

Neuropathy Hope

Hope through caring, support, research, education, and empowerment

A newsletter for members of Western Neuropathy Association (WNA)

MARCH 2024 Issue 02 Volume 22

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WESTERN NEUROPATHY ASSOCIATION

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ELOSAN CABIN C1 ELECTROSTATIC THERAPY SAFE, EFFECTIVE IN TREATING CHRONIC PAIN Lisa Kuhns, PhD; Clinical Pain Advisor; January 9, 2024

Elosan Cabin C1 is a novel whole-body therapeutic device for treating chronic pain. It alleviates pain via application of a high-voltage electrostatic field to the outside of the body in an enclosed space (a booth in which the patient stands). It was previously evaluated in a small pilot study as an adjunct to multimodal treatment for chronic pain, with promising results. However, current data on its use and efficacy are limited. Therefore, researchers conducted a larger prospective, multicenter, observational phase IV clinical trial (ClinicalTrials.gov Identifier: NCT04818294) to evaluate the efficacy and safety of electrostatic therapy using the Elosan Cabin C1 in daily practice in adults with a history of chronic pain. Between May 2021 and June 2022, a total of 192 patients aged 18 years and older were enrolled in the study; 143 completed 8 treatment sessions with sessions occurring once per week. The majority (73.4%) of patients were women, and the mean patient age was 55.4 years.

Following treatment, all patients experienced an average 30.9% reduction in pain scores.

- Most (61%) achieved a response (defined as a pain score reduction of at least 15 points).
- Women had significantly lower pain scores at the end of treatment vs at baseline.
 - Specifically, women with a pain duration of 1 year or less were more likely to respond to treatment.
- In contrast, men had moderate pain score decreases.
 - Among men in the study, those with poor-quality sleep were more likely to respond to treatment.
- There was a higher percentage of responders among women (67%) vs men (45%).
- Pain scores in both groups improved most significantly within the first 5 treatment sessions.

During treatment, quality of life increased by 18%. Patients with a 5-year history of chronic pain had the lowest QoL at the start of treatment and the lowest response to treatment vs patients with a shorter history of chronic pain.

Overall sleep quality improved from an average of 4.6 points on the 7-point Likert Scale (with 1 indicating always restful sleep and 7 indicating never restful sleep) to 3.73 points, and women responded to treatment better than men in terms of sleep quality.

Study limitations include a high variance in the measured outcome parameters and the lack of a control group.

The researchers concluded, "The *Elosan Cabin C1* can be an effective, well-tolerated, and non-invasive addition to the range of treatment options available for chronic pain conditions." They added, "The treatment is ideally combined with physiotherapy and other complementary pain therapies."

REFERENCE

Steinhauser S, Ganter MT, Stadelmann V, Hofer CK; ELES Study Group. Whole-Body Electrostatic Pain Treatment In Adults With Chronic Pain: A Prospective Multicentric Observational Clinical Trial. *Pain Ther.* Published online November 28, 2023. doi:10.1007/s40122-023-00560-8

Unfortunately, this device is currently available only in Switzerland. The company is looking for physicians to spread the use to other locations.

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PERIPHERAL NEUROPATHY SUPPORT GROUPS VIRTUAL AND IN-PERSON FOR MARCH 2024

Encourage, inform, share, support, and hope.

Join a meeting to help others, learn something new, and/or share experiences.

In-person or virtual – connect to others with peripheral neuropathy

In-Person Houston TX Quarterly Peripheral Neuropathy Support Group Saturday, 1pm - 2:30pm Central

Memorial Drive United Methodist Church, 12955 Memorial Drive Room DS100, enter at back (south) of building, follow signs

Hosts – Katherine Stenzel and John Phillips

In-Person Auburn CA Peripheral Neuropathy Support Group

Monday, 11am - 12:30pm Pacific

Beecher Room at the Auburn Library, 350 Nevada St., Auburn, CA

Monday

Host - Sharlene McCord (530) 878-8392, Kathy Clemens (916) 580-9449, kaclemens@earthlink.net

