)**
2. **Degenerative Disc Disease**
3. **Peripheral Radiculopathy**
4. **Failed Back Surgery**
5. **Posterior Facet Syndrome**

VAX-D Lumbar Contraindications & Precautions

1. **Primary or metastatic neoplasm**
2. **Vertebral fracture (Recent)**
3. **Cauda equina syndrome**
4. **Unstable spondylolisthesis (eg Pars Defects)**
5. **Osteoporosis (T-Score -2.5 or lower)**
6. **Severe or unstable medical disorder**
7. **Pregnancy**
8. **Ankylosing spondylitis**
9. **Arthrodesis with retained hardware**
10. **Abdominal aortic aneurysm**
11. **Spinal infections (include osteomyelitis and septic discitis)**
12. **Severe osseous stenosis**
13. **Hemangioma that invades endplate, greater than 1 cm**

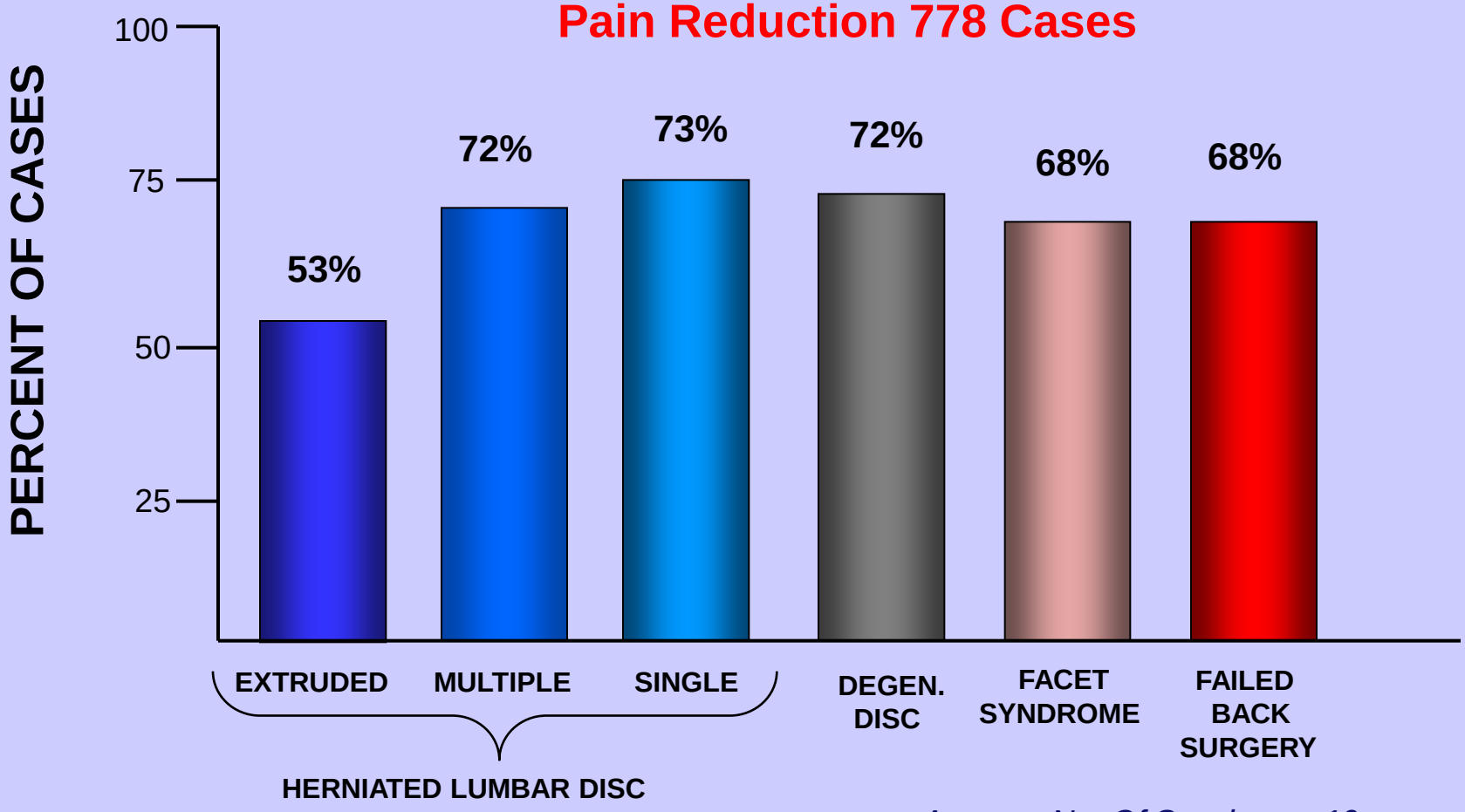
    (may compromise vertebral integrity or that may represent risk of bleeding)
14. **Pelvic or abdominal cancer**

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

Drs. E. Gose, R. K. Naguszewski, W. K. Naguszewski

Journal of Neurological Research Volume 20, 1998

Pain Reduction 778 Cases



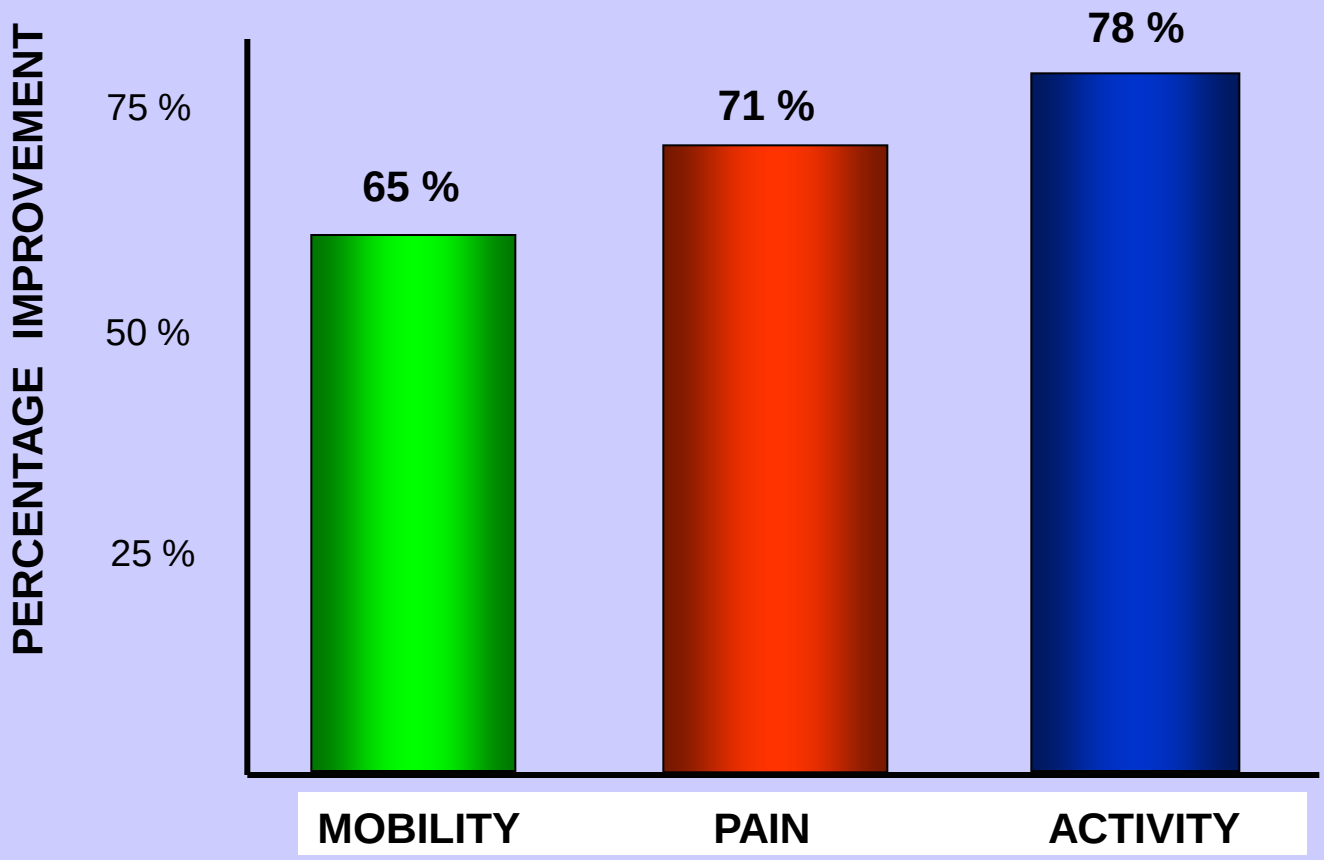
Average No. Of Sessions = 19

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

Earl E. Gose, William K. Naguszewski and Robert Naguszewski

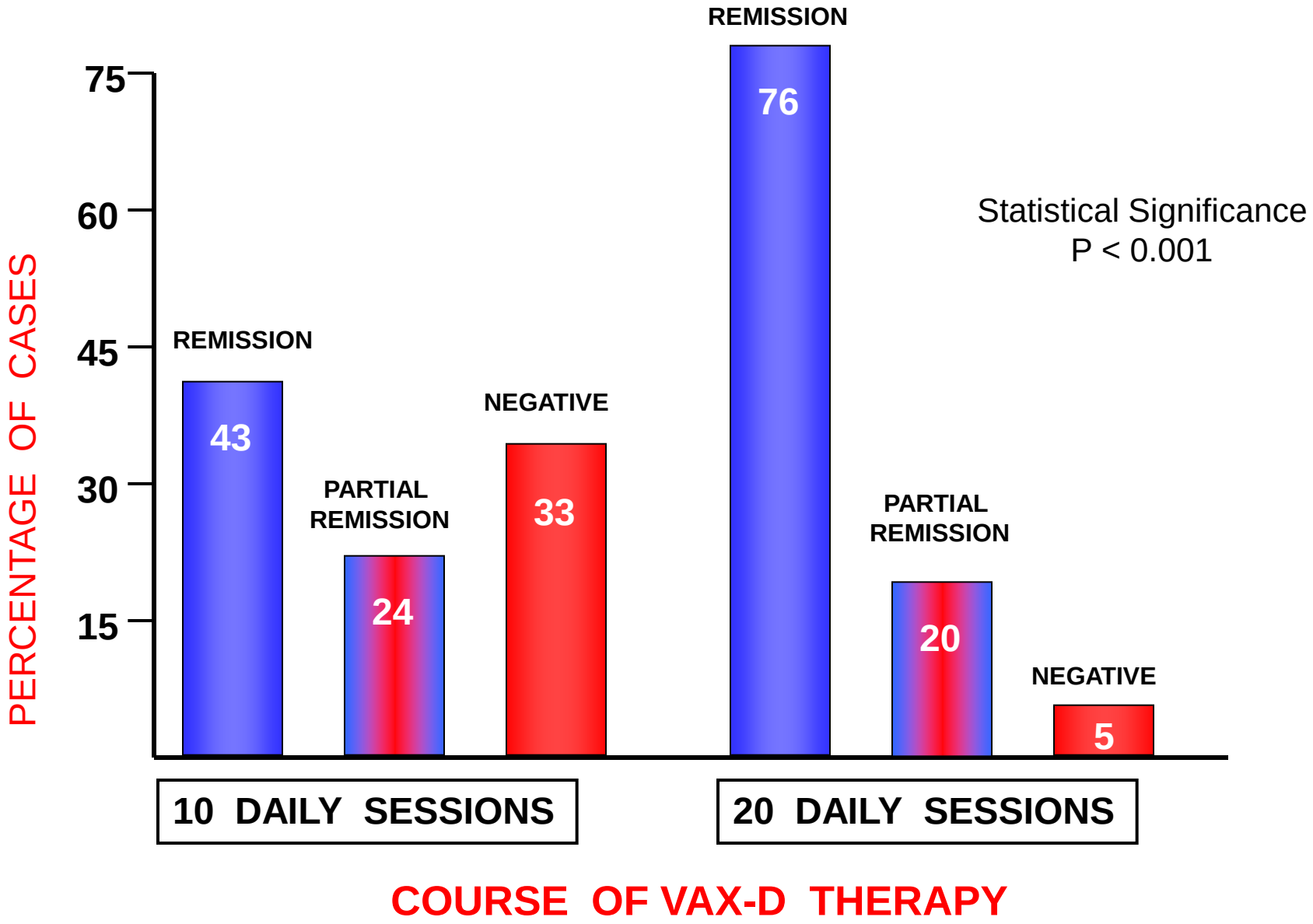
[Journal of Neurological Research, April 1998]

Relief of Pain and Disability



Dosage Regimen Study • 158 Patients

Journal of Neurological Research - Vol. 26, April 2004



Cervical Pain & Causes

Neck pain may result from abnormalities in the muscles, ligaments, nerve, bones and joints of the spine.

