# **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), <sup>1</sup> 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<sup>2</sup>.

### 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		81- 100%	61- 80%	41- 60%	21- 40%	0- 20%	Mean abs change ODI* (pts)	Mean change ODI** (%)					
(Function													
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%					

<sup>\*</sup>Mean (average) absolute percentage point change in ODI [Pre-ODI – Post ODI]

<sup>\*\*</sup> 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-treatme	7-10 4-6 1-3 0 (no Pain)			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 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%					

## 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)<sup>1</sup>
- 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.

<sup>\*</sup>Mean (average) absolute point change in NRS [Pre-NRS – Post NRS]

<sup>\*\*</sup> Mean (average) percentage change in NRS [Pre-NRS – Post NRS] / Pre-NRS]

	A practice b	ased p	rospectiv	e study o	of 31 conse	ecutive p	atients w	ith low back						
	pain with or	without	radiculo	pathy utili	izing the Ex	xtentrac	Elite M3I	D therapy.						
	Each patient	t compl	leted the	Oswestry	y Disability	Questic	naire and	d Numeric						
	Rating Scale													
	based upon	the Os	westry D	isability Ir	ndex (ODI)	and Nu	ımeric Ra	ating Score						
	(NRS-11).													
	Numeric (Pain)	Dating S	cala (NDS-	14\										
	7-10- Severe Pair				s).							+		
	4-6 - Moderate P													
	1-3 - Mild Pain ( I 0 - No Pain	Nagging,	annoying, i	nterfering littl	e with ADLs)									
	U - NO Falli											+		
	Oswestry disabi													
	81-100% Bed Bo		exaggerating	symptoms)										
	61-80% Cripple 41-60% Modera		lity									+		
		al Disabili												
	PATIENT DATA										D T.			
	PATIENT DATA	Ì			Number of	Pain	Pain	Disability	Disability		Post Tx Reduction in	Post Tx Disability		
	Patient ID	Age	Imaging				NRS Post			Imaging Report	NRS 50 or >	50%or >	NRS %chg	Osw %chg
1	Mark B (M)	48	X-Ray	Sciatica	10	9	5	72%	40%	not available		0	0 449	6 44%
										Diffuse degenerative disc disease, right lateral herniation L3-4, central herniation				
2	Verissim o P	60	MRI	Sciatica	10	6	3	54%	20%	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%	6 42%
										Moderate to large HNP at L4-L5 causing spinal canal compromise, left sided		+		
4	Ed C (M)	62	MRI	Sciatica	17	10	2	37%	14%	herniation at L3-4 with mild stenosis.		3	2 80%	62%
-	Bill S(M)	36	MRI	Facet Syn.	10	8	2	18%	C0/	not available		4	3 75%	67%
3	DIII O(IVI)	30	IVIIVI	racei Syn.	10	0		. 1076	076	Disc Herniation (right paramedian and foraminal disc herniation, right lateral		4	3 737	0 077
6	Patricia S (F)	75	MRI	Facet Syn.	19	6	1	26%	10%	recess stenosis		5	4 839	62%
-	Rachel D(F)	52	MRI	0.1.1	10	10	3	60%	00/	L5-S1 left posterolateral/foraminal disc herniation. Lumbar levoscoliosis.		6	5 70%	6 87%
- /	Rachel D(F)	52	IVIRI	Sciatica	10	10	3	00%	8%	L5-51 Ten posterolatera/roraminal disc nemiation. Lumbar levoscollosis.		6	5 707	6 87%
8	Jane S (F)	64	MRI	Sciatica	10	7	0	44%	0%	L5-S1, L4-5 disc herniation		7	6 100%	100%
	E	70	MDI	0.1.1	q	7	2	500/	000/	05501000050104145		8	210	( 400
9	Francis M (F)	72	MRI	Sciatica	9		2	50%	30%	Spinal Stenosis L3-4, L4-5		8	0 719	6 40%
10	Antoinette F (F)	71	MRI	Sciatica	15	8	8	42%	42%	SPINAL STENOSIS, DJD, SPONDYLOLISHESIS			0 0%	6 09
-	Pamela V (M)	C4	MDI	Calatian			2	40%	400/	Spondylolishesis Grade 1 L5 on S1, L5-S1 Foraminal Stenosis, and central canal			7 75%	6 75%
11	Pameia v (M)	ľσ	MRI	Sciatica	10	8	2	40%	10%	Sporioyionishesis Grade 1 L5 on S1, L5-S1 Foraminal Stenosis, and central canal		9	/ /5%	6 75%
12	Walter F(M)	40	MRI	Sciatica	12	7	5	76%	42%	Left paracentral, spinal disc herniation, disc bulge.		0	0 299	6 45%
										L5/S1 disc bulge with bilateral nerural foraminal extension, abutting left nerve root, L4/5 disc bulge, slight spondylolishesis and left neural foraminal disc				
13	Barry G (M)	53	MRI	Sciatica	9	4	1	54%	20%	herniation and annular tear.		10	8 75%	639
										Multi-level degenerative disc disease, spinal canal stenosis due to Grade 1		$\overline{}$		
14	Joan C	76	X-Ray	Sciatica	14	8	5	68%	60%	spondylolisthesis of L5/S1.		0	0 389	6 129
15	Steven F (M)	48	MRI	LBP	10	7	4	42%	3/10/	Sondylolisthesis L5 grade 1 on S1, bilateral spondylolysis of L5. Right		0	0 439	6 199
15	Steven F (IVI)	+0	IVITAL	LDF	10	·	4	42%	34%	paramedian annular tear and impinging L5 nerve root.			437	197
										Central herniated disc at L4-L5, (right worse) Degenerative disc disease from L1-				
16	Phil M (M)	48	MRI	LBP/sciatic	10	9	2	72%	4%	S1.		11	9 78%	6 949
								-		L3-4 left HNP, L4-5 disc space narrowing, right foraminal ridge formation, L1-2		+		
17	Anita C (F)	59	MRI	Sciatica	16	10	4	48%	38%	bilateral periforaminal stenosis		12	60%	6 21%

