SHOULDER PAIN: EFFECTIVENESS OF MICROCURRENT TREATMENT FOR PAIN IN A SINGLE OUTPATIENT VISIT

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RA-CSR-140922-03 A

OBJECTIVES

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 in an open study.

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, cleared by the US FDA for treating pain.

Data has not been reviewed by the FDA.

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OBJECTIVES

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.

Data has not been reviewed by the FDA.

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METHODS

Participants

7 participants

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

Principal Investigator

Dr. Thomas Lenahan, DC, Cornerstone Wellness

Chiropractic clinic in the North Texas

Study Coordinators

Devyn Pontzer, Avazzia, Inc.

Tammy Lahutsky, Avazzia, Inc.

Disclosure of Compensation

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

Principal Investigator did not receive any compensation for participation in this study. He 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 Tammy Lahutsky and Devyn Pontzer are employees of Avazzia, Inc.

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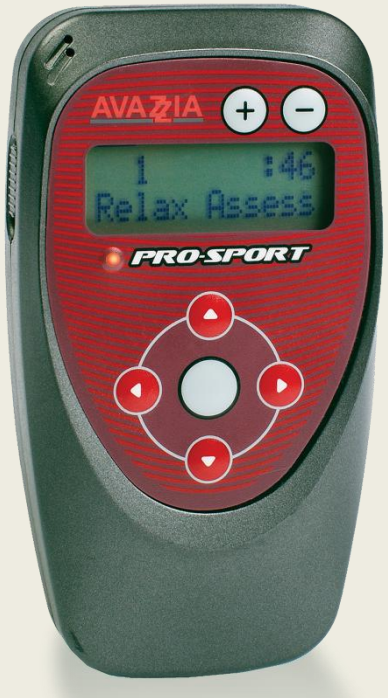
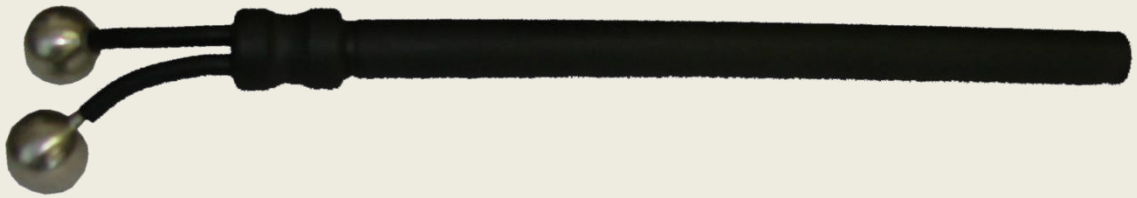
EQUIPMENT