The most common causes of neck pain are soft-tissue abnormalities due to injury or prolonged wear and tear.

Common causes:

Neck and Head injury
Disc disorders
Whiplash
Neck sprain / strain
Muscle disorder
Ligament disorder
Spinal disorder
Arthritis

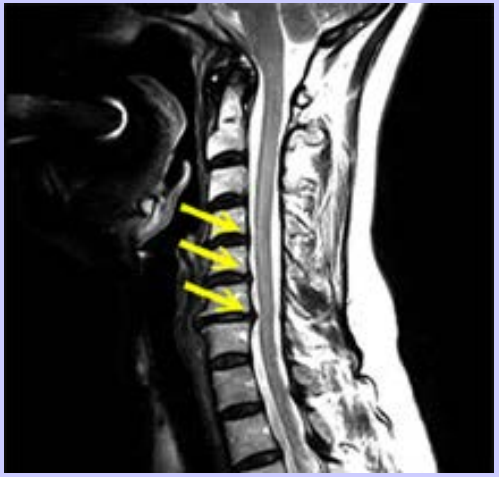
Inflammatory Disease
Infection
Lymphedema
Mononucleosis
Rubella
Cancer

Disc Disorders In The Cervical Spine

Disc Protrusion

Disc Extrusion

Disc Sequestration



Cervical Radiculopathy

*A chemical radiculitis is a key element in the pain caused by cervical herniated discs.

Degenerative Disc Disease

- Decreased disc height, age related foraminal narrowing, facet hypertrophy, bony stenosis

FDA Public Health Notification - July 1, 2008

This is to alert physicians to reports of life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) used in cervical spine surgery. The FDA Recommends That Practitioners Use Approved Alternative Cervical Treatments.

FDA has received at least 38 reports of complications with the use of rhBMP in cervical spine fusion. These complications were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck.

roximity of the cervical spine to airway structures in the body has contributed to the seriousness of the events reported and the need for emergency medical intervention.

When airway complications occurred, medical intervention was frequently necessary. Treatments needed included respiratory support with intubation, anti-inflammatory medication, tracheotomy and most commonly second surgeries to drain the surgical site.

In light of the serious adverse events described above, FDA recommends that practitioners use approved alternative treatments.

Cervical Traction Devices

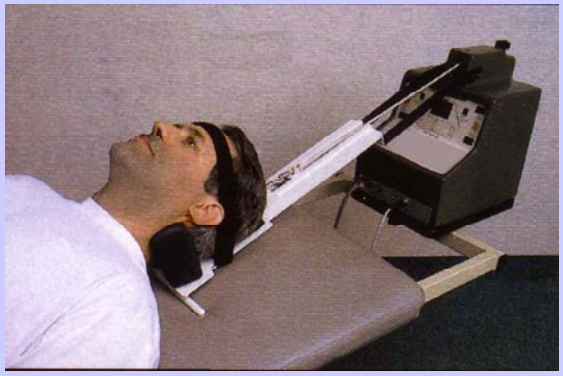
Most traction applied by a clinician utilizes the following guidelines:

1. **Treatment Tension:** Traction uses forces in the 25-50 lb range. Traction device protocols conclude that 20 lbs is not a sufficient therapeutic force for separation of the intervertebral spaces or for a therapeutic effect

2. **Angle of Pull:** Protocols call for an angle of 15-20 degrees of flexion for nearly every clinical indication, and for most patients

3. **Treatment Times:** For treatment of herniated disc, traction protocol recommends treatment times of 5-10 minutes.

4. **Mode of Traction (Static vs. Intermittent):** The static mode of traction is often suggested as the preferred mode.



Obstacles To Successful Cervical Decompression

1. HEAD HARNESS: With standard harnesses such as occipital cradles, forehead straps, and chin straps:
   How does the tension become distributed circumferentially to the head and neck?

2. BALANCE OF TENSION: Traction uses harnesses such as occipital cradles, forehead straps, and chin straps:
   How are the forces distributed from TMJ to the Occiput?

3. LINEAR TENSION: Traction uses linear tension in a static or intermittent mode.
   Fechner's Law of physiology tells us that the body's proprioceptors respond to the ***logarithm*** of the stimulus. Linear forces elicit muscle contraction.

4. STRAIGHT LINE FORCE VECTOR: Traction uses straight line angles of pull.
   Head and neck vectors for movement are all curved. Straight line vectors will elicit muscle guarding response.

5. ANGLE OF PULL: Traction devices raise or lower the straight line angle to attempt to target specific discs.
   It is thought that a 15-20 degrees angle can be used for all patients.

6. TREATMENT TIME: Standard is 7-10 minutes; to avoid fatigue.
   If the treatment is designed to decompress, 10 minutes is not sufficient for diffusion or to change the pathology.

VAX-D Genesis G2 System

In 2007 VAX-D released the *Genesis G2* System with *'Biofeedback Motion Control'* for absolute accuracy in decompression of the lumbar and cervical spine.

The equipment has a unique ability, in that the tensioning source can be programmed to move simultaneously in the horizontal plane and the vertical plane to follow the curves of the spine.

This system also accurately tracks the horizontal and vertical movement curves and adjusts position and tension (instantly) at the same time.

These advances are significant because variability in flexion or extension curves greatly increases patient comfort and muscle relaxation.

G2 Cervical: A System Like No Other

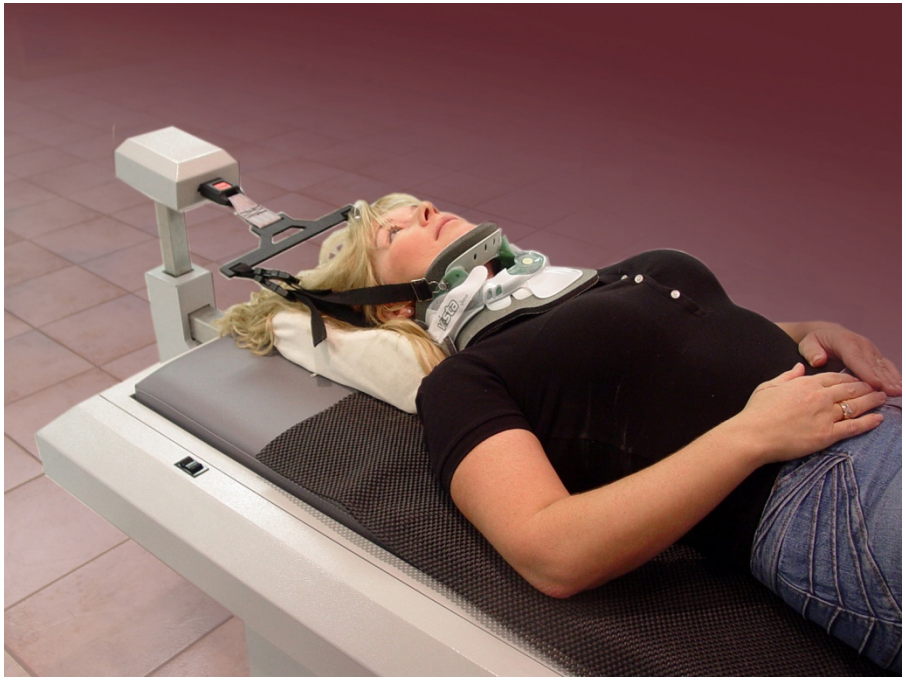
- **Patients are treated wearing a harness with an integrated supportive cervical collar.**

- **The collar is designed to allow some mobility of the patient's head and neck during decompression, while providing a *circumferential lift system.***

- **The collar provides the necessary immobilization and protection for patients in the post treatment period when the muscle guarding reflexes have been reduced.**

- **Without the protection of the collar, head and neck movements will trigger muscle spasm, increase intradiscal pressure and neck pain.**

- **Patients wear the collar for 20-40 minutes after to provide stability and to help the proprioceptors accommodate to movements of the head and neck.**



VAX-D Cervical Treatment Parameters

1. Patients are treated wearing our cervical collar/head harness.

2. 15 cycles = 60 seconds of distraction, 40 seconds of retraction, 40 seconds rest

3. Pre-Tension Range: 6-12 lbs

4. Treatment tension Range:12 -24 lbs

5. Treatment is fully attended/supervised

6. Dynamic logarithmic decompression is applied. The tension source moves in an 'arc' designed to allow the neck relax during distraction.

