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Scrambler Therapy: An Innovative and Effective Treatment for Chronic Neuropathic Pain

Frank Sparadeo, Ph.D.
Salve Regina University

Cheryl Kaufman, RN, BScN, CLCP, CNLCP
CK Medical-Legal Consulting Services

Stephen D'Amato, M.D.
Boston University School of Medicine

Abstract

This study examined the results of 173 people treated for chronic neuropathic pain with the use of a new electrical modulation technique called Scrambler Therapy (ST). Follow-up analyses were applied to 91 people who agreed to have symptoms 3 to 6 months following the treatment using the Visual Analog Pain Rating Scale (VAS) and the Brief Pain Inventory (BPI). The VAS and BPI were administered prior to treatment. The VAS was also administered twice per treatment session (prior to initiation of a treatment session and at the completion of the treatment session). The VAS was administered along with the BPI again at a minimum of 3 to a maximum of 6 months following treatment. Statistical analyses were applied to 4 neuropathic diagnostic groups (single site spine pain, neuralgia, complex regional pain syndrome and multi-site pain patients). The results indicate that ST is a viable and effective low-cost treatment that is more efficacious than most, if not all, standard treatment approaches to chronic neuropathic pain. All four diagnostic groups demonstrated statistically significant improvement. Implications for life care planners are discussed.

Scrambler Therapy: An Innovative and Effective Treatment for Chronic Neuropathic Pain

Chronic pain impacts the lives of millions of individuals and their families. The Institute of Medicine's recent report (IOM, 2011), estimates that there are 116 million Americans burdened by chronic pain at a cost of between $560-635 billion annually. This estimate was determined by combining the intermediate cost of healthcare ($261-300 billion) and the cost of lost productivity ($297-336 billion) attributable to pain. In 2008, federal and State programs including Medicare, Medicaid and Veteran's Affairs paid out $90 billion in medical expenditures. Lost tax revenues secondary to lost productivity compounds the problem.

While acute pain is a normal sensation triggered in the nervous system to alert you to possible injury and the need to take care of yourself, chronic pain is different. Chronic pain persists beyond the expected period of healing (Flor & Turk, 2011). Pain signals keep firing in the nervous system for months or even years. An arbitrary time continuum of 3 and/or six

months is often referred to as the point at which acute pain is then reported as chronic pain (Fler & Turk, 2011). A person may have developed pain following a physical trauma or severe infection and despite medical interventions and/or corrective surgeries the pain persists. Catastrophic injuries also include chronic pain among several other conditions. When this occurs, the treatment or management of the chronic pain is often either neglected or poorly attended to. Some people suffer chronic pain in the absence of any past injury or evidence of body damage.

Chronic pain hazardous undulative and destroys the balance in every aspect of a person's life; mood, activities of daily living, interpersonal relationships, ability to work and be productive, enjoyment of hobbies and activities and general social interactions (Ashburn & Staats, 1999). It is not uncommon for people experiencing chronic pain to reduce socialization and isolate themselves. The management of chronic pain requires assessment of a complexity of syndrome components in addition to the pain complaint (Fler & Turk, 2011).

The effectiveness of treatment of chronic pain has been poor. Professionals working in the chronic pain field frequently drift to reduce pain or improve quality of life for the individuals suffering from chronic pain (Fler & Turk, 2011). The interventions with the most empirical support for the treatment of chronic pain are psychological (e.g. cognitive behavior therapy) (Robinson & O'Brien, 2010). The use of epidural steroid injections is of questionable utility with very poor results in controlled studies (Arnon et al., 2007). Despite the lack of efficacy of epidural steroid injections they are commonly used in pain clinics and they are quite costly (as high as $1,800 per injection). Attempts to manage pain through the use of various medications (including opiates) have been poor with estimates of over 50% addiction rates (Højsted & Sjøgren, 2007), and pain relief is not always satisfactory. Until now implantable neuromodulation (Spinal Cord Stimulation—SCS) has had limited positive impact (Turner, Loeser, Deyo & Sanders, 2004) and is costly (up to $50K). Neuromodulation through the use of standard transcutaneous electrical nerve stimulation (TENS) has been very disappointing with very low long-term success rates (Brousseau et al. 2002, Johnson & Walsh, 2010). Because of the desperation felt by people experiencing chronic pain they cycle through various pain clinics, pain specialists and emergency departments, driving up the cost of their care with little sustained impact. The continued failure of chronic pain interventions remains a major cause of increased costs in healthcare as implied in the Institute of Medicine report in 2011.

