

Dr. Hemang Shah

7-12-19

SCRAMBLER THERAPY (SUMMARY VERSION)

A BIOPHYSICAL TREATMENT FOR CHRONIC NEUROPATHIC PAIN

YOUTUBE

- ✘ [Mayo clinic](#) video for patient with chemotherapy induced peripheral neuropathy (CIPN)
- ✘ [scrambler video](#) (phantom limb pain video)
- ✘ [Grand rounds](#) about ST @ Osher Center for Integrative Medicine, [Harvard Medical School](#) / Brigham and Women's Hospital (1 hr long video)
- ✘ How to perform [therapy](#)

WHAT IS IT?

- ✘ Scrambler Therapy* is a proven, non-invasive, long lasting, electroanalgesia method for rapid treatment of chronic intractable neuropathic and cancer related pain.



[Inside the Scrambler Therapy, a Noninvasive Treatment of Chronic Neuropathic and Cancer Pain: From the Gate Control Theory to the Active Principle of Information](#)
[Integr Cancer Ther.](#) 2019 Jan-Dec;18:1534735419845143. doi:
10.1177/1534735419845143.

WHERE IS IT AVAILABLE?

- ✘ John Hopkins University (Dr. Thomas Smith MD)
- ✘ Mayo Clinic (Dr. Charles Loprinzi MD)
- ✘ Medical University of South Carolina (Pat Coyne, Dr. John Gison MD)
- ✘ MD Anderson Cancer Center (Dr. Salahadin Abdi MD, PhD)
- ✘ Walter Reed Army Hospital & Air Force
- ✘ VCU (Virginia Commonwealth University)

Sharing Mayo Clinic (<https://sharing.mayoclinic.org>)

Stories from patients, family, friends and Mayo Clinic staff

February 19, 2015

Breaking Away From Pain With the Help of 'The Scrambler'

By Hoyt Finnermore



<https://sharing.mayoclinic.org/2015/02/19/breaking-away-from-the-pain-with-the-help-of-the-scrambler/>

[MUSC Enterprise](#) > [About](#) > [MUSC Catalyst News](#) > [Scrambler therapy](#)

Only machine of its kind in SC appears to get results for patients in pain

[Helen Adams](#) | May 18, 2017



Douglas Foxworth talks with Dr. John Gibson and nurse Julie Watson before she attaches electrodes to try to ease his foot pain. Photos by Sarah Pack



Nerve Scrambler Therapy lessens pain for warfighters, TRICARE patients

By Staff Sgt. Joe Yanik, Air Force District of Washington Public Affairs / Published November 02, 2017



[PHOTO DETAILS](#) / [DOWNLOAD HI-RES](#) 4 of 5

Lt. Col Candy Wilson, 779th Medical Group nurse practitioner, increases the electrical stimulation voltage of a Calmare pain therapy medical device while treating a patient using Nerve Scrambler Therapy May 30, 2017 at Joint Base Andrews, Md. The patients' treatments vary from 20-60 minutes per session. (U.S. Air Force photo by Staff Sgt. Joe Yanik. This photo has been modified to protect PII)

<https://www.af.mil/News/Article-Display/Article/1361150/nerve-scrambler-therapy-lessens-pain-for-warfighters-tricare-patients/>

HISTORY



- ✘ Scrambler Therapy was invented by Prof. Giuseppe Marineo @ The Tor Vergata University of Rome, Italy around 2003 (based on his work since 1990s).
- ✘ Old FDA clearance (#K081255) “Calmare device” - 2009
- ✘ New 510 (k) #K142666 only for Scrambler Therapy® Technology MC-5A
- ✘ Prototype used for clinical studies in Italy (2297 cases of various types of serious neuropathic pain that was resistant to medications and/or electro-analgesia) until 2007. (above is a prototype)

SCRAMBLER THERAPY® TECHNOLOGY MC-5A

- ✘ It is the new OEM version of the device, in production **since 2014**. Aesthetically there are no variations with the previous version, but the OEM artificial neuron core support technology external has undergone significant improvements in its reliability.
- ✘ This new OEM version is recognizable by the 510 (k) # K142666 and CE marking 0476.



