# CHRONIC PAIN: EFFECTIVENESS OF MICROCURRENT TREATMENT
# EFFECTIVENESS OF PRO-SPORT™ MICROCURRENT TREATMENT IN A SINGLE OUTPATIENT VISIT

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## Purpose

To document educational training modules in the use of Avazzia technology for reducing chronic shoulder pain in a diverse population of patients with varying degrees of pain, and limited mobility.

1.Effectiveness of the Avazzia PRO-SPORT™ microcurrent device in:
- decreasing pain levels
- increasing range of motion
- in a diverse population of patients with
- varying degrees of chronic pain, and limited mobility.

2.Correspondence between areas of pain and reactions data if any.

Participants showing symptoms consistent with shoulder pain or frozen shoulder varied by age, gender, reported pain level, and length of time

Participants: 7 patients, ages 40 to 78; 5 females / 2 males with chronic pain symptoms from 3 to 84 months.

Participants exhibited physical symptoms such as pain, muscle tension, limited range of motion and pain in shoulder before treatment in open label study. Protocol was compliant with FDA guidelines for Avazzia B.E.S.T. units.

**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.

**Protocol**

| Location to Treat | Mode settings | Treatment time |
|---|---|---|
| Visible scars on the torso, extremities, or back | Blue Relax | 2-5 minutes per scar |
| Affected and non – affected shoulder and area around joint capsules | Blue Relax | 3-5 minutes |
| Sternocleidomastoid muscle and vagus nerve | Acute | 5 cycles |

* See report for details

## Methods

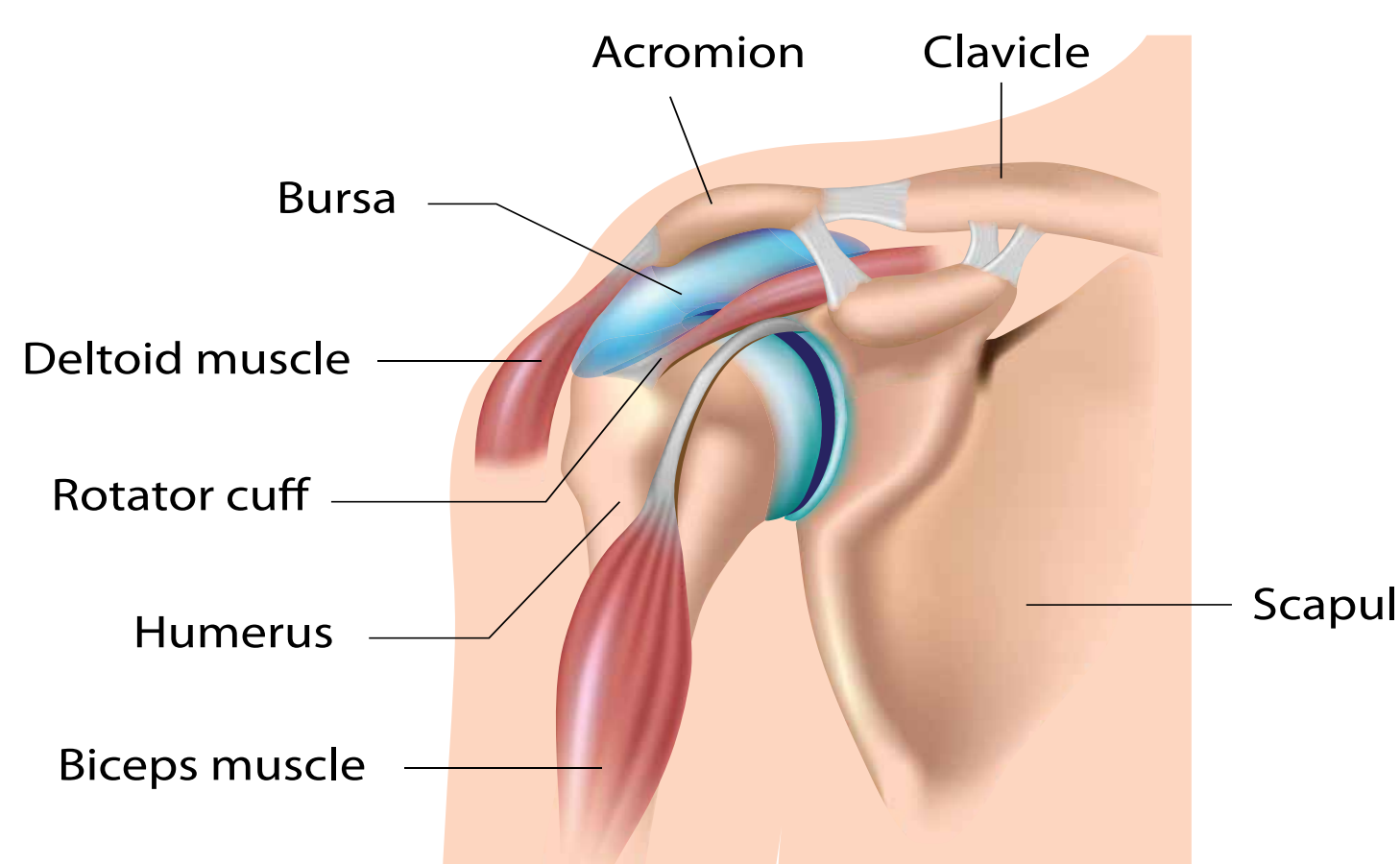
Each patient received four microcurrent therapies using the PRO-SPORT Ultra ™ device.