Neuropathic chronic pain

Neuropathic pain results from damage or disease affecting the somatosensory system. It may be associated with abnormal sensations called dysesthesia, and pain produced by normally non-painful stimuli (allodynia). Neuropathic pain may have continuous and/or episodic (paroxysmal) components. The latter are likened to an electric shock. Common qualities include burning or coldness, "pins and needles" sensations, numbness and itching (Woolf et al. 2008).

Scrambler Therapy

Scrambler Therapy (ST) is a new approach to pain treatment that relieves pain by providing "non-pain" information (to the brain) via cutaneous nerves to block the effect of pain information (Marineo, Iorno, Gandini et al. 2011). Scrambler therapy synthesizes 16 different types of nerve action potentials similar to endogenous ones, assembles them into

sequences, and uses algorithms to determine a patient-specific cutaneous electrostimulation to reduce pain (Marineo et al, 2011). There are complex modifications activated by the nervous system in response to a painful stimulus which are the focus of a wide variety of reactions designed to re-establish conditions of homeostatic equilibrium that the pain information signals have provoked (Sabato, Marineo & Gatti, 2008). Returning to homeostasis usually occurs rapidly and involves many biological factors. In chronic pain, homeostasis does not occur, perhaps due to damage to the pain system itself (e.g. neuropathies) or due to the activation of the pain neuromatrix (Melzak 1999). Essentially, Melzak has proposed that there is a "pain neuromatrix" that is activated in chronic pain that occurs in the brain and disrupts homeostasis. The pain neuromatrix is the activation of specific brain regions that ultimately result in pain independent of the sensory source of the pain. Phantom limb pain is an example of the pain neuromatrix in which a person who has undergone hand amputation will continue to feel pain in the hand despite the hand having been amputated. Scrambler Therapy theorists state that there is an iterative nociceptive process that is activated (sensitization) and chronic pain is established. Chronic neuropathic pain tends to render all known therapeutic strategies gradually ineffective (Sabato, Marineo & Gatti, 2008). Scrambler Therapy attempts to replace the "pain" information with artificial "non-pain" information. Sabato et al., (2008) note: "An artificial neuron was developed that behaves as a pain scrambler" (p. 480). They further describe the process of ST as interfering with pain signal transmission by "mixing" a "no-pain" signal, into the transmission channel (the nerve fibers), for the purpose of masking the original pain information. The "no-pain" signal is still recognized as "self" by the nervous system.

Marineo (personal communication, September 1, 2012) notes that by providing corrective information (bioelectrical codes) through the periphery (dermatomes) to the dorsal horn of the spinal cord and CNS, the new code "tricks" the brain to read a discernable non-pain code as real and generated from self. Through plasticity the brain will then learn to expect and look for the non-pain signal and prefer it thus returning to an improved state of homeostasis.

Evidence of the Validity and Efficacy of Scrambler Therapy

In one of the first published investigations of ST, Marineo (2003) reported on the treatment of 11 individuals with terminal cancer suffering from drug-resistant neuropathic pain. He applied ten treatment sessions of ST to these individuals and reported that 81.8% were able to discontinue pain medications and 18.2% were able to reduce their dosage of pain medication. These results led to a follow-up investigation (Marineo, Spiriev, Sabato & Marotta, 2003) in which 33 individuals suffering from drug-resistant chronic neuropathic pain were treated with 10 sessions of ST. The entire sample responded positively to the treatment with significant declines in VAS (Visual Analog Scale) scores. Seventy-two percent of the sample suspended treatment with pain medications while the remaining 28% significantly reduced their dose taken prior to ST.

