EFFECTIVENESS OF PULSED HIGH VOLTAGE MICROCURRENT TREATMENT WITH TISSUE REACTION READINGS FOR CHRONIC PAIN IN A SINGLE OUTPATIENT VISIT

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1

OBJECTIVES

To determine:

1. Effectiveness of the Avazzia PRO-SPORT™ microcurrent device in:
   - reducing self-reported chronic pain levels
   - in a diverse population of patients with
   - varying degrees of chronic pain.
2. Correspondence between areas of pain and reactions data if any.

Data has not been reviewed by the FDA.

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METHODS

Participants

18 patients
diagnosis consistent with chronic pain and other symptoms and diagnoses
varied by age, gender and reported pain level

Principal Investigators

2 chiropractic clinics in the North Texas

Study Coordinators

Arielle Lafond and Devyn Pontzer, Avazzia, Inc.

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Disclosure of Compensation

Patient participants received a free protocol treatment, and did not receive any compensation or product for participating.

Principal Investigators did not receive any compensation for participation in this study. They already owned Avazzia devices.

Study Coordinator Devyn Pontzer was present during study appointments and managed patient study record documentation during the appointment and treatment.

Study Coordinators Arielle Lafond and Devyn Pontzer are employees of Avazzia, Inc.

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EQUIPMENT

The PRO-SPORT device

- FDA cleared for pain relief
- Device cannot diagnose or treat disease condition

Y-electrode accessory attachment

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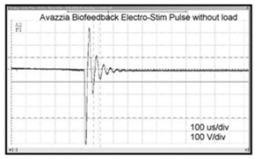
PRO-SPORT Unique Waveform

The PRO-SPORT device delivers a

- pulsed high voltage
- damped, biphasic sinusoidal waveform
- microcurrent
- frequencies ranging from 0.5Hz to 1,524Hz
- variability of power intensity.



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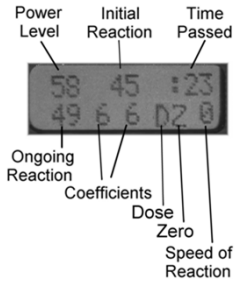
Reactions Mode Display

The PRO-SPORT device enables tissue conductance-impedance monitoring



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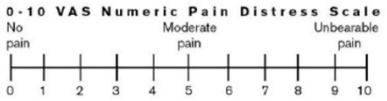
OBJECTIVE EVIDENCE

Outcomes measured were

- self-reported pain levels
- numeric visual analog scales,
- initial reaction and ongoing reaction data obtained
- measurements recorded pre- and post- treatment



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TREATMENT PROTOCOL

Each patient received four microcurrent therapies using the PRO-SPORT™ device.

1. Major **scars** reported by the patient.
   (Mode = Deep Stimulation, Frequency Modulated 15 to 120Hz)
2. The **point of pain**, as indicated by the patient, and four to eight points directly surrounding the point of pain that is no more than two inches apart. The **contralateral side** of the point of pain (same position, opposite side of body) was then treated using the same method. (Mode = Relax Assess , Frequency 60 Hz, or RSI 30Hz packets of multiple pulses)
3. **Vertebras C5 through L4** along the spine and the corresponding left and right spinal nerves with the placement of the electrodes at each vertebrae and the device set at a comfortable power intensity as determined by the patient. (Mode = Relax Assess or RSI)
4. The **vagus nerve and sternocleidomastoid muscle** with the device set at a frequency of 120Hz with power intensity modulation.
   (Mode = Acute, Frequency 121Hz modulated 3:1 seconds)

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9

Patient History Example

Circle the words that best describe your pain. Circle as many as applicable.

gradual sudden occasional (continuous) onset (aching) (sharp) (penetrating)
throbbing shooting gnawing (tiring) throbbing unbearable (burning) tender
(nagging) (exhausting) numbing (miserable)

Rate your pain by circling the number that best describes your pain at its **worst** in the last month:

0 1 2 3 4 5 6 7 (8) 9 10
No Pain — Extreme Pain

Rate your pain by circling the number that best describes your pain at its **least** in the last month:

0 1 2 3 4 (5) 6 7 8 9 10
No Pain — Extreme Pain

Rate your pain by circling the number that best describes your pain **on average** in the last month:

0 1 2 3 4 5 6 (7) 8 9 10
No Pain — Extreme Pain

Is there anything else you think contributes to your medical condition(s)? (Y) N
If yes, explain in the space below.
diving accident