7. Patients should be treated once per day for 20 days or twice per day for a ten-day period.

VAX-D Cervical Head Harness

1. Distributes the force circumferentially around the head and neck

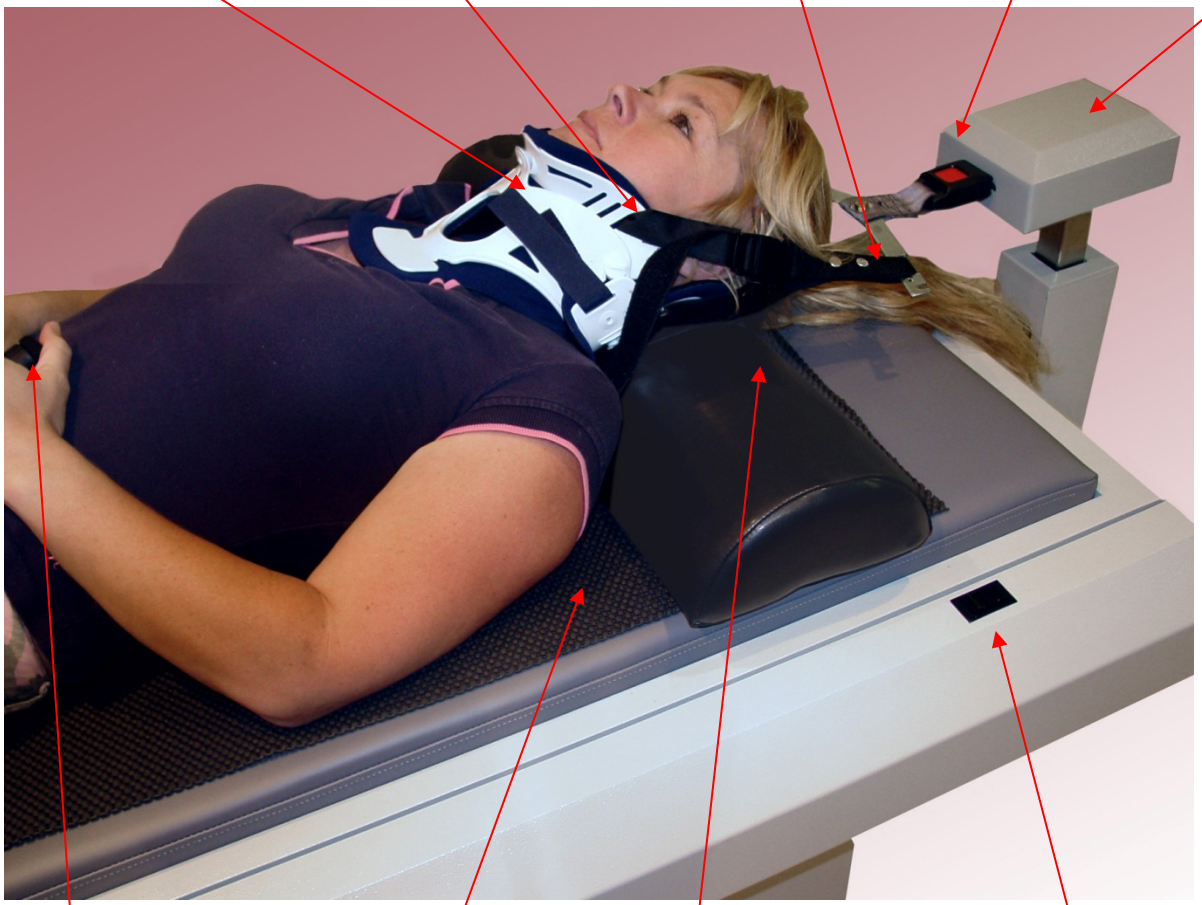
2. Allows some mobility of patient's head during distraction but stabilizes the neck. Polyethylene collars reduce motion from C3-C7 to 60% of normal.

4. Adjustable ventral and dorsal straps on each side for adjusting force more to TMJ or Occiput

5. Provides immobilization and protection when rising from Table, and in the post treatment period.

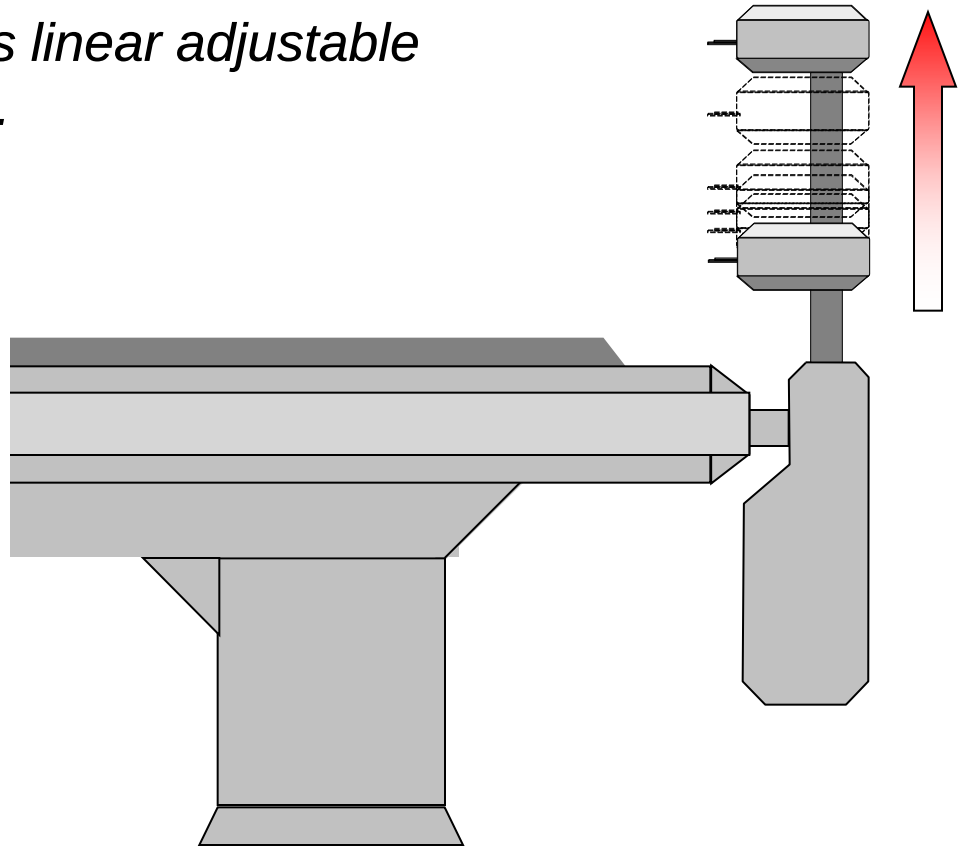
6. Prevents trigger point muscle spasm after treatment. Successful treatment effectively reduces the patient's pain and protective reflexes.

VAX-D Patient Set-up



Static Height Mode

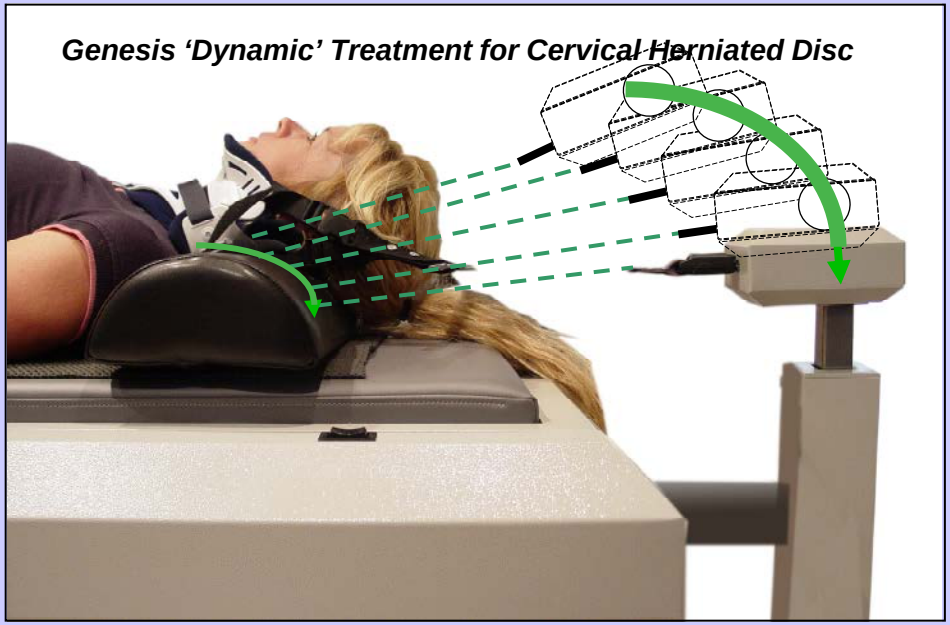
Tensionometer can be used in static mode were head has linear adjustable vertical height.



Genesis Dynamic Mode for Cervical Decompression

The Genesis *Dynamic Mode* allows the operator to program the tensionometer to move synchronously in the horizontal and vertical plane in order to apply tension in a logarithmic time/force progression that can be designed to follow a curvature comfortable for the spine.

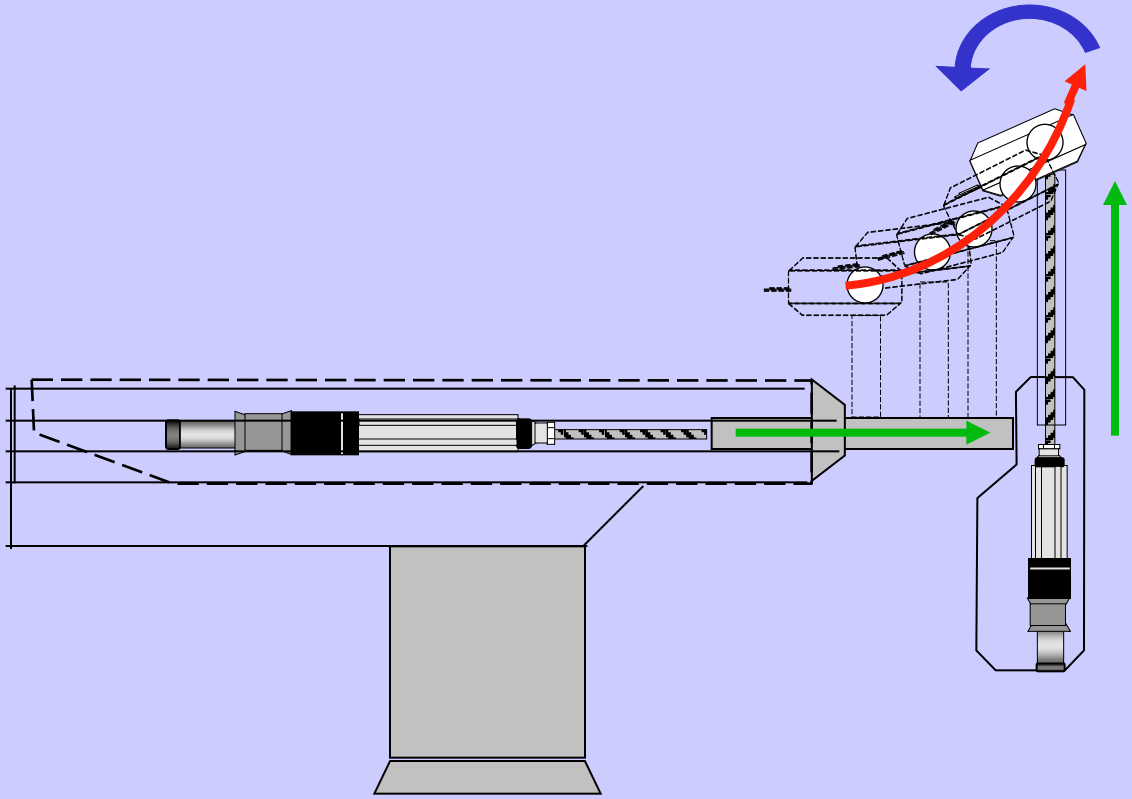
The tensionometer head moves in an 'arc' from the starting point to the end point. It can be programmed to move in an upward (flexion) or downward (extension) arc. Communication with the patient will determine the most comfortable settings for the Dynamic Mode.



