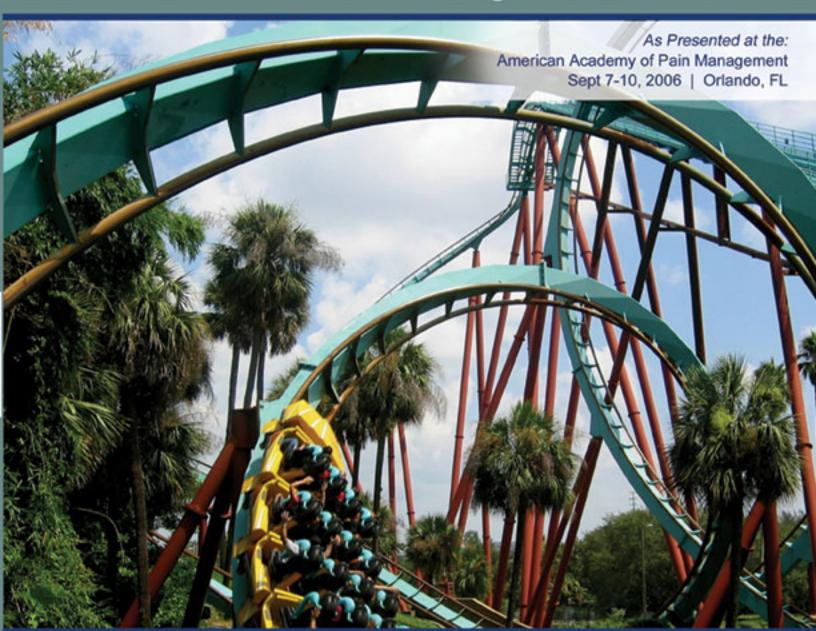
Non-Surgical Spinal Decompression Via Motorized Distraction for Chronic Discogenic Low Back Pain



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Joseph V. Pergolizzi, Jr., MD, Johns Hopkins University & Nema Research

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ABSTRACT

Objective: 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 1 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.

Results: Subjects (62% female, 94% white, 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. No patient required more invasive therapies (e.g., surgery).

Conclusion: Overall, patients' pain improved after DRX treatment, requiring fewer analgesics, with better function. Practice variability exists in how clinics use the DRX 9000. We didn't have control groups, making it difficult to know how much of the benefit was placebo or spontaneous recovery and how much was due to the intervention. Randomized double-blinded clinical trials are needed to measure the efficacy of non-surgical spinal decompression systems.

OBJECTIVE

 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.

RESULTS

 Subjects (62% female, 94% white, 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).

DISCLOSURE:

This study was partially funded by Axiom Worldwide.

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То	tal Numbe	r of Patients = 100	
Mean Age	55	Mean Height	68 in
Female	62%	Mean Weight	89 kg
Employed	53%	White	94%
Retired	40%	Hispanic	3%
Disabled	5%	Black	2%
Housewife	1%	Asian	1%

FIGURE 1

S	Medical Diagnor	sis	Symptoms	H.
5 5	Herniated Disc	74%	Nonspecific LBP	86%
NO.	Degenerative Disc Disease	66%	Leg Radiation	62%
S E	Herniated & Degenerative Disc	26%	Radiation to Buttocks	22%
S S	Sciatica	11%	Leg Pain > Back Pain	16%
MEDI	Mean Duration Low Back Pain	260 wks	Prior Surgery	12%

FIGURE 2

MRI Results		Level of Pathology		
Disc bulge	36%	L5-S1	35%	
Degenerative Changes	28%	L4-L5	40%	
Protrusion	28%	L3-L4	13%	
Extrusion	5%	L2-L3	8%	
		L1-L2	196	
	\top	T12-L1	2%	

FIGURE 3

Other MRI Results	A44 (1 (5 - 6)
Neural foramen compromise	24%
Facet arthropathy	16%
Central stenosis	14%
Nerve root compression/impingement	9%
Endplate changes	5%
Annular tears	4%

FIGURE 4

TES		Site	Site B	Site	Site
IL SI	Balance musculoskeletal system before DRX	Y	N	Y	Y
2	Heat before DRX	N	Υ	N	N
RE/	Ice after DRX	Y	Υ	Y	Y
ROT	Muscle stimulation after DRX	Υ	N	Y	Υ

FIGURE 5

	Pre-DRX9000	Post-DRX9000
Bathing	25%	0%
Dressing	25%	0%
Walking	50%	1%
Sitting	50%	3%
Standing	51%	4%
Sleeping	21%	0%
None	1%	10%
Other	59%	1%
Unknown	9%	59%

FIGURE 6

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%

FIGURE 7



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0-3	3-6	6-9	> 9
months	months	months	months
50%	22%	9%	19%

FIGURE 8

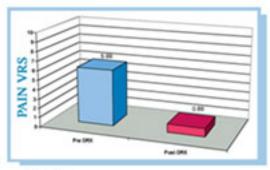


Figure 9

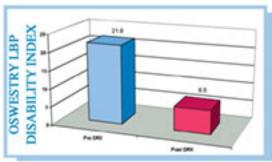


FIGURE 10

RESULTS CONTINUED

 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).

DRX	Mean satisfaction with DRX (0-10 scale) 0=not satisfied 10=Very satisfied	8.98
開	Improvement in LBP provided by DRX	90%
E	Recommend DRX to someone else	100%
3	Data based on 20-25% of patients contacted in follow up	_

FIGURE 11

CONCLUSION

- · Chronic LBP improves after treatment
- · Require fewer analgesics after treatment
- · 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

