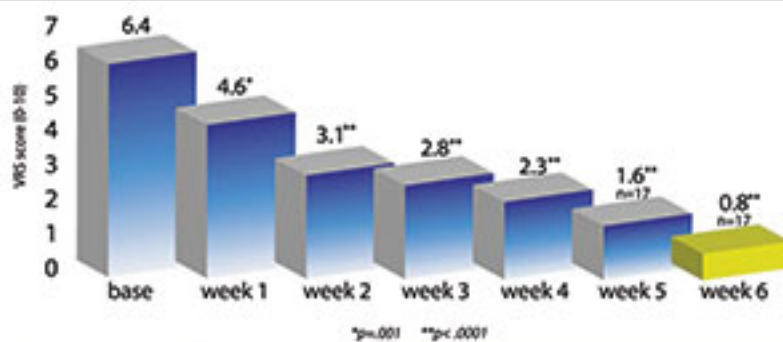


# Dr. Leslie of the Mayo Clinic Proves Spinal Decompression to be **Up to 88.9% Effective** for **NECK** and **BACK PAIN**!



**CHANGE IN PAIN SCORE BY TREATMENT WEEK**



**PILOT: Effectiveness &  
Safety of Non-Surgical  
Spinal Decompression**

# PILOT: Effectiveness and Safety of Non-Surgical Spinal Decompression

## ABSTRACT

**OBJECTIVE:** Prospective, multicenter, phase II, non-randomized, clinical study to evaluate the effectiveness and safety of the Axiom Worldwide DRX9000™ for active treatment of chronic LBP utilizing a standardized clinical research multimodal protocol.

**METHODS:** 20 patients with chronic LBP based on a diagnosis of musculoskeletal or mechanical LBP, herniated discs, bulging or protruding discs, degenerative disc, pain from failed back surgery more than 6 months previously, posterior facet syndrome or sciatica underwent a series of 20 DRX™ treatments (28 mins each) for 6 weeks with 5 sessions the first week tapering to 1 session/wk. Treatment multimodal protocol included ice after DRX™ sessions, lumbar stretching exercises, and adjunct analgesics as required. Assessments of pain, analgesic use, functionality, satisfaction, activities of daily living and safety were collected through examinations, questionnaires and patient diaries.

**RESULTS:** 18 evaluable subjects (33.3% female, 83.3% white, mean age 46.6, 77.8% employed) had mean pain score 6.4 on a 0 to 10 scale (0=no pain 10=worst pain) prior to first DRX™ treatment that decreased to 0.8 after last DRX™ treatment. 88.9% of patients (16 out of 18) reported an improvement in back pain, and better function as measured by activities of daily living. On a 0 to 10 scale (0=Not satisfied 10=Very satisfied) patients rated the DRX9000 an 8.1. No patient required any invasive therapies (e.g., epidural injections, surgery).

**CONCLUSION:** Overall, patients' pain improved after DRX™ treatment, requiring fewer analgesics, with better function. There were no safety issues identified with the multimodal treatment routine. Non-treatment or control groups were not included making efficacy outcome versus placebo or spontaneous recovery difficult to determine. Randomized double-blinded or comparative long-term outcome trials are needed to further prove the efficacy of the DRX9000™ non-surgical spinal decompression system for the routine treatment of chronic LBP.

## BACKGROUND

- Paucity of literature on benefits of non-surgical spinal decompression over other non-surgical treatments
- Previous studies are poorly designed
- Results are descriptive in nature
- Efficacy versus placebo or spontaneous recovery difficult to determine
- Over 1,200 DRX9000™ in use today

## MATERIALS AND METHODS

### METHODS

- Prospective, multi-center, phase II, non-randomized clinical trial
- 3 free-standing clinics (2 MDs and 1 DC)
- Diagnosis: Low back pain > 12 weeks
- Outcome measures assessed:
  - Daily Pain Diary
  - Verbal Rating Scale (VRS)
  - Oswestry Pain Questionnaire
  - Adverse Events
  - Satisfaction Survey