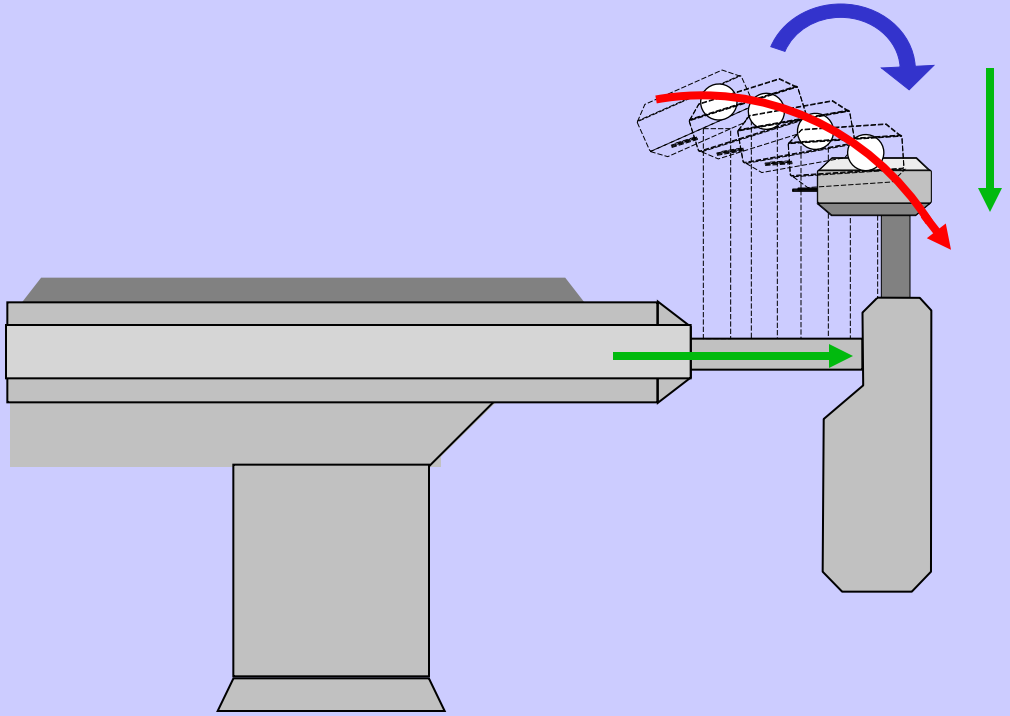
A lower angle of tension tends to place more force on the mandible and TMJ. A higher angle of pull tends to transfer more of the tensile forces to the occiput, because of the circumferential (collar) harness system.

Once the most comfortable treatment parameters have been established, they will be recorded and remembered by the system for future treatm**ents.**

Dynamic Decompression Curve In Flexion



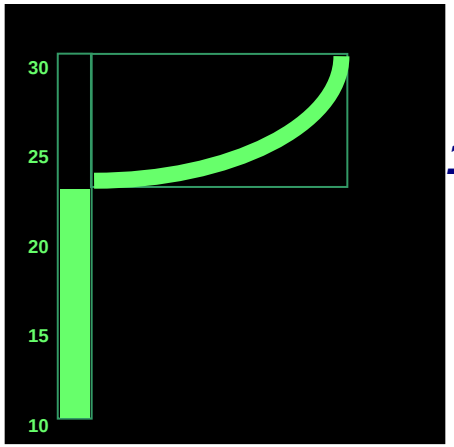
Dynamic Decompression Curve In Extension

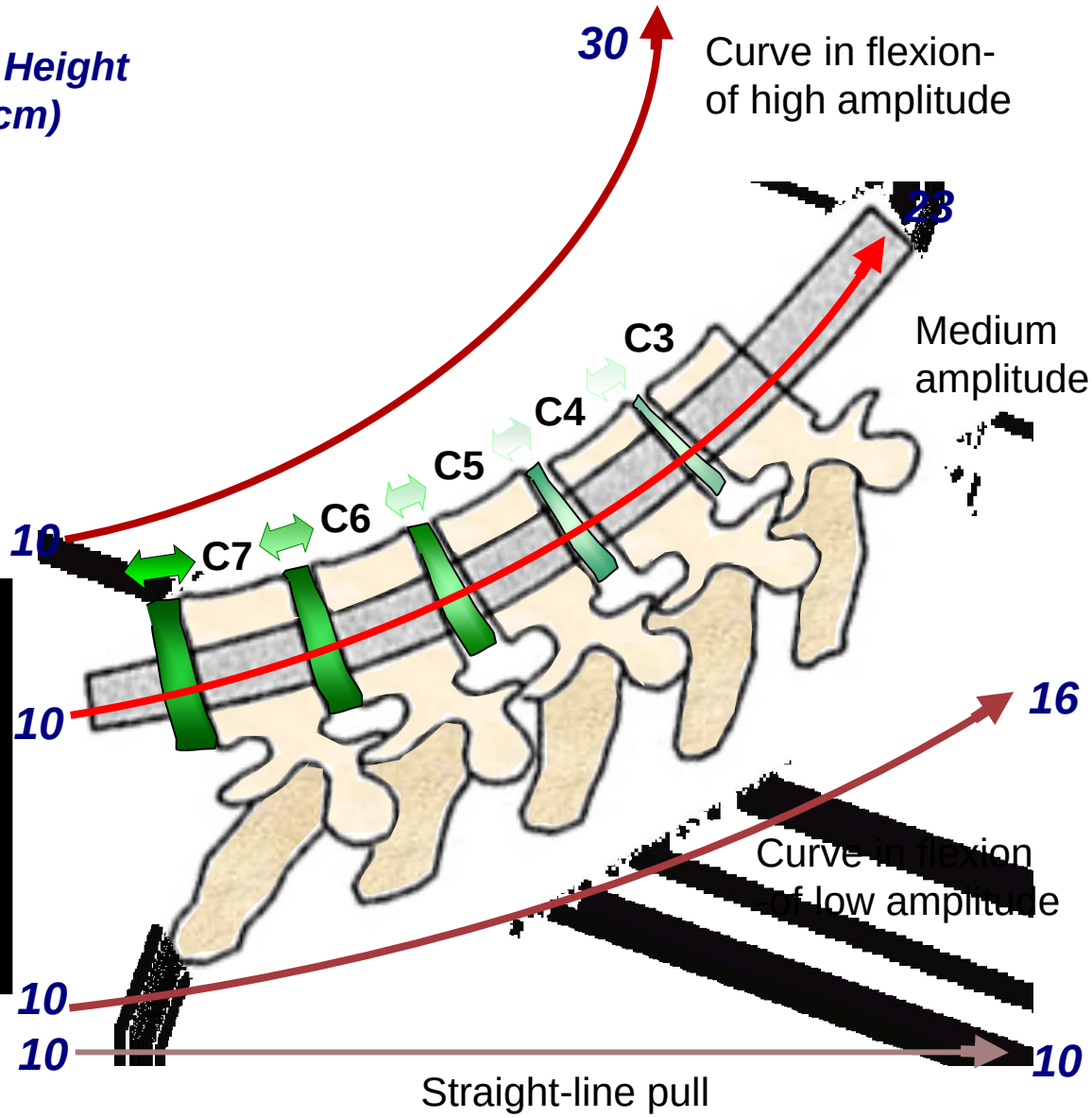


Dynamic Arc Selection • Flexion

(Start Height / End Height Range 10 cm – 30 cm)

The steeper the curve the more the force will be targeted lower in the cervical chain. The maximum tension of the logarithmic curve will be applied lower in the chain.