Virtual 2nd Saturday Peripheral Neuropathy Support Group

Saturday, 11am - 1pm Pacific / 1pm - 3pm Central / 2pm - 4pm Eastern

9 Meeting ID: 856 7106 1474, Passcode: 114963

Saturday Host - Katherine Stenzel, contact Katherine for Zoom link

In-Person | Santa Cruz CA Peripheral Neuropathy Support Group

Wednesday, 1pm - 2:30pm Pacific
Trinity Presbyterian Church, 420 Melrose Avenue, Santa Cruz, CA

Wednesday Host - Mary Ann Leer (831) 477-1239

Virtual 2nd Wednesday Chemo-Induced Peripheral Neuropathy (CIPN) Support Group

Wednesday, 2pm - 3pm Pacific / 4pm - 5pm Central / 5pm - 6pm Eastern
Meeting ID: 830 5538 3243 / Passcode: 396320

Wednesday Host - Glenn Ribotsky, contact Katherine for Zoom link

Virtual 3rd Wednesday Peripheral Neuropathy Support Group

Wednesday, 10am - Noon Pacific / Noon - 2pm Central / 1pm - 3pm Eastern
Meeting ID: 833 4473 0364 / Passcode: 341654

Wednesday Host - Glenn Ribotsky, contact Katherine for Zoom link

Virtual

3rd Wednesday CIDP and Autoimmune Support Group

Wednesday, 3pm - 4pm Pacific / 5pm - 6pm Central / 6pm - 7pm Eastern

Wednesday Host - John Phillips, contact John for Zoom link

Virtual 4th Saturday Peripheral Neuropathy Open Discussion

Saturday, 11am -1pm Pacific / 1pm - 3pm Central / 2pm - 4pm Eastern
Meeting ID: 851 7949 9276 / Passcode: 159827

Saturday Host - John Phillips, contact Katherine for Zoom link

VIRTUAL SUPPORT GROUP CONTACTS

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John Phillips johnphillips.wna@gmail.com
Shana Phelps shanapnhelp@gmail.com

Support Groups meeting days and times can also be found in the Calendar on the home page of the website, **www.pnhelp.org**, and in the Support Group tab.

NEW

FROM THE PRESIDENT Pam Hart, WNA President

Wow, what wild weather we have been having – all across the country! I hope that each of you has come through it unscathed. In California we have been experiencing power outages. Of course, one of those happened the night before our in-person support group meeting in Auburn, CA. We had thirteen people who managed to make it. The lure was Arlan Deutsch, a twenty-year member of WNA who promised to tell us about a new patch he has been testing.

Arlan has tried many potions and drugs over the years, yet he is not afraid to try another. He has given up his gabapentin except for an occasional nighttime half pill when necessary. He found that it affected his balance – wow! How many others may have this side effect? About three and a half years ago he began using the Nerve Renew and Nerve Repair cream (https://nerverenew.com). This helped him – as a bandage would help a wound – but certainly did not stop the neuropathy as it has now progressed to his lower legs and hands.

Arlan has started a new product – X39. He is very enthusiastic about it, but cautions that he really needs to try it for a year to be able to give a credible endorsement. X39 is a stem cell activator in a patch form. "The X39 activates pluripotent stem cells which have the unique ability to turn into any cell the body needs for repair and regeneration of critical issues such as our skin, connective tissues and organs." (www.startX39now.com)

It always amazes me that our members will search and search to find that hidden answer to their pain. This is so commendable because they can then share with the rest of us...and that is what our support groups are all about. Please see the list of support groups on the adjacent page and if you would like to start an in-person group in your area, please contact me. We have materials to assist group leaders get started.

Cheers, Pam

■ MARTIN (MARTY) PRICE – RETIREMENT FROM BOARD OF DIRECTORS

Marty joined WNA nearly nine years ago when it was called The Northern Chapter of the Neuropathy Association. He had just retired and been diagnosed with peripheral neuropathy. He only had a little understanding of his doctor's explanation of neuropathy but realized it was going to be very important to learn to cope with it since he already had burning pain symptoms. Two years later his support group leader left the area, and he was asked to lead. That is when he learned there was no cure but there was hope and management of his neuropathy symptoms. He was awarded a group leader achievement award during this time.

In 2022 Marty joined the Board of Directors with the goal to continue to learn and help others who have peripheral neuropathy. He presented a webinar on nutritional supplements and wrote a couple of articles on the same for our newsletter, Neuropathy Hope. Unfortunately, his pain and reduced mobility has caused him to step down from the Board of Directors.