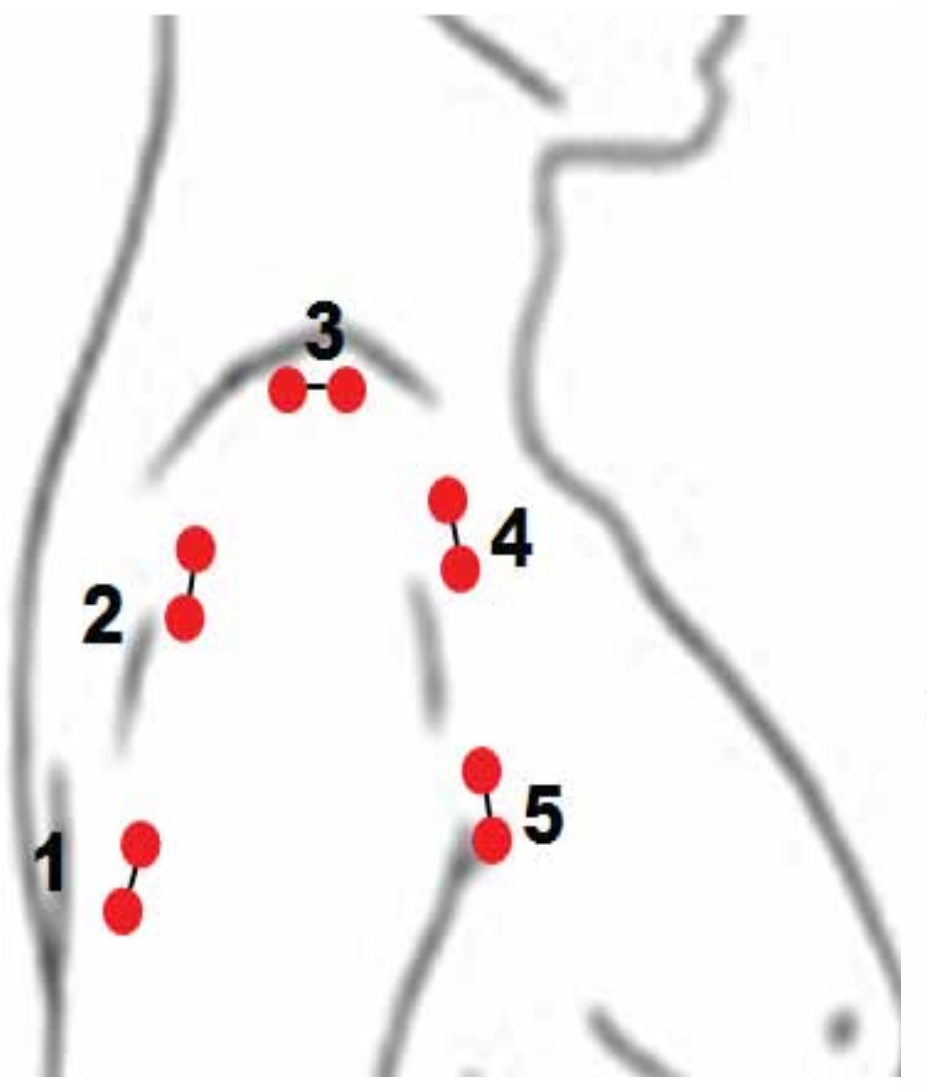
1.SCAR TREATMENT – Painting over any visible scars on the patients back, shoulder, arms, or hands.
(Mode = Blue Relax, Frequency Modulated.)