ICD9 codes included: 338.4 chronic pain, 724.5, Back pain (postural)

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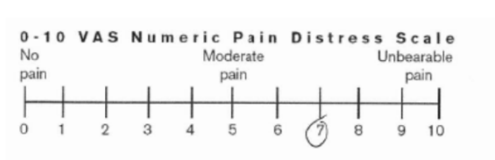
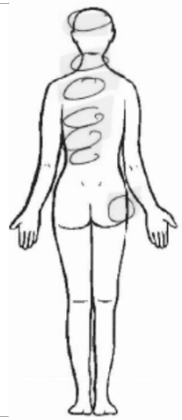
Pre-Treatment Data Example





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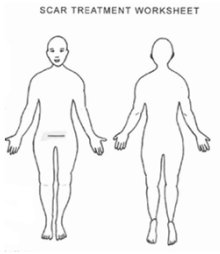
Scars Example



Location	Type	Appearance Before Treatment	Mode/Duration/ Power Level	Appearance After Treatment
Pelvis Abdominal area	Surgical Hernia	3	Deep stim 49 2 min	3

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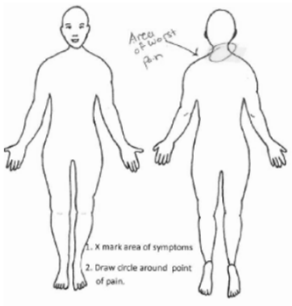
Point of Pain Example



Power 54

POINT OF PAIN OR CONTRALATERAL			SPINE	POINT OF PAIN OR CONTRALATERAL		
3 X	2 45	9 X	20 78	9 X	2 83/143	3 X
4 55	1 33	8 64/174	19 83/135	8 35	1 39/174	4 43/126
5 X	6 45	7 X	21 78	7 X	6 37	5 X

Additional notes and power level during treatment:

Working on such a small area did ABC method
Right side of the body shakes; patient has shaking on the entire rest of the right body

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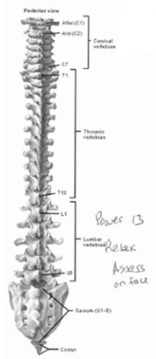
Vertebras C5 through L4 Example



	Left Paraspinal Readings	Spinal Readings	Right Paraspinal Readings
C5	79/133/	59/128	65/
C6	33/	61/106	61/117
C7	58/	50/	48/
T1	46/	30/	41/
T2	41/	38/	40/
T3	39/	38/	46/
T4	36/	54/	37/
T5	27/	33/	42/
T6	46/	46/	40/
T7	37/	41/	32/
T8	32/	27/	32/
T9	23/	38/	32/
T10	72/	33/	34/
T11	33/	30/	30/
T12	40/	30/	37/
L1	38/	32/	32/
L2	39/	32/	37/
L3	30/	39/	37/
L4	38/	41/	52/

Relax Assess pain 50 on back
Relax Assess pain 13 on face
Patient sleeps on the floor may cause the pain/discomfort in lower back
Doctor said patient probably has degenerated discs in the neck - which was
probably caused by diving accident.
C5 was highest reading for patient.
Routinely monitor patients report of highest pain

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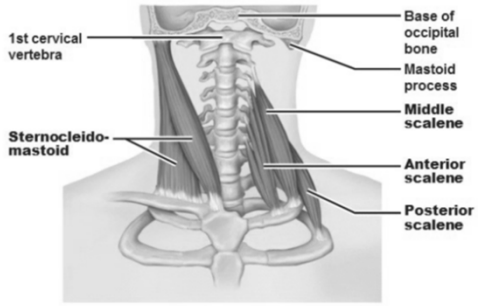
vagus nerve and sternocleidomastoid muscle



(a) Anterior

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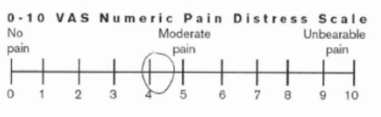
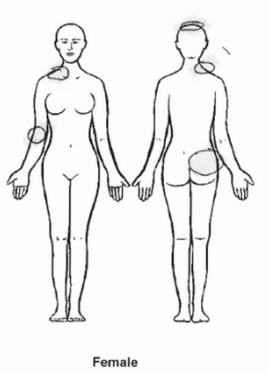
Post Treatment Example

- Self-reported pain levels using visual analog scales
- Pain reduced from a 7 before to 4.1 after.





