Shoulder Pain: Effectiveness of Microcurrent Treatment

Subtitle: Effectiveness of Pro-Sport™ Microcurrent Electro-Therapy for Pain in a Single Outpatient Visit with Patients Exhibiting Shoulder pain and/or symptoms consistent with Shoulder Pain: PRO-SPORT Open-Label Shoulder Pain Study

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ABSTRACT

Objectives

Microcurrent electrical stimulation for pain has been researched and reported effective in a number of recent studies. The purpose of this preliminary study is to document educational training modules in the use of Avazzia technology for reducing shoulder pain in a diverse population of patients with varying degrees of pain, and limited mobility. Self-reported chronic pain levels associated with shoulder pain symptoms, and increasing range of motion were measured and reported indicating effectiveness of the microcurrent therapy using the Avazzia PRO-SPORT™ device, a non-invasive hand-held microcurrent device that utilizes microchip and interactive technology to produce an electrical current with the skin as a conduit, cleared by the US FDA for treating pain.

Overview Results

All participants reported pain relief. The average pain reduction experienced, as reported in the pain scores, were reduced from 5.64 out of 10 was the average Initial Pre-Treatment VAS Reading. The average Post-Treatment VAS Reading was 2.50 out of 10. These results represented an average pain score reduction of 59.5% across the patient population.

Overview Discussion

The Avazzia PRO-SPORT™ device can reduce pain levels in patients with various degrees of chronic pain. The statistically significant reduction in pain of this degree in a single treatment indicates 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.

Overview Key Words

Microcurrent technology, chronic pain, alternative medicine, neurostimulation, biofeedback.

INTRODUCTION

Microcurrent electrical stimulation for pain has been researched and reported effective in a number of recent studies. [1,2,3,4,5] Despite its efficacy in treating pain, it is not widely used as a therapy for chronic pain.

In recent years, the use of opioids in the U.S. to manage pain has grown to alarming levels.[6] The U.S. makes up 4.6% of the world's population yet consumes 80% of the world's pain pills[7,8]. In addition to the U.S. federal government looking for ways to manage the spike in these often addictive drugs[9], many local governments also aim to manage the use and abuse of these prescriptions[10] as well as the future increase in long-term costs of prescription medications.

Microcurrent electrical stimulation offers an appealing alternative to pharmaceutical treatment for pain. Often the purchase price of a device is comparative to ongoing drug costs. Home use reduces costs for therapy treatments between doctor appointments. Home use stimulators are typically, handheld, battery operated devices that require minimal training and have fewer options, buttons, or switches, are easier-to-use than a television remote ,cellular telephone, or electronic game. There is no risk for addiction, which is especially important in populations where addiction risk is high, and, unlike opioid prescription drugs, the device has no "street value."

Microcurrent is often compared to TENS (transcutaneous electrical nerve stimulation) technology. Some TENS applications are designed to saturate nerves, thus blocking or preventing pain signals to the brain. These types of TENS are often effective for acute injuries, but becomes ineffective once the patient's body accommodates or habituates to the signal. Microcurrent technology, as found in the Avazzia PRO-SPORT™ devices, incorporates advanced TENS technology with the use of low-level electrical currents (10^{-6} amperes) and interactive feedback technology to treat nerve and muscle pain, and other chronic health challenges. Tissues in the human body conduct electrical frequencies which may be disrupted by injury. Microcurrent restores normal frequency conduction within the cells, resulting in remarkable improvements in pain, inflammation and function. [11]

PRO-SPORT™ reaction data readings display and monitor measurements related to each output pulse, relative tissue conductance, and rate of change of electronic tissue characteristics. Reaction data includes Initial Reaction (IR) and Ongoing Reaction (OR) information on how the tissue reacts to treatment thus providing data about the tissue.

Therefore, it is proposed that microcurrent treatment using the Avazzia PRO-SPORT™ device is an effective stand-alone treatment for varying degrees of chronic pain over a diverse population as seen in a single visit. We conducted an open-label clinical study to measure effectiveness for treating shoulder pain with the Avazzia Pro-sport microcurrent neurostimulator to support our hypothesis.

