Research Article

David F. Cuccia, D.C.
ADVANCED BACK TECHNOLOGIES, INC.

Case Study Report

A practice based retrospective study of 133 patients utilizing the Extentrac Elite multi-functional therapy table

Design: Practice-based retrospective data analysis to determine the effectiveness of the Extentrac Elite multifunctional therapy table on low back pain (LBP) with or without radiculitis. Patient outcome data below (Table 1.) is based on the use of an Active Control Group. Successful patient outcome through the application of Extentrac Elite's various treatment options enabling the clinician to implement Evidence Based therapies, (the application of therapeutic procedures which have been subject to research outcome studies) not limited to axial decompression or linear traction.

Subjects: An Active Control Group (ACG) consisted of 133 consecutive patients presenting acute or chronic low back pain with or without radiculits. Acute duration is defined as symptoms with duration less than 4 weeks and chronic as symptoms greater than 4 weeks. Patients' inclusion criteria included degenerative disc disease, degenerative joint disease (spondylosis), herniated discs, bulging discs, and spinal stenosis demonstrated by X-ray or MRI.

Outcome Measures:

Data for patient outcome measurement presented below was based on numerical changes to the patient Visual Analogue Pain Scale (VAS). Expansion of this study will include pre and post Oswestry Disability Index data. Outcome measurement is from the patient's initial visit to conclusion of course of care or termination of treatment. The following VAS scale parameter definitions were used in qualification of outcome data:

VAS of [0-1] - No pain. Successful Outcome.

VAS of [1-2] – Mild Pain - Fair Successful Outcome.

VAS of [3-4] – Nagging/ Uncomfortable – Minimal / Partial improvement.

VAS of [4-10] – No improvement.

Intervention:

A placebo controlled case study format was not utilized, as this researcher believes that to do such would **mean the withholding of the known benefits of Extentrac Elite treatment demonstrated in practice over many years of treatment,** therefore, this researcher embraced an alternative method of scientific methodology (ACG), as the ethically proper way for gathering data. This researcher believes support for this position is set forth in the FDA in the Code OF Federal Regulations 21, 860.7 ©, which states that where **"such use of a placebo or the withholding of treatment would be inappropriate or contrary to the interest of the patient."**
Treatment consisted of utilization of Extentrac Elite's Multifunctional Therapy table design for 15-minute treatment sessions providing a wide range of comprehensive and versatile treatment protocols which uniquely allow the selection of various therapeutic options that best fit the patient's presentation of symptoms, examination findings and posture. Extentrac Elite enables the application of individual conventional therapy treatment modalities for LBP in one treatment platform which include axial decompression, multi-axis decompression, manual traction, flexion-distraction protocols, spinal mobilization, therapeutic exercise, McKenzie-like extension protocols, and vertical to semi-horizontal gravitational postural treatment. Unique combinations of evidence based individual therapies may be combined into protocols creating a synergy of treatment not able to be applied through any application of singular therapy.

Frequency: 3 to 5 times per week as dictated by severity of pain and disability. Additional physiotherapeutic procedures were permitted and may have included ice, heat, electrical muscle stimulation and ultrasound.

Results: (Please see Table 1.)

Changes in VAS scales indicate that overall, Extentrac Elite is approximately 91% effective in reducing pain. Specifically, 103 patients out of 133 patients or 77% having no pain following treatment, 18 out of 133 patients or 14% having had mild annoying pain remaining following treatment and 12 patients or 9% had no improvement with an unchanged VAS.
The statistically relevant outcomes indicate strong support that intervention with Extentrac Elite has good clinical benefit when used for the non-surgical treatment of LBP and Sciatica.