Female

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16

RESULTS

18 patients

diagnosis consistent with chronic pain and other symptoms and diagnoses

varied by age, gender and reported pain level

Average pain reduction, as reported in the pain scores, went from 4.93 to 2.93 out of 10.

Results represent average reduction in pain scores of

63%.

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PATIENT DEMOGRAPHICS

TABLE 1. Patient Demographics, Average Pain Scores

	Total Participants (n = 18)	
Age	*51.83*	*15.80*
Sex(male/female)*	5/13	
Self-Reported Pain Score (pre-treatment)	4.93	1.97
Self-Reported Pain score (post-treatment)	2.39	1.87
Amount Decrease in Pain Score	3.06	1.95
Pain Relief from treatment	63.71%	33.22%

Data are expressed as mean SD.

*Data is expressed as number of males to number of females

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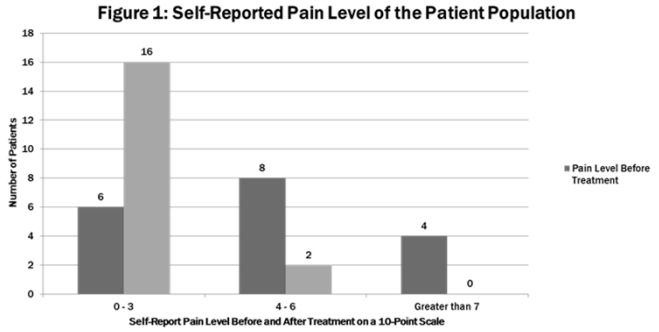
18

Pain Level of the Patient Population



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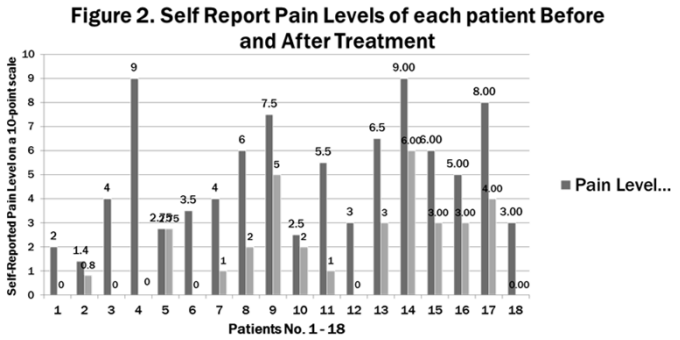
Patient VAS Before/After



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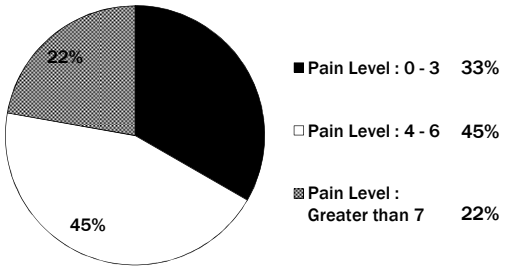
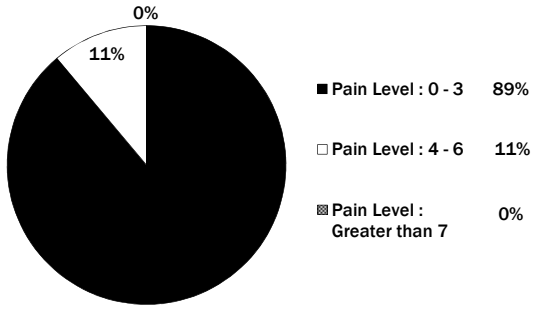
20

Figure 3. Average Self-Reported Pain Level Before Treatment



21

Figure 4. Average Self-Reported Pain Level After Treatment



22

Data Summary for Single Treatment

The Avazzia PRO-SPORT™ device safely and effectively improves pain levels in diverse patient populations with various degrees of chronic pain.

Avazzia PRO-SPORT and treatment protocol for 18 patients resulted in

- Average reduction in pain (>40%) and
- Average decrease in pain score of 3.06 ±1.95 in a single treatment.

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PRO-SPORT OPEN STUDY CONCLUSION

Data suggest that the Avazzia PRO-SPORT™ microcurrent electrostimulation device may reduce pain levels in patients with various degrees of chronic pain over a diverse pain population versus a single condition.