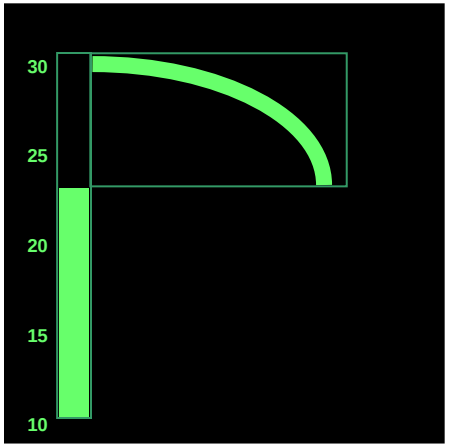


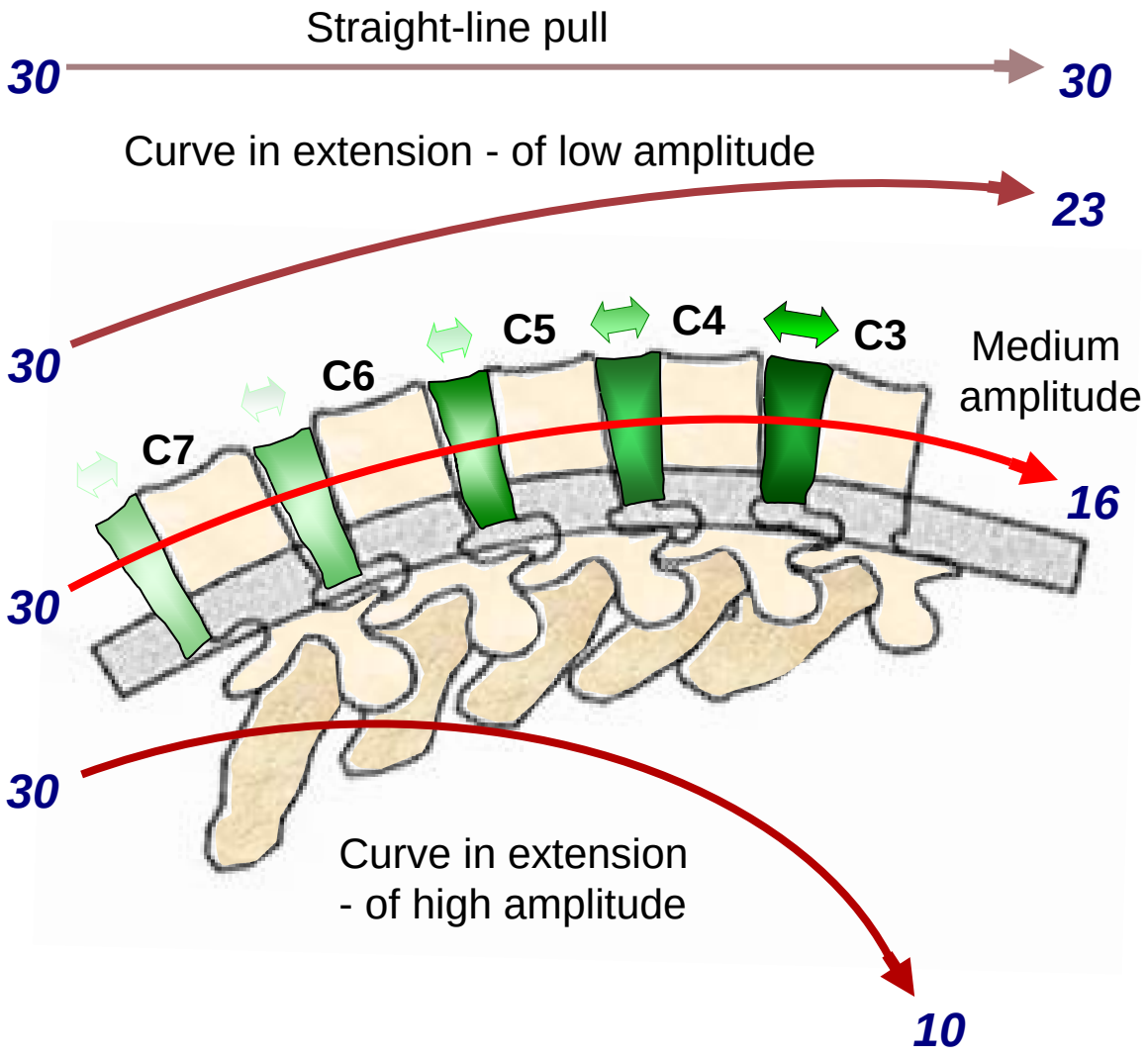


Dynamic Arc Selection • Extension

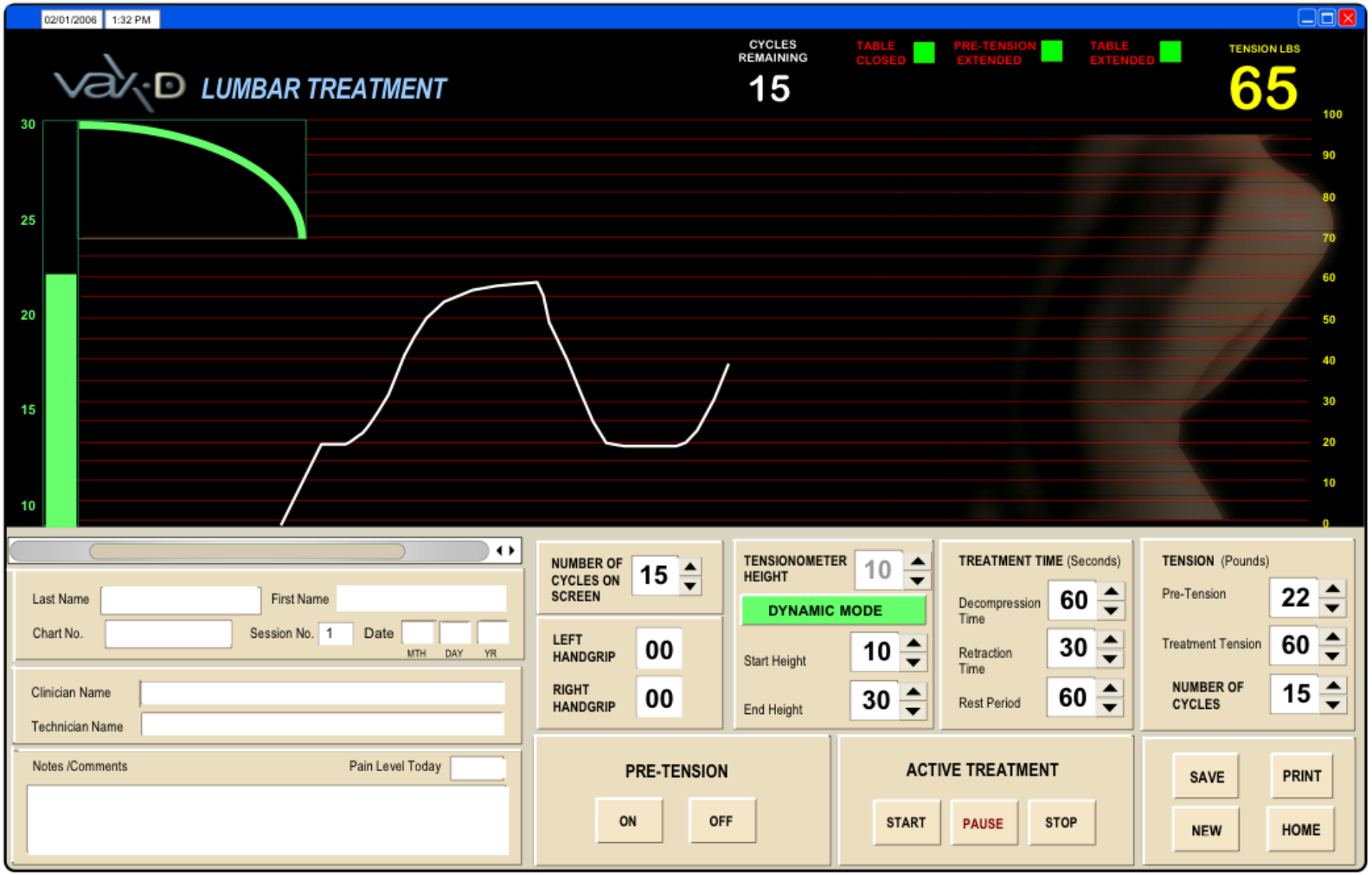
(Start Height / End Height Range 30cm – 10 cm)

The steeper the curve the more the force will be targeted higher in the cervical chain. The maximum tension of the logarithmic curve will be applied higher in the chain.





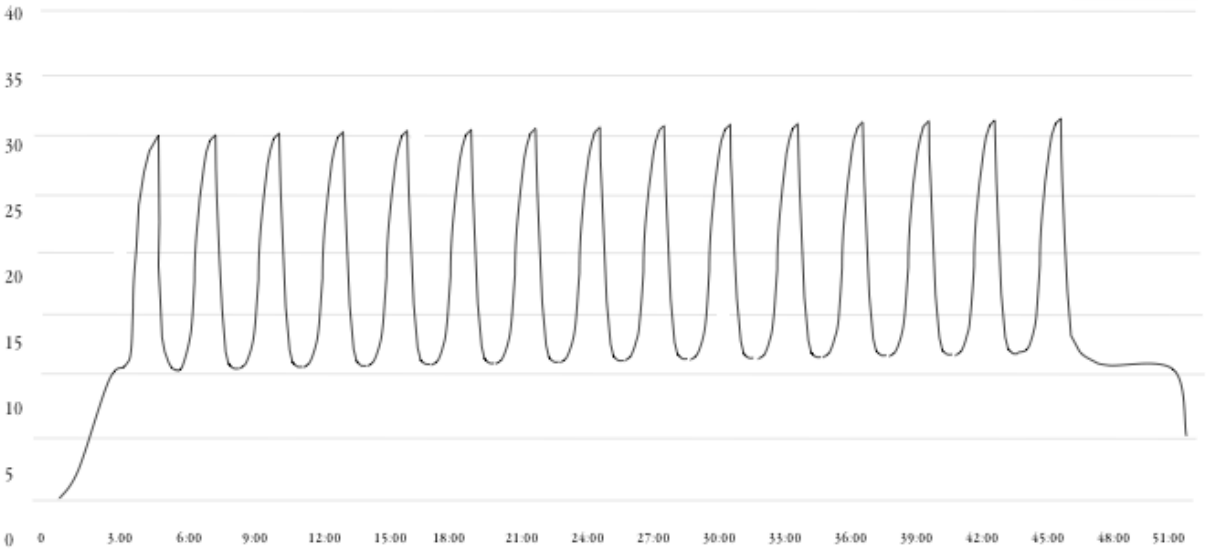
Lumbar Control Operating Screen



Cervical Control Operating Screen

Cervical Treatment Record

Session: 6



VAX-D CERVICAL TREATMENT RECORD: Hancock, John A. **DATE:**

01/01/2007

Clinic Name: VAX-D Back Pain Center,
Address: 310 Mears Blvd.,
Oldsmar FL 34677

Clinician: Dr. Smith
Chart No. 345678

Pain Level: 1

Technician: Thompson

Signature: _____

Notes:

No. Of Cycles:	15
Decompression Time:	60 sec
Retraction Time:	40 sec
Rest Time:	60 sec
Pre-Tension	12 lbs
Treatment Tension:	31 lbs
Tensionometer Height	
Dynamic Mode	
Start Height	20
End Height	10

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

Eugene Sherry MD, FRCS

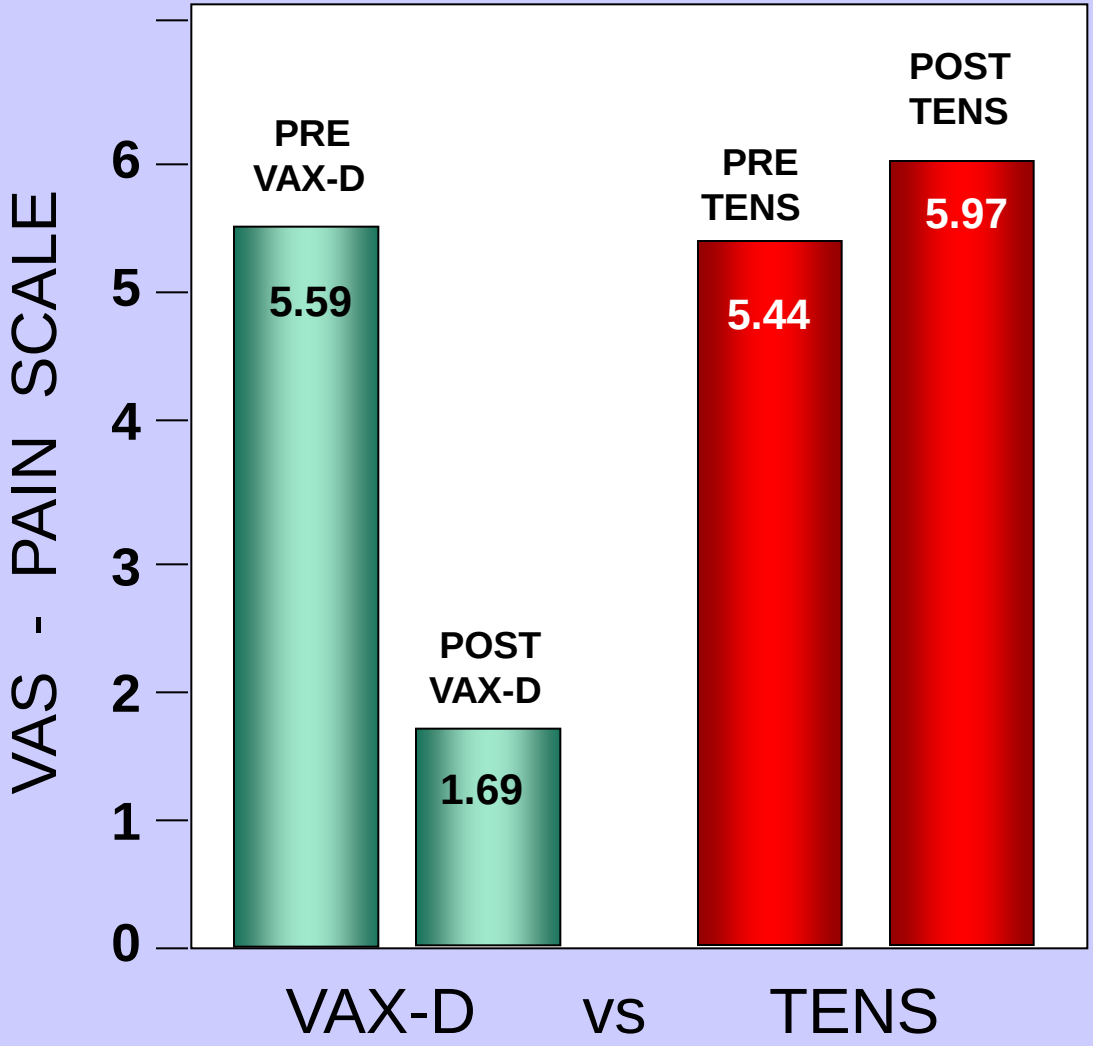
Peter Kitchener M.D., B.S., FRANZCR

Russel Smart M.D., Ch.B.