### TREATMENT PROTOCOL

- DRX9000™ sessions
  - 28-minute sessions for 6 weeks
  - Total of 20 treatments
    - 5 sessions week 1 & 2
    - 3 sessions week 3 & 4
    - 2 sessions week 5 & 6
- Additional Therapy
  - Ice therapy post DRX™
  - Back exercises after week 2

## RESULTS

### DEMOGRAPHICS

Total Number of Subjects = 18

Male	66.7%	Mean Age	46.6 yrs
LBP Symptom Duration (mean)	526 weeks	Mean Height	175 cm
Employed	77.8%	Mean Weight	102 kg
Retired	16.6%	White	83.3%
Other	5.6%	Hispanic	16.7%

### SUMMARY OF LOW BACK PAIN

DIAGNOSIS		LOCATION	
Bulging/Protruding Disc	15	L1-L2	1
Degenerative Disc	8	L2-L3	3
Herniated Disc	6	L3-L4	4
Posterior Facet Syndrome	2	L4-L5	14
Failed Back Surgery	1	L5-S1	12

### FAILED THERAPY PRIOR TO DRX9000™

Procedure	#	Procedure	#
Chiropractic	16	TENS	5
Muscle Stimulation	10	Acupuncture	3
Ice Therapy	9	Lumbar support	3
Massage Therapy	9	Epidural Injections	3
Exercise	6	Facet Injections	1
Heat	5	Ultrasound	1
Physical Therapy	5	Other Decompressive Therapy	1

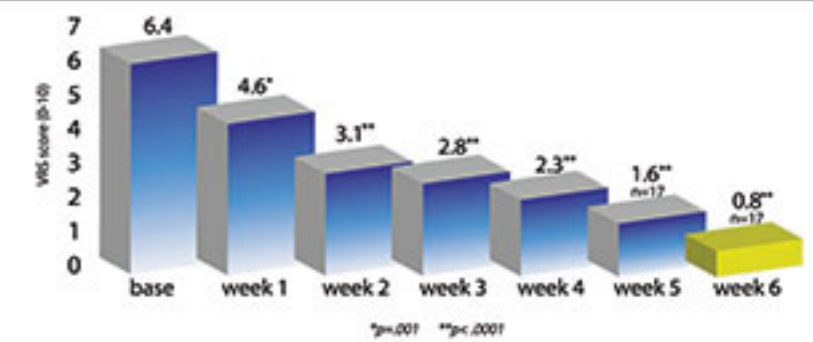
### ADVERSE EVENTS

Adverse Event	Related to device	Adverse Event	Related to device
Neck Pain	Possibly	Shoulder Pain	No
Head Cold (2)	No	LBP/flu-like symptoms	No
Sinus headache (2)	No	Vertigo	No
Sinus infection	No	Adrenal Insufficiency	No

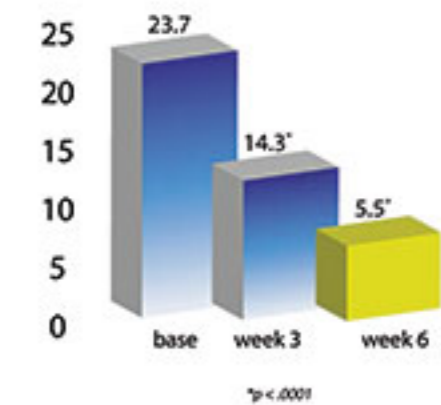
Disclaimer: This study was funded by Axiom Worldwide, LLC.