WHO IS IT FOR? (INDICATIONS)

- ✘ Painful Peripheral Neuropathy
- ✘ Complex Regional Pain Syndrome (CRPS / RSD)
- ✘ Chemotherapy-Induced Peripheral Neuropathy (CIPN)
- ✘ Intractable Cancer Pain Failed Back Surgery Syndrome
- ✘ Sciatic and radicular cervical and lumbar pain
- ✘ Post-Herpetic Neuralgia (PHN)
- ✘ Brachial Plexus Pain
- ✘ Chronic Neuropathic Pain, Allodynia, Hyperalgesia

Minerva Anestesiol. 2005 Jul-Aug;71(7-8):479-82.

Scrambler therapy. (all articles have PubMed hyperlinks)

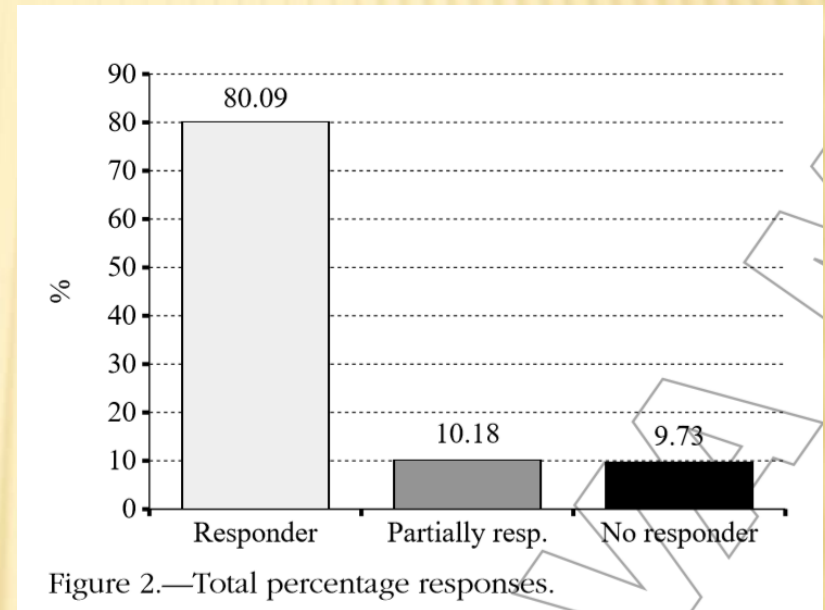
Sabato AF¹, Marineo G, Gatti A.

NOT USEFUL IN

- ✘ Joint and ligaments related pain
- ✘ Acute pain (can be used for temporary pain relief but it doesn't last long as there is ongoing tissue injury)
- ✘ Visceral pain
- ✘ Non neuropathic pain

HOW EFFECTIVE IS IT?

- ✘ Efficacy is variable based on study you look at. (slides 53 to 67)
- ✘ The total results show 80.09% of responders (pain relief >50%), 10.18% of partially responders (pain relief from 25% to 49%) and 9.73% of no responders (patients with pain relief <24% or VAS >3)*



[Minerva Anestesiol.](#) 2005 Jul-Aug;71(7-8):479-82.

[Scrambler therapy.](#) (all artricales have PubMed hyperlinks)

[Sabato AF¹](#), [Marineo G](#), [Gatti A](#).

HOW EFFECTIVE IS IT?

- ✘ At one month, the mean VAS score was reduced from 8.1 to 5.8 (28%) in the control group, and from 8 to 0.7 points (91%) in the Scrambler group ($P < 0.0001$).