Methods

MATERIALS AND METHODS

Seven patients of Thomas Lehanan, D.C., were enrolled in the shoulder pain study. Each clinician has experience with microcurrent therapy.

Participants

Patients at least 18 years of age and who had been diagnosed with chronic shoulder pain or frozen shoulder like symptoms were eligible to participate. Each patient had a treatment diagnosis ICD-9 code consistent with frozen shoulder or symptoms associated with frozen shoulder or chronic shoulder pain. Seven patients presented with symptoms and a diagnoses consistent with pain in the affected shoulder of frozen shoulder, tenderness, impingement, or other chronic shoulder condition. All participants presented with a history of chronic pain of at least three months and a limited range of motion in the affected shoulder of varying degrees of pain. The patient population varied by age, gender and reported pain level. Each patient received four microcurrent therapies in a single outpatient visit using the PRO-SPORT™ device. Outcomes measured were self-reported pain levels prior to treatment using numeric visual analog scales, initial reaction and ongoing reaction data obtained using the PRO-SPORT™ device during treatment, and self-reported pain levels post-treatment using numeric visual analog scales.

All participants signed a written informed consent to participate in the study before treatment was administered. See Table 1 for details of patient demographics and pain average scores.

Exclusions: Patients with an implanted pacemaker, defibrillator or neurostimulator or who were pregnant or nursing were excluded from the study.

Table 1. Patient Demographics

Number of Participants	7
Age	43 to 78 years
Average Age	52.43 ± 12.07
Sex (male/female)	2 male / 5 female
Affected Shoulder (left/right)	3 left / 4 right
Length of Condition	3 to 84 months
Average length of condition	23 months

Data is expressed to mean ± SD.

Equipment

The equipment used in this study was the Avazzia PRO-SPORT™ device, a US FDA cleared microcurrent electro-neurostimulation medical device with Reaction data (Avazzia Inc., Dallas, TX, USA) cleared for indication of use for pain relief. The PRO-SPORT™ device delivers a pulsed, high-voltage, damped, biphasic asymmetric sinusoidal waveform with frequencies ranging from 0.5Hz to 2500Hz and variability of power intensity.

The clinician can control the power intensity, frequency, number of pulses per output and waveform damping. The device is equipped with electrodes on the back face of the device to be used for administering treatment.

Diagram 1. Built in Electrode (left) and Y-Electrode (right)

The clinician was also given a Y-electrode accessory attachment that has two stainless steel electrode balls attached to an eight inch handle, to administer interactive treatment. The Y-electrode tool differs from traditional TENS technology in which self-adhesive, conductive electrode pads are applied for passive treatment. The Y-electrodes enable tissue conductance-impedance monitoring as opposed to the TENS pads that provide false hydration and override the actual subtle tissue conductivity characteristics.

Sessions/Protocol

The study was designed as an open-label study. The patients were seen over a single 60 minute visit at the office of Thomas Lehanan, D.C. Eligible participants completed a medical history and study intake form to further detail their frozen shoulder or frozen shoulder-like symptoms and their current state.

Objective Measurements

For this study, two forms of measurements were used to compare before and after treatments. They were a self-reported VAS score to determine the strength of the pain, and measurement of the range over which the pain occurred.

Prior to treatment being administered, each patient identified which shoulder was affected and described their pain by rating their pain level on a numerical visual analog scale (VAS) from 0 to 10, with 10 meaning the patient was currently experiencing unbearable pain and 0 meaning no pain, and identifying the location of where they were experiencing pain on a diagram of the male or female body based on gender.

As an objective measurement related to pain, range of motion was also recorded to measure the point at which the shoulder pain occurred using a double-armed digital goniometer to record shoulder flexion, shoulder extension, shoulder adduction, and shoulder abduction.

Limited joint flexibility in the affected shoulder is a common symptom of those suffering from shoulder pain, including frozen shoulder. The joint is usually stiff and painful to use. Joint Flexibility is defined as the range of motion (ROM) allowed at a joint. The joint's ROM is usually measured by the number of degrees from the starting position of a segment to its position at the end of its full range of movement. The most common way this is done is by using a double-armed goniometer. A stationary arm holding a protractor is placed parallel with a stationary body segment and a movable arm moves along a moveable body segment. The pin (axis of goniometer) is placed over the joint. When anatomical landmarks are well defined, the accuracy of measurement is greater. If there is softer tissue surrounding the joint area, measurement error can be more frequent[15.]