Sabato, Marineo and Gatti (2008) expanded their population to the treatment of 226 patients with various forms of neuropathic pain (e.g. sciatic and lumbar pain, post-herpetic pain, post-surgical nerve injury pain, pudendal neuropathy, brachial plexus neuropathy and others). They applied 5 ST treatments of 50 minutes and were able to demonstrate significant improvement with 89% of the sample reporting a better than 50% relief from pain and only 9.7% with no positive response to the treatment. The treatment effect was measured by comparing VAS levels immediately following the treatment to pre-treatment levels.

Several recent studies have continued to demonstrate the efficacy of ST. In a study of 40 individuals with cancer and 33 people with non-cancer pain, VAS scores were compared at the initiation of treatment, after 10-session treatments, and again at 2 weeks following treatment (Bird et al. 2011). In their sample, the average VAS score was 6.2 prior to any treatment. Following the 10th ST session, the average VAS was 1.6. Two weeks following treatment the average VAS score was 2.9.

Marineo et al. (2013) conducted a clinical trial with patients randomized to either guideline-based pharmacological treatment or ST. Patients were matched by type of pain (i.e. post-herpetic neuralgia, postsurgical neuropathic pain, and spinal canal stenosis). The VAS score was recorded prior to the initiation of the first treatment and after each of ten treatment sessions. The control group VAS was 8.1 and the ST group 8.0. At one month following the past ST treatment session the ST group VAS score was .7 while the control group was 5.8. At two and three months, the mean VAS scores in the control group were 5.7 and 5.9. The ST group scores were 1.4 and 2. These results continue to suggest that ST may be more "effective" for relieving neuropathic pain than drug management. The mechanisms by which this treatment effect occurs was speculated as to include raising the "pain" threshold for pain at the spinal cord, reducing "wind-up" (central sensitization of the spinal cord and brain that amplifies the abnormal feelings), reducing impulses from the damaged nerve, and reducing psychological maladaptation to pain (Jensen, 2010). The most recent investigation by Smith and associates has demonstrated similar levels of treatment efficacy in the treatment of post-herpetic pain with ST (Smith, Maniteo, Coyne & Dodson, 2012).

Method

Sampling and Procedures:

This investigation applied ST to 270 consecutive individuals entering a chronic pain treatment program with a diagnosis of chronic neuropathic pain of varying etiologies by a licensed board certified physician. The diagnostic groups in this study included people with Complex regional pain syndrome (CRPS), Single site spine-based pain (e.g. spinal stenosis or low back pain), Neuralgia (e.g. peripheral neuropathy, post-herpetic neuropathy, chemotherapy-induced peripheral neuropathy) and persons with complex medical histories (Multi-site) that included more than three co-occurring medical disorders (more than one site of pain and the use of combinations of medications that includes psychiatric medications). Exclusion criteria included individuals diagnosed with psychosis, non-neuropathic pain, neuropathic pain outside of the diagnostic groups chosen for this study, and acute pain (less than 6 months of pain).

Data for this study was collected in the Calvert Pain Relief center in Rhode Island. This center was the first clinic in the U.S. to offer Scrambler Therapy (ST) exclusively to treat chronic pain. All patients were weaned from anticonvulsant medications used exclusively for the treatment of their chronic pain prior to initiating the treatment. A total of 91 patients agreed to participate in follow-up (32% of the total population studied). The average age of the participants in this study was 59.7, comprised of 42 males and 49 females. Overall, the mean age and standard deviation for the four diagnostic groups were: Single site spine pain ($N = 33$, $M = 57.52$, $SD = 15.7$), Neuralgia ($N = 19$, $M = 59.00$, $SD = 17.2$), CR PS ($N = 20$, $M = 44.95^{*}$, $SD = 56.9$), and Multi-site pain ($N = 19$, $M = 61.47$, $SD = 20.7$). Only the CR PS group scored statistically significantly different in mean age at $p < .05$.