Department of Orthopaedics
Sidney University - Australia

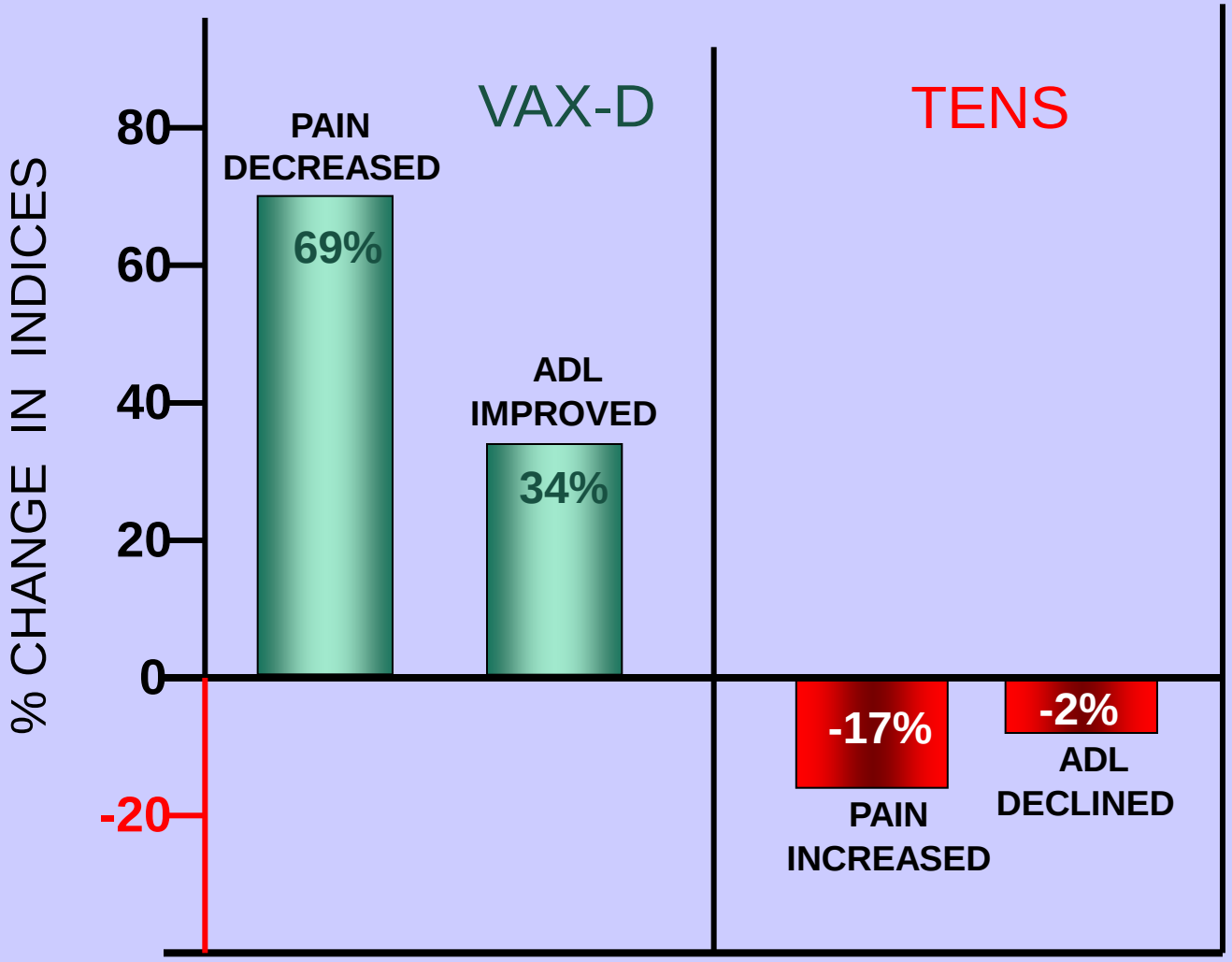
Journal of Neurological Research
Volume 23, No. 7, 2001

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



Statistical significance
$p < 0.001$

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



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*

VAX-D Cervical Treatment Indications

- **Herniated Cervical Discs** (One or more levels)
- **Degenerative Disc Disease**
- **Posterior Facet Syndrome**
- **Peripheral Radiculopathy**
- **Failed Cervical Surgery (Other than retained hardware)**

Cervical Contraindications and Precautions

1. Primary or metastatic neoplasm in the spine
2. Vertebral fracture (recent)
3. Unstable spondylolisthesis
4. Osteoporosis- plain films show greater than 45% bone loss or a T-Score of -2.5 standard deviations below the mean (or lower) on a DEXA test
5. A severe or unstable medical disorder
6. Temporomandibular Joint (TMJ) Syndrome / Disorder
7. Pregnancy
8. Ankylosing spondylitis
9. Surgical Fusion
10. Spinal infections including osteomyelitis and septic discitis
11. Severe osseous stenosis
12. Hemangioma that invades the endplate, greater than 1 cm in size that may compromise the vertebral integrity or that may represent a risk of bleeding
13. Cervical Disc / Extrusion with sequestration

Independence Blue Cross Sponsored Study

Outcomes After a Prone Lumbar Traction Protocol for Patients With Activity-Limiting Low Back Pain: A Prospective Case Series Study 2008

P.F. Beattie, R.M. Nelson, L.A. Michener, J. Cammarata, J. Donley

Arch. Phys. Med. Rehabil. , Vol 89, Feb 2008,

VAX-D Research Studies:
Outcomes After a Prone Lumbar Decompression Protocol for Patients With Activity-Limiting Low Back Pain: A Prospective Case Series Study (2008)

Paul F. Beattie, PhD, PT, OCS, Roger M. Nelson, PhD, PT, Lori A. Michener, PhD, PT, ATC, SCS, Joseph Cammarata, DC, Jonathan Donley, DPTS
Archives of Physical Medicine And Rehabilitation, Volume 89, February 2008

- A two and one-half year study on the treatment of chronic back pain sponsored by *Independence Blue Cross,* a leader in the insurance industry, confirmed the effectiveness of VAX-D.

- The purpose of the study was to determine short- and long-term outcomes after VAX-D treatment in a large sample of patients with activity-limiting low back pain that had failed at least two previous, non-surgical treatments.

- A total of 296 subjects with low back pain and evidence of a degenerative and/or herniated intervertebral disk at 1 or more levels were enrolled in the study.

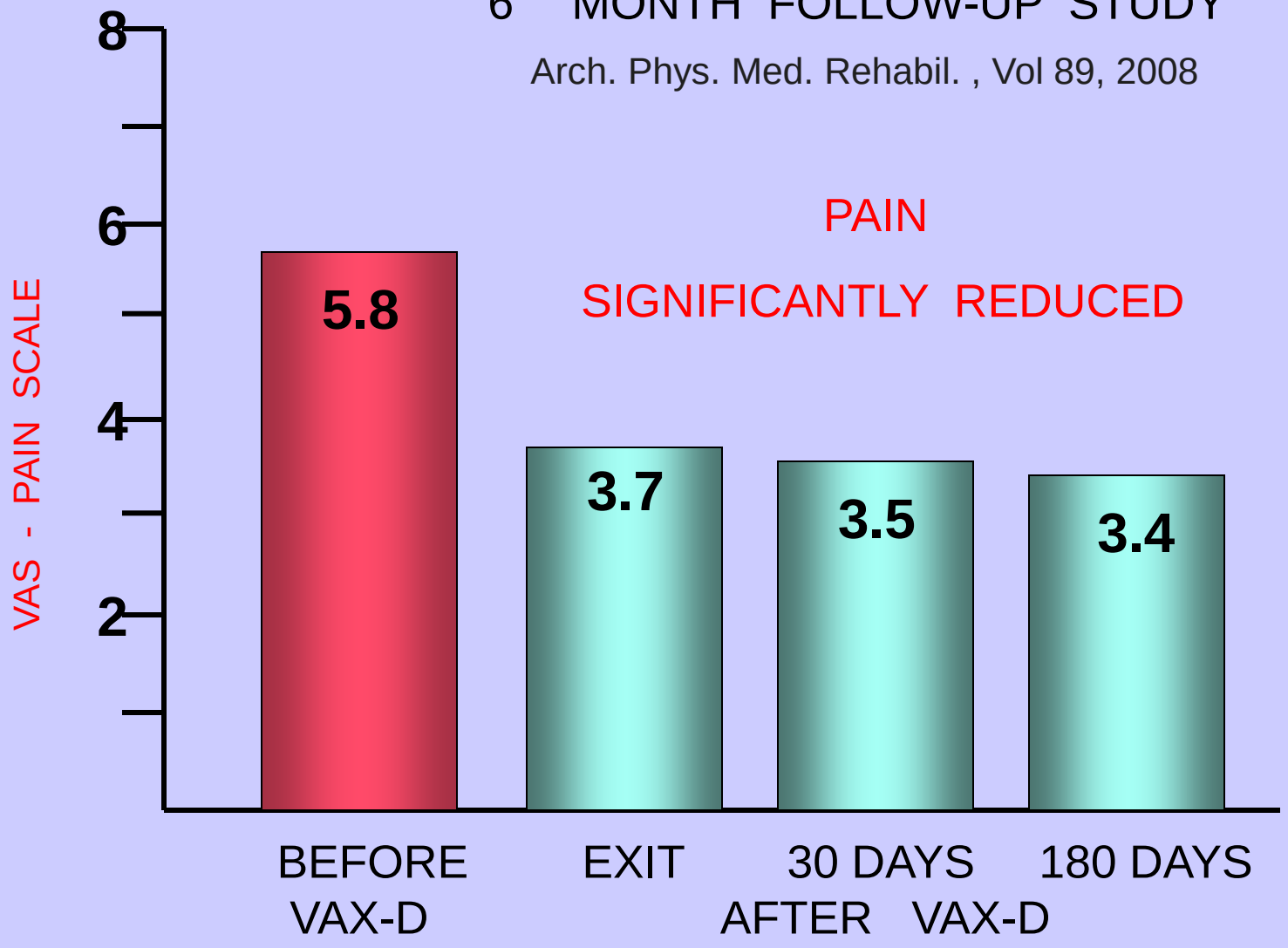
- In this study all subjects had pre-intervention imaging evidence of lumbar intervertebral disk degeneration and/or herniation.

- The study showed that patients had significantly improved pain and disability scores at end of treatment, at 30 days and at 180 days post-discharge.