Shoulder pain often occurs in some positions of the shoulder and not in other positions. For example, when the shoulder and arm in are in a comfortable unstressed position, pain may be non-existent, but as soon as the arm is moved or stressed, pain may occur. Therefore, it is important to identify under what conditions pain occurs in order to measure differences and compare pain levels before and after treatment.

Methods.

For each participant, the clinician administered treatment with the following designed protocol to address the local pain site and nerve regions:

1. Visible Scar Treatment. Scars were treated with continuous painting motion of the

device or Y electrodes over and around the patient's back, shoulder, arms, or hands at a comfortable power intensity as determined by the patient. The settings used a 82 Hz frequency without damping (Mode = Blue Relax.)

2. Internal Scar Treatment. The area around the joint capsule of the glenohumeral joint and glenoid cavity, in the affected and the healthy shoulder on the contra-lateral side were treated with continuous painting motion of the device or Y electrode over and around the areas. The device was set at a comfortable power intensity as determined by the patient. The contra-lateral side (same position, opposite side of the body) was then treated using the same method. The settings used a 82 Hz frequency without damping (Mode = Blue Relax.)

3. Shoulder Point Treatment. Treatment was applied to various points over the affected joint capsule of the glenohumeral joint, glenoid cavity, and the scapula. Fifteen points surrounding the glenohumeral joint and glenoid cavity were treated on both the affected shoulder and the healthy shoulder on the contra-lateral side. The device was set at a comfortable power intensity as determined by the patient. Starting in Zone 1, the Initial Reaction (IR) readings of points 1 to 5 are taken, following Diagram 2.

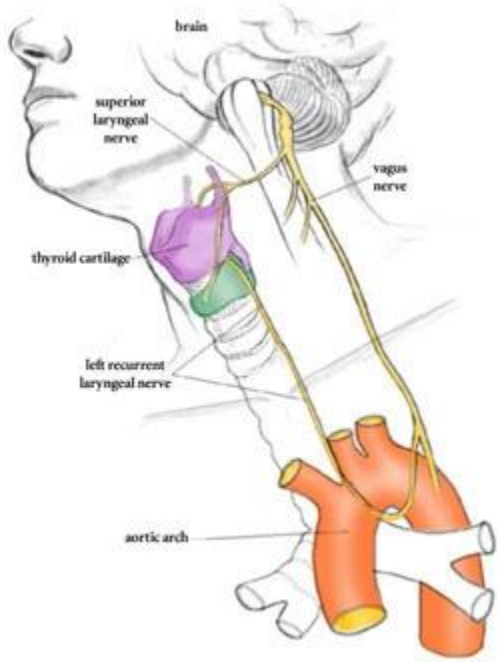
Diagram 2: Shoulder Zone 1, 2, and 3

The highest IR readings in Zone 1 were treated until a "D" and a "Zero" occurred on the Pro-Sport device. This step was repeated for Zone 2 and Zone 3 as shown in Diagram 2.

Changes in conductance-impedance reaction readings as displayed on the Pro-Sport device were recorded. The area with the highest Ongoing Reaction (OR) Reading when the device indicates a Zero was then painted with the device or Y electrode for two minutes at the same comfortable power setting as determined by the patient. For taking measurements and treating until D and Zero occurred, the settings used were a constant frequency of either 59.35Hz (Relax Assess mode on the Pro-Sport) or 30Hz packets of 10 pulses separated by 200 microseconds (RSI mode on the Pro-Sport). For painting, the settings used an 77 Hz frequency without damping (Mode = Blue Relax.)

4. Vagus Nerve and Sternocleidomastoid Muscle Treatment. The area behind the ear where the sternocleidomastoid muscle attaches to the mastoid bone near the scalene muscle was stimulated causing a mild muscle contraction. The device was set at a comfortable power intensity as determined by the patient. The settings used a frequency setting of 121Hz with a modulated stimulation amplitude of three to one generating output signals for three seconds at the user-selected power intensity, ramping down the amplitude to zero, remaining at zero output power for one second, and then ramping the amplitude power back up to the user-selected power intensity to repeat the On-Off pattern.