Thank you, Marty, for all of your support to WNA and to others that suffer from this disease.

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Health Care Challenges Websites (updated)

SHIPs State Health Insurance Assistance Programs www.shiphelp.org (877) 839-2675

Help for navigating the complexities of Medicare. Search the website for your specific state program.

Medicare Rights Center

www.medicarerights.org (800) 333-4114

Non-profit that works to ensure access to affordable health care for older adults and people with disabilities.

Medicare

www.medicare.org (800) MEDICARE (800) 633-4227

Get started with Medicare, options, news.

Benefits and Insurance for People with Disabilities

www.usa.gov/ disability-benefitsinsurance (844) USAGOV1 (844) 872-4681

For those with a disability, learn how government programs and services can help in your daily life.

■ PERIPHERAL NEUROPATHY THERAPIES FROM THE MAYO CLINIC WITH FOCUS ON SCRAMBLER THERAPY

Besides the typical medications (anti-convulsant and antidepressants) and topicals (lidocaine and capsaicin), the Mayo Clinic suggests the following therapies and procedures:

- **Scrambler therapy.** This treatment uses electrical impulses to send non-pain messages to the brain. These messages replace the pain messages the nerves send to the brain. The goal is to retrain the brain to think there is no pain.
- **Spinal cord stimulation.** This type of therapy works through devices put into the body. These devices are called neurostimulators. They send low-level electrical impulses that can block pain signals from reaching the brain.
- **Plasma exchange, steroids and intravenous immune globulin.** These treatments are often used if inflammation or autoimmune conditions are causing neuropathy with weakness, numbness or imbalance. These therapies are not used to treat pain alone.
- **Physical therapy.** If you have muscle weakness or issues with balance, physical therapy can help improve your ability to move. You also may need hand or foot braces, a cane, a walker, or a wheelchair.
- Surgery. Neuropathies caused by pressure on nerves, such as from tumors, might require surgery.

REFERENCE

MayoClinic.org, Diseases & Conditions, Peripheral Neuropathy

(Editor - This is the first time I've noticed Scrambler therapy on a website as a listed treatment for peripheral neuropathy. Here's more information.)

Scrambler therapy was invented by Giuseppe Marineo at the University of Rome Tor Vergata during the early 1990s. It was approved by the Food and Drug Administration (FDA) in 2009 for professionally supervised treatment sessions in patients with chronic or neuropathic pain. It is based on the theory that an electrical stimulus on the skin can activate particular sodium—calcium channels to produce action potentials and sensations perceived as non-noxious (not painful) instead of painful. The scrambler therapy signal output comprises 16 waveforms that vary slightly, combined into 256 distinct sequences that are continuously changed by a proprietary software algorithm. By "scrambling" noxious (painful) stimuli into non painful sensations, scrambler therapy is theorized to mitigate continuous pain input and reduce central sensitization (increased responsiveness of the central nervous system to afferent input).

APPLICATION

Scrambler therapy is delivered in scheduled sessions at a health care facility where the treatment is available. Up to five pairs of electrodes are placed on the healthy (not impacted by neuropathy) skin both proximally (close) and distally (further away) to the site/sites of pain. The scrambler machine is then connected and activated, at which point patients perceive a non painful sensation between the electrodes. This sensation is commonly described as being bitten by electrical ants. The operator gradually increases the magnitude of the electrical stimulation in intervals of 5 to 10 minutes until the pain is relieved or the patient reaches a maximal threshold, below any perception of pain. As the current is increased, the operator says at each interval, "Tell me when you feel something," to confirm that any changes in stimulation magnitude are being perceived, and then says, "Tell me when enough is enough — the stimulus should be tingling and tolerable," to prevent excessive stimulation. Treatment is continued for 30 to 40 minutes total per day. Given the resistance of skin changes from day to day, the process is repeated anew at each treatment session to find the optimal lead placement and stimulation settings.

Clinically, a treatment session is judged to be successful if neuropathic pain, tingling, or numbness is relieved. If there is no relief, a different pattern of electrode placement or signal intensity is attempted. The therapeutic goal is to replace painful signals in the affected field with the scrambler therapy signal, such that the patient's usual pain is reduced as much as possible during the treatment session. The duration of relief usually increases with each day of treatment, and analgesic effects have been reported to last for weeks, months, or even years after a treatment course. If identical pain symptoms recur, re-treatment is likely to induce remission, according to case reports showing successful repeat treatments, but data on actual percentages are lacking.