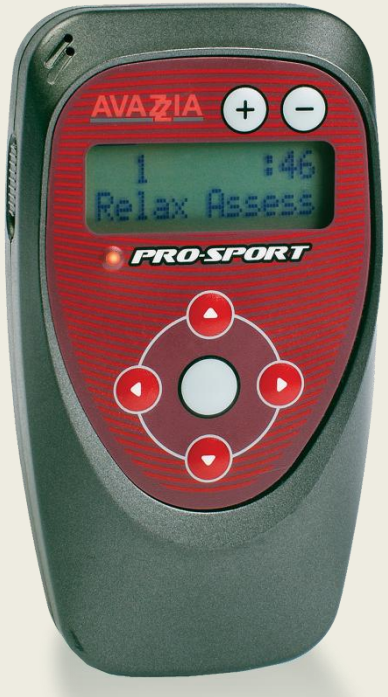
The PRO-SPORT Ultra device

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

Y-electrode accessory attachment

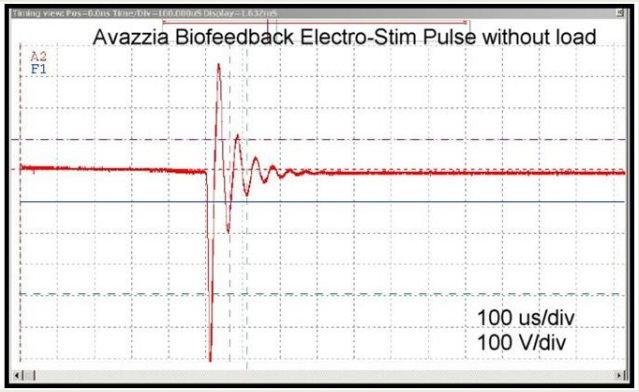


PRO-SPORT Unique Waveform



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



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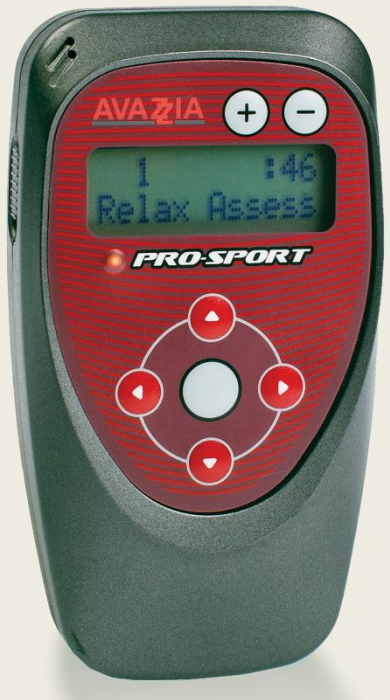
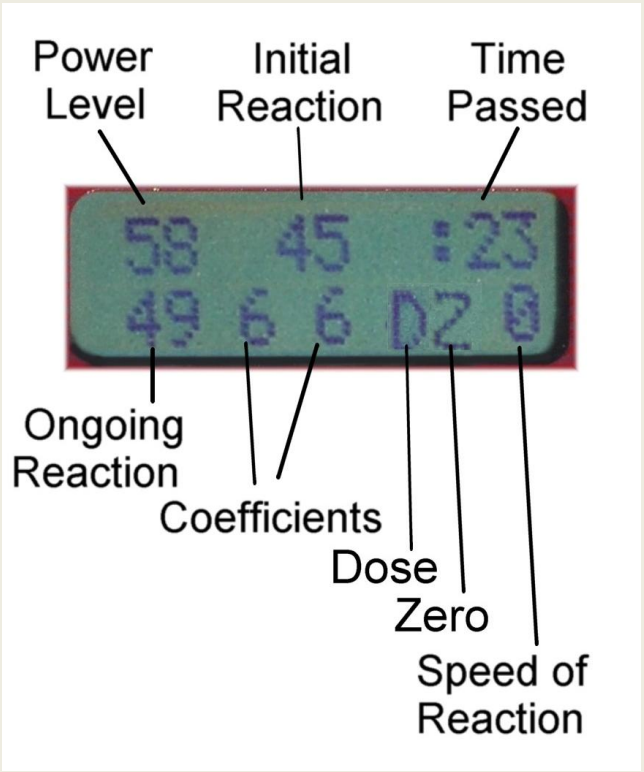
Reactions Mode Display

The PRO-SPORT device enables tissue conductance-impedance monitoring





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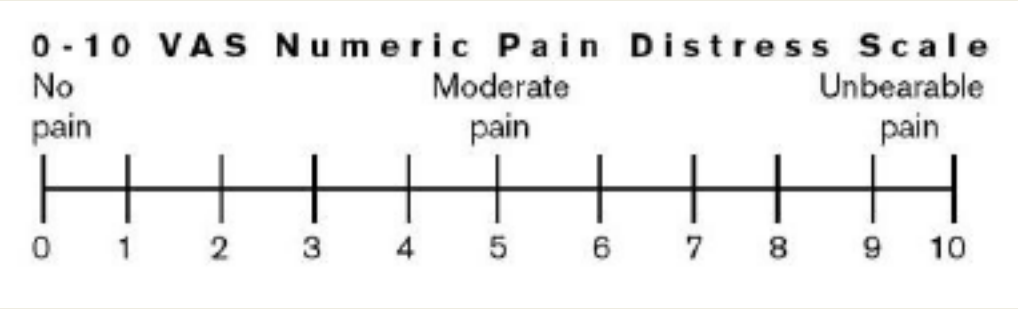
OBJECTIVE EVIDENCE

Outcomes measured were

- self-reported pain levels
- numeric visual analog scale
- Meridian Energy Analysis Device Readings
- goniometer readings on Flexion, Extension, Adduction, and Abduction
- initial reaction and ongoing reaction data obtained
- measurements recorded pre- and post- treatment