Diagram 3: The Vagus Nerve



Recording Results.
At the end of the visit, the patient detailed their current pain level by rating on a numerical visual analog scale (VAS) from 0 to 10, with 10 meaning the patient was currently experiencing unbearable pain and 0 meaning no pain. Pain scores post-treatment were collected approximately 5 to 10 minutes after the end of the treatment session. As an objective measurement related to determining areas of complete pain relief, range of motion was also recorded to measure the point at which the shoulder pain occurred using a double-armed digital goniometer to record shoulder flexion, shoulder extension, shoulder adduction, and shoulder abduction.

RESULTS
After the single outpatient microcurrent treatment was administered, 100% of patients reported a reduction in pain score, and 100% of patients reported an increase in range of motion before feeling pain indicating that over a range, all participants experienced a complete relief of pain. There were no adverse side effects reported with the use of this treatment.

Pain VAS Scores
Before treatment, two (28.57%) patients reported a pain level between 0 and 3, associated with mild pin, three (42.86%) patients reported a pain level between 4 and 6, associated with moderate pain, and two (28.57%) patients reported a pain level greater than 7, associated with severe pain.

After microcurrent treatment was administered, five (71.43%) patients reported a pain level between 0 and 3, two (28.57 %) reported a pain level between 4 and 6 and none of the patients reported pain levels greater than 7.

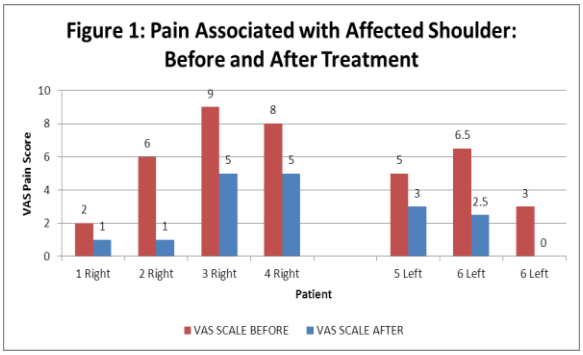
The average pain score before treatment was 5.64 ± 2.53 before treatment and 2.5 ± 1.98 after, yielding an average decrease in pain score of 3.14 ± 1.35. This is an average decrease of 59.5% ± 23.8%.

Table 2. Affected Shoulder and Pain Scales

Male / Female	Right or Left shoulder affected	Age	Months Affected	VAS SCALE BEFORE	VAS SCALE AFTER	Reduction in VAS Pain score	% decrease in VAS Pain Score
F	Right	46	7	2	1	1	50%
F	Right	78	42	6	1	5	83%
M	Right	45	84	9	5	4	44%
F	Right	56	3	8	5	3	38%
F	Left	51	9	5	3	2	40%
M	Left	43	16	6.5	2.5	4	62%
F	Left	48	6	3	0	3	100%
Average		52.4	23.9	5.64	2.50	3.14	59.5%
Standard Deviation		12.1	29.6	2.53	1.98	1.35	23.8%

Table 2 shows detailed average pain scores before and after treatment and average percent of pain reduction. Patients reported experiencing 38% to 100% pain relief with more than 50% of participants reporting 50% or greater pain relief.

Figure [1] shows the pain reduction VAS scores for each patient Before and After treatment.



Range of Motion
Range of motion was measured to determine at which positions the pain occurs and to provide measureable objective evidence of positions at which the pain score was reduced.

Measurements for range of motion without pain included:

Diagram 4 Flexion:

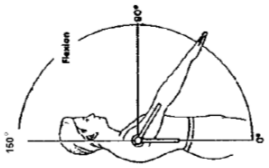


Diagram 5 Extension:

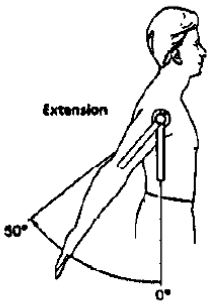


Diagram 6 Abduction:

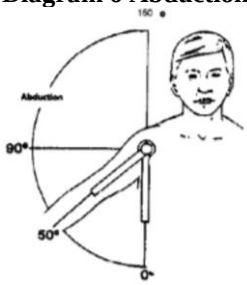
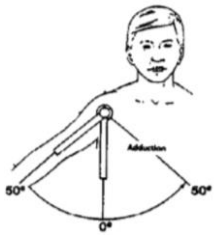


Diagram 7 Adduction:



In the data that follows, the first column, M/F VAS column, indicates if the participant was male or female and the reduction in VAS score so that the reported shoulder pain reduction could be compared to the reported change in shoulder range of motion.

