Clinical Study

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Overview

A practice based prospective study of 31 consecutive patients (21 men, 10 women - mean age 57 years) with low back pain with or without radiculopathy.
Each patient completed the Oswestry Low Back Pain Disability Questionnaire (Ver.2) and the Numeric Rating Scale (NRS-11) - pre and post treatment. Disability assessment was based upon an absolute percentage point change in the Oswestry Disability Index (ODI). An absolute 6% point change is defined to be the Minimum Clinical Important Difference (MCID), [1] between patients who have improved with Extentrac treatment and those that remained stable.
Pain outcome assessment was based upon the total mean percentage change in the Numeric Rating Scale. Scientific papers have used a 50% pain reduction as a statistically significant reduction in pain[2].

Oswestry Disability Index (ODI) [0-100%]

81-100%	Bed bound or exaggerating	61-80%	Crippled
41-60%	Severe disability		
21-40%	Moderate disability		
0-20%	Minimal disability		

Numeric (Pain) Rating Scale (NRS-11)

7-10- Severe Pain (interferes significantly with ADLs). 4-6 - Moderate Pain (interferes significantly with ADLs)
1-3 - Mild Pain (nagging, annoying, interfering little with ADLs) 0 - No Pain

Pre-Treatment ODI:

75% (23 of 31) patients had a minimum ODI of 41% (severe disability or worse).

Pre-Treatment NRS:

68% (21 of 31) patients had a minimum NRS-11 score of 7 (severe pain).

Treatment Intervention

The Extentrac Elite M3D therapy

ODI Post-Treatment Summary of Data

The following table provides the number of patients within each ODI range pre-treatment, and the outcome ODI range post-treatment per each pre-treatment ODI range.

		Post Treatment ODI						
Pre-treatment ODI (Function)		81-100%	61-80%	41-60%	21-40%	0-20%	Mean abs change ODI* (pts)	Mean change ODI** (%)
81-100%	0	0	0	0	0	0	00.0 %pts	00.0%
61-80%	8	0	0	2	3	3	39.2 %pts	56.8%
41-60%	15	0	0	3	4	8	22.3 %pts	46.9%
21-40%	6	0	0	0	0	6	20.8 %pts	63.1%
0-20%	2	0	0	0	0	2	13.0 %pts	72.2%
Total	31	0	0	5	7	19	23.8 %pts	59.8%

*Mean (average) absolute percentage point change in ODI [Pre-ODI – Post ODI]

** Mean (average) percentage point change in ODI [Pre-ODI – Post ODI] / Pre-ODI]

NRS Post-Treatment Summary of Data

The following table provides the number of patients within each NRS range pre-treatment, and the outcome NRS range post-treatment per each pre-treatment NRS range.

		Post-treatment NRS					
Pre-treatment NRS		7-10	4-6	1-3	0 (no Pain)	Mean abs change NRS* (pts)	Mean change NRS** (%)
7-10	21	2	7	11	1	4.76 pts	58.10%
4-6	8	0	0	6	2	3.50pts	68.30%
1-3	2	0	0	1	1	2.00 pts	40.00%
Total	31	2	7	18	4	3.42 pts	55.46%

*Mean (average) absolute point change in NRS [Pre-NRS – Post NRS]
** Mean (average) percentage change in NRS [Pre-NRS – Post NRS] / Pre-NRS]

Results (Oswestry Disability and Numeric Pain Rating Outcome Data)

- 94% (29 of 31) patients experienced an improvement of at 6% points or greater in ODI , where 6 points is defined to be the Minimum Clinically Important Difference (MCID)[1]
- 62% (19 of 31) patients experienced a reduction in disability ODI of 50% or greater.
- Mean (average) absolute improvement in ODI was 23.8% points or 3.9 X the MCID.
- Mean (average) percent improvement in ODI was 59.8%.
- 74% (23 of 31) patients reported post NRS treatment decrease of 50% better.
- Mean (average) percent improvement in NRS was 55.46%

1. Julie M Fritz and James J Irrgang. A Comparison of a Modified Oswestry Low Back Pain Disability Questionnaire and the Quebec Back Pain Disability Scale. PHYS THER. 2001; 81:776-788.
2. Rowbotham MC *(*2001*)* What is a 'clinically meaningful' reduction in pain? *Pain* **94***,* 131–132*.*

A practice based prospective study of 31 consecutive patients with low back pain with or without radiculopathy utilizing the Extentrac Elite M3D therapy. Each patient completed the Oswestry Disability Questionaire and Numeric Rating Scale for Pain - pre and post treatment. Outcome measurement was based upon the Oswestry Disability Index (ODI) and Numeric Rating Score (NRS-11).