The statistically significant reduction in pain (>40%) and average decrease in pain score of 3.06 ±1.95 in a single treatment indicate there is a high probability (>90%) of these results being replicable over a larger pain population and an increased reduction of chronic pain with extended use.

However, sustainability of the beneficial effect over an extended period of time and larger population will need to be considered to further conclude the effectiveness of this treatment.

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24

OPEN STUDY

For more information, contact

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25

Patient History

History of Pain

Where is your pain typically? low back radiation to left

Is there a recognizable traumatic injury associated with any of this pain? (Y) N

If yes, explain: herd fall on a hiking trip

When did the symptoms start? April (month) 2013 (year)

gradual sudden (occasional) continuous onset (aching) sharp penetrating
stabbing shooting gnawing tiring (throbbing) unbearable burning (tender)
nagging exhausting numbing (miserable)

Rate your pain by circling the number that best describes your pain at its **worst** in the last month:

0 1 2 3 4 5 6 7 8 (9) 10
No Pain Extreme Pain

Rate your pain by circling the number that best describes your pain at its **least** in the last month:

0 1 (2) 3 4 5 6 7 8 9 10
No Pain Extreme Pain

Rate your pain by circling the number that best describes your pain **on average** in the last month:

0 1 2 3 4 (5) 6 7 8 9 10
No Pain Extreme Pain

Name of Medication	Dose (mg)	Frequency (x/day)	Duration	Purpose
1. Clonazepam	.5 mg	1	3yrs	Anxiety
2. Ambien	10 mg	1	15yrs	sleep issues

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26

Pre-Treatment Data

Is there anything else you think contributes to your medical condition(s)? (Y) N
If yes, explain in the space below.
high activity - I'm a personal trainer

0-10 VAS Numeric Pain Distress Scale

No pain — Moderate pain — Unbearable pain

0 1 2 3 4 5 6 7 8 9 10

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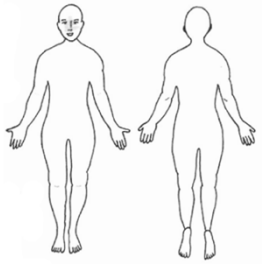
27

Scars



Location	Type	Appearance Before Treatment	Mode/Duration/ Power Level	Appearance After Treatment
Face	Trauma Childhood	1	Standard 1 2min	1

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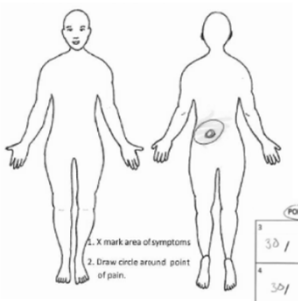
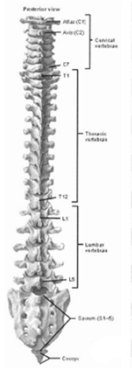
28

Point of Pain



POINT OF PAIN OR CONTRALATERAL			SPINE	POINT OF PAIN OR CONTRALATERAL		
30 /	33 /	32 /	34	29/	27/	32 /
30/	36/48	29 /	48/30	31 /	32 / 53	29/
40/55/75	34/	34 /	34	68 / 105/120	47 72	40 /57

Vertebras C5 through L4 Reaction Data



	Left Paraspinal Readings	Spinal Readings	Right Paraspinal Readings
C5	47 /75	48 /	57 /77/112
C6	45 /	40 /52	51 /70
C7	32 /	37 /	31 /
T1	30 /	33 /	30 /
T2	30 /	30 /	29 /
T3	30 /	30 /	29 /
T4	30 /	30 /	29 /
T5	31 /	31 /	32 /
T6	31 /	28 /	29 /
T7	33 /	31 /	35 /
T8	33 /	32 /	34 /
T9	32 /	28 /	32 /
T10	32 /	27 /	34 /
T11	32 /	30 /	31 /
T12	31 /	28 /	32 /
L1	29 /	29 /	31 /
L2	31 /	28 /	31 /
L3	32 /	29 /	32 /
L4	29 /	28 /	29 /

May have damaged nerve on tailbone due to injection
Most pain is caused when patient is sitting down

Post Treatment

- Correlation to reaction data from Vertebras C5 through L was unclear.
- Pain was reduced from 5.5 before to 1.2 after.

Questions?