Discussion:

"Gravitational traction" has been demonstrated to distract more than 3 mm of intervertebral disc space.[15] Extentrac's design provides conventional gravitational traction protocols and proprietary vertical treatment protocols. Patients simply walk up to the unit and they or their practitioner effortlessly position the comfortable contoured underarm supports. Treatment begins while the patient remains standing. Patient height is accommodated through raising or lowering the vertical patient platform using a hand-held keypad or a hand-held computer mouse with display monitor. Gravitational treatment

protocols can be applied manually using the practitioner's hand-held keypad, or automatically using pre-programmed treatment cycles for hands-free operation. Patients may use the control buttons on the handgrip or in the overhead bar to effect patient platform rotation and lumbar pad extension in order to participate in their treatments (under practitioner supervision).

Extentrac's proprietary protocol begins as the patient platform gradually and progressively rotates in a backward direction towards the horizontal. Extentrac's convex lumbar support pad places the lumbar vertebrae into extension, stretching the longitudinal ligaments, producing a centripetal force causing any extruded and herniated discs to move in an anterior direction in a vector opposite the direction of vertebrae tilt. This helps reverse the posterior drift of herniated nuclear material toward the disc center and away from contact with pain-producing tissues. No other treatment or traction device combines the spinal positioning of extension (bending/arching backwards) simultaneously with natural body traction (the force of gravity provided by the weight of the individual patient). The incorporation of McKenzie-enhanced extension protocols into Extentrac's **"**gravity protocols" act synergistically to provide a rapid and more effective means of relieving low back pain than the individual therapeutic techniques.

While retaining all vertical treatment and traction protocols, the Extentrac, when fully rotated into the horizontal, permits the use of either of two separate decompression motorized systems located in the lumbar and leg assemblies. Extentrac's multi-axis leg and lumbar pad assembly movement offers almost unlimited positioning - flexion, extension, and lateral flexion prior to disc decompression for optimal treatment efficacy. Patients may also be moved into pain-relieving positions prior to decompression through selected leg movement. Similarly, the application of manual mobilization, a passive range of motion techniques using the practitioner foot control bar, has never been easier.

Achieving treatment disc level specificity is clinically important and Extentrac incorporates a direct method to position the spine in order to target specific disc levels. A simple 'click' of the computer mouse button highlights one of three designated disc level icons, which causes the lumbar support pad to rotate to the corresponding disc level. Extentrac's multi-axis foot assembly is moved by manual control using the practitioner leg control bar or through computer data entry. Its position is also automatically linked to each pre-selected disc level. For example, as disc level L2-L3 is selected and the lumbar support pad rotates, the leg support adjusts its spatial orientation, moving upward or downward. Traditional harnesses may be optionally used during treatment protocols, but underarm supports adequately restrict the upper torso's normal downward movement.

Motorized Horizontal Treatment

Extentrac offers practitioners motorized decompression capability via the leg support assembly or the lumbar assembly during horizontal treatment modes of operation. Consensus is that at least 60% of the patient's body weight is necessary for dimensional changes in lumbar discs to occur with concomitant decreases in intradiscal pressure necessary to "suck back" and reposition the extruded disc. Extentrac delivers up to 200 pounds of gradual and progressive distractive force in its two power systems. Operational control is achieved through a choice of automated programs and manual

controls. The gradual application of traction begins after inputting essential vital treatment data such as weight and maximum and minimum traction force and disc level with manual pre-treatment positioning. This will orient the patient's overall position in flexion, axial, lateral flexion and extension prior to decompression therapy. Output results in automated rotational movement of both lumbar and leg support assemblies to treat specific disc levels, one of the Extentrac's proprietary features.

Extentrac offers "optional" patient participation for patient application of gravitational traction, exercise, stretching, and McKenzie-enhanced extension and flexion protocols with patient controlled hand-mounted switches, which allow patients to control table movements, while under close practitioner supervision. All motorized and decompression protocols are under practitioner control only. Once accustomed to Extentrac, the patient can easily be instructed to operate the unit and follow the clinician's treatment guidelines. The patient need only be under the general supervision of a nearby clinician during operation. This not only appears to increase patients' acceptance and satisfaction, but it also frees up the clinician who can attend to other income producing activities. Over the course of thousands of Extentrac sessions, patients have almost always been enthusiastic about taking an active role in their therapy. There is no physical size or age limitation for patient participation. Frail, 80-year-old women and 350-pound men have successfully carried out their own treatment plan on Extentrac.