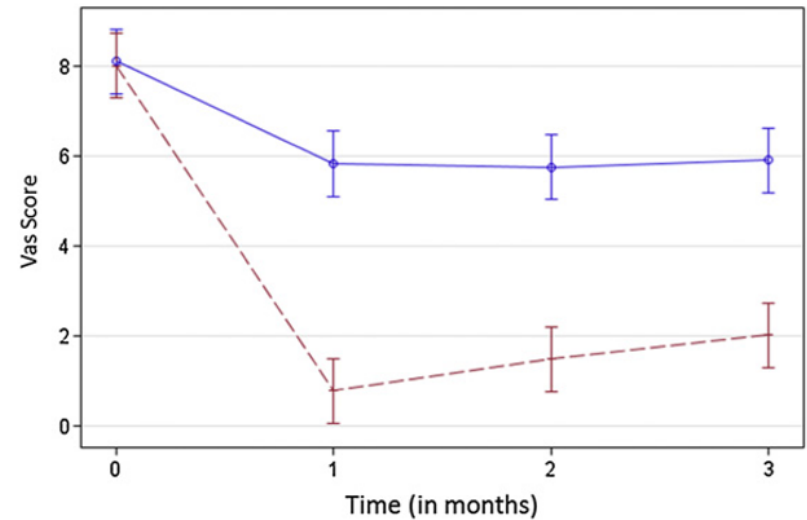


Fig. 2. Effect of treatment on pain scores over time. A repeated-measures ANOVA with the VAS score as the dependent variable and time (baseline, one month, etc.), treatment (treated or control), and treatment by time interaction terms as the independent variables. The repeated-measures model accounts for the correlations that might arise from the same individuals being observed over time. The treatment by time interaction term was significant ($P < 0.0001$), suggesting that the decline in the VAS score over time in the treated group was significantly steeper than that in the control group.

[Scrambler Therapy May Relieve Chronic Neuropathic Pain More Effectively Than Guideline-Based Drug Management: Results of a Pilot, Randomized, Controlled Trial.](#)

[J Pain Symptom Manage.](#) 2012 Jan;43(1):87-95. doi: 10.1016/j.jpainsymman.2011.03.015. Epub 2011 Jul 16.



a



d

HOW IS IT DONE?

- ✘ The patient visits the practice for 10 treatment sessions on average.
- ✘ One session per day over a period of two weeks (weekdays).
- ✘ Treatment sessions may last from 30 to 45 minutes.
- ✘ During the first session, after the correct electrode positioning and fine-tuned stimulation levels, the patient may notice significant improvements in a short period of time.
- ✘ In the subsequent sessions, the patient may realize that pain relief is prolonged (reduced intensity and duration).
- ✘ So far Scrambler Therapy does not have any known side effects except mild irritation at the site of electrode placement.
- ✘ Benefit may last up to 3-6 months
- ✘ Booster cycles are given when needed for symptoms recurrence.

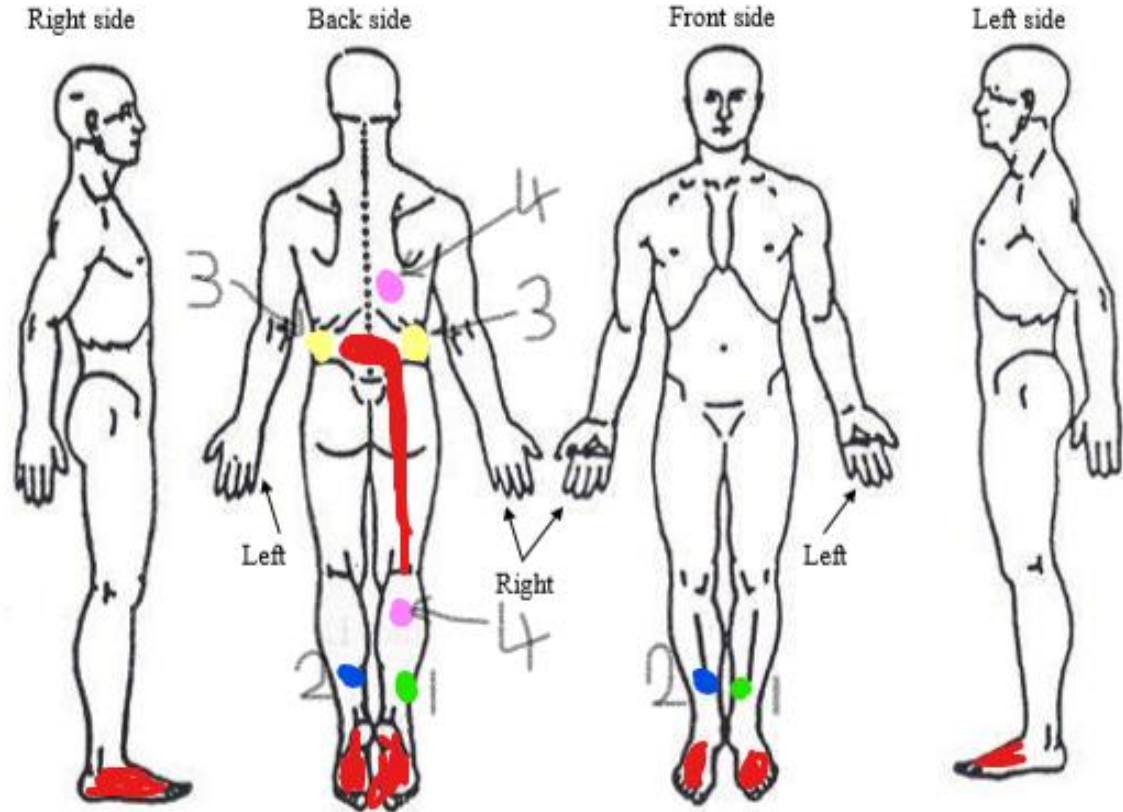
<https://www.scramblertherapy.org/clinical-practice.htm>

