

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

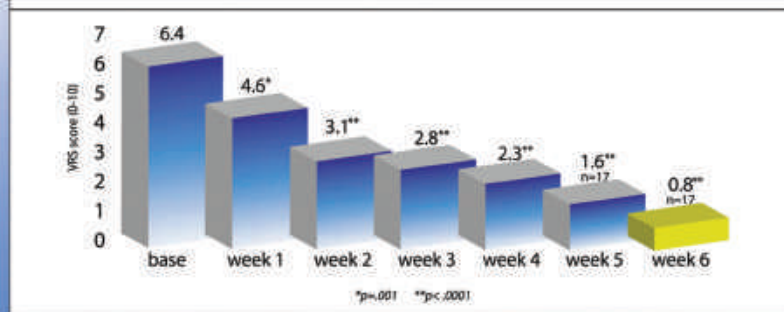
- 20 Treatments

Post Treatment

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



CHANGE IN PAIN SCORE BY TREATMENT WEEK



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Study Team:

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CHIROPRACTIC
ASSOCIATES
OF GAINESVILLE

Individual results may vary. These statements have not been evaluated by the FDA. All spinal decompression devices currently marketed in the USA have received their FDA clearance by copying their device's substantially similar to predicate traction devices.

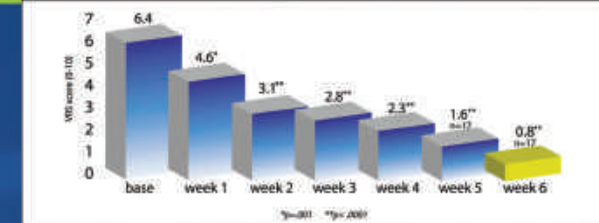
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ChirosOfGainesville.com

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

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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 System 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%

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

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

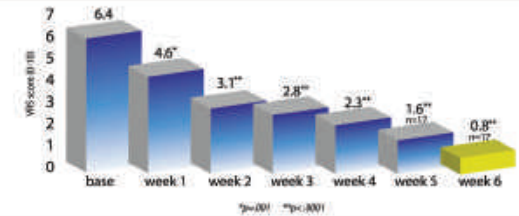
ADVERSE EVENTS

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

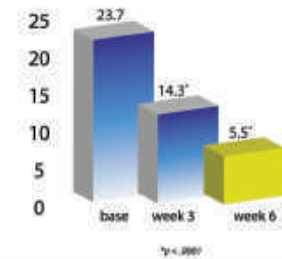
Disclaimer: This study was funded by Axiom Worldwide, LLC.

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	88.9%
Week 6	8.1	No	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