The proprietary multi-functional technology of Extentrac facilitates the implementation of different conventional therapies resulting in synergies of treatment not possible with singular devices and approaches for therapy. It is therefore a versatile treatment platform capable of matching treatment to diagnosis, allowing the clinician to implement "Evidence-Based" therapeutic procedures which have been subject to research outcome studies.

Table 1 – VAS Case Study Report Data

	Patient ID	AGE		DX		
	Patient ID	AGE		Diagnosis	VAS PRE	VAS POST
1	**MD (M)**		36	Sciatica	VAS 10	0
		MRI				
2	**JA(M)**			Sciatica	VAS 8	0
		X-Ray		Acute		
3	**FB(M)**		83	Stenosis	VAS4	4
		MRI		Chronic		
4	**SC (F)**		54	LBP	VAS 9	2
		X-Ray		Acute		
5	**AS(M)**		56	Sciatica	VAS 8	1
		MRI		Acute		
6	**HB(M)**		50	Sciatica	VAS 9	2
		X-Ray		Chronic		
7	**JB. (F)**		31	Sciatica	VAS 10	0
		MRI				
8	**TD (F)**			Sciatica	VAS 10	4
		MRI		Chronic		
9	**RD (M)**	MRI		Sciatica	VAS 5	2
10	**CE (F)**		56	Sciatica	VAS 8	8

		MRI HNP Chronic				
11	**RF (M)**		65	Sciatica	VAS 4	0
12	**BF (M)**		81	LSS	VAS 6	6
13	**DG (M)**	MRI	42	Sciatica HNP L5	VAS 9	1
14	**KH (M)** Left Lateral	MRI	45	Sciatica L5-S1 HNP	VAS 10	6
15	**EK (F)** DJD	x-ray	71	LBP chronic	VAS 2	0
16	**IL (M)**	MRI	42	Sciatica L5 HNP	VAS 8	4
17	**PM (F)**	MRI	40	Sciatica HNP L5	VAS 9	0
18	**SM (F)**	MRI	52	LBP HNP L3-L5	VAS 9	1
19	**EM (F)**	X-ray	73	LBP	VAS 7	2
20	**MR (M)** CHRONIC DDD/DJD	MRI	58	Sciatica HNP	VAS 10	3
21	**DR (M)**	MRI	43	Sciatica L1-L2 R, L2-L3 R, L5-S1 L	VAS 10	0
22	**RR (M)**	X-ray	50	Sciatica	VAS 9	0
23	**DT (F)**	X-ray		SCIATICA	VAS 6	1
24	**RV** ACUTE	X-Ray	29	LBP	VAS 7	0
25	**BW (M)** ACUTE	X-Ray	45	LBP DDD SEVERE	VAS 9	0
26	**MK (F)** ACUTE	X-Ray	54	LB LBP	VAS 6	0
27	**(BG) (F)** ACUTE	MRI	69	SCIATICA HNP	VAS 8	0
28	**RK (M)** CHRONIC	X-ray	67	LBP	VAS 6	2
29	**(JC) (M)**		65	SCIATICA	VAS 8	1
30	**ME (F)** ACUTE	X-RAY MRI	68	SCIATICA	VAS 3	0
31	**EC (M)** ACUTE	X-Ray	57	LBP	VAS 6	0
32	**EW (M)** CHRONIC	X-RAY	62		VAS 6	1
33	**VU (F)**		47	SCIATICA	VAS 6	0