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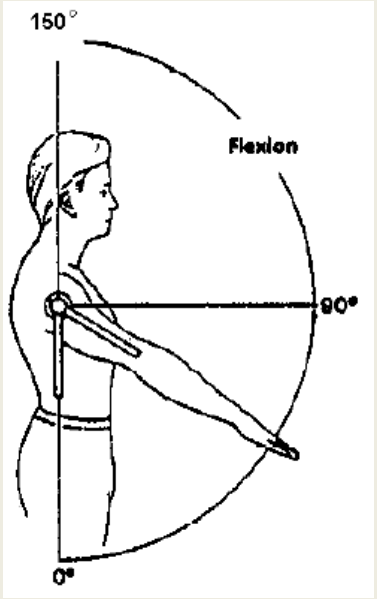
SHOULDER FLEXION MEASUREMENT

Measurement Tool: Goniometer

Testing Position: Patient can be lying flat on back (supine) with hips and knees bent and lumbar spine flat or standing. Arm is at the side with palm facing down.

Directions: Using a goniometer, record the measurements. Record a check mark in the box next to the side of the body affected.

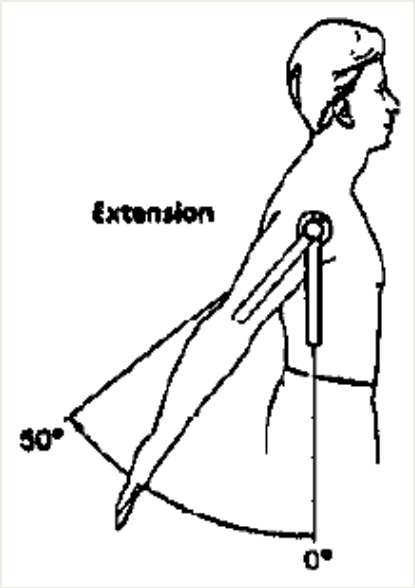
Shoulder Flexion Measurements		Diagram
o Left Shoulder	o Right Shoulder	
Flexion 150°	Flexion 150°	
_____ Degrees	_____ Degrees	

SHOULDER EXTENSION MEASUREMENT

Measurement Tool: Goniometer

Testing Position: Patient can be lying flat on stomach (prone) with hips and knees bent and flat or standing. Arm is at the side with palm towards the back.

Directions: Using a goniometer, record the measurements. Record a check mark in the box next to the side of the body affected.

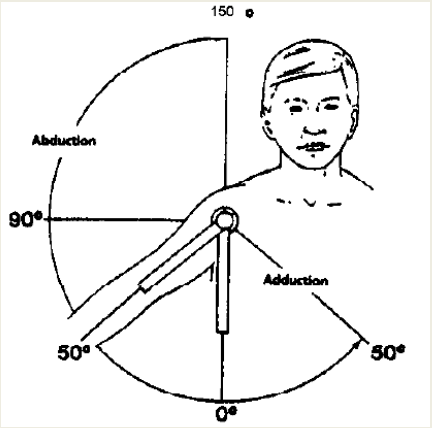
Shoulder Extension Measurements		Diagram
o Left Shoulder	o Right Shoulder	
Flexion 50°	Flexion 50°	
_____ Degrees	_____ Degrees	

SHOULDER ADDUCTION MEASUREMENT

Measurement Tool: Goniometer

Testing Position: Patient is standing. Arm is at side with palm open and facing inside towards body.

Directions: Using a goniometer, record the measurements. Record a check mark in the box next to the side of the body affected.

Shoulder Adduction Measurements		Diagram
o Left Shoulder	o Right Shoulder	
Adduction 50°	Adduction 50°	
_____ Degrees	_____ Degrees	

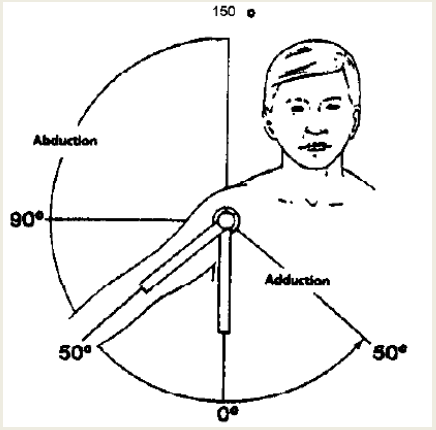
SHOULDER ABDUCTION MEASUREMENT

4. Shoulder Abduction (Horizontal)

Measurement Tool: Goniometer

Testing Position: Patient is standing. Arm is at side with palm open and facing inside towards body.

