IDD observational study, outcomes for pain and disability index measures.

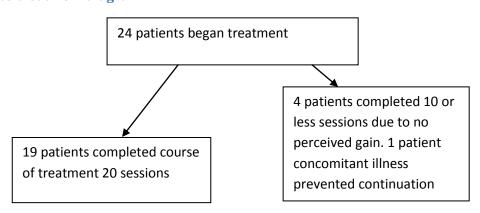
Introduction

Low back pain is a significant problem in today's society and persistent low back pain can result in many costly invasive interventions. Intervertebral Differential Dynamics (IDD) therapy is a non-surgical spinal decompression for back pain, neck pain and sciatica. IDD was developed in the late 1990s to overcome the failings of traditional traction and manual therapy. Cholewicki et al (2009) investigated the effect of traction on muscle activity and flexibility pre and post traction in healthy volunteers. They found muscle activity to be minimal and fluid exchange in the disc provides the biomechanical effect in traction. Shealy and Borgmeyer (1997) reported it was possible to distract isolated lumbar segments by angling the distraction force and thus decompress a specific disc. The Accu-Spina device using the IDD therapy protocol is able to focus distraction force to a specific lumbar segment and combing this with multiple primary waveforms and secondary oscillatory wave forms apply a neuromuscular component (Shealy 2009).

Method

The observational study has 24 subjects who had IDD treatment consisting of 20 sessions within a 6 week period. Treatment began with a distraction force of half body weight minus 20 lbs increasing gradually to half body weight plus 20lbs. Angle of distraction was directed to most symptomatic level if more than one lumbar level was affected. The data included intention to treat results as well as completed treatment results

Intention to treat flow diagram



Inclusion criteria

- Prior failed treatment from osteopathy, physiotherapy, chiropractor for low back pain due to disc or facet dysfunction
- Prior failed facet joint injections or failed nerve ablation for low back pain due to disc or facet dysfunction
- MRI scan to indicate, either herniated or prolapsed disc bulge, degenerative disc disease, sciatica, foraminal stenosis with or without radicular pain.

• Low back pain of 1 year duration or greater

Exclusion criteria

- Osteoporosis (T score -2.5 to -2.8 or greater)
- Unresolved compression fractures on the spine
- Spondylolithesis
- Spondyloysis
- Open growth plates
- Severe canal stenosis
- Surgical hard ware in spine
- Severe scoliosis
- Abdominal aortic aneurysm
- Vertebral fusions
- Pacemaker
- Pregnancy
- Genetically unstable or defects of the spine.

Demographic profile of subjects

Sex	16 male	8 female
Age range	34-71 years male	40-68 years female

Results

Patient	Oswestry DI	Oswestry DI	Change (10%	VAS before	VAS after
number	score before	score post	change is	treatment	treatment
	treatment	treatment	clinically		
			significant)		
1	8	16	+8	1	1
2	32	22	-10	8	1
3	66	32	-34	8	1
4	44	12	-32	3	0
5	44	28	-16	2	0
6	18	4	-14	6	0
7	64	40	-24	8	0
8	12	26	+14	0	0
9	16	16	-10	3	1
10	60	34	-26	8	3
11	6	2	-4	3	0
12	68	68	0	8	6
13	20	10	-10	8	1

14	26	8	-18	8	2
15	30	13	-17	7	3
16	26	14	-12	5	1
17	35	34	-1	8	7
18	12	4	-8	6	0
19	24	20	-4	5	1
20	4	12	+8	1	1
21	40	14	-26	5	0
22	48	40	-8	7	3
23	32	32	0	7	0
24	24	18	-6	6	0

Data analysis

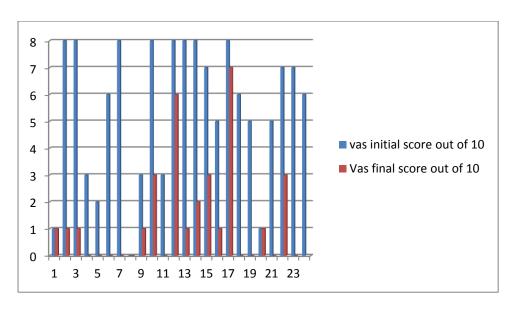
Pain score

Median score before treatment was 6/10 with lower quartile 3/10 and upper quartile 8/10, mode was 8/10

Median pain score post treatment was 1/10 with lower quartile 0/10 and upper quartile 2/10, mode was 0/10

Standard deviation was ±2.85 before treatment and ±2.09 after treatment

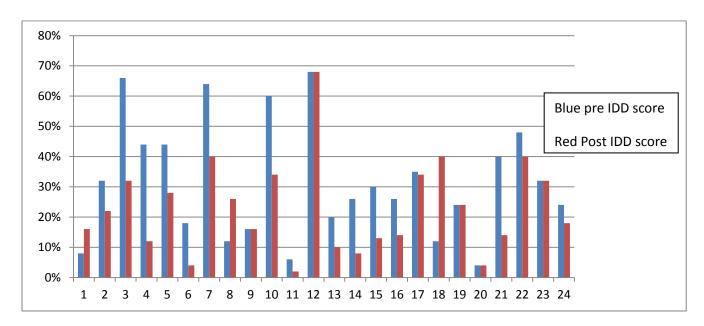
Student t-test (96% CI) p=0.0000054 (statistically significant)



Graph to show individual pre and post treatment pain scores.

Oswestry disability index scores

Number patients with a greater than 10% change	13
Percentage of patients with a clinically significant	
change	54



Graph to show individual pre and post Oswestry DI scores

Discussion

The results found to date are reflective of those in other studies with a reduction in pain from VAS 6 to 1 (83% reduction). Schimmel et al (2009) report a statistically significant reduction in pain from a VAS of 61 to 32 and a statistically significant reduction in ODI in their study of 60 patients with low back pain of more than 3 months duration. Shealy (2005) for a cohort of over 500 patients with chronic low back pain found a 65% reduction in pain after IDD therapy with an average pain reduction of 78% one year after treatment. Schaufele and Newsome (2011) found IDD was as effective and remained as effective as an intensive physiotherapy routine of lumbar stabilization exercises after 1 year with a 36% decrease in pain scores for 48 patients with chronic low back pain.

Conclusion

IDD therapy appears to be a clinically effective treatment to lower pain and decrease disability due to low back pain for those patients who failed physiotherapy, osteopathy or chiropractor treatments and steroid and epidural injections.

References

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