		X-ray				
34	**AW (F)**		56	SCIATICA	VAS 6	3
	L5-SI HNP	MRI				
	CENTRAL LBP			CHRONIC		
35	**JT (M)**		40	SCIATICA	VAS 9	1
		MRI				
36	**DL(M)**		66		VAS 10	10
	POST SURGICAL	MRI		STENOSIS		
	59					
37	**BP (M)**		68		VAS 7	7
		MRI		SCIATICA		
38	**RD (M)**		68	LBP	VAS 2	0
38	**LC (M)**		86	STENOSIS	VAS 9	4
		MRI				
40	**KC (M)**		38	SCIATICA	VAS 3	0
	L4-L5 R	MRI				
41	**JZ (M)**		61	45L	VAS 8	2
				L		
	DISC BLG L5-S1	MRI		SCIATICA		
42	**ML (M)**		54	45R	VAS 9	0
	S-DDD SCIATICA	MRI		HNP		
43	**ER (M)**		47	SCIATICA	VAS 9	0
	HNP	MRI				
44	**CN (F)**		53	SCIATICA	VAS 6	0
		MRI				
45	**NZ (M)**		46	SCIATICA	VAS 10	0
	L4-L5 L	MRI		SCIATICA		
46	**KJ (M)**		34		VAS 8	1
				HNP-L4-5		
	HNP L3-4 L	MRI		C		
47	**IW (M)**		60	SCIATICA	VAS 6	0
	CHRONIC	MRI				
48	**PC (M)**		55	LBP	VAS 6	5
	CHRONIC	MRI		DDD,HNP		
49	**IM (M)**			SCIATICA	VAS 4	1
		MRI				
50	**LC (F)**		50		VAS 4	3
	DDD	MRI		L4-5, L5-S1		
51	**SM (M)**		41	LBP	VAS 6	1
	CHRONIC	X-ray				
52	**AC**		55	LBP	VAS 7	0
	ACUTE	X-Ray				
53	**SL (F)**		49	SCIATICA	Vas 6	3
	MULTI-LEVEL	MRI		10 YEARS		
54	**ML (M)**		50	SCIATICA	VAS 10	1
	HNP	MRI				
55	**EG (F)**		73	SCIATICA	VAS 10	1
	DDD	X-ray				
56	**JC (F)**		27	SCIATICA	VAS 10	0
	ACUTE	X-Ray		LBP		

57	**TL (M)**		72	LBP	VAS 8	0
	DJD, DDD	MRI		STENOSIS		
58	**RD (M)**		68	SCIATICA	VAS 10	0
	ACUTE	MRI		HNP L5-S1		
59	**LL (M)**		55	LBP	VAS 9	0
	ACUTE	X-ray				
60	**FS (F)**		47	SCIATICA	VAS 7	1
	ACUTE	X-ray				
61	**SS (M)**		51	LBP	VAS 7	1
	chronic	X-ray				
62	**JS (F)**		58	SCIATICA	VAS 3	0
		X-ray				
63	**FL (F)**		52	SCIATICA	VAS 6	0
		MRI				
64	**JG (M)**		53	SCIATICA	VAS 8	0
	L-LEG	MRI				
65	**BH (M)**		58		VAS 10	9
	stenosis	MRI		SCIATICA		
66	**NQ (M)**		78	LBP	VAS 8	0
	DDD/SPONDYL4	X-Ray				
67	**HO (M)**		48	SCIATICA	VAS 9	0
		HNP- L4-				
	MRI	L5L				
68	**BD (F)**		72	SCIATICA	VAS 4	0
		X-Ray				
69	**PA (M)**		43	LBP	VAS 6	0
	ACUTE	X-Ray				
70	**SN (M) 54**		53	SCIATICA	VAS 10	0
	ACUTE	X-Ray				
71	**TN (M)**		52	SCIATICA	VAS 10	0
	CHRONIC	MRI				
72	**RB(M)**		65	SCIATICA	VAS 10	1
	ACUTE HNP	MRI				
73	**JH (M)**		52	SCIATICA	VAS 9	0
		MRI				
74	**JM (S)**		77	SCIATICA	VAS 8	1
		MRI				
75	**JK (M)**		52	LBP	VAS 6	0
		X-Ray				
76	**JB (M)**		65	SCIATICA	VAS 6	0
	LBP	MRI				
77	**MG (F)**		69	SCIATICA	VAS 10	0
		MRI				
78	**JW (F)**		57	SCIATICA	VAS 6	3
	CHRONIC					
79	**CT (F)**		60	LBP	VAS 6	0
	ACUTE	X-Ray				
80	**IR (F)**		76	LBP	VAS 4	0
	CHRONIC	X-Ray				
81	**AD**		96	LBP	VAS 6	3
		MRI				
82	**MG**		37	SCIATICA	VAS 8	3
		HNP				
		CLINICAL				
83	**AR (F)**		45	SCIATICA	VAS 6	6
	SCIATICA	MRI				
84	**MD (M)**		45	SCIATICA	VAS 5	1