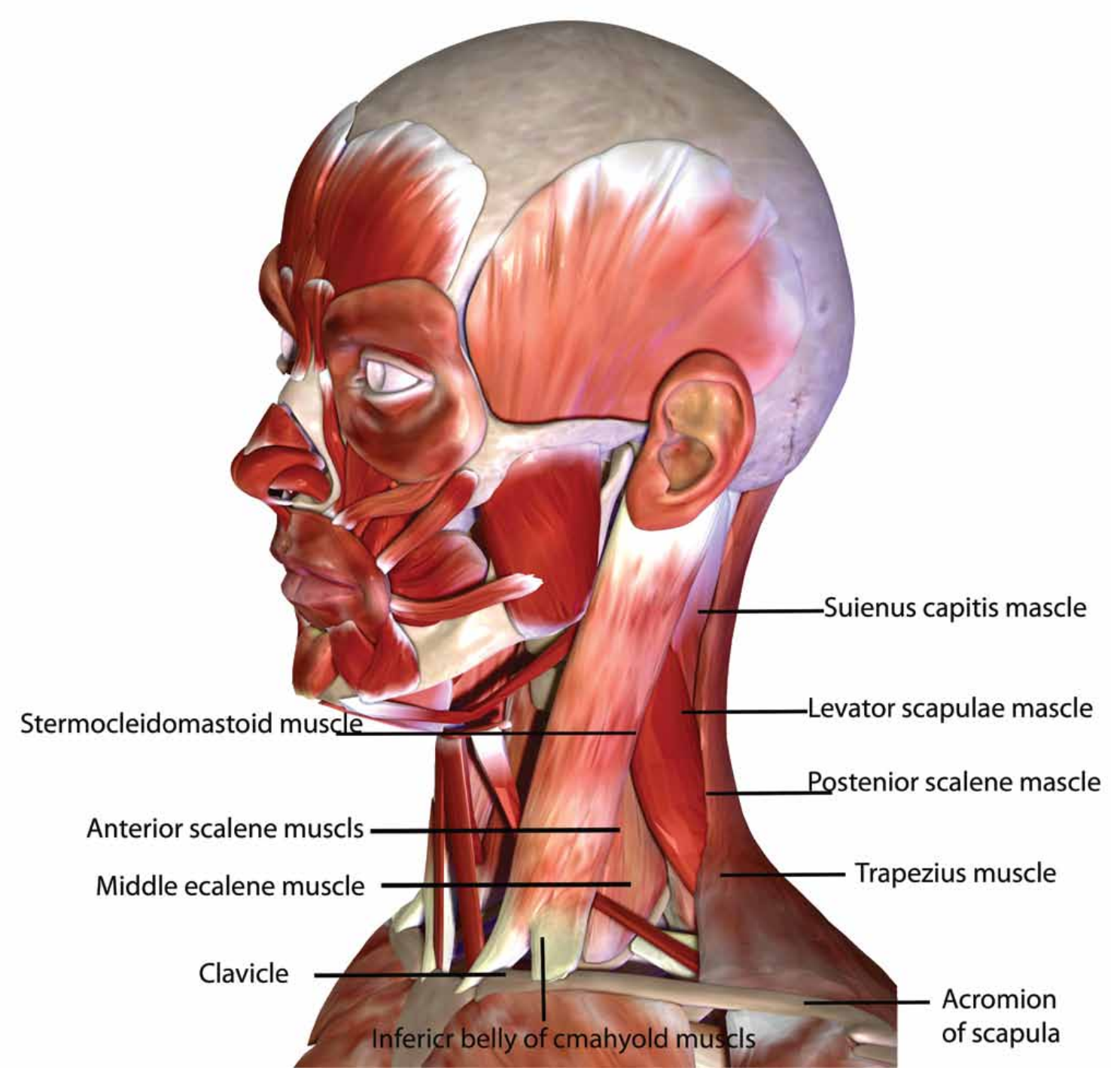
2.INTERNAL SCAR TREATMENT- Painting over the inflamed joint capsule of the glenohumeral joint and glenoid cavity.
(Mode = Blue Stimulation, Frequency Modulated.)