AVAILABILITY

The FDA restricts the sale and use of the scrambler therapy device to physicians or to health care personnel operating under

■ TIDBITS FROM VIRTUAL SUPPORT GROUPS

January and February sessions, Katherine Stenzel, Editor

At the January 17th session, there was a discussion about working with your doctors. Jeff Haber suggests to "Invite your doctor to become your advocate", and to realize that doctors do not have all the answers as sometimes they just don't know. Jeff also suggests that we "should not let peripheral neuropathy dictate our lives."

John Phillips, Director, is very big on "achievable goals." Meaning we should set goals that that are possible for us to obtain, possible to achieve. To not set impossible goals. Achievable may be small, may be easy, but by achieving them, we show ourselves that we are capable of moving forward.

Lynn Carpenter discussed changing medications during the February 10th session. The side effects from gabapentin – brain fog, etc., were not contributing to a good quality of life. Her doctor changed her to Lyrica and the side effects went away while the benefits continued. She delivered this update with a smile on her face!

And a funny. During the January 27th session, the use of a massage gun was suggested to Laura Sherman to help with her leg pain. When she was providing an update during the February 10th session, and having brain fog as many of us do due to meds or age or just life, she said "And I have that ...(pause)...gun." After a couple of seconds, we realized what word was missing, but still laughed at the unintended result.

PERIPHERAL NEUROPATHY THERAPIES FROM THE MAYO CLINIC WITH FOCUS ON SCRAMBLER THERAPY

- Continued from page 4

the supervision of a physician. Practitioners are required to complete several days of training in its use, though there is no official certification process. Patients must travel to a health care facility that offers scrambler therapy.

USE IN PATIENTS WITH CHRONIC, REFRACTORY PAIN

Data from several randomized clinical trials suggest an analgesic (*pain relief*) benefit with the use of scrambler therapy in patients who have chronic pain. One of the difficulties in conducting randomized, placebo-controlled clinical trials of scrambler therapy is that the operator must use patient feedback to guide adjustments in lead placement and the magnitude of stimulation. This makes masking of active scrambler therapy difficult and is likely to result in a bias in favor of scrambler therapy.

Marineo et al. randomly assigned 52 patients with conditions involving refractory neuropathic pain (e.g., post-herpetic neuralgia, postsurgical pain, and spinal stenosis) to the best medical management provided by physicians with experience in pain management or to scrambler therapy plus the continuation of current medications. The group receiving scrambler therapy had a 91% reduction in pain (as measured on a scale from 0 [no pain] to 10 [the most severe pain]), from 8.0 to 0.7, a 7.3-point difference, which persisted for at least 3 months. Allodynia decreased, and the doses of opioids and other analgesic drugs were reduced by 75%. The control group had a 28% reduction in pain but no decrease in the use of drugs for pain. Because the treatment groups were not blinded, reporting biases against medical management alone could not be ruled out.

A recent meta-analysis of seven randomized trials involving 287 patients showed that scrambler therapy decreased pain scores by a large effect between the active-treatment group and the control group. Use of analgesic medications was also decreased to a moderate effect. The authors concluded that scrambler therapy appeared to be effective in patients with chronic pain, but larger randomized trials are needed. Several systematic reviews of scrambler therapy have shown evidence of a benefit in patients with chronic pain, neuropathic pain, or pain from cancer or other disorders. Some of the largest reviews and reports indicate that 10 to 20% of patients have no analgesic response to scrambler therapy, whereas approximately 80 to 90% have a favorable response.

REFERENCE

Smith, Thomas J et al. Cutaneous Electroanalgesia For Relief Of Chronic And Neuropathic Pain. *New England Journal of Medicine* 2023(389)158-164. DOI: 10.1056/NEJMra2110098



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TREATMENT OF PERIPHERAL NEUROPATHY USING MULTI-MODAL PROTOCOL

Objective: The study's objective was to assess whether a multi-modality treatment protocol effectively reduced the pain and other symptoms of Peripheral Neuropathy (PN). The authors postulated from previous clinical observations that a multi-modality approach could have a synergistic effect that would be more beneficial in reducing PN symptoms than the use of any one modality alone.

