



CALMARE®

Pain Therapy Treatment

FEATURING

SCRAMBLER THERAPY™ TECHNOLOGY

***FOR TREATMENT OF DRUG-RESISTANT
CHRONIC NEUROPATHIC & CANCER PAIN***



*A Technologically Advanced
Solution For Chronic Pain Management*

A Bold Effective Solution to Intractable Chronic Pain

A proven, unique, non-invasive method for rapid treatment of chronic intractable Neuropathic and Cancer-related pain.

Indications for Use:

Chemotherapy-Induced Peripheral Neuropathy (CIPN)
Intractable Cancer Pain
Failed Back Surgery Syndrome
Sciatic and Lumbar Pain
Post-Herpetic Neuralgia (PHN)
Post-Surgical Pain
Brachial Plexus Pain
Low Back Pain (LBP)
Chronic Neuropathic Pain

Calmare[®] Pain Therapy Treatment (MC-5A) patented technology creates a series of complex artificial neuronal messages that are transmitted to the brain via the body's dermatome pathways.

Calmare[®] is Non-invasive

Five independent channels are available to transmit the artificial messages via surface electrodes attached to the skin in the dermatome region of the patient's pain.

How Calmare[®] Works

The perception of pain during the treatment is inhibited by artificial messages of "no pain" that replace those of pain.

During therapy sessions, when proper electrode placement is attained, patients typically report zero pain.

After a series of treatments, the patient may experience significant pain reduction for an extend period of time. The duration of time depends upon the underlying cause and intensity of the pain and other factors.

Calmare[®] Pain Therapy Treatment Protocol

- The patient visits the practice for 10 to 12 consecutive treatments.
- One treatment per day over a period of two weeks.
- Treatment sessions may last from 30 to 60 minutes.
- Booster cycles are given when needed.

CALMARE®

Pain Therapy Treatment

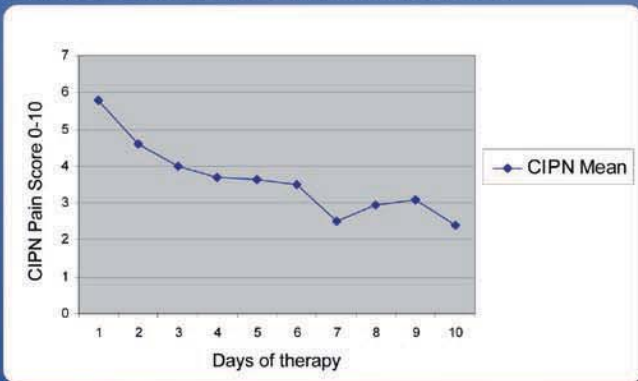
Thirty-three terminal cancer patients suffering from severe drug-resistant pain were treated with Calmare® Pain Therapy.

Tests of the method's effectiveness were performed by measuring pain intensity (visual analogue scale (VAS)) before and after each treatment session.

During the treatment sessions, pain was reduced to zero. The chart shows pain reduction before and after each treatment during 10 treatment sessions¹.

¹(Marineo G. et al, International Congress Series 1255 (203) 381-388)

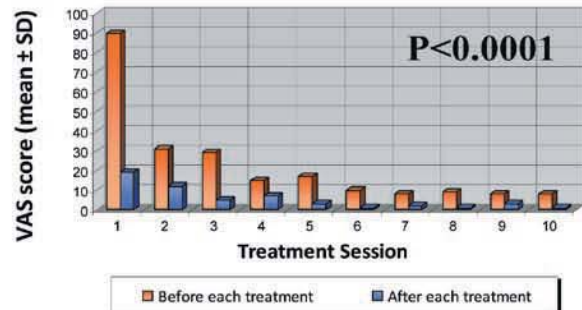
Calmare® Pain Therapy helped even drug-refractory CIPN patients. Overall pain score reduction of 64%.