even 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 degenerive changes L3-4 mild stenosis.	13	10	89%	50%
imothy 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%
len K (M)	55	X-Ray	Sciatica	10	7	3	44%	20%	DDD, Spinal Stenosis	15	11	57%	55%
pe 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%
ivian K (F)	65	MRI	LBP	12	7	5	46%	32%	MULI-LEVEL HNP'S , DISC BULGES			29%	30%
ussain I (M)	38	Acute	Sciatica	10	2	0	44%	8%	Not available	17	13	100%	82%
om 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%
arl D (M)	35	Acute	LBP	10	6	2	28%	10%	clinical assessment only	19	14	67%	64%
ank 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%
dward 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%
say C (M)	60	MRI	Sciatica	10	8	8	42%	42%	SPONDYLOLISTHESIS, CANAL STENOSIS, DIFFUSE DISC BULGING		0	0%	0%
ance 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%
lichael 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%
chard M (M)	39	MRI	LBP	10	9	2	70%	12%	Herniated discs L3-L-4, L5-S1	23	19	78%	83%
on arrangement of the control of the	n K (M)  F (M)  an K (F)  ssain I (M)  h K (M)  H D (M)  h K C (M)  y C (M)  y C (M)  hael C (M)	n K (M) 55 F (M) 55 an K (F) 65 ssain I (M) 38 n K (M) 67 H D (M) 35 nk C (M) 66 ard M (M) 78 ny C (M) 60 cce C ( M) 43 hael C (M) 50	n K (M) 55 X-Ray  F (M) 55 MRI  an K (F) 65 MRI  ssain I (M) 38 Acute  n K (M) 67 MRI  I D (M) 35 Acute  n K C (M) 66 MRI  ard M (M) 78 MRI  y C (M) 60 MRI  ccc C (M) 43 MRI  hael C (M) 50 MRI	N K (M)   55   X-Ray   Sciatica	n K (M) 55 X-Ray Sciatica 10  IF (M) 55 MRI Sciatica/LB 4  an K (F) 65 MRI LBP 12  ISSAIN I (M) 38 Acute Sciatica 10  In K (M) 67 MRI Sciatica 10  In K (M) 67 MRI Sciatica 10  In K (M) 66 MRI Sciatica 10  In K (M) 66 MRI Sciatica 10  In K (M) 66 MRI Sciatica 10  In K (M) 67 MRI Sciatica 10  In K (M) 68 MRI Sciatica 10  In K (M) 78 MRI LBP  In K (M) 78 MRI LBP  In K (M) 60 MRI Sciatica 10  In K (M) 78 MRI Sciatica 10  In K (M) 50 MRI Sciatica 10  In K (M) 50 MRI Sciatica 10	n K (M) 55 X-Ray Sciatica 10 7  IF (M) 55 MRI Sciatica/LB 4 5  an K (F) 65 MRI LBP 12 7  ISSAIN I (M) 38 Acute Sciatica 10 2  IN K (M) 67 MRI Sciatica 10 8  IN D (M) 35 Acute LBP 10 6  IN C (M) 66 MRI Sciatica 10 8  IN C (M) 67 MRI Sciatica 10 8  IN C (M) 68 MRI Sciatica 10 8  IN C (M) 69 MRI Sciatica 10 8  IN C (M) 60 MRI Sciatica 10 8	n K (M) 55 X-Ray Sciatica 10 7 3  IF (M) 55 MRI Sciatica/LB 4 5 0  an K (F) 65 MRI LBP 12 7 5  ssain I (M) 38 Acute Sciatica 10 2 0  n K (M) 67 MRI Sciatica 10 8 4  ID (M) 35 Acute LBP 10 6 2  n K (M) 66 MRI Sciatica 10 8 2  vard M (M) 78 MRI LBP 6 3  vy C (M) 60 MRI Sciatica 10 8 8  acute C (M) 43 MRI Sciatica 10 8 8  hade C (M) 50 