Directions: Using a goniometer, record the measurements. Record a check mark in the box next to the side of the body affected.

Shoulder Abduction Measurements		Diagram
o Left Shoulder	o Right Shoulder	
Abduction 150°	Abduction 150°	
_____ Degrees	_____ Degrees	

TREATMENT PROTOCOL

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)

SCAR TREATMENT

1. Instruct the patient to indicate up to three of their most noticeable scars, on their back, shoulder, arms, or hands.
2. Catalog the scars on the diagram in the Scar Treatment Worksheet.
3. Set device to Blue Relax mode.
4. Adjust the power of the device to the patient's comfort by testing areas around the scar.
5. Using the painting method, paint the area over the scar. Make sure to cover the entire area of the scar for two minutes.

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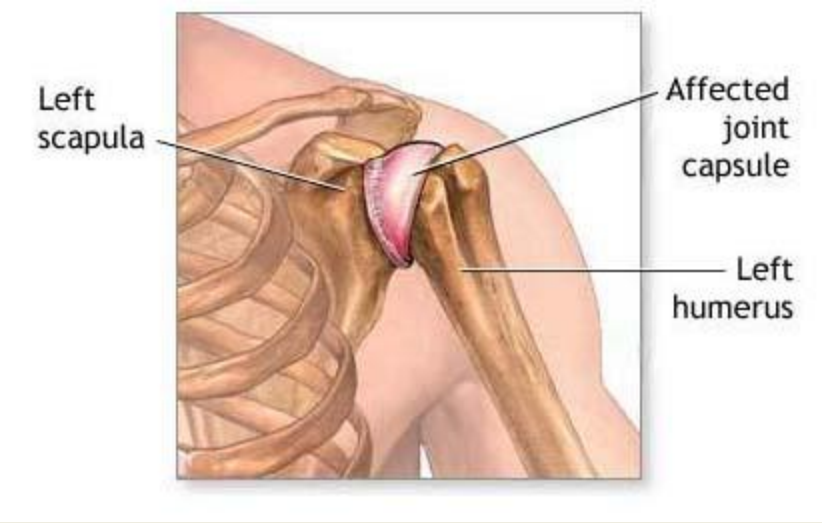
INTERNAL SCAR TREATMENT



1. Set device to Blue Relax mode.
2. Adjust the power of the device to the patient's comfort by testing areas around the inflamed joint capsule of the glenohumeral joint and glenoid cavity. Make sure the areas surrounding the shoulder are at a comfortable power level for the patient.
3. Using the painting method, paint the area over the glenohumeral joint. Make sure to cover the entire area of the shoulder joint, and the surrounding scapula.
4. Pause over sticky spots or where the device seems to drag, and spend time painting over those areas until the stickiness appears to dissipate.
5. Continue using the painting method over the entire area of the shoulder, also pausing over sticky spots for a minimum of three minutes each location of drag.
6. Use this method on the contra lateral side, or the healthy shoulder.

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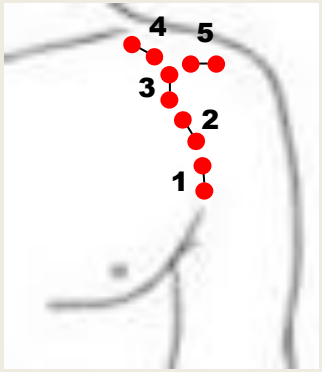
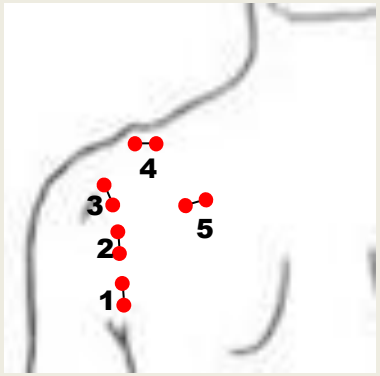
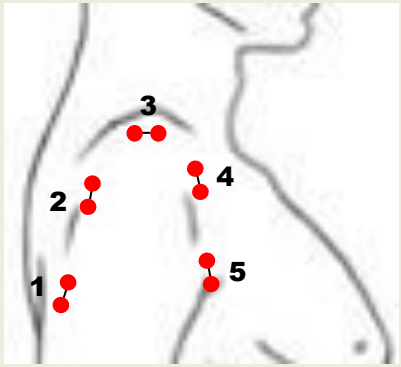
SHOULDER POINT TREATMENT