Procedurally, the data was composed of a pre-treatment visual analog measure of pain (VAS) and pre-treatment administration of the Brief Pain Inventory (BPI) (Cleeland & Ryan,

1994). Each treatment session also included a VAS measure at the time of treatment initiation and at the conclusion of each treatment session. All data at all treatment sessions was recorded in the medical record. Finally, each participant was contacted at a follow-up period of 3-6 months. The average follow-up period for the entire sample was 4.2 months. At the time of follow-up, the VAS and BPI were re-administered and recorded in the medical record.

Measures

The Brief Pain Inventory (BPI) (Cleeland & Ryan, 1995) is a 7 item rating scale from 0-10 in which the patient rates the degree of negative pain effect with 10 the most severe. The specific variables are: the impact of pain on: activity level, mood, ability to walk (ambulate), ability to work or conduct household activities, interpersonal relations, sleep and joy. A summary score was derived by simply adding the total number of points (level of pain interference) across all 7 variables. An example is as follows: In the past 24 hours pain has interfered with your General Activity (0 = not at all, 10 = completely interferes).

Visual Analog Scale (VAS) is a commonly used approach that allows the clinician the ability to measure their subjective level of pain based upon a 10-point scale administered as a 10-inch line numbered from 0-10. The patient circles the number he/she believes represents the level of pain (0 meaning no pain, 10 meaning severe pain) experienced at the time of the measurement. Numerous studies have demonstrated validity and reliability (see Price, McGrath, Rafii, & Buckingham, 1983).

Data Analysis

An Analysis of Variance (ANOVA) comparing the diagnostic groups on the pre-treatment VAS score and age was conducted. The BPI pre-treatment summary score means were also compared utilizing ANOVA. Pre and Post-treatment Paired t-tests were conducted on the VAS, BPI summary score and each of the seven BPI variables.

Results

Figure 1 demonstrates mean VAS score by treatment session for the entire sample. The data is the mean VAS at the beginning of the treatment session and the mean VAS at the end of the treatment session across 10 treatment sessions. Participants rated their pain prior to the beginning of each session (incoming pain) and in the last minute of the ST session (outgoing pain). Overall, the mean VAS score at treatment 1 "pain in" (immediately prior to treatment) was rated over 7.24. In the 10th and final session, the mean VAS rating prior to treatment was rated at 3. The VAS scores immediately following each treatment "pain out" dropped significantly from 7.24 to under 3 in the first treatment, and from approximately 3 before and immediately following the final treatment. In all 10 treatment sessions, the mean VAS ratings for each treatment dropped by well over 50% (See figure 1).

Figure 1. Pain level at the beginning and end of each of 10 ST sessions (N=91)

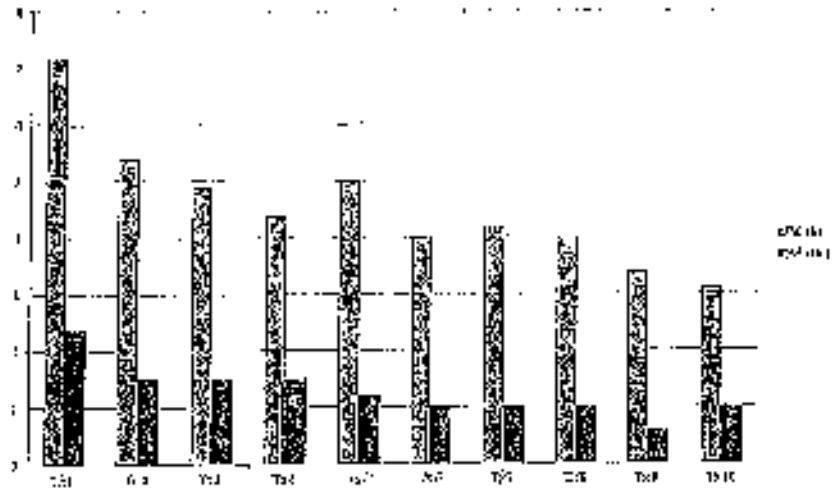

Figure 1. Pain-In is the VAS score prior to beginning the treatment session. Pain-Out is the VAS score at the time the treatment session has been completed. The Y-axis is actually an 11-point scale (0 to 10). The highest mean VAS was 7.24.