Numeric (Pain) Rating Scale (NRS-11)
7-10- Severe Pain (interferes significantly with ADLs).
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0 - No Pain

Oswestry disability Index (ODI) [0-100%]
81-100% Bed Bound (or exaggerating symptoms)
61-80% Crippled
41-60% Moderate disability
0-20% Minimal Disability

PATIENT DATA

	Patient ID	Age	Imaging	Diagnosis	Number of Treatments	Pain NRS Pre	Pain NRS Post	Disability ODI Pre	Disability ODI Post	Imaging Report	Post Tx Reduction in NRS 50 or >	Post Tx Disability 50%or >	NRS %chg	Osw %chg
1	Mark B (M)	48	X-Ray	Sciatica	10	9	5	72%	40%	not available	0	0	44%	44%
2	Verissimo P	60	MRI	Sciatica	10	6	3	54%	20%	Diffuse degenerative disc disease, right lateral herniation L3-4, central herniation at L3-4	1	1	50%	63%
3	Lois S(F)	73	MRI	Sciatica	10	8	3	66%	38%	Herniated lumbar discs multilievel and spinal stenosis.	2	0	63%	42%
4	Ed C (M)	62	MRI	Sciatica	17	10	2	37%	14%	Moderate to large HNP at L4-L5 causing spinal canal compromise, left sided herniation at L3-4 with mild stenosis.	3	2	80%	62%
5	Bill S(M)	36	MRI	Facet Syn.	10	8	2	18%	6%	not available	4	3	75%	67%
6	Patricia S (F)	75	MRI	Facet Syn.	19	6	1	26%	10%	Disc Herniation (right paramedian and foraminal disc herniation, right lateral recess stenosis	5	4	83%	62%
7	Rachel D(F)	52	MRI	Sciatica	10	10	3	60%	8%	L5-S1 left posterolateral/foraminal disc herniation. Lumbar levoscoliosis.	6	5	70%	87%
8	Jane S (F)	64	MRI	Sciatica	10	7	0	44%	0%	L5-S1, L4-5 disc herniation	7	6	100%	100%
9	Francis M (F)	72	MRI	Sciatica	9	7	2	50%	30%	Spinal Stenosis L3-4, L4-5	8	0	71%	40%
10	Antoinette F (F)	71	MRI	Sciatica	15	8	8	42%	42%	SPINAL STENOSIS, DJD, SPONDYLOLISHESIS		0	0%	0%
11	Pamela V (M)	61	MRI	Sciatica	10	8	2	40%	10%	Spondylolishesis Grade 1 L5 on S1, L5-S1 Foraminal Stenosis, and central canal	9	7	75%	75%
12	Walter F(M)	40	MRI	Sciatica	12	7	5	76%	42%	Left paracentral, spinal disc herniation, disc bulge.	0	0	29%	45%
13	Barry G (M)	53	MRI	Sciatica	9	4	1	54%	20%	L5/S1 disc bulge with bilateral nerural foraminal extension, abutting left nerve root, L4/5 disc bulge, slight spondylolishesis and left neural foraminal disc herniation and annular tear.	10	8	75%	63%
14	Joan C	76	X-Ray	Sciatica	14	8	5	68%	60%	Multi-level degenerative disc disease, spinal canal stenosis due to Grade 1 spondylolisthesis of L5/S1.	0	0	38%	12%
15	Steven F (M)	48	MRI	LBP	10	7	4	42%	34%	Sondylolisthesis L5 grade 1 on S1, bilateral spondylolysis of L5. Right paramedian annular tear and impinging L5 nerve root.	0	0	43%	19%
16	Phil M (M)	48	MRI	LBP/sciatic	10	9	2	72%	4%	Central herniated disc at L4-L5, (right worse) Degenerative disc disease from L1-S1.	11	9	78%	94%
17	Anita C (F)	59	MRI	Sciatica	16	10	4	48%	38%	L3-4 left HNP, L4-5 disc space narrowing, right foraminal ridge formation, L1-2 bilateral periforaminal stenosis	12		60%	21%