Blue Cross Sponsored Study • 296 Patients

6 MONTH FOLLOW-UP STUDY

Arch. Phys. Med. Rehabil. , Vol 89, 2008



STATISTICAL SIGNIFICANCE P < 0.01

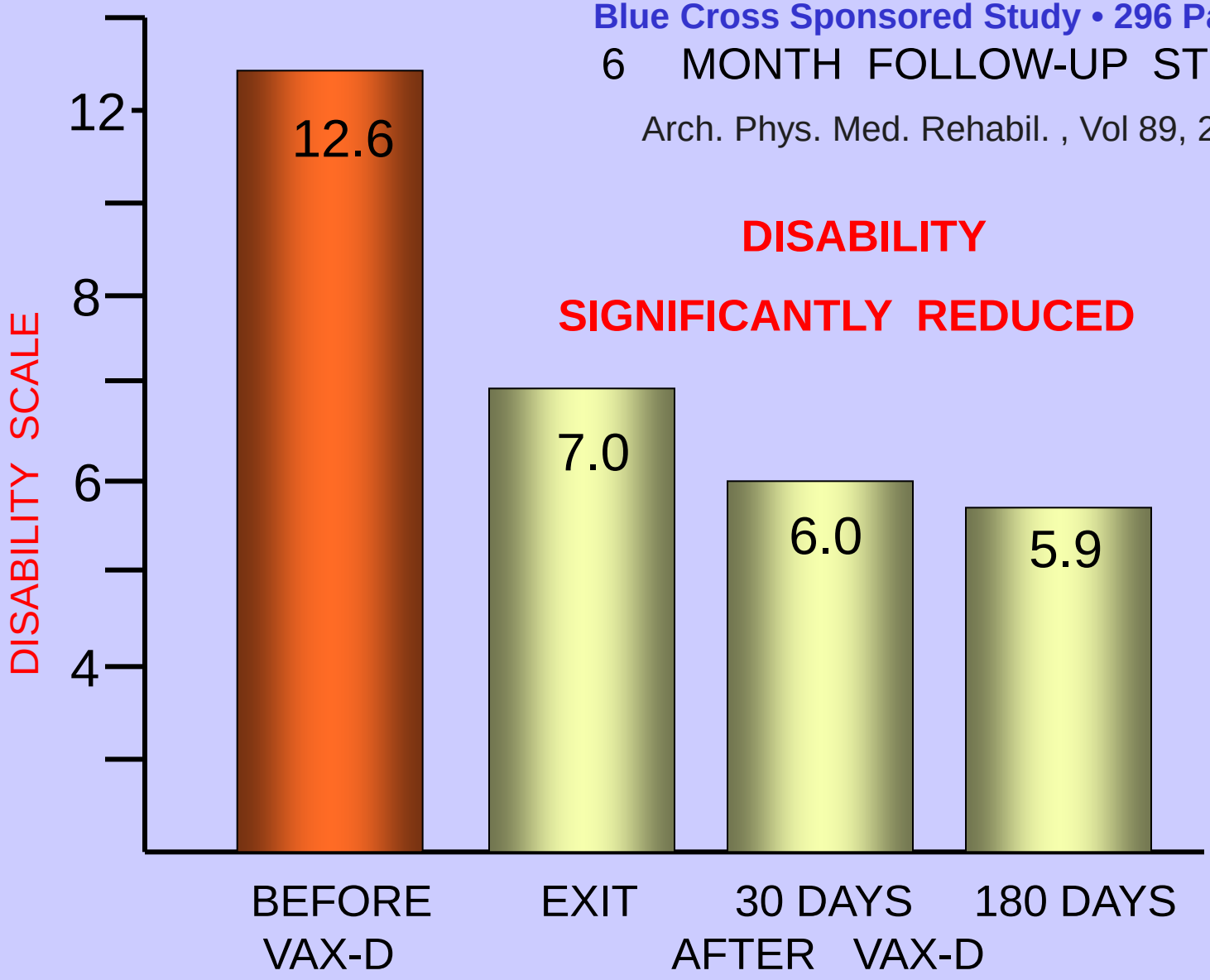
Blue Cross Sponsored Study • 296 Patients

6 MONTH FOLLOW-UP STUDY

Arch. Phys. Med. Rehabil. , Vol 89, 2008

DISABILITY

SIGNIFICANTLY REDUCED



STATISTICAL SIGNIFICANCE P < 0.01

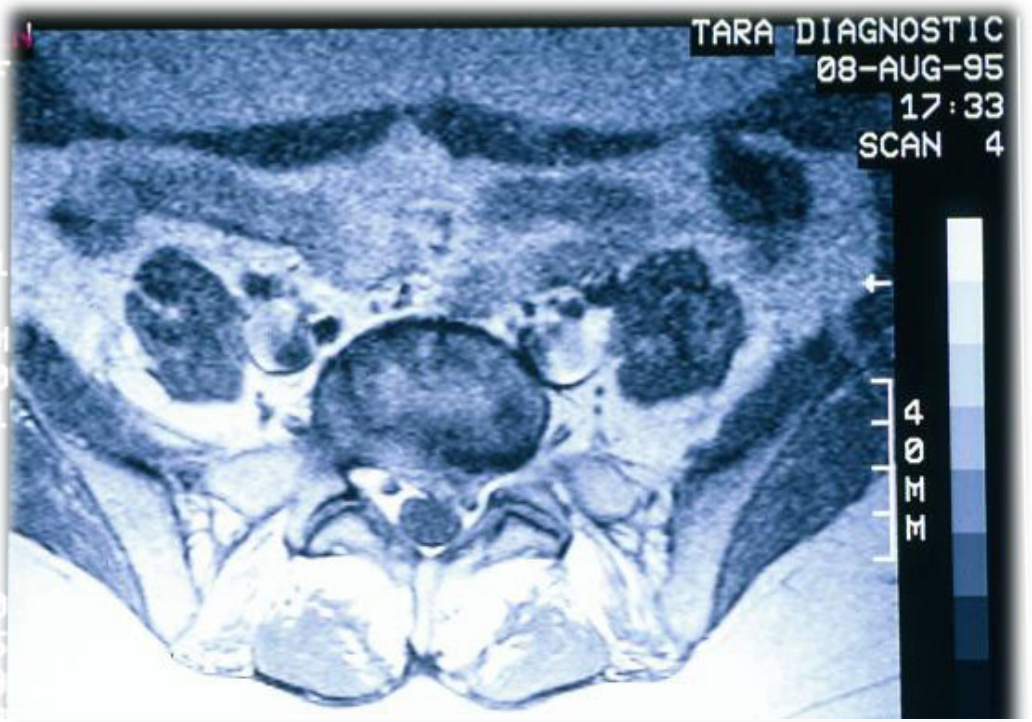
BEFORE VAX-D

L4 -L5 left posterior large extruded disc compressing the thecal sac

AFTER VAX-D

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

Radiologist: Curvel A. Ferrari MD



BEFORE VAX-D

Left posterior - L4-L5
Extruded disc
compressing &
retro-displacing
left nerve root

AFTER VAX-D

Extruded disc
retracted
Left nerve root
decompressed

Radiologist: Curvel A. Ferrari MD

VAX-D PROTOCOL • PHARMACOLOGICAL AGENTS

Steroid

Methylprednisolone 4 - 8 mg 2-3 hrs before Tx (10 days)
Prednisone 20 mg tid (10 days)
Medrol Dosepak

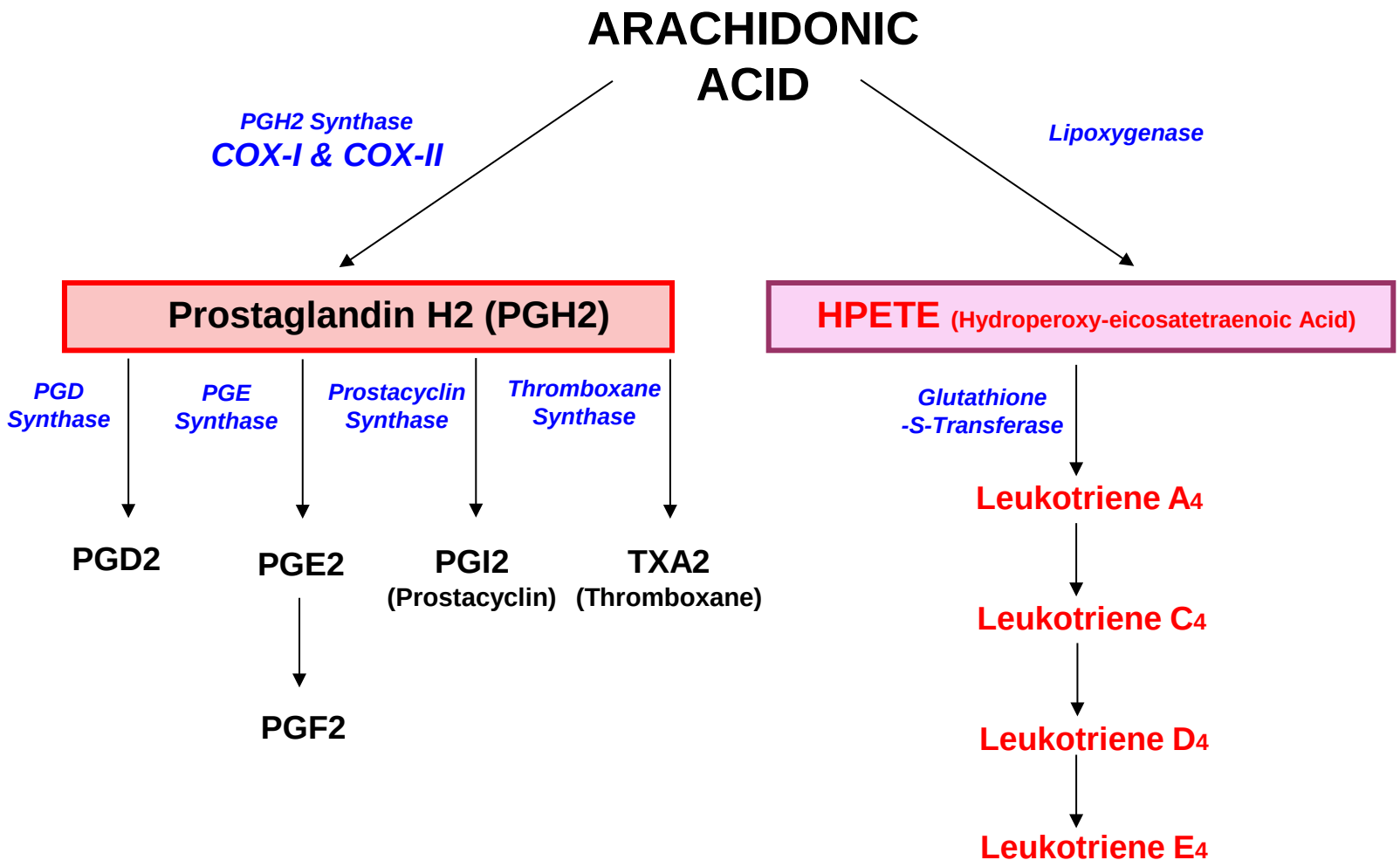
Non-steroidal Anti-inflammatory Drugs

Naproxen Sodium (Aleve) 220mg bid
Diclofenac (Voltaren) 50 mg bid
COX-II Inhibitors

Analgesics - When necessary

Muscle relaxants - When necessary

Inflammatory Cascade



Pain & Inflammation

Internal Disc Disruption

IDD arises as a result of degradation of the nuclear matrix following fracture of the vertebral endplate, an inflammatory reaction, and a disturbance of the pH of the nucleus.

The disc becomes painful as a result of inflammation about the peripheral end of the radial fissure, and mechanically increased strain in the outer annulus.

The matrix contains degradative enzymes whose activity is normally limited by tissue inhibitors of metalloproteinases. The balance of synthesis and degradation of the matrix is very sensitive to changes in pH.