	CHRONIC	MRI					
85	**CP (F)**		46	SCIATICA		VAS 10	0
		HNP		SCIAITICA			
86	**NL (F) 15**		15	LBP		VAS 4	0
	CHRONIC	X-Ray					
87	**SL (F)**		49	SCIATICA		VAS 10	0
				SLR+45			
88	**JM (F)**		48	SCIATICA		VAS 6	0
	L3-L4	HNP					
89	**JD (M)**		84	SCIATICA		VAS 3	1
	X-Ray			LBP			
90	**(JE)**		49	SCIATICA		VAS 9	0
		MRI					
91	**JM (F)**		62	SCIATICA		VAS 8	1
		MRI					
92	**CD (F)**		61	LBP		VAS 5	1
	CHRONIC	X-Ray					
93	**PG (M)**		63	SCIATICA		VAS 8	1
	CHRONIC	X-Ray					
94	**IB (M)**		73	SCIATICA		VAS 6	1
					M		
	SPINAL			MULTILEV	R		
	STENOSIS			L	I		
95	**KH (M)**		42	LBP		VAS 4	0
96	**NR (F)**		63	SCIATICA		VAS 6	0
		MRI					
97	**IH (F)**		68	SCIATICA		VAS 10	1
	CHRONIC	MRI					
98	**VV (M)**		41	SCIATICA		VAS 6	1
99	**GP (F)**		78	SLR70L		VAS 8	0
	CHRONIC/MRI	HNP		SCIATICA			
100	**CG (M)**		26	SCIATICA		VAS 8	0
	DDD/L4						
	SPONDYLOLISH						
	TESIS			LBP			
		MRI					
101	**AC (F)**		75			VAS 8	0
	CH RONIC	X-Ray					
102	**DL (M)**		45	SCIATICA		VAS 8	0
	CHRONIC L5 L	HNP					
103	**GQ (M)**		49	SCIATICA		VAS 10	3
	CHRONIC HNP			SLR30R			
104	**PA (M)**		52	SCIATICA		VAS 6	1
		HNP L4-					
	MRI	5R					
105	**CR (M)**		82	LBP		VAS 3	2
	X-ray	LBP					
106	**(MJ) (F)**		50	SCIATICA		VAS 4	1
	MRI	LBP					
107	**(LB) (F)**		40			VAS 8	0
		LBP					
108	**MN (M)**		41	SCIATICA		VAS 4	0
		SCIATIC					
	MRI	A					
109	**AF(F)**		67			VAS 8	1