Zone 1



Zone 2



Zone 3

1. Set device to RSI, Relax Assess, or Blue Relax mode.
2. Adjust the power of the device to the patient's comfort by testing areas around the inflamed joint capsule of the glenohumeral joint and glenoid cavity.
3. Starting in Zone 1 take the IR readings of points 1-5, following the diagram on the left. The highest IR reading in Zone 1 will be brought to a "D" and then a "Z." Record the OR when the device is brought to a "D" and a "Z"
4. Repeat step 3 for Zone 2, and Zone 3.
5. Paint the area with the highest "Z" in Blue Relax for two minutes.
6. Repeat steps 1-5 on the opposite shoulder or contra lateral side.

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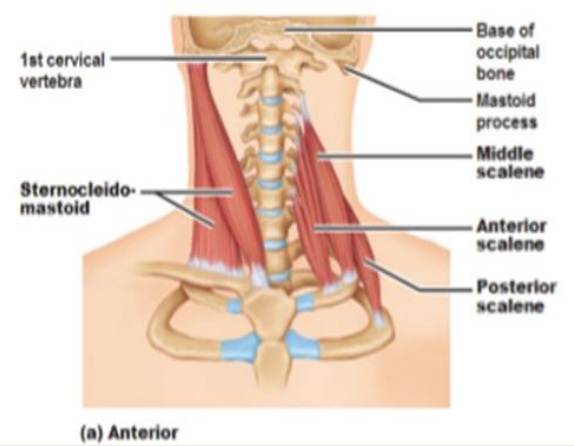
LITTLE WINGS TREATMENT



1. Set device to **Blue Relax mode** to find the location to treat.

2. Place onboard electrode or Y-electrode in the general area of the upper shoulder and ramp up power on the unit until the patient has sensation on the skin.

3. Stimulate the area behind the ear in the general area of where the sternocleidomastoid muscle attaches to the mastoid bone, and near the scalene muscle. Move the electrodes (whether onboard or Y-electrode) in the general area until the patient indicates he/she can begin to feel "tingling" in the ear lobe. (There will be no visible sign to the healthcare provider.) Hold the electrode in that spot that produces the tingling sensation.

Begin Treatment:

4. Ensure patient is secure/can't move (this may possibly require an assistant). Keep the device on the spot where the ear tingling occurs. Switch to **Acute mode** (regardless of which device is being used) without removing device (or Y-electrode) from the skin. Ramp up the power, stopping after about 5 seconds or when patient expresses discomfort.

5. Still holding the device or Y-electrode in the same spot, treat the area for five cycles. (One cycle is when the digital display shows power ramping up and then dropping to zero. Count five power shifts for a complete treatment protocol.) Immediately remove device after the treatment protocol is finished.