Shoulder Flexion

After treatment, 100% of the participants experienced a noticeable increase in shoulder extension range of motion, and 57% of the participants experienced a 50% or more increase in shoulder flexion.

Table [2] . Shoulder Flexion for Affected Shoulder

M/F VAS	Right or Left	Before	After	Change	% Change
F – 1	Right	132.5	185.0	52.5	39.6%
F – 5	Right	130.4	150.4	20.0	15.3%
M – 4	Right	109.8	164.6	54.8	49.9%
F – 3	Right	112.1	120.3	8.2	7.3%
F – 2	Left	106.8	143	36.2	33.9%
M – 4	Left	133.3	154.9	21.6	16.2%
F – 3	Left	115.1	150	34.9	30.3%
Average		120.0	152.6	32.6	27.5%
Standard Deviation		11.6	19.8	17.2	15.2%

The average shoulder flexion range of motion increase experienced in the affected shoulder, as reported in the goniometer readings, went from 120.0°± 11.6° to 152.6°±19.8°. The results represent an average increase of shoulder flexion in the affected shoulder of 32.6°±17.2° for an average increase of 27.5%±15.2%.

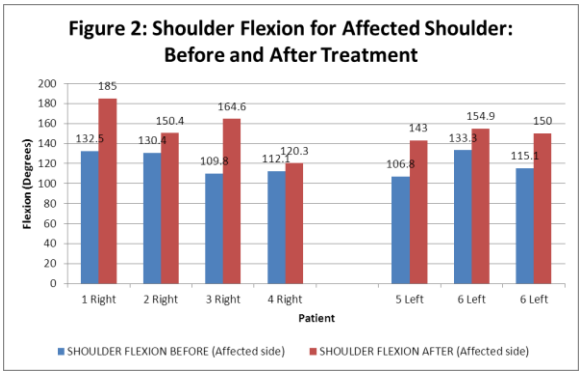


Figure 2. Shoulder flexion for Affected Shoulder: Before and After Treatment

All of the participants started with a less than 135° shoulder flexion range before treatments, and all of the participants experienced an increase in flexion range with 72% reporting an increase to more than 150° shoulder flexion range.

Shoulder Extension

After treatment, 72% of the participants experienced greater than 22% increase in shoulder extension range of motion.

Table [3] Shoulder Extension for Affected Shoulder

M/F VAS	Right or Left	Before	After	Change	% Change
F – 1	Right	54.0	55.6	1.6	3.0%
F – 5	Right	69.7	97.4	27.7	39.7%
M – 4	Right	70.5	92.2	21.7	30.8%
F – 3	Right	48.4	66.6	18.2	37.6%
F – 2	Left	61.4	74.9	13.5	22.0%
M – 4	Left	56.2	54.5	-1.7	-3.0%
F – 3	Left	58.3	91.6	33.3	57.1%
Average		59.8	76.1	16.3	26.7%
Standard Deviation		8.1	17.9	12.9	21.2%

The average shoulder extension range of motion increase experienced in the affected shoulder, as reported in the goniometer readings, went from 59.8°±8.1° to 76.1°±17.9°. The results represented an average increase of shoulder flexion in the affected shoulder of 26.7% or 16.3°±12.9°.