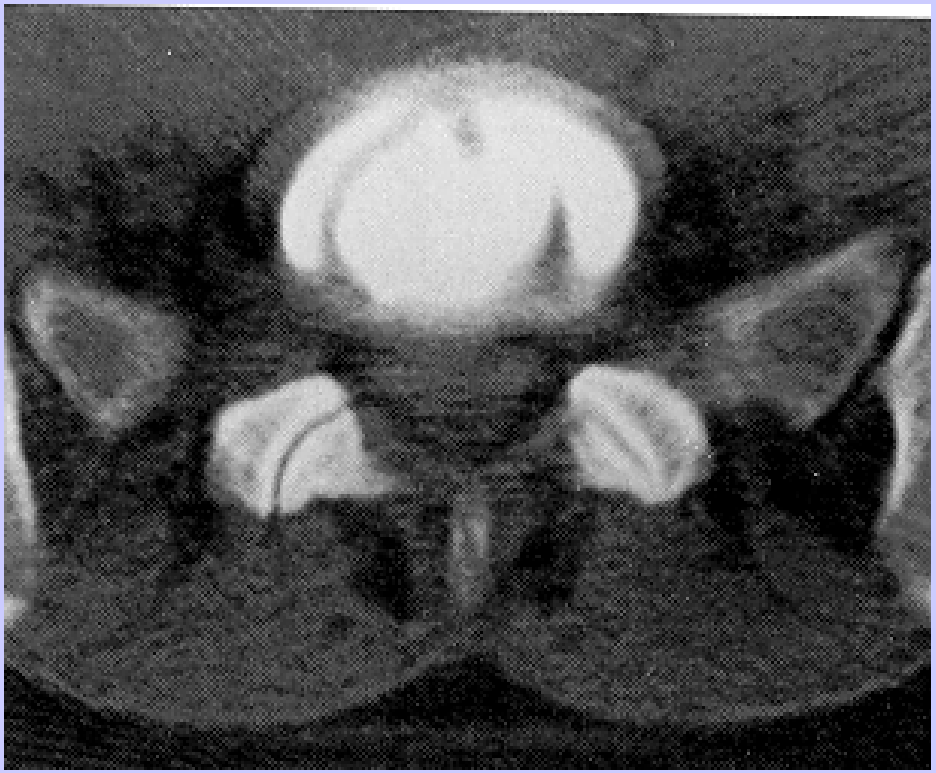
Proteolysis and degradation of the nuclear matrix results in a progressive loss of water-binding capacity and deterioration of nuclear function.

An HIZ represents a circumferential extension of a radial fissure. IDD can't be diagnosed clinically; only on the basis of a positive response to disc stimulation; demonstration of radial fissures on CT-discography; and MRI HIZ.

According to these criteria, the prevalence of IDD is approximately 40% in patients with chronic low back pain .

A recent study showed that HIZ is predictive of pain from IDD.

Internal Disc Disruption



DISCOGRAM
DYE PENETRATES
ANNULUS FIBROSUS
INDICATES DISRUPTION OF
INTERNAL STRUCTURES

Internal Disc Disruption • Treatment Options

1. **Medication**

2. **Intradiscal Injection** (Chondroitin Sulfate, Glucosamine Hydrochloride, DMSO, Marcaine, Dextrose)

3. **Selective Endoscopic Discectomy** (SED Yeung Technique)

4. **Radio Frequency Annuloplasty**

5. **Intradiscal ElectroThermal Therapy** (IDET)

6. **Surgical Interbody Fusion**

7. **Artificial Disc Replacement**

8. **VAX-D** coupled with **Metalloproteinase Inhibitors** + **Methylprednisolone**

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

Ankylosing Spondylitis & Inflammatory Back Pain

Ankylosing Spondylitis (AS) is a chronic, painful, degenerative inflammatory arthritis primarily affecting spine and SI joints in patients 20 to 40 years of age. Men are affected more than women by a ratio of 3:1.

The diagnosis is delayed in primary care physicians due to the difficulties in differentiating **Inflammatory Back Pain (IBP)** from **Mechanical Back Pain.**

The 8 Hallmark Indicators of Inflammatory Back Pain *(Calin's/Rudwaleit Criteria)* :

1. **Insidious onset**
2. **Duration >3 months**
3. **Back pain relieved by exercise**
4. **Back pain not relieved by rest**
5. **Morning stiffness >30 min**
6. **Nocturnal pain**
7. **Alternating back pain / buttock pain**
8. **Good response to anti-inflammatory drugs** (NSAIDS)

Associated Pathology & Symptoms

SI Joint Inflammation
Psoriasis
Uveitis (Eye inflammation)
Genitourinary/gut infection in the last month
Enthesitis (Inflammation of the tendon/bone insertion)
Dactylitis (Finger /Toe inflammation)
Apthous Ulcers in mouth (canker sore)
IBD (Irritable Bowel Disease)
General Fatigue

Diagnosis of Ankylosing Spondylitis

1. Clinical Evaluation: (with history of IBP / family history of IBP)

2. X-Ray: X-rays to detect spine and/or SI-joint involvement can be problematic because it can take 7- 10 years of disease progression for the changes to appear.

3. Inflammatory Markers (Blood Tests): HLA-B27 (Human Leukocyte Antigen B*27) - Erythrocyte Sed Rate (ESR) - C-Reactive Protein (CRP)

Treatment of Ankylosing Spondylitis

1. Exercises & Physical Therapy: To maintain mobility and control pain.

2 . Non Steroidal Anti-Inflammatory Drugs (NSAIDs) to reduce pain and inflammation.

3. Corticosteroids are used to help reduce inflammation (may be injected intojoints).

4. DMARDs (Disease-Modifying Anti-Rheumatic Drugs) The most common is **sulfasalazine** (oral).

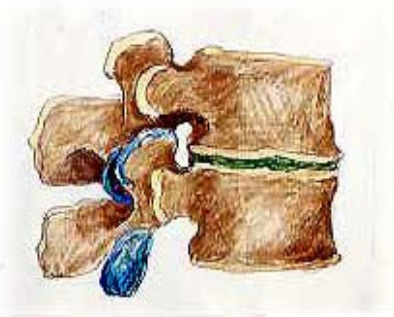
5. Anti-TNF-alpha drugs reduce inflammation by blocking a protein called tumor necrotizing factor (TNF) that causes inflammation (most common is Etanercept)

The use of ***Etanercept (Enbrel)*** has now revolutionized the management of AS with treatment leading to rapid, significant and sustained improvement of clinical symptoms.

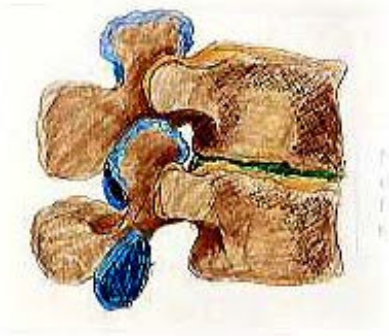
STENOSIS

LATERAL FORAMENAL

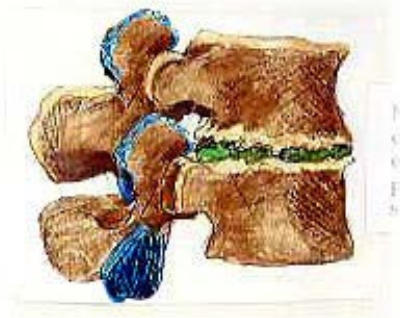
NORMAL
DISC HEIGHT &
LATERAL FORAMEN



DEGENERATED DISC
FACET SUBLUXATION
NARROWS
LATERAL FORAMEN

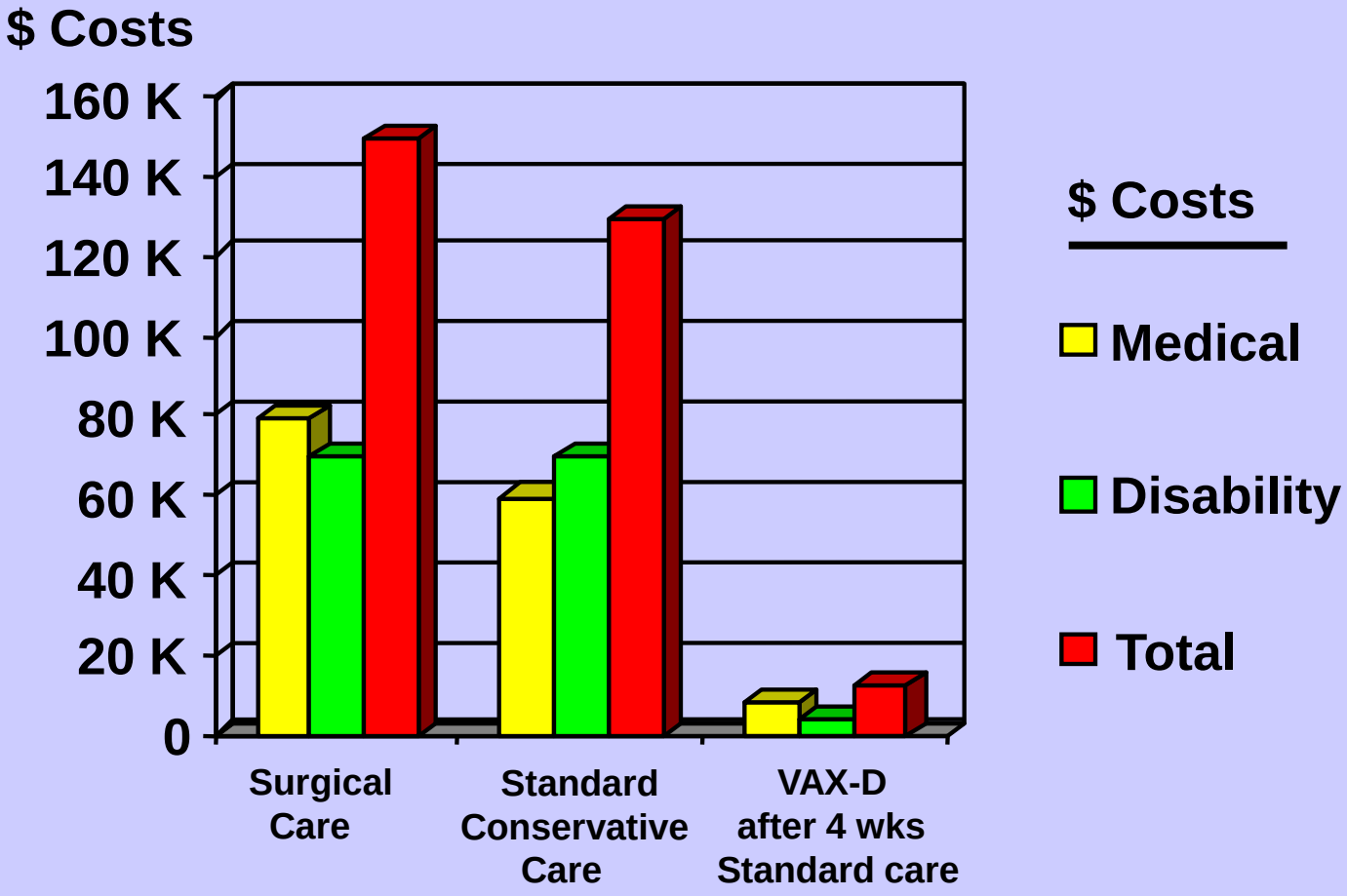


DEGENERATED DISC
FACET HYPERTROPHY
IMPINGES
LATERAL FORAMEN



DEGENERATED DISC
FACET HYPERTROPHY
OSTEOPHYTIC SPURS
IMPINGES
LATERAL FORAMEN

A Graphic Comparison of Costs




VANS