6. Follow same treatment procedure as above (through Part 5) on the opposite side of the neck.

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Results

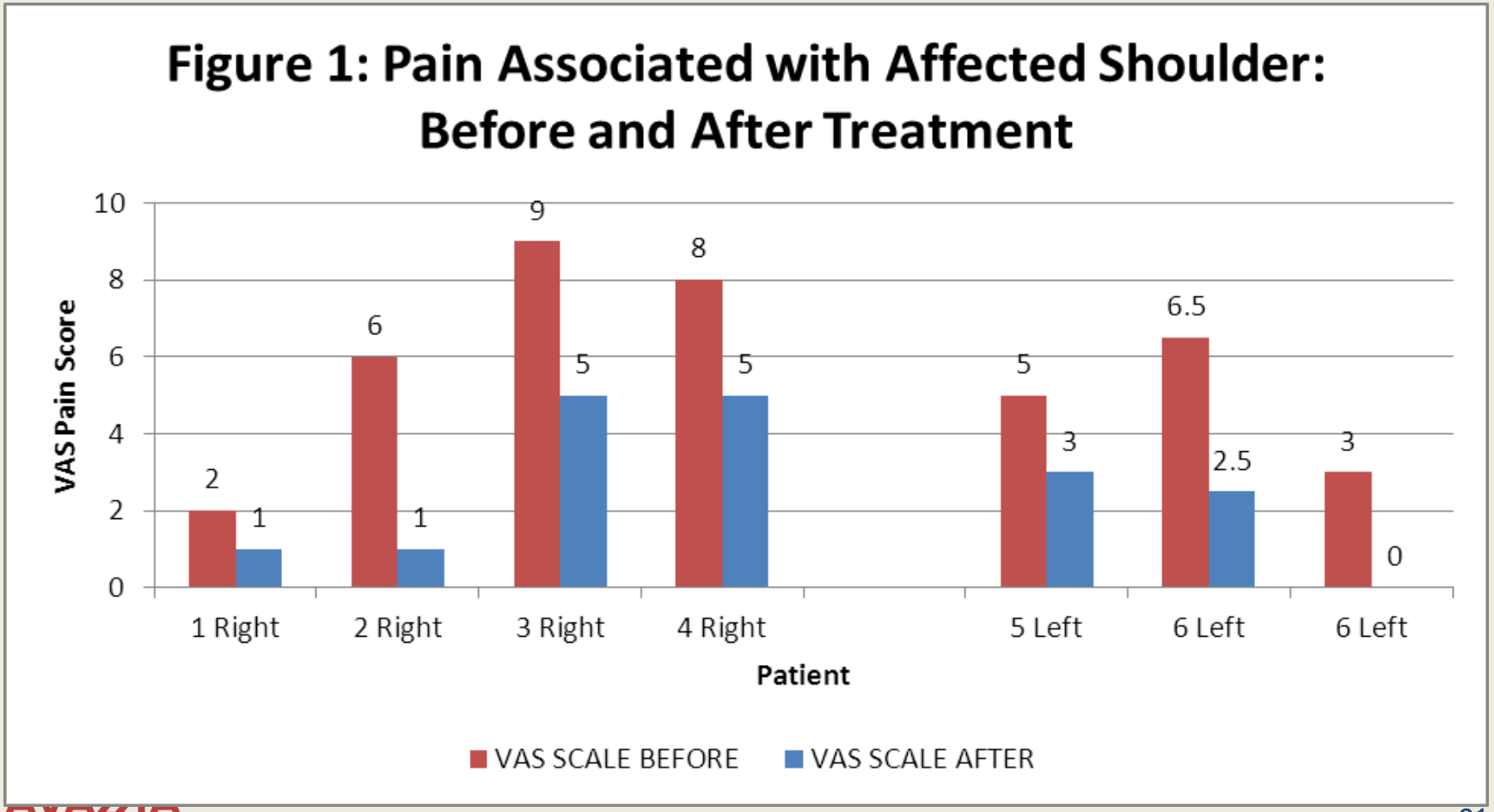
EVERY patient reported reduced pain and increased range of motion.

Participants

Seven patients presented presented with symptoms and a diagnoses consistent with pain in the affected shoulder of frozen shoulder, tenderness, impingement, or other chronic shoulder condition.

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

Patient VAS Before/After



VAS Pain Reduction for Affected Shoulder Average % Change

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%

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RESULTS

7 patients

Diagnosis symptoms consistent with frozen shoulder and other symptoms and diagnoses

varied by age, gender, range of motion and reported pain level

Average pain reduction was 3.14 on the VAS Pain Scale out of 10

Results represent average reduction in pain scores of

59.5%.

