

ADMINISTRATION CASE REPORT:

PAIN ASSOCIATED WITH SPASTICITY

This case report represents the individual experience of Dr Paul Winston and is intended to demonstrate his methodology for using iovera[®] to treat pain associated with spasticity.

Pacira BioSciences, Inc. recognizes that there are alternative methodologies for administering the iovera[®] treatment, as well as individual patient considerations.

CASE INFORMATION

Physician Name	Paul Winston, MD, Medical Director of Rehabilitation and Transitions
Affiliation	University of British Columbia, Island Health Victoria, BC, Canada
Treatment Performed	Ultrasound-guided iovera [®] treatment (with iovera [®] Smart Tip 190 with nerve stim) for pain associated with spasticity

PATIENT CHARACTERISTICS

Gender	Female
Age	71 years
Patient History and Characteristics	Patient had a right middle cerebral artery stroke in 2015 with painful left spastic hemiplegia She has a history of chronic back pain and a parietal meningioma with equinovarus right foot
Chronic Medications	Gabapentin 300 mg orally twice daily Hydromorphone 3 mg orally every 12 hours Hydromorphone controlled release 9 mg at bedtime

DAY OF iovera[®] TREATMENT

Day of Treatment Clinic Setup	iovera [®] handheld device, Smart Tip 190 with nerve stim, peripheral nerve stimulator, ultrasound gel, 4x4 gauze pads, alcohol prep pads, adhesive bandages, antiseptic skin prep, local anesthetic, 27-gauge needle, 5-mL syringe, skin marker, lidocaine for skin wheal, 16-gauge x 1.16-inch peripheral IV catheter (if you choose to use an introducer), linear ultrasound probe (and probe covers, if desired)
Patient Pain Assessment and Medications	Pretreatment pain: the worst pain lasts 24 hours and average pain was reported as 8/10 Patient reported inability to participate in rehabilitation therapy and had difficulty sleeping due to the shoulder pain Pain on arrival to clinic: 7/10 Modified Ashworth Scale Shoulder: 3
Patient Positioning	Seated
Pain Location	Left neck, shoulder, elbow pain at rest With movement, significant spasticity and decreased range of motion in the shoulder and elbow
Nerves Selected for Treatment	Suprascapular, lateral pectoral, medial pectoral, and musculocutaneous nerve to brachialis

Pretreatment Nerve Block



A peripheral nerve block with lidocaine 2% was performed under ultrasound guidance at each target nerve a week before the iovera[®] treatment to verify the reduction of pain and subsequent reducibility of the deformity with reduction in spasticity and improved range of motion.

Treatment Site Preparation



To address the pain associated with spasticity in this patient, a stepwise approach was taken. Treatment started with the left suprascapular nerve to reduce overall pain and to facilitate shoulder positioning. The lateral and medial pectoral nerves were addressed next facilitating external rotation of the shoulder so that the musculocutaneous nerve to the brachialis could be approached from the medial upper arm.

At each location of treatment, the patient was positioned so that the desired anatomy could be easily visualized under ultrasound. Throughout, the Handpiece remained more than 45 degrees from the floor. A sterile skin prep was performed, and a small local anesthetic wheal was administered to provide patient comfort at the site of planned catheter insertion. To avoid a false block, which could mask the result of the cryoneurolysis treatment, caution was taken to not deposit local anesthetic at the level of the nerve. A 16-gauge x 1.16-inch peripheral IV catheter was inserted at each treatment location to facilitate Smart Tip 190 nerve stim placement.

Treatment Details



SUPRASCAPULAR NERVE

The patient was in a seated position. The ultrasound probe was oriented in a transverse position so that the trapezius, supraspinatus and suprascapular notch could be visualized. The intended insertion site was marked, and a local anesthetic wheal was administered. The catheter was placed in the intended Smart Tip trajectory. The Smart Tip 190 needle was inserted through the catheter and positioned with the tip slightly beyond the suprascapular nerve (**Fig 1**). Due to positioning, an-out-of-plane approach was used to place the Smart Tip at the suprascapular notch. A treatment cycle was performed in this location (**Fig 2**). The Smart Tip was then repositioned 1 cm medially and an additional cycle was performed.

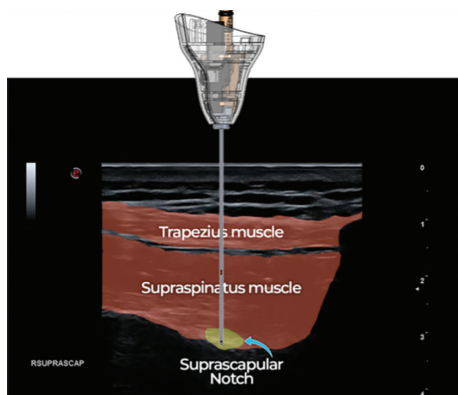


FIGURE 1: Placing the iovera[®] Smart Tip needle at the suprascapular notch

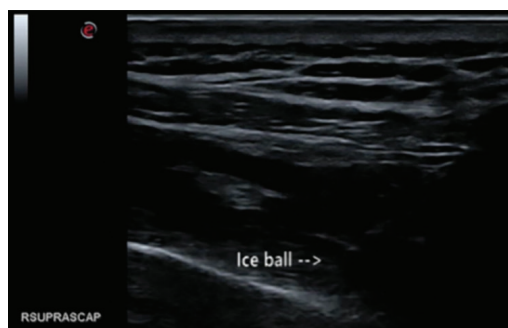


FIGURE 2: Ultrasound images of the ice ball formed at the suprascapular notch

Treatment Details (continued)

LATERAL AND MEDIAL PECTORAL NERVES

The patient was positioned with direct access to the anterior chest wall. The ultrasound probe was in a transverse position so that the subcutaneous tissue, pectoralis (PEC) major, PEC minor, and serratus anterior could be visualized.