Method: They conducted an open-label, multicenter pilot trial with 34 subjects (19 males and 15 females ranging from 40 - 85 years of age). All of the participants were diagnosed with peripheral neuropathy and had bilateral symptoms in their feet, and many reported the same symptoms (pain, numbness, tingling, burning, and cramping) in their lower legs. Thirty-one of the participants were diagnosed with Type 2 Diabetes (T2D) with diabetic neuropathy. Three participants presented with prediabetes (total patients, n = 34).

Subjects were given:

- 90-day supply of the Bedrock Bioscience Nerve Support supplement and were instructed to take two capsules of the supplement twice daily
 - The Bedrock Bioscience Nerve Support supplement is a vitamin supplement containing ALA, B-12, B-1, B-6, and folate. ALA has been shown to ease the numbness, burning, and pain associated with peripheral neuropathy. It is a powerful antioxidant that improves blood flow and glutathione levels. Methyl B-12 is one of the most critical nutrients for proper nerve function. This B vitamin helps repair and maintain healthy myelin and is associated with decreased PN. Folate has been shown to significantly improve endothelial cell function and normalize blood flow to nerves. Improved nerve conduction velocities are beneficial in treating diabetic polyneuropathy.
- Twice daily treatment for 20 minutes by Bedrock Bioscience LED Light Therapy Device
 - The LED Light Therapy Device has 60 red light LEDs (660 nm wavelength) and 60 infrared LEDs (880 nm wavelength). Such devices are FDA approved and are used to increase local circulation and decrease pain. This effect is believed to be accomplished by dilating vessels to increase local blood circulation as it has been postulated that poor circulation, which can be secondary to the weakening of the walls of capillaries caused by elevated blood sugar, and reducing pain by decreasing inflammation.
- Three platelet-rich plasma (PRP) injections in both lower extremities on Day 0
 - Platelet-rich plasma (PRP) injections have been shown to promote nerve regeneration. PRP injections act as fillers of nerve conduits or vein-muscle grafts to bridge the nerve gaps after the nerves have been severed by trauma. PRP infiltrates the stumps of the nerve perineurally as well as intraneurally. Moreover, PRP can also act as a scaffold to bridge or wrap nerve stumps. In T2D patients PRP treatments for neuropathy have been shown to decrease neuropathic pain and numbness while increasing nerve function. A recent study also showed promising results by presenting evidence of nerve regeneration of damaged peripheral nerves.
- Extracorporeal shockwave therapy (ESWT) treatment for each foot twice per week for the first six weeks, then once weekly for the duration of the study
 - Extracorporeal shockwave therapy (ESWT) has also been used to protect nerves against PN development. A study by Seabaugh showed that ESWT, when applied after PRP injections, caused the release of growth factors from platelets and showed beneficial responses. The biological effects of ESWT include: improved vascularization, the local release of growth factors, and local anti-inflammatory effects. ESWT has been shown to promote axonal regeneration.

Subjects filled out the Brief Pain Index (BPI) at weekly intervals. On Day 90, subjects completed the Patient Global Impression of Change (PGIC) survey.

Results: Analysis of the final day PGIC survey showed a favorable outcome for 73% of participants, with the majority reporting 'Very Much Improved'.

Conclusions: By utilizing a multi-modality treatment protocol that includes PRP, LED light therapy, ESWT and an oral dietary supplement, the authors observed significant reductions in BPI scores. Quality of life and the overall impression of change (PGIC) were significantly improved, and there were no significant side effects.

■ FDA Approves Two Treatments For Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

FDA Approves Takeda's HyQvia® for CIDP

Diana Ernst, RPh; Clinical Pain Advisor; January 16, 2024

The Food and Drug Administration (FDA) has approved Takeda's *HyQvia*® (immune globulin infusion 10% [human] with recombinant human hyaluronidase) for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) as <u>maintenance therapy</u> to prevent relapse of neuromuscular disability and impairment in adults.

The approval was based on data from the placebo-controlled ADVANCE-1 trial (ClinicalTrials.gov Identifier: NCT02549170) and a single-arm, open-label, extension study (ADVANCE-3 trial; Phase 3b extension, ClinicalTrials.gov Identifier: NCT02955355).