MRI Sciatica 10 8 8  hade C (M) 50 MRI Sciatica 10 8 8  hade C (M) 50 MRI Sciatica 10 8 8  hade C (M) 50 MRI Sciatica 10 8 8  hade C (M) 50 MRI Sciatica 10 8 8  hade C (M) 50 MRI Sciatica 10 8 8	n K (M) 55 X-Ray Sciatica 10 7 3 44%  IF (M) 55 MRI Sciatica/LB 4 5 0 42%  an K (F) 65 MRI LBP 12 7 5 46%  ssain I (M) 38 Acute Sciatica 10 2 0 44%  in K (M) 67 MRI Sciatica 10 8 4 27%  ID (M) 35 Acute LBP 10 6 2 28%  in K (M) 66 MRI Sciatica 10 8 2 44%  ard M (M) 78 MRI LBP 6 3 40%  ard M (M) 78 MRI LBP 6 3 40%  ard M (M) 78 MRI Sciatica 10 8 8 42%  ard M (M) 78 MRI LBP 6 3 40%  ard M (M) 78 MRI Sciatica 10 8 8 42%  ard M (M) 78 MRI Sciatica 10 8 8 42%  ard M (M) 78 MRI Sciatica 10 8 8 42%  ard M (M) 78 MRI Sciatica 10 8 8 42%  ard M (M) 78 MRI Sciatica 10 8 8 6 3 40%  ard M (M) 78 MRI Sciatica 10 8 8 6 3 40%  ard M (M) 78 MRI Sciatica 10 8 8 6 3 40%  ard M (M) 78 MRI Sciatica 10 8 8 8 42%  ard M (M) 78 MRI Sciatica 10 8 8 8 42%  ard M (M) 78 MRI Sciatica 10 8 8 8 42%  ard M (M) 78 MRI Sciatica 10 8 8 8 42%	IF (M) 55 X-Ray Sciatica 10 7 3 44% 20% 20% ARI Sciatica/LB 4 5 0 42% 20% ARI Sciatica/LB 4 5 0 42% 20% ARI LBP 12 7 5 46% 32% ARI CM Sciatica 10 2 0 44% 8% ARI CM Sciatica 10 2 0 44% 8% ARI CM SCIATICA 10 8 4 27% 15% ARI CM SCIATICA 10 8 4 27% 15% ARI CM SCIATICA 10 8 10 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Sociatica   Soci	14	Othy B (M)   53   MRI   Sciatica   LB   8   4   0   18%   4%   thecal sac. Minimal degenerative disc disease.   14   20	orbity B (M)         53         MRI         Sciatica/LB         8         4         0         18%         4% thecal sac. Minimal degenerative disc disease.         14         20         100%           n K (M)         55         X-Ray         Sciatica         10         7         3         44%         20%         DDD, Spinal Stenosis         15         11         57%           F (M)         55         MRI         Sciatica/LB         4         5         0         42%         20%         DDD, Spinal Stenosis         15         11         57%           F (M)         55         MRI         Sciatica/LB         4         5         0         42%         20%         bulge and right foraminal stenosis, L4-5 disc buldge, L5-S1 disc hemiation.         16         12         100%           ank (F)         65         MRI         LBP         12         7         5         46%         32% MULI-LEVEL HNP'S, DISC BULGES         29%           ssain I (M)         38         Acute         Sciatica         10         2         0         44%         8% Not available         17         13         100%           1D (M)         35         Acute         LBP         10         6         2         28%