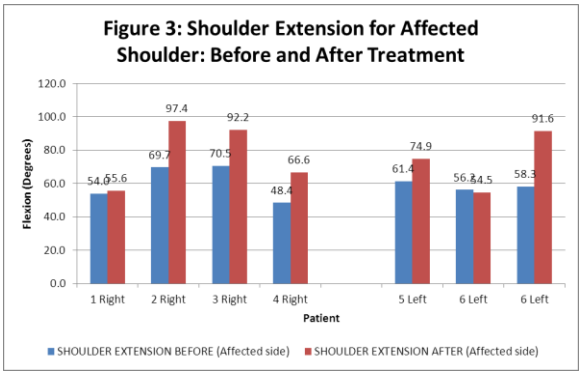


Figure 3: Shoulder Extension for Affected Shoulder: Before and After Treatment

One participant, M-4-Left-arm, experienced a slight decrese in shoulder extension range of motion of 1.7° and at the same time a pain reduction of 4 out of 10 VAS score points. It is possible, that the difference is non-significant because it was a change, and because this patient began with more than a 50° range of motion before treatment. It is also possible that if the patient had moved the arm to the same pain score as reported before treatment that the range might have been greater.

All participants except one started with at least a 48° shoulder extension range.

Table [4] Normal Values for Range of Motion of Joints*As Provided From Washington State Department of Social and Health Services Range of Joint Motion Evaluation Chart

Shoulder	Flexion	0-150°
	Extension	0-50°
	Adduction	0-50°
	Abduction	0-150°

*Ranges are for people of all ages. Age-specific ranges have not been established; however, values are typically lower in fully functional elderly people than in younger people.

Shoulder Adduction

After treatment, 57% of the participants experienced greater than 22% increase in shoulder adduction range of motion, and for 14% of the participants the range of motion was decreased.

Table [5]Shoulder Adduction for Affected Shoulder

M/F VAS	Right or Left	Before	After	Change	% Change
F – 1	Right	41.0	58.5	17.5	42.7%
F – 5	Right	23.9	36.2	12.3	51.5%
M – 4	Right	51.4	55.4	4.0	7.8%
F – 3	Right	41.3	54.8	13.5	32.7%
F – 2	Left	37.8	41.6	3.8	10.1%
M – 4	Left	58.9	44.4	-14.5	-24.6%
F – 3	Left	43.0	52.6	9.6	22.3%
Average		42.5	49.1	6.6	20.3%
Standard Deviation		11.0	8.3	10.5	25.5%

The average shoulder adduction range of motion increase experienced in the affected shoulder, as reported in the goniometer readings, went from 42.5°± 11.0° to 49.1°± 8.3°. The results represented an average increase of shoulder flexion in the affected shoulder of 20.3% or 6.6°±10.5°.

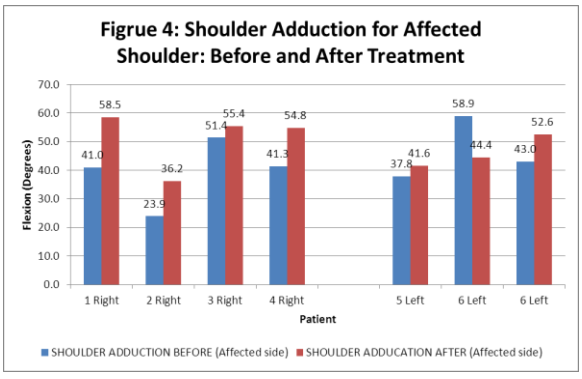


Figure 4: Shoulder Adduction for Affected Shoulder: Before and After Treatment

One participant, M-4-Left-arm, the same participant as in the extension, also experienced a decrease in shoulder adduction range of motion with a reported pain reduction of 4 out of 10 VAS score points. It is possible, that the difference is non-significant because this patient began with more than a 50° range, see Table 4 for more information, of motion before treatment. It is also possible that if the patient had moved the arm to the same pain score as reported before treatment that the range might have been greater.

It is also possible that for this patient if the arm was moved to the same position of 58.9° as at the start, that possibly, the patient would have experienced the same pain as before treatment, and the pain score reduction might not have been as much.

Shoulder Abduction

After treatment, 57% of the participants experienced greater than 25% increase in shoulder adduction range of motion, and for 14% of the participants the range of motion was decreased.

