

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 5.8 on a 0 to 10 scale (0=no pain 10=worst pain) at initial presentation that decreased to 2.9 after last DRX™ treatment. Patients reported a mean 88.9% (16 out of 18) 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 immediately 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.

DISCLOSURE: This study was funded by Axiom Worldwide.

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

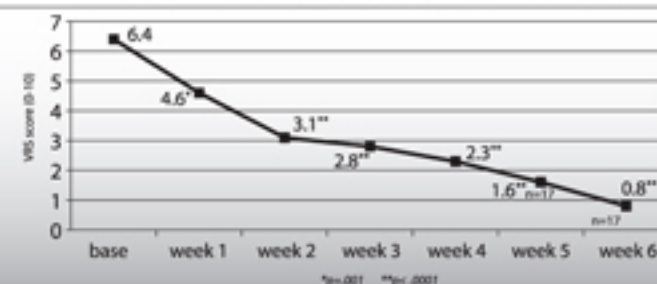
ADVERSE EVENTS

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

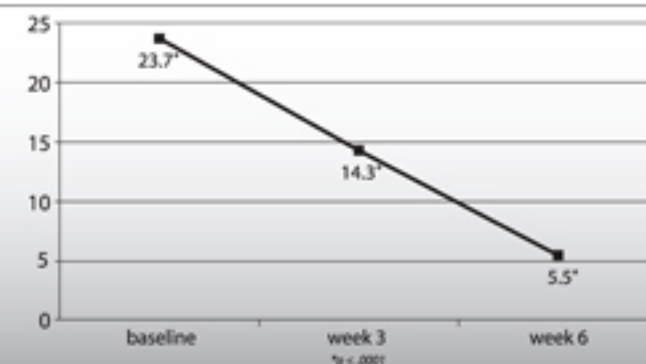
Disclaimer: This study was funded by Axiom Worldwide, LLC.

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