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	A practice based prospe	ctive stu	dv of 13 con	secutive pa	tients with	neck pair	with or w	ithout radicu	llopathy utilizi	ing the	e Extentra	c Cervical	Traction A	Accessory.		
	Each patient completed												1	1		
	patient completion	1		 	1			g ••••	, pam pro an	T POO						
	Cervical outcome	13 coho	ort size													
	70% (9 patients)post trea	tment, ac	hieved a clinic	cally signific	ant reductio	n in ODI	DISABILIT	Y) of 50% or	greater.							
	85% (11 patients) post-ti	reatment	achieved a c	linically sign	nificant redu	ction in Pa	in of 50%	or greater (N	RS) score							
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	Average number of treatm	ents utiliz	zing Extentrac	Elite - 10.												
	•															
	Patient ID		No. Treat	NRS Pre	NRS Post	ODI Pre			NRS % Chg			udies - MRI'				
1	Maura W (F)	MRI	10	8	0	33%	0%	100%	100%	52	HNP, RETR	OLISTHESIS	, DDD, DISC	BULGING, S	TENOSIS	
2	Tony M (F)	MRI	10	10	4	47%	21%	56%	60%	55	C4-5 Disc h	erniation, C5-6	Disc Hernia	ation, C6-7 Dis	sc Herniation	
		1												,		
3	PhilipV (M)	X-ray	10	8	4	50%	26%	48%	50%	37	DISC HERN	IATION, DD	D			
4	David O (M)	MRI	10	9	3	50%	16%	68%	67%	37	HNP, MULT	1-LEVEL, DJI	HYPERTRO	OPHIC CHAN	GES	
5	Stephanie S (F)	Clinical	10	10	3	32%	12%	63%	70%	47	clinical asse	eemant only				
3	Stephanie S (i )	Cittical	10	10	3	32 /0	12 /0	0370	1076	41	Cillical asse	Someth only.				
6	Scott B (M)	MRI	10	7	3	44%	16%	64%	58%	45	DISC HERN	NATION, DD	D			
7	Janet F (F)	MRI	10	5	2	42%	22%	48%	60%	47	C2/3 centra	disc hemiation	n, multi-level	l cervical spor	idylosis with f	foraminal
8	Erin S (F)	MRI	10	6	3	44%	20%	55%	50%	42	DISC HERN	NIATION , MU	SCLE SPAS	М		
a	Lisa B (F)	MRI	8	10	4	48%	24%	50%	60%	44	DISCHERN	IIATIONS MI	II TI-I EVEI	DJD, DDD, F	ACET ARTH	IROPATH'
	2100 2 (1 )	14	Ŭ			1070	2170	0070	0070		DICCTILIT	1,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		1	7.0217	
10	Terry C (F)	MRI	15	9	3	72%	12%	84%	67%	59	DISC BULG	ING, DDD, D	JD			
11	Ellen W (F)	MRI	10	10	3	56%	28%	50%	70%	62	clinical asse	essment only				
40	1.1. 5 (11)	MDI				00/	00/	00/	201	40	DIECHOLD	DD MUUTU	EVEL BUILD	INO DIOCUE	DAHATION	
12	John F (M)	MRI	9	6	6	8%	8%	0%	0%	48	DIFFUSE D	טטי, MULII-L	EVELBULG	ING. DISC HE	KNIATION	-
13	Tom D (M)	MRI	8	8	8	66%	66%	0%	0%	36	C4-5 moder	ate broad ba	sed disc herr	niation. C6-7 b	road based	disc hernia
10		1000 41		8.15384615		46%	21%	49%			O . O IIIOGGI	5. 5dd ba	300 0.30 11011		Juda Dadou I	0.00 .1011110
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