²(Smith T, et al, JPSM 2010)

Effective Pain Relief For Cancer Pain

Scrambler Treatment Results - 33 Cancer Patients



“Chemotherapy-induced peripheral neuropathy (CIPN) is a major dose-limiting and persistent consequence of numerous classes of antineoplastic agents, affecting up to 30%-40% of patients.”²

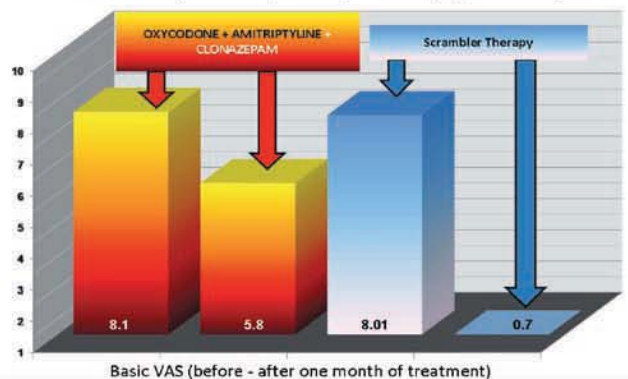
RCT vs. MDT

The chart compares pain reduction between the control group (drugs) and the one treated with Calmare® Pain Therapy (Scrambler Therapy).

Seventy-two percent (72%) of the patients no longer needed drugs after the Calmare® applications. The remaining twenty-eight percent (28%) considerably reduced the drug dosage they were taking after Calmare® Pain Therapy Treatment. (Submitted)

Chronic Neuropathic Pain

VAS for all patients (26/drugs + 26/ST). (P<0.0001)



Safe, effective, non-invasive relief without drugs or negative side-effects



It is critical to the success of the treatment for the clinician to place the electrodes at the proper areas to produce the best analgesia. The duration of pain relief will depend upon the patient's underlying cause and intensity of the pain, and the correct application of the treatment protocol.

The type of cancer, or the advanced stage of cancer, does not allow long periods of "no pain". Similar to drug protocols, the patient is treated whenever the patient has pain present. The key to successful treatment is the proper training of the clinician.

advancing **PAIN** **MANAGEMENT**

Pain reduction with Calmare® is similar to that of other interventional therapies in RCT vs. medical management.

- ❖ Intraspinal bupivacaine plus opioid, VAS pain 7.57 to 3.67 (-52%). Smith T, et al, J Clin Onc 2002
- ❖ Spinal cord stimulators in neuropathic pain, 7.6 to 3.8 (>50% reduction). Kumar K, et al, Pain. 2007;132:179-88
- ❖ MC5-A Calmare, CIPN, (-59%), Smith T, et al, JPSM 2010
- ❖ MC5-A Calmare chronic neuropathic pain in RCT, 9 to 0.7 (-91%). Marineo G, et al, submitted

Because of the manner in which the Calmare® Pain Therapy Treatment operates, the following considerations may exclude some patients:

- ❖ pacemaker or implantable defibrillator
- ❖ vena cava, aneurysm clips, coronary or other vascular stents
- ❖ pregnancy
- ❖ history of epilepsy, brain damage, use of anti-convulsants, symptomatic brain metastases
- ❖ prior celiac plexus block, or other neurolytic pain control treatment within 4 weeks
- ❖ wounds or skin irritation in areas where the electrodes are required to be placed
- ❖ cardiac Ischemia within the previous 6 months, or severe arrhythmia
- ❖ implanted device such as a stimulator device
- ❖ latex allergies



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1. Artificial neurons in oncological pain: the potential of Scrambler Therapy to modify a biological information G. Marineo*, S. Spazianib, A.F. Sabato, F. Marotta a Delta Research & Development, Medical Bioengineering Research Centre, University of Rome Tor Vergata, Via di Mezzocammmino 85, 00187 Rome, Italy Pain Service, Umberto I Hospital, Via A. Fabi, 003100 Frosinone, Italy Surgery Department, University of Rome Tor Vergata, Pain Service (PTV), Viale Oxford 81, 00133 Rome, Italy Received 27 February 2003; accepted 28 March 2003
2. Pilot Trial of a Patient-Specific Cutaneous Electrostimulation Device (MC5-A Calmare) for Chemotherapy-Induced Peripheral Neuropathy. Thomas J. Smith, MD, Patrick J. Coyne, RN, MSN, Gwendolyn L. Parker, RN, MSN, Patricia Dodson, RN, MSN, and Viswanathan Ramakrishnan, PhD. Journal of Pain and Symptom Management, 2010:Epub Sept 7