3.SHOULDER POINT TREATMENT - Treating various points over the inflamed joint capsule of the glenohumeral joint, glenoid cavity, and the scapula. (Mode = Relax Assess or RSI)

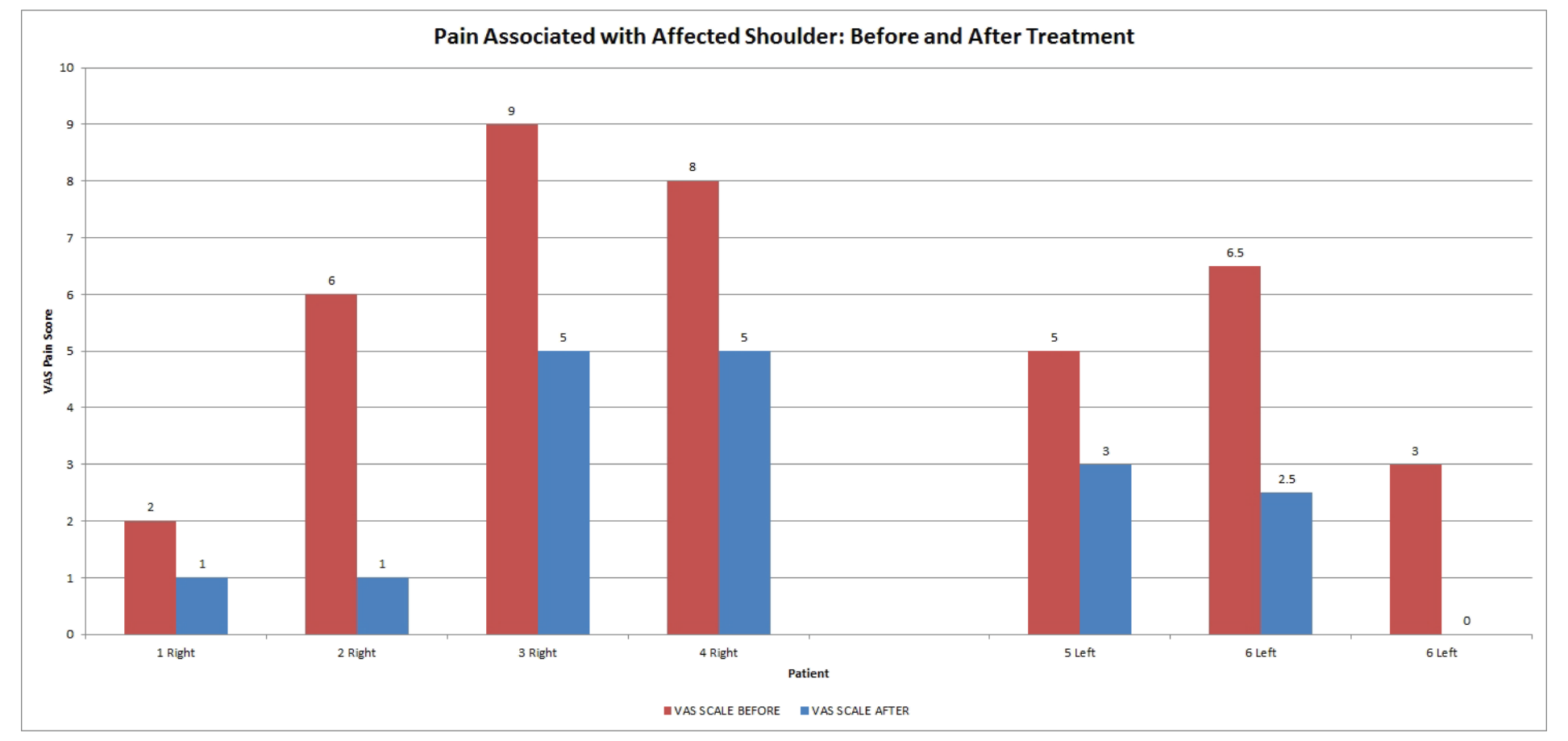
4.LITTLE WINGS TREATMENT- Stimulate the vagus nerve and sternocleidomastoid muscle with the device set at a frequency of 121Hz with power intensity modulation.
(Mode = Acute, Frequency 121Hz modulated 3:1 seconds)