https://www.scramblertherapy.org/10_basic_rules.htm

Scrambler Therapy Session Form

Name of patient: _____
Date: ____/____/____ Session Number: _____

- ✘ Red – area of neuropathic pain
- ✘ Green – channel 1
- ✘ Blue – channel 2
- ✘ Yellow – channel 3
- ✘ Pink – channel 4



Patient - Please shade your area of pain.

Name of nurse / technician: _____

Scrambler Therapy Treatment Response Form

Name of patient: _____

Name of nurse / technician: _____

Date: ___/___/___

Session Number: _____

Numeric Rating Scale



Wong-Baker FACES® Pain Rating Scale



Location: **Session 1 2 3 4 5.6 7**

Immediately before the procedure	6	7	6	5	3	1	0
When leaving the clinic	1	0	0	0	0	0	0
1 hour after treatment	1	0	0	1	0	0	0
2 hours after treatment	2	1	0	1	0	0	0
3 hours after treatment	4	4	3	0	0	0	0
4 hours after treatment	6	6	2	0	0	0	0
5 hours after treatment	7	6	4	1	0	0	0
6 hours after treatment	6						
7 hours after treatment							
8 hours after treatment							
Pain score before bedtime	6	6	4	3	1	0	0
Pain score the next morning	7	6	5	3	1	0	0

POST PROCEDURE INSTRUCTIONS

- ✘ Scrambler Therapy doesn't help with non neuropathic pain (e.g. arthritic, muscular etc.).
- ✘ Few patients may have short lasting subjective worsening of pain when it returns due to significant reduction of pain during and after treatment session.
- ✘ Some patient may perceive short lasting worsening of non neuropathic pain as brain is paying more attention to previous areas of less severe pain.
- ✘ If patient is pain free for more than 48 hours, scrambler therapy is considered complete.
- ✘ Patient should receive booster sessions (1 to 3) on recurrence of neuropathic pain, usually in 3-6 months.

HOW DOES IT WORK?

- ✘ Scrambler Therapy (ST) works on active principle of replacing information of pain into perception of “self” generated “non-pain” signals transmitted via “C” fibers to brain.
- ✘ Gate control theory may explain acute pain but it has many limitation in explaining chronic neuropathic pain.

<https://www.scramblertherapy.org/scrambler-therapy-theory-bases.htm>

Inside the Scrambler Therapy, a Noninvasive Treatment of Chronic Neuropathic and Cancer Pain: From the Gate Control Theory to the Active Principle of Information.

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COST SAVINGS TO HEALTH SYSTEMS

- ✘ Patient will have less visits to ER, urgent care, physicians, less medications and medications related side effects.
- ✘ Less number of invasive procedures and potential complications (infections, hemorrhages etc.)
- ✘ Increased productivity and quality of life.
- ✘ Less days out of work.