Table [6] Shoulder Abduction for Affected Shoulder

M/F VAS	Right or Left	Before	After	Change	% Change
F – 1	Right	91.0	157.0	66.0	72.5%
F – 5	Right	79.4	101.2	21.8	27.5%
M – 4	Right	120.6	137.3	16.7	13.8%
F – 3	Right	89.9	84.6	-5.3	-5.9%
F – 2	Left	86.6	90.4	3.8	4.4%
M – 4	Left	91.4	134.5	43.1	47.2%
F – 3	Left	94.8	119.1	24.3	25.6%
Average		93.4	117.7	24.3	26.4%
Standard Deviation		12.9	26.9	24.0	26.6%

The average shoulder abduction range of motion increase experienced in the affected shoulder, as reported in the goniometer readings, went from 93.4°±12.9° to 117.7°±26.9. The results represented an average increase of shoulder flexion in the affected shoulder of 26.4% or 24.3°±24°.

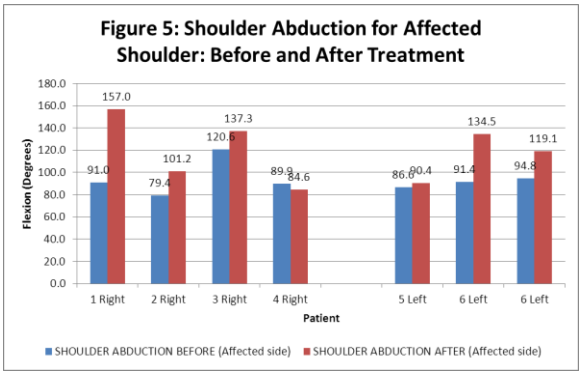


Figure 5: Shoulder Abduction for Affected Shoulder: Before and After Treatment

FLEXION

% Change

One participant, F-3-Right-arm, experienced a decrease in shoulder abduction range of motion with a reported pain reduction of 3 out of 10 VAS score points. It is possible, that the difference is non-significant because it was a small change compared to the normal range of 180°. It is also possible that if the patient had moved the arm to the same pain score as reported before treatment that the range might have been greater.

Change per Participant

Comparison of negative results to positive results by participant, the data shows that every participant reported an overall reduction in pain as well as an overall increase in range of motion in the affected shoulder.

Table [7] Percent Change for the Affected Shoulder per Patient Before/After Treatment

M/F VAS R/L	VAS	FLEX	EXT	ADD	ABD	AVG
F-1-R	50.0%	39.6%	3.0%	42.7%	72.5%	41.6%
F-5-R	83.3%	15.3%	39.7%	51.5%	27.5%	43.5%
M-4-R	44.4%	49.9%	30.8%	7.8%	13.8%	29.4%
F-3-R	37.5%	7.3%	37.6%	32.7%	-5.9%	21.8%
F-2-L	40.0%	33.9%	22.0%	10.1%	4.4%	22.1%
M-4-L	61.5%	16.2%	-3.0%	-24.6%	47.2%	19.5%
F-3-L	100.0%	30.3%	57.1%	22.3%	25.6%	47.1%
Avg	59.5%	27.5%	26.7%	20.3%	26.4%	32.1%
SD	23.8%	15.2%	21.2%	25.5%	26.6%	11.7%

The data for participant F-3-Right-arm shows average overall reported improvement was 21.8%. The data for participant M-4-Left-arm shows average overall reported improvement was 19.5%.

Total range of freedom of movement indicates that every participant reported increased range of motion.

Table [8] Total Range of Motion for Affected Shoulder

M/F VAS	Right or Left	Before	After	Change	% Change
F – 1	Right	318.5	456.1	137.6	43.2%
F – 5	Right	303.4	385.2	81.8	27.0%
M – 4	Right	352.3	449.5	97.2	27.6%
F – 3	Right	291.7	326.3	34.6	11.9%
F – 2	Left	292.6	349.9	57.3	19.6%
M – 4	Left	339.8	388.3	48.5	14.3%
F – 3	Left	311.2	413.3	102.1	32.8%
Average		315.6	395.5	79.9	25.2%
Standard Deviation		23.1	48.2	35.8	11.0%