## Results



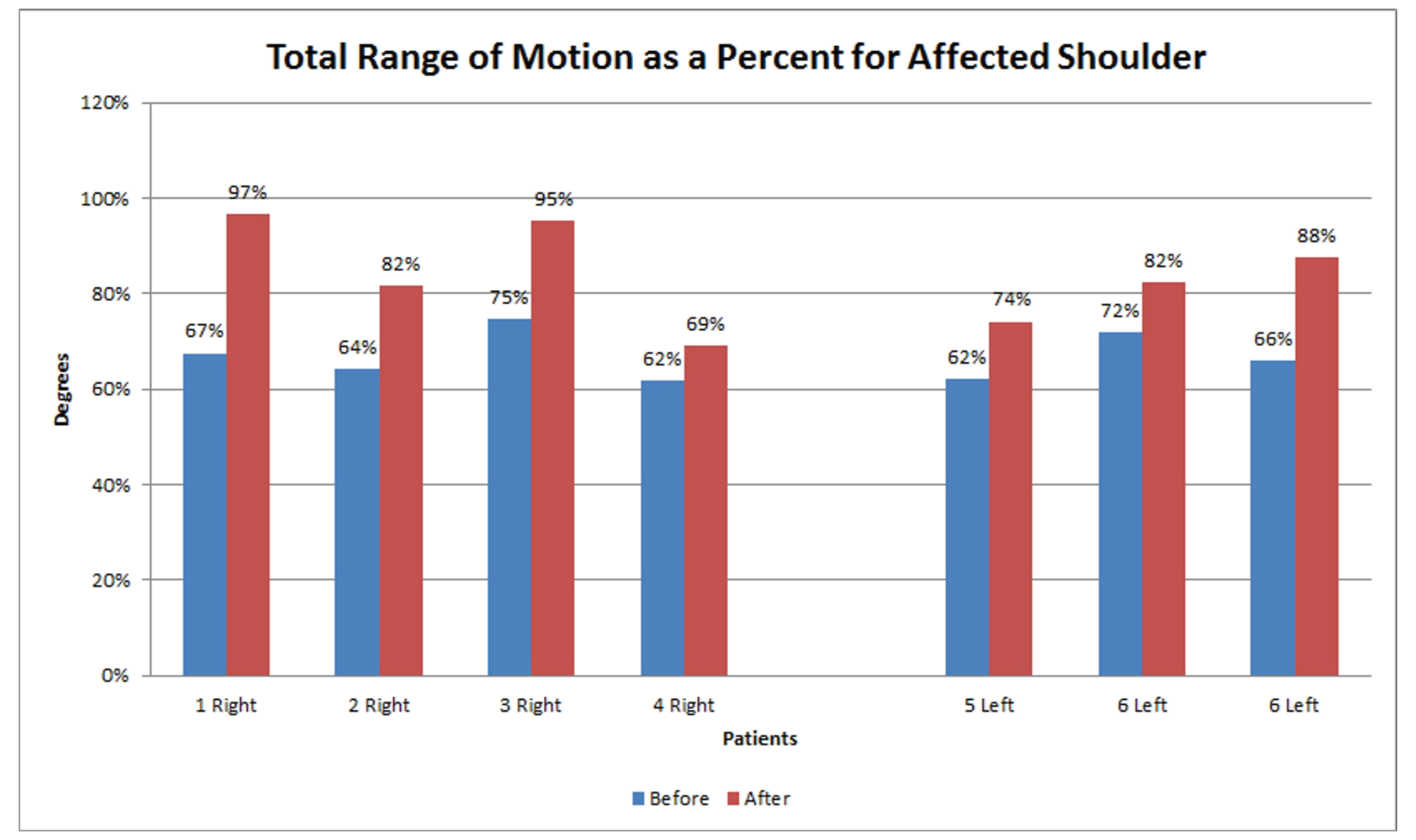


**Table 2. Affected Shoulder and Pain Scales**

| 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 [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% |

## Conclusions

Average pain reduction was 3.14 on the VAS Pain Scale out of 10. Results represent average **reduction in pain scores** of

59.5%.

EVERY patient reported reduced pain and increased range of motion.

Pain reduction based on self-reported pain intensity before and after treatment on a one-to-ten point VAZ scale. Average VAZ pain intensity of symptoms for all partipants before treatment was 5.6, and dropped to 2.5 at study end decreasing 3.1 points 59.5% decrease in reported pain.

Range of motion based on digital goniometer measured degrees for flexion, extension, abduction, and adduction. Average range of motion increase for the affected shoulder was: Flexion 32.6°; Extension 14.9°; Adduction 5.7°; Abduction 24.3°.

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.

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.