Findings showed a statistically significant difference in relapse rates indicating that *HyQvia*® was superior to placebo in preventing relapse of CIDP. Separation from placebo was observed as early as week 4. The 6-month relapse rate was reported to be 1.6%.

FDA Approves Takeda's Gammagard Liquid for CIDP

Isabella Ciccone, MPH; NeurologyLive; January 29, 2024

Following the approval of Takeda's *HyQvia*®, the FDA has approved the company's immune globulin (IG) infusion 10% (human) (*Gammagard Liquid*) as an intravenous immunoglobulin (IVIG) therapy to <u>improve neuromuscular disability and impairment</u> in adults with chronic inflammatory demyelinating polyneuropathy (CIDP).

The approval is based on results from the prospective, open-label, single-arm, multicenter ADVANCE-CIDP 2 trial (NCT02549170) which comprised of adults with CIDP who developed a relapse in the previously-completed, placebo-controlled ADVANCE-CIDP 1 trial (NCT02549170) evaluating efficacy, safety and tolerability of $HyQvia^{\circ}$. Among 18 patients with CIDP in the trial, findings showed a 94.4% responder rate suggesting an improvement in functional disability.

"As the standard of care for the treatment of CIDP, IG therapy is thought to help normalize compromised immune systems through immunomodulatory mechanisms," Mamatha Pasnoor, MD, professor in the Department of Neurology at the University of Kansas Medical Center, said in a statement. "Because CIDP is a progressive and complex disease, multiple treatment options are needed, and clinicians now have an additional therapy that can help adults with CIDP manage their disease."

In ADVANCE-CIDP 2, *Gammagard Liquid* was administered to participants at an induction dose of 2 g/kg body weight, followed by maintenance infusions every 3 weeks for 6 months. At 6 months, 17 of the 18 patients demonstrated symptoms that returned to baseline values prior to joining the study. Overall, investigators observed that participants showed improvement in functional ability, grip strength, or Rasch-built Overall Disability Scale score.

With the approval of *HyQvia*® and *Gammagard Liquid*, Takeda provides clinicians with induction and maintenance therapy options, addressing the varied treatment needs of adults with CIDP.

TREATMENT OF PERIPHERAL NEUROPATHY USING MULTI-MODAL PROTOCOL—Continued From Page 6

Limitations: Although the results were promising, there were some limitations of the study. A larger number of subjects would be recommended with pre- and post-neurological evaluations. Also, it would be interesting to see if a longer treatment schedule would improve outcomes even more than the results reported here. In this multi-modality study protocol the authors could not compare the results to individual treatments alone. Most importantly, this study should be eventually repeated with a larger placebo-controlled Random Clinical Trial (RCT).

REFERENCE

Spinoso, A., Settineri, R., McLaren, C. and Nicolson, G. (2023) Treatment Of Peripheral Neuropathy: Combination Therapy Using Led Light, Extracorporeal Shockwave Therapy, Platelet Rich Plasma, And An Oral Dietary Supplement. *International Journal of Clinical Medicine*, 14, 250-259. doi: 10.4236/ijcm.2023.145021.



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In This Issue

Our support groups are continuing to grow! The Calendar on Page 2 includes our new group for those with Chemotherapy-Induced Peripheral Neuropathy. March is a full month with every support group having their meeting!

The front-page article on a potential treatment for chronic pain shows the direction of innovation — away from medications. This device uses an electrostatic field to alleviate pain. Next time you are in Switzerland, check it out! Hopefully coming soon to a closer location.

Check out Page 4 for a detailed explanation of Scrambler therapy. I was surprised to find it listed on the Mayo Clinic's treatment page for peripheral neuropathy and decided we needed more information. Data from clinical trials looks promising.

Page 6 is the first pilot trial I've seen on using more than one treatment at a time to reduce symptoms. It's a little biased as Bedrock Bioscience supplied two of the treatments. Results indicated a "very much improved" outcome from the participants.

May these give you Hope.

..Katherine

klstenzel@hotmail.com



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Our mission is to provide support, information and referral to people with neuropathy and to those who care about them, to inform and connect with the health care community, and to support research.

Dues - \$30 a year <u>All contributions and dues are tax-deductible.</u>

We are supported by dues-paying members, contributions by members and friends, and occasionally, small grants and fundraisers.

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