110	**VD (M)**	X-ray 36	SCIATICA	VAS 9	2
111	**DW. (M)**	SCIATIC A 54		VAS 7	0
	CHRONIC	HNP L4-5L			
112	**RD (M)**	58	SCIATICA	VAS 4	0
113	**SS (M)**	X-ray 39	SCIATICA	VAS 8	1
	CHRONIC	HNP L4-5R			
114	**ZS (M)**	MRI 86	LBP	VAS 4	1
	LBP	X-ray			
115	**KU (F)**	72	LBP	VAS 6	0
116	**MB (F)**	X-ray 47	SCIATICA	VAS 10	1
	CHRONIC	HNP L5-S1 C			
117	**CB (F)**	36	SCIATICA	VAS 10	0
118	**EW (M)**	X-ray 67	SCIATICA	VAS 5	1
119	**KV (F)**	X-ray 48	SCIATICA	VAS 10	0
120	**PM (F)**	X-ray 69		VAS 10	0
	MRI	HNPL4-5 FRAGMENT	SCIATICA		
121	**BQ (F)**	78	LBP	VAS 6	3
122	**JC (M)**	X-ray 63	SCIATICA	VAS 4	1
123	**EC (M)**	X-ray 52	LBP	VAS 10	0
124	**FH (M)**	X-ray 40		VAS 10	0
	MRI	HNPL5-S1	SCIATICA		
125	**JC (F)**	45	SCIATICA	VAS 5	1
126	**RR (F)**	X-ray 57		VAS 9	0
		MRI	SCIATICA		
127	**JR (M)**	27		VAS 10	1
	ACUTE	MRI	SCIATICA		
128	**IG (M)**	48	LBP	VAS 10	1
129	**SL (M)**	X-ray 53	LBP	VAS 8	0
130	**LD (F)**	X-ray 49	SCIATICA	VAS 10	0
131	**DZ (M)**	55	SCIATICA	VAS 10	0
	X-ray	DJD/DDD			
132	**JH(40)**	HNP-L5	SCIATICA	VAS 9	2
133	**SM(45)**	MRI HNP-L4	LBP	VAS 10	0

FOOTNOTES

1 Carey TS, Garrett J, Jackman A, McLaughlin C, Fryer J, Smucker DR. The outcomes and costs of care for acute low back pain. N Engl J Med 1995; 333:913-917.

2 Pedinoff S, Pinals RS, Schwartz A, Spengler DM. Motion and progress in low-back pain: prompt, aggressive rehabilitation can keep an acute problem from becoming a lifetime disability. Patient Care 1991; v25 n9 p 71 (9)

3 Frymoyer J. Back pain and sciatica. N Engl J Med 1988; 318: 291-299.

4 Frymoyer JW. Predicting disability from low back pain. Clin Orthop Rel Res 1992; 2779:101-9

5 Quittan M. Management of back pain. Disability Rehabilitation 2002; 24 (8): 423-434.

6 Polkinghorn BS, Colloca J. Treatment of symptomatic lumbar disc herniation using activator methods chiropractic technique. J Manipulative Physiol Ther 1998; 21 (3): 187-196.

7 Dan NG, Saccasan PA. Serious complications of lumbar spinal manipulation. Med Journal Aust 1983; 2:672-673.

8 Reinert O. Extension verses flexion practices in low back rehabilitation. The American Chiropractor. Feb 1992; 10-11.

9 Lewis T, Kellgren JH. Observations relating to referred pain, visceromotor reflexes and other associated phenomena. Clin Sci 1939: 4:47-71 (as referred in Frymoyer's "Back pain and sciatica N Engl J Med 1988; 318: 291-299.)

10 Southern Medical Journal. Oh, my aching back: evaluation and surgical treatment of lumbar spine disorders. Southern Medical Journal. Oct. 1996.

11 Good House Keeping, Feb.93, Vol.216 Issue 2: 64 -3p, 2c. item #9302010527

12 Weber H. Lumbar disc herniation: a controlled prospective study with ten years of observation. Spine 1983; 8:131-140

13 Carette S, LeClaire R, Marcoux S, et al. Epidural corticosteroid injections for sciatica due to herniated nucleus pulposus. N Engl J Med 1997; 333; 1634-40.

14 Stabholz LM, Grober. A new approach to treatment and prevention of lumbar disc herniations by innovative traction. Chiropractic Products. Feb. 1992

15 Ibrahim T, Burhan A, Bozhurt M, Gurbuzoglu. Distraction of Lumbar Vertebrae in Gravitational Traction. Spine 1998: 23: 1061-1063

16 Ramoos G, Martin W. Effects of vertebral axial decompression on intradiscal pressure. J of Neurosurg 1994; 81:350-