Figure 2 represents the BPI summary score means pre and post treatment by diagnosis prior to beginning the 10 treatment sessions and then once again at the end of the 10 session program. The total score calculated was the addition of each of the 7 variables on the 0-10 scale and averaging the mean BPI summary score. The higher score equals a greater level of pain interference. Overall, paired t-tests comparisons of the mean BPI summary scores indicated statistically significant improvement across all four groups before and following the 10 ST treatment sessions ($p < .01$) with the CRPS group evidencing the largest decrease in mean scores.

Figure 2. Mean BPI Summary Scores pre and post treatment for each diagnostic group.

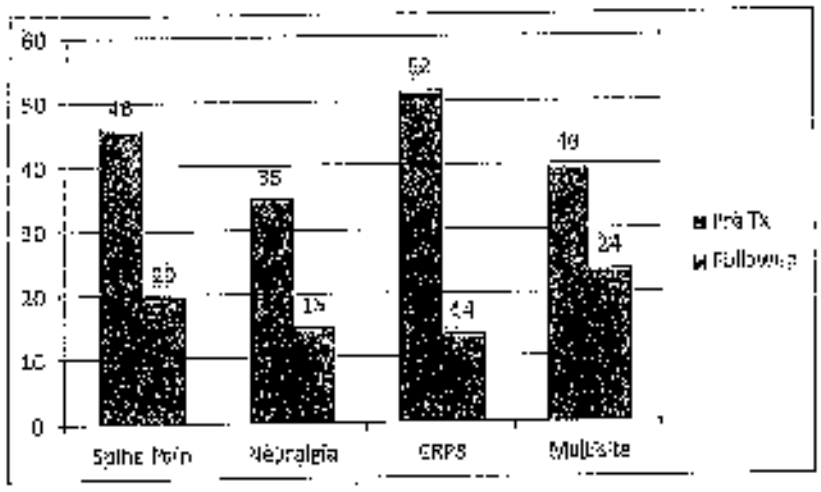

Figure 2. The BPI Summary Scores with simple summation of the interference level on a 0-10 scale for each of the 7 BPI measures. These summary scores were computed at the time of admission to the ST program and also at follow-up (3-6 months following the last treatment session). Paired t-test comparisons were computed and all comparisons were statistically significant ($p<.01$).

Analysis of Variance results with means comparisons on all dependent variables (BPI and VAS) prior to treatment was significant indicating the Neuralgia group had significantly lower BPI summary scores than the CRPS group and the Single site spine pain group. Analysis of Variance results for the VAS was non-significant indicating that pain levels were equivalent across diagnostic groups prior to entering treatment (See Table 1). In other words, the four diagnostic groups experienced the same level of pain entering treatment but the Neuralgia group had less severe impact on life areas measured by the BPI.

Table 1

Means and Standard Deviations by Diagnosis for BPI and VAS Summary Scores

Diagnosis	BPI SS I	SD	BPI SS II	SD	VAS1	SD	VAS 2	SD
Spine (N=33)	43.8	13.9	20.1	17.8	7.1	1.7	2.5	2.5
Neuralgia (N=19)	34.7	13.8	14.7	17.9	7.5	1.9	2.7	3
CRPS (N=20)	51.6	11.3	14.4	20.5	7.4	1.8	2.1	2.8
Multi-site (N=19)	39.7	18.1	25.7	21.7	7.2	1.8	7.2	3

Note: This table summarizes the Means and Standard Deviations for the Brief Pain Inventory (BPI I) and Visual Analog Scale (VAS1) prior to SI and the Brief Pain Inventory at follow-up (BPI II) and Visual Analog Scale at follow-up (VAS2)

Direct comparisons of change from pre-treatment to follow-up (paired t-tests) indicated statistically significant treatment effects ($p < .01$) on all variables among the Single site spine pain and the CRPS participants. The Neuralgia group demonstrated significant change on 6/7 BPI variables; however, the impact of pain on walking and interpersonal functioning variables was non-significant. This finding is likely due to the fact that the beginning level of interference on these variables was low to begin with. The Multi-site pain group demonstrated significant change on 6/7 BPI variables. The impact of pain on sleep comparison was not significant. Once again, the beginning level of pain interference regarding sleep was relatively low to begin with.

