PILOT: Effectiveness & Safety of Non-Surgical Spinal Decompression

John Leslie, MD[1]; Charlotte Richmond, PhD[2]; Alex Macario, MD[3]; Christian Apfel, MD[4]; Frank Florio, DC[5]; Darren Clair, MD[6]; Martin Auster, MD[7]; Joseph Pergolizzi, MD[2,7]

[1]Mayo Clinic Arizona, [2]NEMA Research, [3]Stanford University, [4]University of California at San Francisco, [5]Axiom Worldwide, [6]Vibrance Medical, [7]Johns Hopkins University

AXIOM WORLDWIDE

9423 Corporate Lake Drive
Tampa, Florida 33634
Tel: 813/249-6444 Fax: 813/249-6445
www.AxiomWorldwide.com
www.AxiomPainSolutions.com

MKT0251 REVA

PILOT: Effectiveness & Safety of Non-Surgical Spinal Decompression

www.AxiomWorldwide.com

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

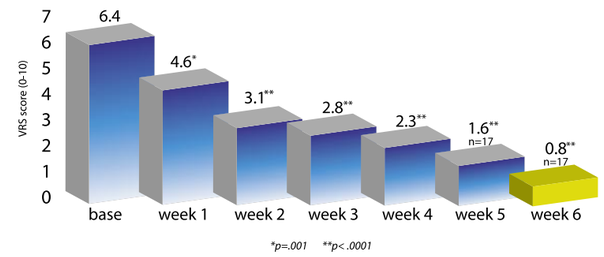
ADVERSE EVENTS

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

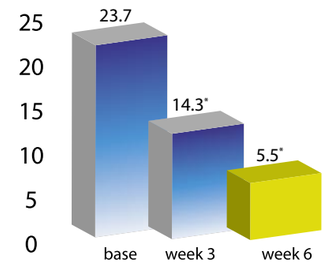
Disclaimer: This study was funded by Axiom Worldwide, LLC.

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	Week 6		Yes	No
7.6	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