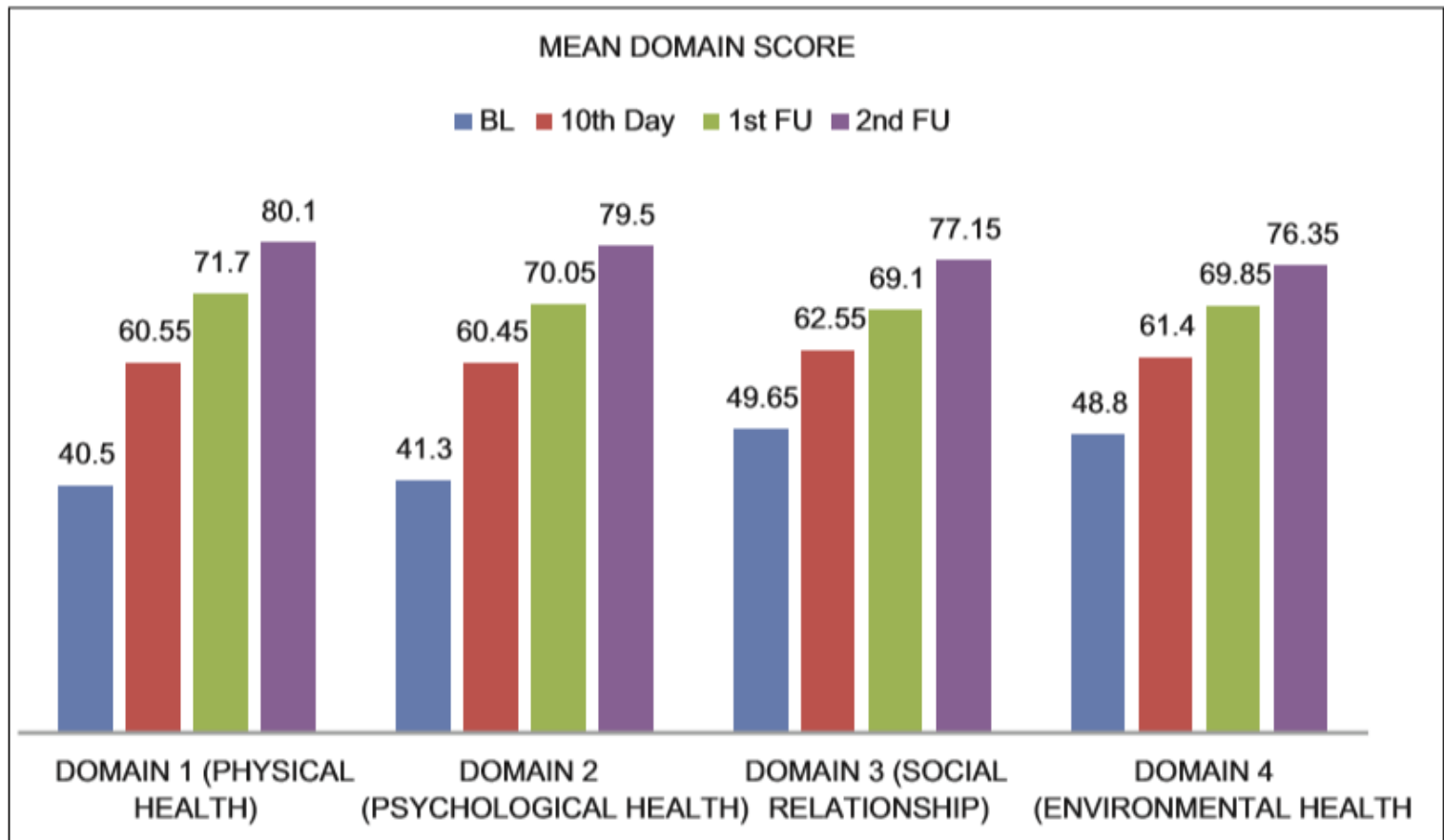


Figure 3: Impact of scrambler therapy on World Health Organization domains of quality of life. As seen in the figure, improvement in all four domains of life according to World Health Organization Quality of Life was seen with scrambler therapy after the ten sessions and on each follow-up (BL - baseline, FU - follow-up).

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