## RESULTS

### CHANGE IN PAIN SCORE BY TREATMENT WEEK



### CHANGE IN OSWESTRY SCORES



### SATISFACTION SURVEY

Satisfaction by Week		Would you recommend DRX9000™ to anyone else?	
Week 3	7.6	Yes	No
Week 6	8.1	88.9%	11.1%

## CONCLUSION

- A 6-week course of 20 DRX9000™ treatments significantly reduced the severity of chronic LBP in 89% (16 of 18) of treated patients from 6.4 to 3.1 after 2 weeks and to only 0.8 (scale 0-10) after completion of treatment
- Oswestry Disability scores improved from 23.7 to only 5.5 at end of therapy
- Adjunctive pain medication consumption was decreased by DRX9000™ treatments
- No significant adverse events or safety issues resulted from DRX9000™ treatments
- The DRX9000™ shows great promise in treating chronic LBP arising from multiple causes
- Comparative outcome trials utilizing a set of standardized and validated multiple outcome variables, as was utilized in this study, are being planned to document the value of DRX9000™ non-surgical spinal decompression system in routine treatment of chronic LBP

# SUMMARY of PILOT STUDY

Conducted by: Mayo Clinic Supervised by: John Leslie, M.D.

## Subjects Conditions

- Herniated Discs
- Bulging Discs
- Degenerative Discs
- Failed Back Surgery
- Facet Syndrome

## Prior to Treatment

- Average Pain Score 6.4 Out of 10
- Pain Greater Than 6 Months

## 6 Week Treatment Protocol

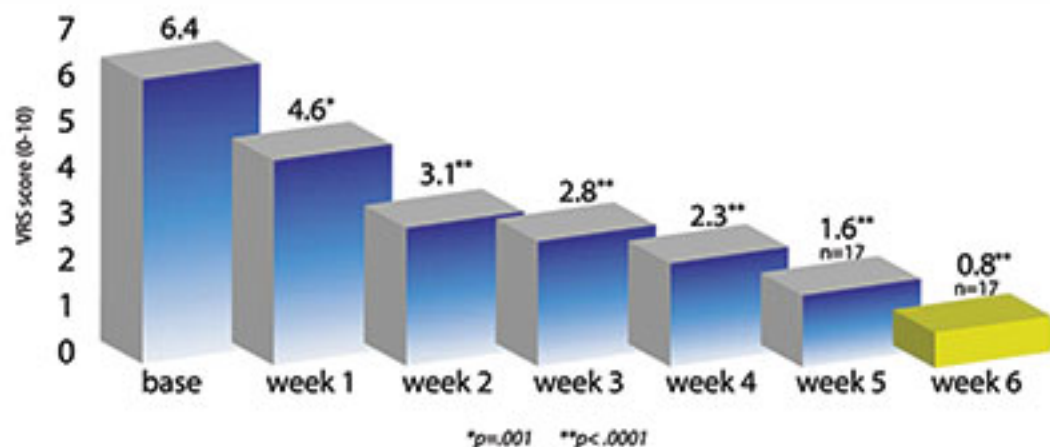
- 20 Treatments

## Post Treatment

- Average Pain Decreased to 0.8 Out of 10
- Decreased Pain
- Improved Function
- Required Fewed Analgesics After Treatment
- No Safety Issues or Adverse Effects



## CHANGE IN PAIN SCORE BY TREATMENT WEEK



### Presented At:

American Academy of Pain Management  
AAPM 18th Annual Clinical Meeting  
Sept. 27-30, 2007 | Las Vegas, NV

New York State Society of Anesthesiologists  
61st Post Graduate Assembly in Anesthesiology  
Dec. 7-11, 2007 | New York, NY

American Conference in Pain Medicine  
April 4-5, 2008 | New York, NY

Parker Seminar  
Feb. 7-9, 2008 | Las Vegas, NV

### Study Team:

John Leslie, MD<sup>1</sup>, Charlotte Richmond, PhD<sup>2</sup>, Alex Macario, MD<sup>3</sup>, Christian Apfel, MD<sup>4</sup>, Frank Florio, DC<sup>5</sup>, Darren Clair, MD<sup>6</sup>, Martin Auster, MD<sup>7</sup>, Joseph Perfoluzzi, MD<sup>1,7</sup>  
<sup>1</sup>Mayo Clinic, Arizona; <sup>2</sup>NEBA Research; <sup>3</sup>Stanford University; <sup>4</sup>University of California at San Francisco; <sup>5</sup>Avicor Worldwide; <sup>6</sup>Vibrance Medical; <sup>7</sup>Johns Hopkins University