Table 2 summarizes means and standard deviations for each of the seven BPI variables, pre and post treatment (follow-up) for the entire sample which includes all 4 diagnostic groups. The table demonstrates significant change following treatment on all variables ($p < .0001$). Each instance once again, overall mean scores in each of the seven categories dropped by over 50% in rated pain.

Table 2

Pre-Post Treatment Means and Standard Deviations for the BPI Variables for the Entire Sample (N=91)

BPI Variables	Mean (Pre-treatment)	SD	Mean (Follow-up)	SD
General Activity	7.2	2.2	3.8[a]	3.1
Temperament/Mood	5.5	2.7	3.5[a]	3.1
Walk	6.1	2.9	3.7[a]	2.9
Work/Threshold	6.6	2.8	3.9[a]	3.1
Interpersonal	4.9	3.1	2.35[a]	3.0
Sleep	5.8	3.2	2.6[a]	3.2
Temperament/Mood	7.0	2.6	2.5[a]	2.6

[a] $p<.000$

Conclusions

The availability of effective treatment for chronic neuropathic pain is very limited. Attempts to manage pain through the use of various medications (including opiates) have been problematic with estimates of over 50% addiction rates and pain relief is not always satisfactory (Hojsted & Sjogren, 2007). Until now implantable neuromodulation has had limited positive impact as well and is costly at approximately $50,000. Neuromodulation through the use of standard transcutaneous electrical nerve stimulation has similarly seen very low long-term success rates (Johnson & Walsh, 2010).

Scramble Therapy is a form of treatment of chronic pain that is based on innovative scientific research (see official site http://www.scramble-therapy.org/english.htm). Clinical data thus far has demonstrated excellent outcomes with pain reduction rates 70-80% across various diagnostic groups. Published research cited in the present study supports ST has demonstrated significant improvement in pain relief for individuals with various forms of neuropathic chronic pain syndrome as evidenced here with the positive changes on the BPI and VAS. The treatment results reported in this study are consistent with previous research.

Limitations of this study relate to generalizability to individuals with other forms of pain. In addition, the protocol regarding where to place electrodes on each individual vary depending on which areas participants indicate they perceive to be having the greatest relief. As a result, standardizing sites for electrode placement are not possible but instead varies on an individualized basis. A third limitation deals with response bias. When participants self-report as in the present study, response bias may occur when the participant responds in a way he or she believes the researcher is seeking. Finally, empirical studies using ST are promising and consistent in their findings thus far; however, such studies are still in their early stages and must be expanded.

Considerations for Life Care Planning

Chronic pain is a disorder of sensation that impacts every aspect of an individual's life, family, friends and work. When researching various options for long term chronic pain management, the life care planner often serves as an intermediary between the treatment team and the client. The life care planner must take into consideration not only the efficacy of each of the prescribed treatment(s), but also the adverse effects and associated risks of individual or combinations of pharmaceuticals and other treatments, and how it may impact one's daily life long activities and functioning as well as the costs. There are many different modalities to be considered when preparing a life care plan such as counseling, biofeedback, various therapies, patient/client preferences, nutrition, etc.

Some of the factors the life care planner must consider with relevant consultation are the adverse effects of pharmaceuticals, whether prescribed individually or in combination and may include constipation, urinary retention, sedation and hypotension. There are also safety concerns with adjuvant medications such as anticonvulsants and antidepressants, although effective in treating neuropathic pain, may affect day to day functioning. The age of the client must also be taken into consideration in order to avoid undesirable adverse effects due to slowed metabolism and/or renal function. Resistant patterns to the medication(s) tend to develop over a period of time and may require higher doses to provide the same benefits as well as additional medications to provide pain relief. This in turn will require additional items, services and costs to be incorporated into the life care plan.

