

SUMMARY OF STUDY

Subjects' Conditions

- Herniated Discs
- Degenerated Discs

Prior to Treatment

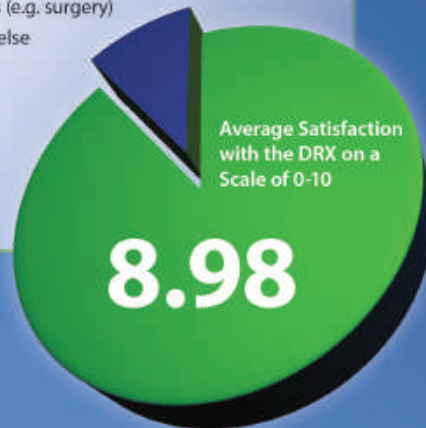
- Average Pain Score 5.99 out of 10
- Pain lasting great than 12 weeks

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



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.



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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



Non-Surgical Spinal
Decompression Via
Motorized Distraction
for Chronic Discogenic
Low Back Pain



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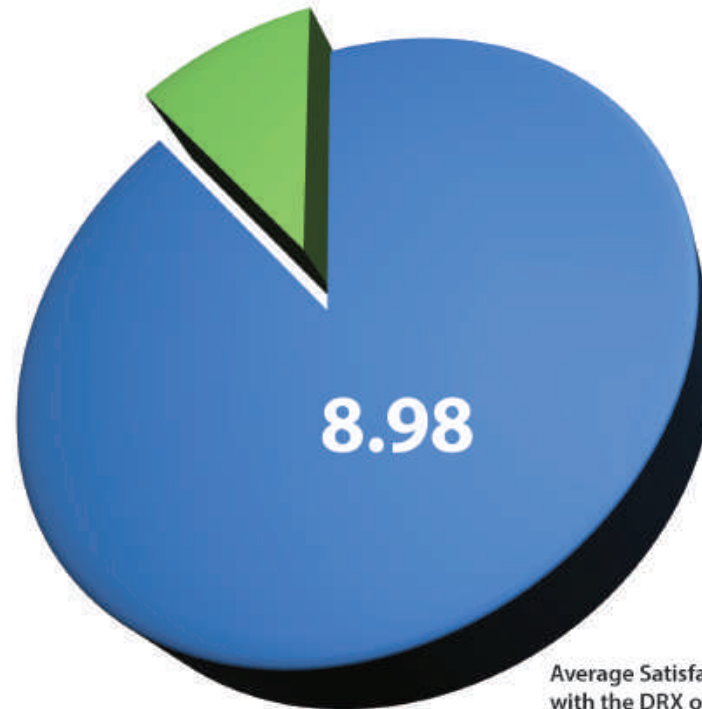


Objectives

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 (Fig. 1- Fig 10).
- 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



Average Satisfaction with the DRX on a Scale of 0-10

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%

- Improvements in LBP provided by DRX 90%
- Recommend DRX to someone else 100%
- Chronic LBP improves after treatment
- Require fewer analgesics after treatment

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