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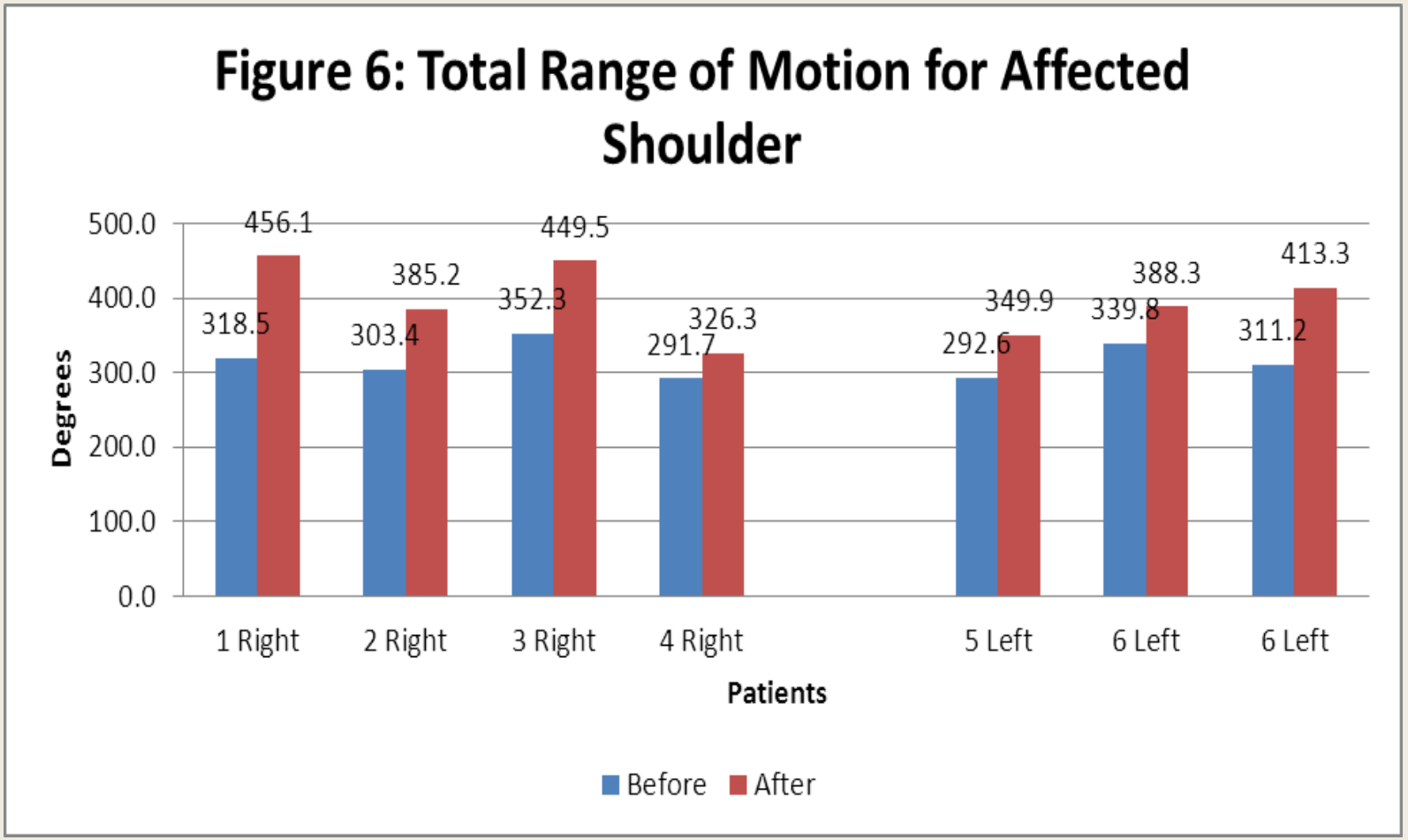
Shoulder Range of Motion Increase



Sum of flexion, extension, abduction, and adduction in degrees of freedom

The 'R' or 'L' after the patient ID indicates the shoulder that the patient reported to have pain.

RESULTS

7 patients

Diagnosis symptoms consistent with frozen shoulder and other symptoms and diagnoses

varied by age, gender, range of motion and reported pain level

Average increase in range of motion of the affected shoulder for Flexion was 32.6°

Average increase in range of motion of the affected shoulder for Extension was 16.3°

Average increase in range of motion of the affected shoulder for Adduction was 6.6°

Average increase in range of motion of the affected shoulder for Abduction was 24.3°

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SHOULDER MOBILITY OPEN STUDY CONCLUSION

Data suggest that the Avazzia PRO-SPORT™ microcurrent electro-stimulation treatment can be used to reduce pain and may increase range of motion without drugs or invasive procedures for patients with symptoms of pain or frozen shoulder over a diverse population versus a single condition.

The statistically significant reduction in pain (>40%) and average decrease in pain score of 3.14 in a single treatment indicate there is a high probability of these results being replicable over a larger pain population and an increased reduction of chronic pain with extended use.

There was a statistically significant improvement in the range of motion of these patients with an average increase (>19°) on the goniometer readings indicating there is a high probability 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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