While spinal cord stimulation and intrathecal administered opioids for control of pain have many advantages for the client with otherwise uncontrolled chronic pain, the life care planner must also consider various lifelong services and items associated with migration and/or clogging of the catheter, surgical replacement schedules of the pump/generator battery in addition to periodic programming and medication refills. Costs of these treatments as well as morbidity associated with an invasive procedure and the associated follow up care and replacement schedules for various treatments must also be taken into consideration as pain management recommendations are incorporated into the life care plan.

Scrambler Therapy is a non-invasive, non-painful, non-pharmacological intervention for eradicating or significantly reducing pain. It is can also be used in conjunction with other methods to control chronic neuropathic pain. Relief of pain permits the client to improve upon daily function, social interaction, return to work performance and activities of daily living, which are of primary concern for the patient as well as the life care planner. This can in turn, have a positive impact upon the client's quality of life, family relationships, sleep patterns and community involvement.

Scrambler Therapy is prescribed as a total of 10 treatments, preferably across five consecutive days, Monday through Friday then again Monday through Friday. Each session takes approximately one hour in duration. The first session includes an additional medical evaluation by the treating physician. The cost of the first session is approximately $600.00, and each of the following sessions is approximately $400.00 depending on location.

Contraindications of scrambler therapy include an intrathecal drug delivery pump, spinal cord stimulator, high doses of Neurontin or other anticonvulsants, the presence of hardware (e.g. pins and rods) and those with psychosis or other severe mental illness which negatively affects long-term success with ST.

There are multiple centers in the United States that offer Scrambler Therapy. These treatment devices are located in Rhode Island (the largest and most experienced center treating chronic pain exclusively with ST), Staten Island, New York and Naples, Florida as

well as in Utah and in Las Vegas. There are Scrambler Therapy devices also located at the Mayo Clinic and the Boston Veterans Administration Hospital. The U.S. Navy has recently purchased seven of the ST devices to use with active duty marines and sailors who have chronic pain.

The development and implementation of ST has already resulted in significant improvement in the treatment of chronic pain in numerous individuals. If clinical experience and future research continues to demonstrate the efficacy of ST this treatment approach to neuropathic pain will likely become the preferred treatment since it is cost-effective, has no side effects and is non-invasive.

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Author bios

Frank R. Spurzdeo, Ph.D.
Certified Scrambler Therapy Practitioner
Salve Regina University
Instructor in the Department of Rehabilitation Counseling

Dr. Spurzdeo is currently a research consultant to Calmare Pain Relief, LLC. He is also an instructor in the graduate school at Salve Regina University where he teaches Psychopharmacology for Counselors and Substance Abuse Rehabilitation. He is also the clinical Director of Spurzdeo & Associates, a private practice specializing in neuropsychology and health psychology. Dr. Spurzdeo has been a practicing neuropsychologist for 32 years.

Cheryl Kaufman, RN, BSoN, CLCP, CNLCP

Ms. Kaufman is owner and principal of CK Medical-Legal Consulting Services in Massachusetts. She brings more than 25 years of nursing experience to the specialty of life care planning. She has provided life care plans both nationally and internationally.

Stephen J. D'Amato, MD., FACEP
Certified Scrambler Therapy Practitioner
Stephen D'Amato, M.D.
Clinical Assistant Professor of Medicine
Boston University School of Medicine

Dr. D'Amato is currently the Medical Director of Calmare Pain Relief, LLC. He is also a Clinical Assistant Professor of Medicine at the Boston University School of Medicine. He is board certified in emergency medicine and has practiced emergency medicine for 33 years. Dr. D'Amato is the most experienced provider of Scrambler Therapy in the United States and he has treated over 500 patients with chronic neuropathic pain.