18	Steven S (M)	58	MRI	Sciatica	9	9	1	66%	33%	L5-S1 disc bulging flattening thecal sac, Left neural foraminal flattening encroaching the left L5 nerve root. Mild degenertive changes L3-4 mild stenosis.	13	10	89%	50%
19	Timothy B (M)	53	MRI	Sciatica/LB	8	4	0	18%	4%	L3/4 thru L5/S1 disc bulges containing annular tears which impinge on the thecal sac. Minimal degenerative disc disease.	14	20	100%	78%
20	Glen K (M)	55	X-Ray	Sciatica	10	7	3	44%	20%	DDD, Spinal Stenosis	15	11	57%	55%
21	Joe F (M)	55	MRI	Sciatica/LB	4	5	0	42%	20%	L2-3 circumf. Buldge with far lateral foraminal narrowing, L3-L4- circum disc bulge and right foraminal stenosis, L4-5 disc buldge, L5-S1 disc herniation.	16	12	100%	52%
22	Vivian K (F)	65	MRI	LBP	12	7	5	46%	32%	MULI-LEVEL HNP'S , DISC BULGES			29%	30%
23	Aussain I (M)	38	Acute	Sciatica	10	2	0	44%	8%	Not available	17	13	100%	82%
24	Tom K (M)	67	MRI	Sciatica	10	8	4	27%	15%	L4/5 disc hernition,, L3/4 grade 1 spondylolishesis, djd of facets	18		50%	44%
25	Carl D (M)	35	Acute	LBP	10	6	2	28%	10%	clinical assessment only	19	14	67%	64%
26	Frank C (M)	66	MRI	Sciatica	10	8	2	44%	18%	Spondylolisthesis Grade 1 L4 on L5. Disc herniation L4-5, degenerative disc diease -mult-level, facet joint hypertrophy,aquired spinal stenosis.	20	15	75%	59%
27	Edward M (M)	78	MRI	LBP		6	3	40%	14%	L3-4 post surgical fusion and bilateral laminectomy, Pedicle screws noted in L3,	21	16	50%	65%
28	Visay C (M)	60	MRI	Sciatica	10	8	8	42%	42%	SPONDYLOLISTHESIS, CANAL STENOSIS, DIFFUSE DISC BULGING		0	0%	0%
29	Lance C (M)	43	MRI	Sciatica	5	3	1	62%	10%	Disc bulging L1-2, L2-3, L3-4, facet and ligament hypertropy and central and right lateral recess herniation.	22	17	67%	84%
30	Michael C (M)	50	MRI	Sciatica	10	4	3	56%	46%	Bulges L2-3,L3-4, L4-5, Right lateral herniation L4-L5. Facet Arthropathy.		18	25%	18%
31	Richard M (M)	39	MRI	LBP	10	9	2	70%	12%	Herniated discs L3-L-4, L5-S1	23	19	78%	83%

A practice based prospective study of 13 consecutive patients with neck pain with or without radiculopathy utilizing the Extentrac Cervical Traction Accessory.
Each patient completed the Oswestry Neck Disability Questionaire and the Numeric Rating Scale for pain pre and post treatment.

Cervical outcome **13 cohort size**

70**%** (9 patients)post treatment, achieved a clinically significant reduction in ODI (DISABILITY) of 50% or greater.

85% (11 patients) post-treatment, achieved a clinically significant reduction in Pain of 50% or greater (NRS) score.

Average number of treatments utilizing Extentrac Elite - 10.

	Patient ID		No. Treat	NRS Pre	NRS Post	ODI Pre	ODI Post	ODI % Chg	NRS % Chg	Age	Imaging Studies - MRI's
1	Maura W (F)	MRI	10	8	0	33%	0%	100%	100%	52	HNP, RETROLISTHESIS, DDD, DISC BULGING, STENOSIS
2	Tony M (F)	MRI	10	10	4	47%	21%	56%	60%	55	C4-5 Disc herniation, C5-6 Disc Herniation, C6-7 Disc Herniation
3	PhilipV (M)	X-ray	10	8	4	50%	26%	48%	50%	37	DISC HERNIATION , DDD
4	David O (M)	MRI	10	9	3	50%	16%	68%	67%	37	HNP, MULTI-LEVEL, DJD HYPERTROPHIC CHANGES
5	Stephanie S (F)	Clinical	10	10	3	32%	12%	63%	70%	47	clinical assessment only.
6	Scott B (M)	MRI	10	7	3	44%	16%	64%	58%	45	DISC HERNIATION , DDD
7	Janet F (F)	MRI	10	5	2	42%	22%	48%	60%	47	C2/3 central disc herniation, multi-level cervical spondylosis with foraminal
8	Erin S (F)	MRI	10	6	3	44%	20%	55%	50%	42	DISC HERNIATION , MUSCLE SPASM
9	Lisa B (F)	MRI	8	10	4	48%	24%	50%	60%	44	DISC HERNIATIONS, MULTI-LEVEL, DJD, DDD, FACET ARTHROPATHY
10	Terry C (F)	MRI	15	9	3	72%	12%	84%	67%	59	DISC BULGING, DDD, DJD
11	Ellen W (F)	MRI	10	10	3	56%	28%	50%	70%	62	clinical assessment only
12	John F (M)	MRI	9	6	6	8%	8%	0%	0%	48	DIFFUSE DDD, MULTI-LEVEL BULGING. DISC HERNIATION
13	Tom D (M)	MRI	8	8	8	66%	66%	0%	0%	36	C4-5 moderate broad based disc herniation, C6-7 broad based disc hernia
			130	8.15384615		46%	21%	49%	55%		