* sum of flexion, extension, abduction, and adduction degrees of freedom

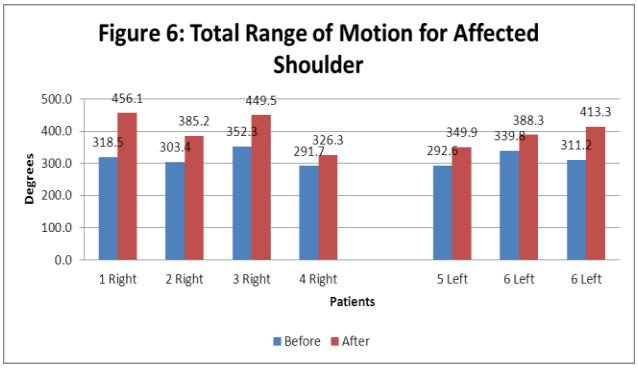


Figure 6: Total Range of Motion for Affected Shoulder

DISCUSSION

This study investigated the effectiveness of microcurrent technology using the Avazzia PRO-SPORT™ device as treatment for varying degrees of chronic pain over a diverse population as seen in a single visit for various types of shoulder pain. More than half of the participants experienced pain relief greater than 40% and an average decrease in self-reported pain score of 3.06 ±1.95 out of a scale from one to ten.

By conducting the study over a diverse population varied by age, gender and the length of time of their chronic condition, applicability over pain populations versus a single condition is assessed. However, the sustainability of the beneficial effect over an extended period of time and larger population[12] will need to be considered to further conclude the effectiveness of this treatment.

The use of the numerical, absolute VAS pain scale, as used in this study, in the assessment of levels of chronic and acute pain has been proven in previous studies to be less sensitive to bias. The use of the absolute type of VAS scale, only assessing current pain levels as opposed to a comparative scale, reduces the risk of patient bias affecting the data.

As an objective measurement related to pain, range of motion was also recorded to measure the point at which the shoulder pain occurred using a double-armed digital goniometer to record shoulder flexion, extension, adduction, and abduction.

The additional complementary indices of range of motion associated with pain adds validity to the self-reported VAS pain score data.

Consideration for reduced range of motion could be that
- the participant did not try as hard after treatment as they did when they started due to being more tired after the treatment, or
- the participant felt more relief when the treatment was over, so that the pain was more noticeable when measuring range of motion, so the patient didn't move the arm to the same pain level. It is possible that before treatment the participant moved the arm until the reported 'before' pain level was reached, and after treatment, and the pain level was decreased, the participant move the arm until the new, decreased pain level was reached.

Since all patients reported reduction in VAS score, and combined pain scores and range of motion scores for each patient indicate that each patient received benefit from the treatment, it can be concluded that overall in a single visit, the Pro-Sport microcurrent electro-therapy treatment safely and effectively reduced the self-reported pain levels for chronic shoulder pain.

No new hazards were identified.

STATISTICAL ANALYSIS

The VAS consists of a 10 cm horizontal line with the two end points labeled 0 (no pain) to 10 unbearable pain). Participants were asked to make a vertical slash across the 10 cm line that corresponded to the level of pain intensity between the limits of no pain felt (left end of line) and unbearable pain (right end of line).

A blank scale was used each time to avoid bias from previous measurements. The VAS has been shown to be a valid and reliable measurement for determining the intensity of human pain; it is minimally intrusive and is easily and quickly administered. As the VAS falls into the ratio level of measurement, parametric tests were conducted to investigate significant differences within and between the groups. Changes in the VAS within the groups were analyzed

Normality was assessed and confirmed prior to each test via the Shapiro Wilk statistic and data are presented as mean standard deviation (SD)[13].

Recommendations

Even though overall results were positive, and every participant reported pain relief, further study would be beneficial.

Future studies may consider

- A comparison of results by specific types of causes of shoulder pain such as arthritis, impingement, inflammation, bursitis, scar tissue, over-extension, frozen shoulder, and others
- Determination of significant change in range of motion prior to the start of the study
- Identify and specify what determines a non-significant change versus significant change for each measurement so that non-significant changes are not counted as either positive or negative if the change was non-significant.
- Identify a way to confirm data measurements.
- Increased number of participants over a larger population.

SUMMARY/CONCLUSIONS

The Avazzia PRO-SPORT™ device safely and effectively improves pain levels in diverse patient populations with various degrees of chronic pain. The statistically significant reduction in pain (>40%) and average decrease in pain score of 3.06 ±1.95 ($p<0.05$) 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.

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