The lateral pectoral nerve can consistently be found by running along the fascia between the PEC major and minor muscles and will run parallel to your ultrasound probe.

The medial pectoral nerve can consistently be found in the PEC minor muscle, usually along its lower border, and will run parallel to your ultrasound probe.

The intended insertion site was marked, and a local anesthetic wheal was administered. The catheter was placed in the intended Smart Tip trajectory. The Smart Tip 190 was inserted through the catheter and positioned slightly beyond the lateral pectoral nerve to elicit a stim response (**Fig 3**). The stimulator was set between 0.8 and 1 mA. Once the location was confirmed, a treatment cycle was performed. The Smart Tip was then repositioned on the other side of the neurovascular bundle, and an additional cycle was performed (**Fig 4**).

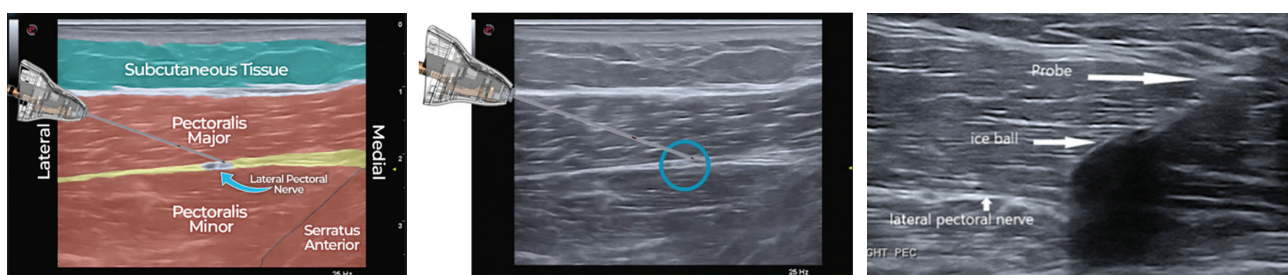


FIGURE 3: Contact of the Smart Tip 190 with the lateral pectoral nerve

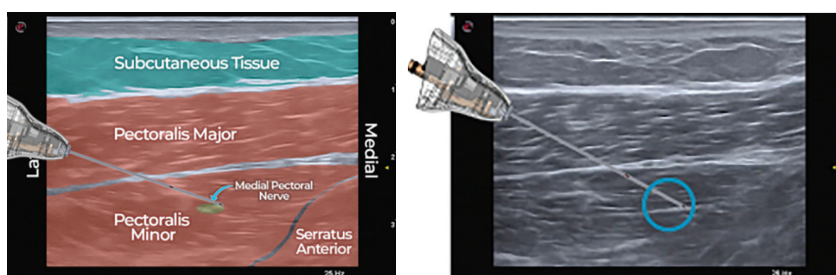


FIGURE 4: Contact of the Smart Tip 190 with the medial pectoral nerve

MUSCULOCUTANEOUS NERVE TO THE BRACHIALIS

The patient was positioned supine with slight supination of the forearm and abduction of the shoulder. The ultrasound probe was in a transverse position two thirds down the upper arm, about four finger breadths above the elbow, so that the biceps muscle, the musculocutaneous nerve, the brachialis muscle, the triceps muscle, the brachial artery and vein, and the distal humerus were visualized.

The intended insertion site was marked, and a local anesthetic wheal was administered. The catheter was placed in the intended Smart Tip trajectory. The Smart Tip 190 was inserted through the catheter and positioned slightly beyond the musculocutaneous nerve to the brachialis to elicit a stim response (**Fig 5**). The stimulator was set between 0.8 and 1 mA. Once location was confirmed, a treatment cycle was performed. The Smart Tip was repositioned at a different site, either along the nerve or intramuscularly to stimulate, and an additional cycle was performed.

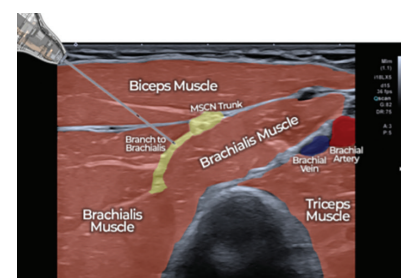


FIGURE 5: Contact of the Smart Tip 190 with the musculocutaneous nerve to the brachialis muscle

TREATMENT SITE AND EFFECT

Treatment Site	Provided Effect
Suprascapular Nerve	Reduced pain in the shoulder girdle
Lateral Pectoral Nerve Medial Pectoral Nerve	Reduced pain in the arm, allowing for increased range of motion and accompanied by a reduction in spasticity
Musculocutaneous Nerve	Reduced pain in the elbow, allowing for improvement in extension and accompanied by a reduction in spasticity

POSTTREATMENT ASSESSMENT

Posttreatment Day 0	Patient reported no pain at rest or with movement of the shoulder, arm, or elbow Modified Ashworth Scale 1 at both shoulder and elbow
Posttreatment at 1 Month	Patient reported "no pain to speak of" in her neck, shoulder, or elbow

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for your patients with pain associated with spasticity.



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Disclosure: Dr Winston is a paid consultant for Pacira BioSciences, Inc.