SOURCE OF FUNDING
Thomas Lenahan, D.C., Cornerstone Wellness Center (Plano, TX) provided the clinical facilities and participants that participated in this study. No additional funding or additional resources from other sources were provided for this study. Tammy Lahutsky and Devyn Pontzer, authors of this publication, are employed fulltime by Avazzia, Inc., Dallas, TX. Avazzia developed, manufactures and sells the PRO-SPORT™, the microcurrent devices used to conduct this study. The principal investigators in this study owned the PRO-SPORT™ and all accessories for this study. The clinicians were provided all necessary study documentation paperwork. The clinician-investigators were not further compensated for this study. Study-participants were not compensated for participation in the study.Data presented has not been reviewed or evaluated by the US FDA. Devices are not intended for the diagnosis or treatment of disease condition.Avazzia devices are US FDA cleared as TENS For symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain. This study is for reducing pain in patients with pain in the shoulder.

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## Equipment

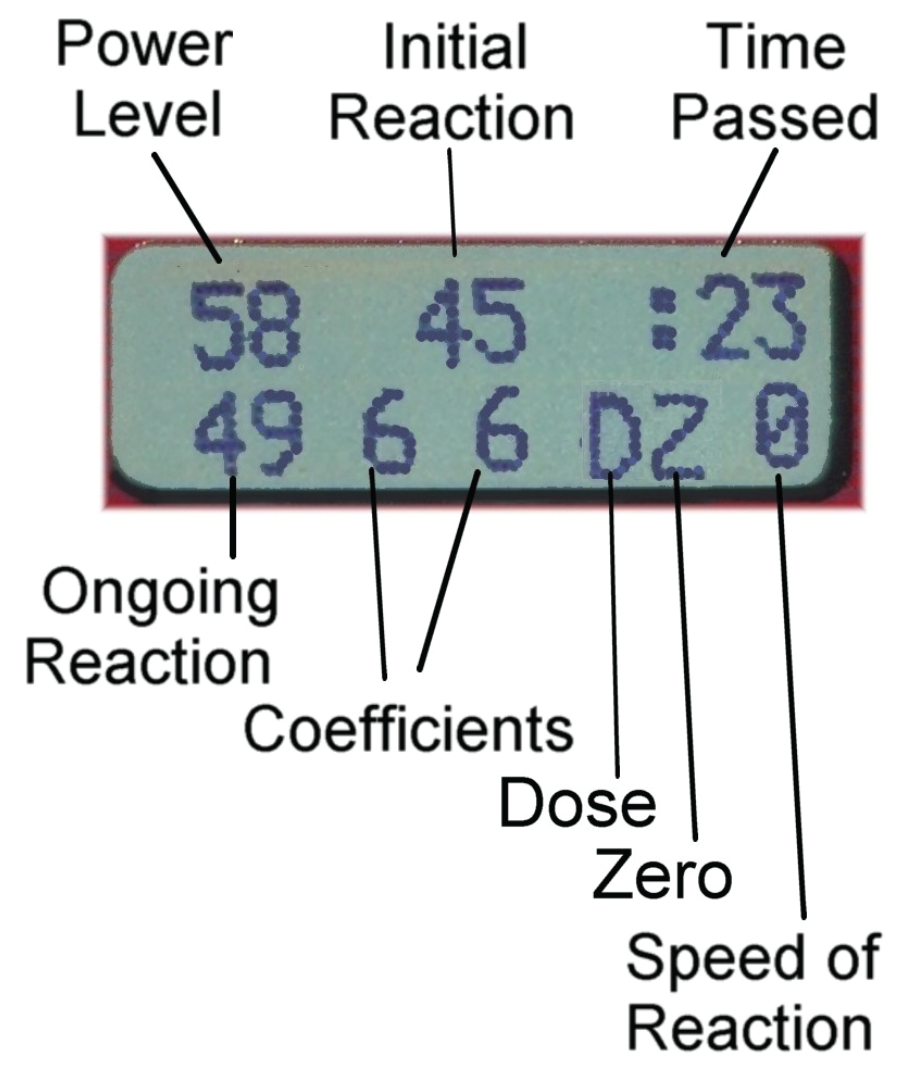
Avazzia PRO-SPORT™ device:
- a non-invasive hand-held microcurrent device that utilizes microchip and interactive technology to produce an electrical current with the skin as a conduit.

FDA cleared for pain relief
- Device not intended to diagnose or treat disease condition

Y-electrode accessory attachment

The PRO-SPORT Ultra device delivers a
- pulsed high voltage damped, biphasic sinusoidal waveform
- microcurrent
- frequencies ranging from 0.5Hz to 2500Hz
- variability of power intensity.
- preset modes

The PRO-SPORT device enables tissue conductance-impedance monitoring



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## Measurements

Measurement Tools

1. Patient reported VAS numberic pain distress scale

2. Digital Goniometer to measure range of motion for Flexion, Extension, Abduction, and Adduction