

Medical Doctors From Stanford and John Hopkins University
Show Patients Rate Spinal Decompression
8.98 Out of 10 In Satisfaction
And 100% would recommend Spinal Decompression

SUMMARY OF STUDY

Subjects' Conditions

- Herniated Discs
- Degenerated Discs

Prior to Treatment

- Average Pain Score 5.99 out of 10
- Pain lasting great than 12 weeks

Treatment Protocol

- 23 DRX sessions Over 8 Weeks
- Lumbar stretching exercises and ice or muscle stimulation

Post Treatment

- Pain decreased from Average 5.99 to .87 out of 10
- NSAID and Opioid use went from 65% of patients to <5%
- Patients reported a mean 90% improvement in back pain
- Better function as measured by activities of daily living.
- Patients rated the DRX9000 an 8.98 out of 10 in Satisfaction
- No patient required more invasive therapies (e.g. surgery)
- 100% Would recommend DRX to someone else

Alex Macario, MD, MBA, Standford University; Sunil J. Panchal, MD, COPE Foundation, Florida Pain Management; Charlotte Richmond, PhD, Nema Research, Biomedical Research & Education Foundation; Joseph V. Pergolizzi, Jr., MD, Johns Hopkins University & Nema Research

Individual results may vary. These statements have not been evaluated by the FDA. All spinal decompression devices currently registered with the FDA have received their 510 K clearance by claiming their device is substantially similar to predicate traction devices.



(888) 639-3332

www.ahlasersla.com

Objectives

Conduct retrospective chart audit to assess outcomes of a random sample of outpatients treated with motorized spinal decompression via the DRX9000 for chronic low back pain lasting more than 12 weeks.

Methods

- Data from charts of 100 adults cared for in 2004-2006 at four clinics, one hospital-based and three free-standing, were abstracted using a standardized data collection form.
 - Protected health information was accessed in accordance with the HIPAA privacy rule. Workman's compensation patients were excluded.
 - DRX sessions (28-30 mins each) were for 8 weeks (mean) with 4-5 sessions the first week tapering to one session/wk (mean treatments = 23).
 - Treatment protocol included instruction on lumbar stretching exercises and ice or muscle stimulation after DRX sessions.
 - Pain, analgesic use, and activities of daily living were assessed pre and post treatment.
 - Subjects (62% female, 94% male, mean age 55, 53% employed) had mean pain score 5.99 on a 0 to 10 scale (0= no pain 10=worst pain) at time of initial presentation that decreased to 0.87 after last DRX treatment. NSAID (41% of patients) and opioid (24% of the patients) use decreased (<5%) after treatment.
 - Patients reported a mean 90% 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 8.98 (Fig. 11).
- No patient required more invasive therapies (e.g. surgery)
 - Mean satisfaction with DRX (0-10 scale) 8.98
0=not satisfied 10=Very satisfied
 - Improvements in LBP provided by DRX 90%
 - Recommend DRX to someone else 100%
 - Chronic LBP improves after treatment
 - Require fewer analgesics after treatment

Analgesic Use	Pre-DRX9000	Post-DRX9000
No Meds	40%	20%
NSAIDs	43%	0%
Opioids	23%	0%
Muscle Relax	12%	1%
Steroids	4%	1%
Unknown	0%	59%

Conclusions

- Achieve better function after treatment
- No patients contacted required surgery
- Practice variability exists in how clinics add adjunct therapies to DRX
- Difficult to assess placebo or spontaneous recovery versus DRX without control group
- Randomized clinical trials are needed to measure efficacy of motorized spinal decompression
- Prospective trials with long-term assessment needed